RF_DIS_5_PART_1_SUDHA

T U B E R C U L O S I S

Sl No	Topic	Author/s	Source
1	TB and Society	Mira Sadgopal	medico friend circle
2	National Tuberculosis Program: Some problems and issues	Binayak Sen	Medico Friend Circle bulletin 105 (Sept 1984)
3	Towards Rational TB care--A continued Commitment	Mira Shiva	Voluntary Health Association of India (VHAI) New Delhi
4	Rational TB Care--A priority	Mira Shiva	VHAI
5	Tuberculosis in India--A Perspective	Nagpaul D R	J Ind Med Association, Vol71, No.2, July 16, 1978, Pp.44-48
6	Tuberculosis Control in India--Current problems and possible solutions	Baily G V J	Ind. J.Tub., Vol.XXX, No.2 April 1983, Pp. 45-56
7	Public Health Perspectives in the formulation of the National Tuberculosis Programme of India	Banerji, D	NTI Newsletter (1983) 18, 50
8	A Sociological Study of Awareness of Symptoms among Persons with Pulmonary Tuberculosis	Banerji, D & Stig Andersen	Bull. Wld Hlth Org: 29, 1963, Pp.665-683
9	A Sociological Inquiry into an Urban Tuberculosis Control Programme in India	Stig Andersen & Banerji, D	Bull. Wld Hlth Org: 1963, 29, 685-700
10	A Socio-epidemiological Study of Out-patients attending a City Tuberculosis Clinic in India to Judge the Place of Specialized Centres in a Tuberculosis Control Programme	Nagpaul et al	Bull. Wld Hlth Org: 1970, 43, 17-34

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11	Tuberculosis Situation in India--Epidemiological Features	Chandrasekhar, P & Kurthkoti, A G	National Tuberculosis Institute Bangalore
12	Epidemiological Data of Tuberculosis	Seetha, M A	National Tuberculosis Institute Bangalore
13	Tuberculosis in a rural population of South India: a five-year epidemiological study	National Tuberculosis Institute, Bangalore	Bull. Wld. Hlth. Org: 1974, 51, 473-488
14	Tuberculosis in a Rural Population of South India: Report on five surveys	Chakraborty et al	Ind. J. Tub., Vol.XXIX, No.3, July 1982, Pp.153-167
15	Incidence of sputum positive tuberculosis in different epidemiological groups during five year follow up of a rural population in South India	Gothi et al	Ind. J. Tub., Vol.XXV, No.2 April 1978, Pp.83-91
16	Prevalence, incidenceand suspect cases of tuberculosis in a rural population of South India	Krishna Murthy, VV	NTI Newsletter (1982) 19, 75
17	Tuberculosis Mortality rate in a South Indian Rural Population	Chakraborty et al	Ind. J. Tub., Vol.XXV, No.4, October 1978, Pp.181-186
18	Distribution of tuberculosis infection and disease in clusters of rural households	Nair SS et al	Ind. J. Tub., Vol.XVIII, No.1 Pp. 3-9
19	Interview as a tool for symptom screening in pulmonary tuberculosis	Radha Narayan et al	National Tuberculosis Institute, Bangalore

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20	An Operational Model of the District Tuberculosis Programme	Srikantaramu et al	Ind. J. Pub. Health, Vol.XX, No.1, Pp.3-8
21	Symptom Awareness and Action Taking of Persons with pulmonary tuberculosis in rural communities surveyed repeatedly to determine the epidemiology of the disease	Radha Narayan and N Srikantaramu	Ind. J. Tub., Vol.XXVIII, No.3, July 1981, Pp.126-130
22	An operational study of alternative methods of case finding for tuberculosis control	National Tuberculosis Institute, Bangalore	Ind. J. Tub. Vol.XXVI, No.1, January 1979, Pp.26-34
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24	District Tuberculosis Control Programme in Concept and Outline	Nagpaul, D R	Ind. J. Tub., Vol.XIV, No.4 Pp.186-198
25	Tuberculosis Control in Primary Health Care	Radha Narayan	J. Com. Dis.14(3):189-191, (1982)
26	A study of tuberculosis services as a component of primary health care	Radha Narayan et al	Ind. J. Tub., Vol.XXX, No.2 April 1983, Pp.69-73
27	Primary Health Care - Evolution in India Part II : The roots	Radha Narayan	NTI Newsletter (1982) 19, 71
28	Feasibility of involvement of the Multi purpose Workers in case finding in District Tuberculosis Programme	Aneja et al	Ind. J. Tub., Vol.XXVII, No.4 October 1980, Pp.158-166

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30	Case-finding by microscopy	Nagpaul et al	WHO/TB/Techn. Information/68.63
31	Potential Yield of Pulmonary Tuberculosis Cases by Direct Microscopy of Sputum in a District of South India	Baily et al	Bull. Wld Hlth Org. 1967, 37, 875-892
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33	Priority to sputum positive cases under NTP--Rationale	Jagota, P & Aneja K S	National Tuberculosis Institute, Bangalore
34	The BCG Story	Mira Shiva	VHAI
35	Present Status of Immunization against Tuberculosis (Review Article)	Baily G V J	Ind. J. Tub., Vol.XXVIII, No.3 July 1981, Pp.117-125
36	The efficacy of BCG Vaccination - A brief Report of the Chingleput BCG trial	Baily G V J	NTI News Letter (1980) 17, 108
37	Chemotherapy in National Tuberculosis Programme	Aneja K S	NTI Newsletter (1982) 19, 58
38	Drug Regimens	National Tuberculosis Institute, Bangalore	Karnataka State Tuberculosis Association, 3 Union Street Bangalore
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41	Short Course Chemotherapy - Retrospect and Prospect	Aneja K S	National Tuberculosis Institute, Bangalore
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43	Collection and consumption of self-administered antituberculosis drugs under programme conditions	Gothi et al	Ind. J. Tub., Vol.XVIII, No.4 October 1971, Pp.107-113
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47	Voluntary Agencies and India's National Tuberculosis Programme	Debabar Banerji	VHAI New Delhi
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49	What you should know about Tuberculosis		The Tuberculosis Association of India, 3 Red Cross Road New Delhi
50	Beat Tuberculosis		The Tuberculosis Association of India and the Karnataka State Tuberculosis Association
51	Diagnosis, Treatment and Prevention of Pulmonary Tuberculosis for General Practitioners		The Tuberculosis Association of India, 3 Red Cross Road New Delhi 110001
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medico friend circle bulletin

MARCH 1985

TB AND SOCIETY

Preamble

It is the first time in the last eleven years since our inception that mfc has taken up a single disease entity for discussion at the annual meet. The disease selected—Tuberculosis—was particularly relevant because of many reasons:

i. To begin with there is greater understanding today of the multifactorial aetiology of the disease where social factors more than biological are known to have a significant impact on incidence, prevalence, spread, diagnosis, management and control;

ii. Secondly unlike most of the national programmes in India the NTP has developed on crucial sociological perspectives derived from relevant field studies;

iii. In its approach in terms of integration with general health services, choice of appropriate investigative technology, alternatives in chemotherapy and other aspects it has shown a greater people/patient sensitivity than most other programmes and a significant shift from the dependence on the industrial aspects of medical care;

iv. Inspite of these salient features the case finding and case holding performance is far from satisfactory and these have become a matter of great concern for TB programme organisers and decision makers.

v. The ICMR/ICSSR Report while analysing the drug situation in the country has highlighted the shocking state of availability of anti-tuberculosis drugs ('one third of minimal requirement') when vitamins, tonics, health restoratives and digestives are being produced in "wasteful abundance";

vi. By its inclusion in the 20 point programme the government has endorsed its relative importance in the health scene of the country though whether this step is part of a 'populist rhetoric' or a national commitment towards control of the problem, only time will tell.

It is in this context that the mfc decision to relook at the whole situation of the TB problem and its control in India as an exercise for 1984-85 is significant.

Scope and Focus

The meet of over 110 friends from various diverse backgrounds (ref mfcb 110 Feb 1985) with its intensive small and large group discussions highlighted that the subject was too large and too important to be tackled in 16 hours of discussion and that rather than expecting a meaningful critique of NTP to emerge from so diverse a group — what would really be more realistic would be to accept the annual meet discussions as the initiating of a process of critical analysis. This would be followed up by further study, small group work and field evaluation through 1985 from which would hopefully emerge an mfc perspective on the problem. This sense of realism was forced on the group after the first session on "Expectations of the Meet" in which participants were asked to raise issues and questions for discussion.

Expectations of the Meet

The exercise identified a phenomenal range of problems far beyond the scope of the meet:

1. Need to understand the organisational structure and implementation of NTP and the deviations from ideal in the actual field situations.

2. Need to identify issues on which we should put pressure on policy makers.

3. Need to discuss the range of non-pulmonary tuberculosis and how it is viewed by the NTP.

4. Need to discuss childhood TB and how it is viewed by NTP.

5. Need to study how NTP actually operates at the PHC level and what are the components of the services actually available at the community (village) level.

6. How do non-allopathic systems view TB as a problem?

INSIDE

7. How far can TB be considered an occupational health problem because greater susceptibility to it after certain types of occupational exposure are well known?

8. Knowledge of cost factors in the range of alternative regimens of chemotherapy.

9. Data on drug production, distribution and availability in relation to total estimate of patients and in the context of recommended drug regimes.

10. Identify genuine constraints in NTP and false limitations accepted by programme planners.

11. Identify genuine constraints and false limitations in TB programmes of voluntary agencies.

12. How far is TB actually integrated with general health services? Is there need for greater integration or greater identity?

13. To develop guidelines for patients who have already received treatment before — be it inadequate or inefficient.

14. Role of voluntary agencies in NTP.

15. Role of private practitioners in NTP. Why are they excluded from the plan?

16. Understanding of the social stigma associated with the disease and its effect on case finding or holding and the measures to combat it.

17. The effects of the over emphasis and pressures of the family planning programme on PHC functioning as well as NTP at PHC level.

18. What is the 7th plan policy decisions on TB programme?

19. TB and its relation to other respiratory diseases occuring in certain occupational environment.

20. How can NGOs support/complement/supplement NTP of government?

21. What is the method of collection, analysis, feed back of statistics of NTP from field level? What is the method of feed back from the centralising agency to the peripheral delivery system?

22. Role of para medicals and community health workers in NTP.

23. What are the legal rights of industrial workers vis a vis TB?

24. What are the differences between NTP performance in different states and regions and the causes for such difference?

25. What are the present efforts in public awareness building? What are the available media? In what way can this be further promoted?

26. What is happening about drug resistance in NTP?

27. In spite of the more holistic epidemiological understanding accepted today, why is NTPs perspective severely clinical and curative?

28. Why/how can TB be seen as a social problem to be tackled by society not as a medical problem to be tackled by the health services only?

29. Why has NTP in its planning not cared to involve other non health sectors like the education department etc.?

30. Why is awareness building given such low priority? Why is there no definite, researched and evaluated communication strategy integrated into NTP?

During the discussions at the meet some of the above expectations were debated in greater detail and some were not, either due to inadequacy of information or time constraint. We report some of the key areas of discussion. Decisions for follow up study or action are given at the relevant places in brackets. Wherever participants have committed themselves to specific action this is indicated. Where it is not indicated it means that volunteers from members/subscribers/readers are welcome to get involved. We also welcome any information, perspectives, opinions on any of the questions listed (get in touch with mfc office immediately).

TB—a socio-economic-political strategy

From the discussions, it evolved that TB control must be discussed in the context of a radical reorganisation of society towards a more equitable and just system where the smallest and most vulnerable person is central and only this can secure some stability to the health and welfare of the people.

In the strategy to achieve this society, all interventions particularly those at the grass roots must be through people's movements and organisations so that demands and decisions are the people's free choice. In this strategy the process of reflection and conscious action (ie., education) is on all fronts: social, economic, political, cultural, health and countering myths and superstitions; and seeks to make the person/group/society self reliant and confident.

Micro level action is primary but also sharply limited. It must be linked to the wider reality. Critical collaboration is necessary with people's movements and wider political action. However, there needs to be a high critical awareness of the danger of 'over politicisation' and a danger of the sabotage of the people's freedom by political conflicts.

Within the context of the above perspective we as a group endorse the following thought currents, action and demands on the SEP front

1. A demand for the reallocation of resources in the Union Budget. There should be more money allocated for health and within the health sector, the rural-urban bias should be eliminated (There is need to study the funding of NTP, the cost allocation, for detection, drugs and personnel as well as the rural—urban bias.)

2. Each block and PHC should make it public to the people as to what are the available and allocated resources for that area. All these resources should be channelised for the benefit of all people in a just manner.

3. Occupational (farming, wood gathering, wage labour) and seasonal constraints do not allow the patient (most often an adult in the working age

group) to go long distances for treatment regularly. This reduces access to and availability of TB treatment. Health services especially those for the detection and treatment of TB should be handled by para medicals and should reach the villages if not the door steps of the people.

4. There should be the least dependence on International agencies for funding and powerful individuals in the first world who influence developing countries— India is strongly so influenced.

5. Multinational corporations symbolise the most centralised economic power and therefore they should not be encouraged particularly in the drug industry. However the local government interests are always linked with that of the MNCs and therefore just removal of MNCs will not eradicate inequalities.

6. The profit motives of the drug industry should be strictly monitored and kept in check by a relevant drug pricing policy.

7. Doctors should correct their own misconceptions about TB. They should realise that the germ theory is inadequate to eradicate TB. They should also get rid of the stigma that they harbour about TB itself. When doctors harbour such stigma they perpetuate and legitimise it. The stigma that the doctor harbours reflects the value system that most of us inculcate during our education which has a certain bias. This stigma is particularly common in our attitudes to the poor, caste problem, leprosy and TB and we need to fight against it.

8. Health problems cannot be solved by doctors or government health departments. They can be solved only by creating people's organisations. Health is an indicator of the quality of life and TB should be seen in this perspective. Enhancement of health would therefore be much more guaranteed if health issues are taken up as a part of wider people's movements, ie., trade unions, rural organisations of the oppressed, feminist groups etc

9. Health education should be aimed at informing people on their right to be healthy and their right to prompt, effective, inexpensive and safe treatment when ill. Health education should also highlight myths related to TB or illness in general and show how many of them are used by the elite classes to perpetuate ignorance.

10. A conscious effort at the grass roots level is necessary to build decentralised people's organisations. People should be the axis when considering the TB problem. There should not be an undue emphasis on extraneous agencies such as doctors or policy makers. Experts should be made answerable to the people and crucial decisions should be made by people. Conscious peoples organisations would lead to socio-economic changes without which general health status or even TB situation would not improve.

11. mfc members have to emphasise that the socio economic factor is the most important aspect in TB and for that matter in other communicable diseases as well. As an organization we should work to explode the fallacies accompanying the concept of TB eg. TB Association of India pamphlet on 'What should you know about Tuberculosis' lists poverty, over crowding, unhygienic living conditions as legends about TB). mfc members who are already involved in organising people should develop a network for communication.

12. Nutrition, housing, environment at the working place and amount of leisure determine resistance or susceptibility to TB. This means that only a fundamental change in the socio economic structure of society will help in the control of TB.

13. Whilst demanding a basic structural change, we should also demand that existing peripheral services are more effective. Voluntary agencies should as far as possible not duplicate the effort of the government.

In fact the government should be made responsible for delivering basic public health services Whilst doing reformist work at grass roots we should work towards basic change and contribute towards this change ideologically and organisationally. Alternatives such as low cost drug production should also be a simultaneous activity.

14. Land reforms, the minimum wages act and the right to work should be implemented strictly. In Kerala these measures have greatly helped to reduce incidence of TB

15. To bring about the above mentioned socio economic changes, a political change aimed towards socialist society is inevitable.

Marie Tobin, Jansaut
Manisha Gupte, Bombay

Towards a relevant TB Control Programme

Many of our members are involved at field level in community health projects organised by various non-governmental agencies in which TB control is an itegral part. Based on their own field experiences and the discussion on the wider social issues highlighted in the earlier report certain guidelines were drawn up at the meet for all who are so involved. These would help to ensure that their involvement in the field of TB control would be based on a clearer focus of the social reality in which the problem exists. It is also an attempt to internalise the ideas and positive experiences from various case studies and projects discussed at the meet.

mfc's Bhopal intervention — First Report

A report entitled **Medical Relief and Research in Bhopal—the realities and recommendations,** was presented by an mfc fact finding team at the Bhopal convention of People's Science, Democratic Rights and Environmental Protection Groups on 17-18 Feb 1985 is available for sale at Rs. 2-00 each. If you have not already received a copy write to the mfc office requesting for copies for sale, publicity, lobbying and support.

1. Broadly speaking TB control programmes should ensure the following three crucial features:

(a) A link with socio-economic and developmental activity

(b) A stress on health education and awareness building at all levels

(c) A commitment to community participation in the decision making process and project evaluation.

It was felt that many of us who are working in the field have already a sufficient rapport with the community and the above could be integrated primarily by sensitising ourselves to these issues.

Ensuring the above principles, certain specific recommendations were made for practical implementation during: A. Case Finding/Case Holding; B. Drug Regimes; C. Training of Workers.

A. Case Finding/Case Holding

1. There is need to have a rough estimate of how many TB patients ought to be in the area and work towards identifying at least that number.

2. Involve health personnel at all levels in the programme and also all the cadres of the governmental health service be they MPWs, CHWs and Dais. Local indigenous practitioners and traditional healers should also be involved.

3. School health check ups could be done as an additional focus for case finding as in leprosy. School teachers and high school students should be involved in general awareness building.

4. People's organisations like organisations of the rural poor, workers, trade unions and other formal and informal groups in the community should be sensitised to the problem and involved.

5. Malnutrition surveys and mantoux testing could be adjuncts to case finding specially for childhood. TB.

6. Patients who are on regular treatment or have been cured should be actively involved.

7. The family of patients should be involved in a positive way in the programe. Once they are sensitised to the problem in a positive way (rather than feeling a fear or social stigma) they can be helpful in making the community aware and also bringing patients from other neighbouring families for treatment.

8. The socio economic difficulties of patients should be assessed and transportation fare and other small compensation for wage loss etc., should be provided.

B. Drug Regimes

There are several regimes which have been recommended and are available in the existing literature and also promoted by the NTI. Certain basic principles to be followed before selecting the appropriate regimen are:

1. Technical — an intensive phase of two bacteriocidal drugs and one bacteriostatic drug followed by a maintenance phase of a bacteriocidal and a bacteriostatic drug.

2. The time period of each phase and the spacing of the drugs depend on factors such as — a. accessibility to clinic and health centre;

b. infrastructure available; c. cost; d. availability of drugs; e. stage of disease—serious and non-serious patients; and f. knowledge of patient compliance.

Many regimes taking these factors into account are already recommended from which a selection can be made.

3. While the regime is being dispensed it is essential to ensure: a. psychological reassurance of the patient; b. maintenance of a satisfactory doctor-patient relationship; and c. tactful information to the patient to increase his ability to identify toxic effects.

4. The use of supportive therapy such as cough mixtures etc., should be done in a rational way taking care not to overuse/misuse supplementary medication.

C. Training of Workers

1. First the present knowledge/myths/perceptions existing in the particular area should be studied;

2. The people should be taken into confidence about the programme envisaged by the team and their participation in decision making ensured.

3. Grass-root workers at village level to be involved in the programme should be selected by the community. The selection should be based among other things on personal motivation and stamina.

4. The training of grass root workers or CHVs should be undertaken in appropriate size of the group (10-15).

5. The content of the training should include cause of disease; symptoms; case holding; side effects of drugs and their management; and motivation of patients.

6. The training should be theoretical along with practical field training. The methodology should include.

a. use of available aids, modifying them to make them more relevant and meaningful to the local area; b. involve the patient and get him to talk about his symptoms/difficulties etc., c. reinforce the learning by continous on-the-job training; d. older CHVs to be involved in training newer ones; e. use simple laymen language and avoid technical jargon; f. concentrate on training to communicate effectively with patients and the community.

7. Periodic evaluations of the training programme should be undertaken eliciting feedback from the CHVs.

8. Similarly an effective supportive supervision plan and a system of continuing education in which problems faced in the field are constantly identified and discussed, should be included.

9. The CHVs should be trained to increase community awareness of the existing NTP and the availability of effective treatment as a right so that

demands for more regular drug supply and more effective government health centre services can be generated. In the absence of such a commitment the programme of NGOs will become ends by themselves duplicating the efforts of government and supporting their inefficiency. In the long run since voluntary agencies cannot build up parallel structures to government health services, the catalyst nature and the 'awareness of rights' generation nature of non-governmental voluntary effort should be promoted.

Mona Daswani, Bombay

Sub-group Report

Para-professional training and community awareness in TB

1. The objectives of health education of the community should be to promote an understanding of the medico-technological aspects of TB, the socio-economic-political aspects, the rights and responsibilities of the patients and people, the common beliefs and superstitions and demystification of all aspects of the TB control programme.

2. The responsibility of providing this education and awareness is the joint responsibility of government and non-governmental agencies. However, it seems that one of the main reasons why health education has not been given top priority in the NTP is because of the field reality that the existing services (even if they are geared up) cannot cope with the increased demands of TB patients, if awareness becomes widespread. There seems to be no other reason why even after decades of NTP, there is still no rationally formulated and researched communication strategy. TB Associations have played their role but their efforts seem to lack continuity, technical competence or creativity and are predominantly urban based.

3. Health education efforts should creatively and competently involve all sections of the community not only as recipients of awareness building efforts but also as promotors of further awareness. While focussing on all sections particular interest should be taken of policy makers, politicians and community leaders including the functionaries of the gram panchayat.

4. Improving the communication skills of all categories of health workers from doctors all the way to the community health workers should be an important part of the strategy. At present this is one of the most neglected areas in the existing curricula.

5. The science syllabus of schools does not equip children with practical knowledge of common diseases in India or for that matter for healthy living. There is considerable scope for incorporating knowledge about TB in the science teaching of schools. Schools could also become a focus of creative involvement of school teachers and children in health promotion.

6. There are a sizeable section of private practitioners of non-allopathic systems who should be involved in awareness building. They should be involved not only in management of TB as a clinical problem but as effective educators of their patients in the preventive/promotive aspects of TB.

CHW training: There was a general feeling that the existing governmental CHW training programmes gave low priority and emphasis to TB control. The lesson plans were limited and not integrated with the rest of the training but given separately at DTCs and PHCs.

From the experience of participants who were involved in health projects in which training of CHWs was being undertaken there emerged the need to include certain innovative methods of training to make the CHWs more effective in the field: These included:— (i) participation of senior CHWs in training; (ii) learning through doing; (iii) decentralised and localised training; (iv) participatory methods; (v) use of locally developed or regionally adapted AV aids and so on.

The group suggested that we in the mfc should undertake to:

A. Review all available educational materials and AV aids on Tuberculosis available from governmental and non-governmental sources and check whether the points included in (1) above are present and whether the social focus as identified in discussions exist.

(Anant Phadke agreed to study the TB Association Pamphlets for a start).

B. Review all available training manuals of health workers (CHWs, MPWs, HAs) for the importance given, content, and focus of teaching of tuberculosis.

(Marie D'Souza and Minaxi Shukla agreed to undertake this exercise).

Based on the above two studies recommendations can be made to policy makers, programme organisers and health educationists in the country.

Narendra Gupta,
Prayas.

Sub-group Report

Tuberculosis in Medical Education

The group focussed upon the problem of producing a socially useful doctor in connection with tuberculosis, and the hurdles in the present medical education system that have to be overcome in this direction. The group itself was a small one and represented five medical colleges only.

Preamble

1. The basic structure of present day medical colleges and medical curriculum, propagates a certain value system, which is predominantly exploitatory in nature;

2. We believe that propagating the attitudes currently plaguing the medical system is a general process, which involves the attitudes and practices of faculty members, the expectations of our families and society, and the 'traditional' role of a doctor

3. That medical education is incomplete in itself, unless the social dimension of disease is stres-

sed upon. It is for this reason, that many of our senior colleagues (even those from NTI) believe in purely technical or medical intervention for TB control.

4. Priority of medical education as it stands today, is directed towards the question of where is the lesion? or what is the lesion? rather than how was it caused and why? Our medical education does not stimulate an average student to ask and seek answers to social questions.

5. That trying to produce primary care doctors in tertiary care centres is a major drawback in itself.

Specific issues

1. We felt that the topic of TB as a disease is dealt with in a fragmented way, and is dealt with by several departments in a medical college. It is for this reason that the dynamic nature of TB as a disease is ill understood, and problems in TB control not even perceived. Some of us even passed MBBS with the notion that TB meningitis is a different disease from pulmonary TB and so on.

2. Specialised departments involved in TB education cater to their own fields (perhaps a part of the bigger problem of medical education in a large set up). Attitudes of the faculty members are built along the same plane. It is for this reason, that physicians in the medicine departments absolve themselves of the responsibility to teach about the social aspects of TB.

3. Clinical medicine is glorified, while preventive aspects are looked down upon. Our system is disease oriented and not health oriented. We look at cavities and not at patients!

4. "Germ theory" of causation of disease is propagated and medical intervention only is stressed during undergraduate teaching. Even PSM departments which undertake instructions in sociological aspects of disease, have a narrow view of the disease process. Most recommend medical interventions as a solution quite like their own colleagues in clinical departments. Those that go a step further, preach 'better housing, more ventilation and more food' without understanding the deeper social aspect of TB.

Social action is almost never undertaken. Even development projects which encourage income generation schemes and other such social schemes suppress a more basic question of unemployment in society and so on.

5. Clinical teaching overemphasises that tuberculosis is a common problem and only classical cases are shown to an undergraduate. This propagates the myth that being a common disease, it is easy to diagnose and manage TB. Realities of TB control are never dealt with or discussed so that an average medical student at the end of his final year never recognizes any problems concerning tuberculosis.

6. There are dictums laid down by clinicians who teach that investigations are essential to make a diagnosis. While this is largely true in places where facilities are available, it introduces a value system into the teaching that unless one's clinical judgement is backed up by labs, one is practising 'poor medicine'.

In fact, making a confident clinical diagnosis with limited facilities available, is 'good medicine'.

7. Emphasis is once again laid out on one therapeutic regimen (ie., SM/INH/TA) for all TB patients. The concept of suiting TB treatment to a particular patient's background is not even touched upon. eg., A labourer who can attend a TB clinic twice a week may be offered a different treatment regimen compared to another who can attend daily for SM injections. It is surprising that in spite of the fact that much of the research work on alternative regimens of chemotherapy emanate from India most of these well accepted findings hardly find a place in medical education in the country.

Limitations of the discussion

We in our group were not able to touch upon the following topics as regards medical education in tuberculosis.

1. Research in tuberculosis and research priority identification. Whether research and intervention of a purely technological nature as is currently practised by the NTI should be pursued or other issues regarding socio-economic-political factors be raised as well. Lack of research in communication and education strategies which is a major lacunae, also could not be discussed.

2. Continuing education of doctors about tuberculosis; whose responsibility it is; and the form of the continuing education programme. The group suggest that in light of the discussion a comprehensive integrated model of teaching of tuberculosis should be drawn up which can be tried out within the existing constraints of the medical curriculum in India. As a preliminary process to this effort a much wider feed back from members in or of different medical colleges should be obtained on their own experiences of TB training in their education. This exercise would establish a continuing link with the annual meet theme of 1984 and probably could also be featured in the Anthology of medical education under preparation.

(Ravi Narayan, Vineet Nayyar, and Srinivas Kashalikar agreed to follow up on this along with other members).

Vineet Nayyar,
Vellore

An Appeal

Thousands of innocent Tamils have been rendered homeless and jobless by the recent atrocities and genocidal acts in Srilanka. Assistance is particularly required in the fields of food supplies, medical supplies, clothing and so on. A group called MUST—Medical Unit for the Service of Tamils—been formed in January 1985. They have requested us to put an appeal in the bulletin. All contributions and support may please be sent to MUST, 144 Choolaimedu High Road, Madras 600094, India.

All India Drug Action Network

Report of The All-India Meeting on 30th & 31st Jan. 1985

The AIDAN meeting was planned immediately after the MFC meet. About a dozen groups from different parts of the country had sent their representatives. First half of 30th January was spent in reporting of what different groups have done during last 6 months. It was nice to know that things are moving forward on the Drug-Action front in different parts of the country. Special mention must be made of some of the activities:

People in the Drug Action Movement

The Drug Action Forum of West-Bengal is quite active. It had organized a protest-March to the U. S. Consulate at Calcutta against the decision of the American Congress to allow, under certain conditions, the export of those drugs which have been banned in the U. S. The March was very well attended. They have brought out a pamphlet in Bengali with the title—"Are medicines meant for the people or are people meant for medicines?" This got a very good response. A calendar to spread this message has also been prepared and is being sold. A convention was organized in Calcutta on 20th January and was attended by 400 delegates representing various organizations working in the people's Science and Health movements. The convention adopted demands like: removal of useless, unscientific, harmful drugs; ban the banned drugs, reduce drug-prices, abolish brand names...etc.

The **KSSP** had organized a campaign on oral rehydration and irrational anti-diarrhoeals in 600 rural units of KSSP. The KSSP is planning a state-wide and then a nation-wide seminar on the drug-industry —"A decade after the Hathi Committee."

The Arogya Dakshata Mandal has setup a few "diarrhoea-centres" in Pune city slums where slum-dwellers are taught the importance of oral rehydration through demonstration. They are also publishing a two-volume book on Rational Drug Therapy.

The Catholic Hospital Association of India (CHAI) held a two-day workshop on "towards a people oriented drug policy" during its 41st Annual National convention from 23rd to 26th November, 1984 at Bangalore. About 500 delegates from different parts of the country listened to the different paper-presentations about drug policy in India and went back with idea of implementing rational drug policy at least in their own hospitals.

The Lok Vidnyan Sanghatana is continuing its campaign against irrational over-the-counter drugs. The Bombay unit of LVS has made available plain aspirin, paracetamol, Chlorpheniramine maleate in a plastic packet along with a proper label, as an alternative to Aspro, Anacin, Coldarin etc.

The Drug Action Forum, Andhra Pradesh had held a convention on Rational Drug Therapy, which was attended by about 100 delegates. A special "Drug Information and communication cell" is being prepared in the 7th Five Year Plan of Andhra Pradesh and District Drug Advisory Committees are being set up to advise the authorities on the Drugs-issue.

Other groups in different areas have started activities on the drug-front and building pressure for implementing Government's "Ban-Order" was seen as an activity that would pick up in coming days.

. Mira Shiva reported that one political party-CPI-ML (Santosh Rana Group) has taken this ban order as an action-plan and they had approached AIDAN for relevant background papers. They have decided to launch in different cities in India, hunger strike until death, to pressurize the Government to implement its own ban-order. This news caused a lot of flutter and all of us would be keenly interested to know what happens to this action-plan, and its impact.

Steering Committee Report

Dr. Mira Shiva, the co-ordinator, reported amongst other things about the recommendations of the Steering— Committee set up by the National Drug Development Council. These recommendations have recommended a smaller span of price-control on the drugs than what exists today. Only 95 drugs and their formulations will be under price-control if these recommendations are accepted. The mark up for the drugs from this priority list is also sought to be increased.

This will lead to a rise in prices of all drugs— both the price-controlled drugs and the decontrolled drugs. This Steering Committee Report does not say anything about irrational drug preparations in the market. Coming a decade after the Hathi Committee Report, this report is retrograde in character and all of us must oppose it. It is likely to come before the Parliament in the coming session.

Mira Shiva had convened an emergency meeting of the Co-ordination Committee of AIDAN in Delhi on 26th. November to discuss this report and to give our response to it in a meeting convened on 29th November by the Ministry of Chemicals and Fertilizers to discuss the "New Drug Policy." A note containing our criticism of these recommendations and our positive suggestions was prepared and Mira Shiva conveyed this to the officials during the meeting on 29th November.

Action-Plan:

1. Action-plan in the coming few months would concentrate on forcing the Government to

implement its own order banning 18 categories of drugs. Mira Shiva has prepared a list of brands belonging to these 18 categories of drugs. This list would be improved upon by rechecking it and earmarking those brands which sell the largest. This improved list would be printed in thousands and made available to doctors and Chemists through different voluntary organizations and they would be requested to stop using, selling these brands.

One specific form of action-plan was suggested during the discussion—After making available, the list of brands belonging to those 18 categories of drugs banned by the Govt, the action-group would go round the city in a Morcha and would request doctors to throw away the samples of medicines bearing these brands into a "Zoli." Chemists would also be requested to throw away some medicines as a token and to return the rest of their stock to the drug-companies. This "Zoli" containing these "banned brands" would be publicly burnt at a prominent place in the city.

2. A short summary of A I D A N's criticism of the Steering Committee recommendations would be published and different groups should give adequate publicity to this criticism in their respective areas. These recommendations are quite likely to be kept before the parliament in the coming session in the form of a New Drug Policy. It is necessary to raise our voice at that time and compel the Government to desist from taking this retrograde step. A summary of the Steering Committee Recommendations and our criticism of it would be available with Mira Shiva, Co-ordinator, AIDAN, C-14; Community Centre, S.D.A. New Delhi-110016.

3. Court cases:

a) E. P. Forte—

Delhi Science Forum has agreed to launch a fresh case in the Supreme Court about E. P. forte.

b) Depo-Provera—

Dr. C. L. Zaveri, a gynaecologist from Bombay has filed a case in Bombay-High Court against the Drug-Controller of India for not allowing him to import Inj. Depo Provera. Considering the importance of this case, Women's Centre of Bombay and Medico-Friend-Circle, have with the help of the Lawyer's Collective in Bombay, applied in the Bombay High-Court to be allowed as co-petitioners on the side of the Government of India. It may be recalled that the Board of Inquiry set up by F.D.A., U.S.A. has recently given its verdict ruling out the use of Depo-Provera as a contraceptive in general use. This notorious contraceptive is, however, sought to be imported in India.

A broad-front of different women's groups and Science-groups is being formed to oppose the introduction of injectable contraceptives in India. Material about the hazards of these drugs would be circulated and a public-campaign would be launched against its introduction.

Besides these co-ordinated efforts, there would be local initiatives and its hoped that in 1985, the Drug—Action—work would strike deeper, wider roots and would create a much stronger public opinion against the irrationalities in the drug-situation in India.

—Anant Phadke, Pune

URGENT

We need urgently contributions and donations to support mfc's studies/investigations in Bhopal and publication of our team's reports for professional and public awareness (cheques/DDs in favour of 'medico friend circle—Bhopal Fund')
We are counting on you!

FORM IV

(See Rule 8)

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TUBERCULOSIS PROGRAMME REVIEW

INDIA, SEPTEMBER 1992

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TUBERCULOSIS PROGRAMME REVIEW - INDIA, 1992

1. EXECUTIVE SUMMARY

The Government of India, recognizing the magnitude of the problem of tuberculosis, the limited progress achieved by previous control activities and the expected increase in incidence as a consequence of the HIV epidemic has decided to give priority to tuberculosis control. In support of this decision the Government requested WHO to carry out a joint programme review together with other interested parties. A Steering Group was designated to coordinate the evaluation of the programme, as a first step to formulating a project for possible external assistance.

The review of the national tuberculosis programme (NTP) of India was carried out by a team representing the Government of India (GOI), the World Health Organization and the Swedish International Development Agency (SIDA). The purpose of the review was to evaluate present policies and practices, analyze their adequacy to reduce the tuberculosis problem and recommend organizational, technical and administrative measures to improve the programme.

The review team analyzed the available documents including epidemiological data and reports of previous evaluations of the programme, discussed with officers of major institutions involved in disease control and in training, and made field visits in three States (Gujarat, Uttar Pradesh and Tamil Nadu) to assess the programme at the State, District and peripheral levels.

The burden of tuberculosis in India is staggering by any measure. More thaN half of the adult population is infected. About 1.5 million cases are notified every year and there are probably well over 500 000 tuberculosis deaths annually. Recent trends show that the programme is not having a measurable impact on transmission and appears to function far below its potential.

The Government of India formulated the NTP in 1962. The major objectives were to prevent tuberculosis through BCG vaccination; to diagnose tuberculosis cases among symptomatics and provide efficient treatment, giving priority to sputum positive patients; and to implement these activities as an integral part of general health services. The District was the basic unit for the NTP organization.

At present, organization of the general health system has been extended to reach the community level with primary health services. The tuberculosis programme is integrated into the general health services, and treatment services are provided at the levels where medical staff is available. However, the population growth and the proliferation of public health services has made many Districts unwieldy for supervision by the tuberculosis team which is based in a single District Tuberculosis Center. Further, monitoring and training are mainly under the responsibility of the National Tuberculosis Institute (NTI), the State TB officers playing only a minor role in these important areas.

Human and financial resources are provided by GOI and the States to cover most of the needs of the programme and current policy is to provide free diagnosis and treatment. Currently available data do not allow analysis of the adequacy or efficiency with which these resources are applied, but preliminary indications and overall TB programme performance point to the need for substantial improvements. If the programme is to operate as intended and begin to make a significant impact on the disease, increased funding will be necessary, emphasizing the need for improvements in programme effectiveness and efficiency.

The present management structure at national level requires strengthening to assume leadership in redefining policies, effectively assisting States and supervising programme implementation, retraining staff involved in TB activities, administering funds, and procuring supplies. The States, which provide health services, need also to assume their responsibility in TB programme management, and will require reorganization and training of the public and non government health institutions involved in TB control.

There is little coordination between hospitals and primary health institutions in rural areas, and between the different services providing tuberculosis care in most urban areas, to ensure the management of tuberculosis patients until cure.

Improvements in the methods and management of case-finding must take place. In spite of the recognized priority of bacteriological diagnosis and cure of sputum positive cases to reduce the problem of tuberculosis, a large proportion of human and financial resources is currently used to treat cases diagnosed only on clinical and radiological evidence. This practice is common both to the NTP and to private practitioners and is reflected in medical college curricula. Bacteriology is not sufficiently used to confirm medical diagnosis and criteria for initiating treatment in sputum negative cases are not well defined. As a result of not identifying correctly smear-positive and smear-negative cases, and newly diagnosed and previously treated patients, some patients may be treated with inadequate regimens. Sputum microscopy examinations are carried out with insufficient standards and microscopy laboratories are inadequately equipped. A TB laboratory network assuring equipment, training and quality control is not in place.

Rationalization of treatment is required. There are currently too many alternative treatment regimens and the conventional regimens are of unnecessary long duration and low effectiveness. Short course chemotherapy regimens of higher cost-effectiveness are slowly being implemented but insufficient priority has been given to ensuring effective treatment of infectious patients, particularly during the initial intensive phase of chemotherapy.

The present system of recording and monitoring patient identification an progress during treatment to ensure health service concentration on achieving cure of infectious cases is seriously deficient. The present system does not allow the systematic evaluation of the results of treatment at health facility or block level. Neither does the registration system permit the use of cohort analysis of patients to assess cure rate as the main indicator of programme efficacy.

Drug supplies are occasionally interrupted by lack of timely funding and of buffer stocks. Additionally, the quality of the drugs supplied is not controlled. The extensive network of multipurpose health workers (MPHW) has not been sufficiently utilized at the community level to prevent defaulting and achieve treatment completion.

The present training system relies mainly on the National Tuberculosis Institute (NTI) courses. The state-level demonstration and training centres do not function. District Tuberculosis Centres (DTCs) are not adequately prepared to provide in-service training for dissemination of policy and standards. It does not make adequate use of training institutions and NGOs at the State level to transmit current policies and procedures. The curricula at medical colleges do not stress the basic principles of TB control and there is no systematic continuing education for medical practitioners.

In spite of extensive national experience in both operational and basic TB research, alternative methods to correct the extremely low proportion of cases diagnosed with bacteriological confirmation and of patients completing the prescribed treatment and cured have seldom been implemented. The findings of previous programme evaluations have not always been applied to improve existing programme procedures, nor has adequate use of the results of research and programme evaluation been made.

Nonetheless, the basic strengths of the India TB programme are considerable. The objectives on which the programme was established thirty years ago - integration, decentralization, free services, priority to treatment of infectious cases - are still valid today. They provide a sound basis for revitalization of the national TB strategy. In addition, the tuberculosis control programme can relatively easily build on its strengths: a well defined structure which provides services within general health care in an integrated manner; a basic managerial unit at District level with Central and State Governments providing support for diagnosis and treatment; experienced training and research institutions; and, a general health care system extended to the community through multipurpose health workers. An updated and strengthened programme can expect to reduce the magnitude of the problem by about half in each 10-15 years with the consequent savings in lives, human suffering and more effective use of financial resources. This will require a political commitment, initial investment and strong leadership, plus the rapid development of an efficient national model to serve as training ground and provide operational experience to programme managers at all levels.

RECOMMENDATIONS

1. The structure of the National Tuberculosis Programme should be strengthened by 1) establishing an apex policy making authority and an executive task force with managerial functions to implement programme reorganization, and 2) upgrading the central tuberculosis control unit in the Directorate to provide strong leadership and enhance the efficiency and effectiveness of the National Tuberculosis Programme.

2. The quality of patient diagnosis should be improved by 1) using three smear examinations to detect infectious cases among symptomatics before deciding on patient treatment, 2) ensuring the quality of microscopy with adequate equipment, training and quality control, and 3) establishing criteria for diagnosis by radiological and clinical methods.

3. National and state tuberculosis programme resources should be directed to ensuring cure of tuberculosis patients, giving priority to infectious cases of tuberculosis by 1) adopting short-course chemotherapy, 2) establishing criteria for treatment completion, cure and discharge from medical care, and 3) ensuring an uninterrupted supply of drugs of good quality.

4. The current NTP system of registration and notification should be revised to emphasize the cohort analysis of treatment results (completion and cure, transfers, defaulters, died, treatment failures) as the main indicator of programme effectiveness.

5. Policies should be developed to ensure decentralization of treatment services closer to the community level to enhance access to care and patient compliance to recommended therapies.

6. Pilot projects should be implemented at block level to test the feasibility and results of different technical and organizational

strategies to be adopted by the tuberculosis programme -- i.e., to test the capacity to implement recommendations 2-5 above.

7. A medical officer or treatment organizer and a laboratory supervisor, with the necessary transport, should be added to the existing administrative structure at the sub-district level (about 500,000 population) to strengthen tuberculosis programme management and to facilitate decentralization of supervision.

8. Training materials must be developed to reflect the proposed changes in programme policies and procedures. The current training infrastructure will need to broaden the scope of its training capabilities by utilizing state training facilities, medical colleges, public health institutes and tuberculosis-oriented voluntary agencies to augment training efforts. International and national training opportunities should be made available for the different levels of tuberculosis programme staff.

9. Operational research must be carried out as an integral part of the revised tuberculosis programme to evaluate programme performance, improve delivery of services, problem solving and obtain baseline epidemiological information to measure reduction in the risk of infection.

INDIA - TUBERCULOSIS PROGRAMME REVIEW 1992

2. INTRODUCTION.

A review of the national tuberculosis programme was carried out from 9/1/92 to 9/17/92 as a collaborative effort of the Government of India (GOI), the World Health Organization (WHO) and the Swedish International Development Agency (SIDA). The purpose of the review was to evaluate present policies and practices, analyze their adequacy to reduce the tuberculosis problem and recommend organizational, technical, and administrative measures to improve the programme. The assessment included:

1. An overall description of the current programme achievements and problems,
2. An analysis of the tuberculosis burden, the programme resources and the programme structure,
3. Specific discussion of the leading issues facing the programme and their underlying causes, and
4. Recommendations for the next steps to improve the programme.

At the central level the team reviewed information relating to the magnitude of the tuberculosis problem in the country and epidemiological trends, programme structure, policies, technical norms and procedures relating to tuberculosis diagnosis and treatment, drug supply and logistics, supervision, monitoring and evaluation, education and training, coordination with other programmes and research. Meetings were held with the Ministry of Health, major referral facilities in New Delhi and voluntary organizations.

Following the review at the central level, the review participants divided into three teams to assess tuberculosis control activities at the State and District levels through facility visits and interviews with responsible staff in three selected States (Tamil Nadu, Gujarat, and Uttar Pradesh). Then the teams reconvened in Delhi for discussion of the review findings, conclusions and development of principal recommendations for submission to the Government of India. A draft summary of the conclusions and main recommendations was presented to the Secretary of Health at the end of the review.

A list of participants is attached in Annex 1, and a list of persons contacted and institutions visited as part of the review is in Annex 2.

This document summarizes the findings of the review. Background information on India can be found in Annex 3.1.

3. LIST OF ABBREVIATIONS

ADGHS	-	ASSISTANT DIRECTOR GENERAL OF HEALTH SERVICES
BCG	-	BACILLI CALMETTE & GUERIN
CHC	-	COMMUNITY HEALTH CENTRE
DGHS	-	DIRECTOR GENERAL OF HEALTH SERVICES
DHO	-	DISTRICT HEALTH (MEDICAL) OFFICER
DOT	-	DIRECTLY OBSERVED TREATMENT
DTC	-	DISTRICT TUBERCULOSIS PROGRAMME
DTO	-	DISTRICT TUBERCULOSIS OFFICER
DTP	-	DISTRICT TUBERCULOSIS PROGRAMME
EPI	-	EXPANDED PROGRAMME OF IMMUNIZATION
GH	-	GENERAL HOSPITAL
GNP	-	GROSS NATIONAL PRODUCT
GOI	-	GOVERNMENT OF INDIA
GP	-	GENERAL PRACTITIONER
H	-	ISONIAZID
ICMR	-	INDIAN COUNCIL OF MEDICAL RESEARCH
IMA	-	INDIAN MEDICAL ASSOCIATION
IMR	-	INFANT MORTALITY RATE
MBTC	-	MASTER BOOK OF TREATMENT CARDS
MC	-	MYCROSCOPY CENTRE
MCH	-	MATERNAL AND CHILD HEALTH
MO	-	MEDICAL OFFICER
MOH/FW	-	MINISTRY OF HEALTH AND FAMILY WELFARE
MPHW	-	MULTI-PURPOSE HEALTH WORKER
NGO	-	NON-GOVERNMENTAL ORGANIZATION
NRR	-	NET REPRODUCTIVE RATE
NTI	-	NATIONAL TUBERCULOSIS INSTITUTE
NTP	-	NATIONAL TUBERCULOSIS PROGRAMME
PHC	-	PRIMARY HEALTH CENTRE
PHI	-	PERIPHERAL HEALTH INSTITUTIONS
PPD	-	PURIFIED PROTEIN DERIVATIVE
R	-	RIFAMPICIN
RC	-	REFERAL CENTRE
RI	-	RISK OF INFECTION
RS	-	RUPEES
S	-	STREPTOMYCIN
SCC	-	SHORT COURSE CHEMOTHERAPY
SIDA	-	SWEDISH INTERNATIONAL DEVELOPMENT AGENCY
STO	-	STATE TUBERCULOSIS OFFICER
STTDC	-	STATE TUBERCULOSIS TRAINING AND DEMONSTRATION CENTRE
T	-	THIOACETAZONE
TAI	-	TUBERCULOSIS ASSOCIATION OF INDIA
TRC	-	TUBERCULOSIS RESEARCH CENTRE
VHAI	-	VOLUNTARY HEALTH ASSOCIATION OF INDIA
XC	-	X-RAY CENTRE

4. TUBERCULOSIS IN INDIA

Prevalence of infection. A number of studies over the past 30 years, mainly in rural southern India, have shown the prevalence of infection among children 0-9 years old to be between 3.1% and 11.2% (Table 1). In the early 1960s, more than 50% of the population 20 years and older was infected with M. tuberculosis and most infections occurred before 15 years of age. By the late 1960s there was no evidence of change in this pattern. Since that time, there is no clear evidence of substantial changes in prevalence of infection among children beyond that which might have been expected from secular trends.

Table 1. India: Prevalence of tuberculosis infection among un-vaccinated children 0 to 9 years old and estimated annual Risk of Infection (RI)

Prevalence of infection	RI	Year	Location	Source
4.9%	1.0%	1961	Tumkur	NTI
9.6%	2.0%	1969	Tiruvallore	TRC
10.1%	2.1%	1983	Bangalore	NTI
10.4%	2.2%	1984	Dharmapuri	NTI
3.1%	0.6%	1985	Bangalore	NTI
9.0%	1.9%	1989	Kadambatmur	TRC
11.2%	2.3%	1989	Thiruvelangadu	TRC
6.7%	1.4%	1989	North Arcot	TRC

Annual risk of infection. The intensity of disease transmission in the community is best reflected by the annual Risk of Infection (RI) which represents the probability of a previously uninfected individual becoming infected with tuberculosis during a one year period.

RIs calculated from prevalence studies presented in Table 1 range from 0.6% to 2.3%. These data are difficult to interpret because methods vary among surveys but they clearly indicate wide variation within limited geographical areas and provide no clear evidence of a substantial decrease of the risk of infection over the last 30 years. This stagnant situation is substantiated by two recently published studies conducted in rural areas of Southern India. One showed that the RI decreased from 1.0% in 1961 to 0.61% in 1985, equivalent to an average decline of 3.2% per year. The other study showed no decrease in the risk of infection between 1969 and 1984 (RI of 1.7% in both years). These results would be consistent with a poorly functioning programme which would be creating chronic cases of tuberculosis and drug resistance.

Because most adults were infected in their youth, a small decrease of the RI would not have any rapid impact on the prevalence of infection in the adult population. It is safe to estimate that at least 50% of the population above the age of 20 years is infected and will remain at risk of disease and death from tuberculosis for their lifetime. A conservative estimate is that, currently, the RI for India is still between 1% and 2%.

Disease prevalence. The Sample Survey of tuberculosis conducted between 1955-58 remains the major source of information used by the NTP to anticipate

the tuberculosis situation in the country. The survey showed wide variations in prevalence of disease among persons aged 5 years or more (sputum-positive tuberculosis by smear or culture), ranging from a low of 229/100,000 to a high of 813/100,000. The overall prevalence was 398/100,000.

In 1960-61 and in 1972-73 surveys conducted by NTI showed the prevalence of radiological disease to be 1900 and 1100 per 100,000 respectively. In 1990, in an area near Madras, the rate was estimated to be 1700/100,000. In the first of these studies, the prevalence of sputum-positive tuberculosis was 410/100,000 and in others studies conducted by NTI between 1961 and 1968 in the Bangalore area the prevalence of bacteriologically confirmed tuberculosis (smear or culture-positive) ranged from 337 to 406/100,000 over the age of 5 years. About half of these cases (45% to 52%) were smear-positive. In a number of surveys and studies since that time, there is no evidence of a significant decrease in TB during the last three decades and there remains a very wide range of prevalence of TB in India. In the 1972-73 follow up of the 1960-61 study, the prevalence of bacteriologically confirmed disease was 440/100,000. Two studies conducted in 1989 and 1990 in two area near Madras in the population above the age of 15 years found prevalence of bacteriologically confirmed disease of 1090 and of 430/100,000 (58% and 69% of confirmed cases were smear-positive).

The only clear exception to this stagnant situation is recent data from the Tuberculosis Prevention Trial[1], in which a 350 000 population of South India is being followed prospectively. This study indicates a decrease in prevalence and incidence of both radiologically active and sputum-positive tuberculosis between 1968 and 1985. Most of the decrease, however, occurred during the first few years of the study. Data from 1978 to 1985 show stagnation with a prevalence about 1700/100 000 above the age of 10 years old (by X-ray or culture) and an incidence of about 450/100 000 over the age of 10 years (X-ray or culture). During the same period, 50% of all cases had bacteriologically confirmed (culture-positive) tuberculosis.

Among the many factors influencing prevalence of disease, the effectiveness of treatment is important. Poor treatment completion significantly increases the prevalence of disease. A recent retrospective cohort study conducted under programme conditions by the Tuberculosis Research Centre (TRC), Madras, illustrates the potential impact of poor treatment completion. It showed that among patients on short course chemotherapy who collected less than 50%, 50% to 79% and 80% or more of their drugs, 44%, 37% and 21% respectively were still sputum smear-positive after the end of treatment[2].

Low effectiveness of the treatment programme explains much of the stagnation in disease trends over the last three decades. Further, with the current treatment completion rate it is probable that chronic and partially treated patients represent a large proportion of patients diagnosed by the programme.

Current tuberculosis rates. Age specific incidence rates (NTI, 1974) estimates suggest that about 870 000 new smear-positive cases of tuberculosis may have occurred in 1992. This number is very similar to the 850 000 estimate obtained on the basis of incidence data from the Tuberculosis Prevention Trial[3]. If the current average annual risk of infection is 1.7%,

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[1] S.P. Tripathy, personal communication, 1992

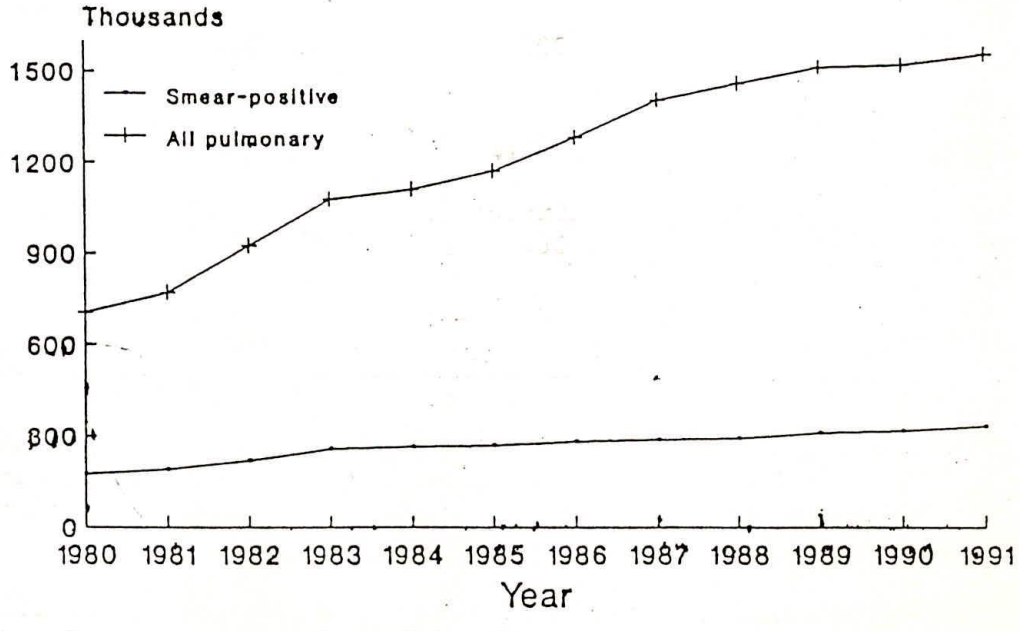
[2] TRC Annual Report, 1990

[3] S.P. Tripathy, personal communication, 1992

1.6 million new cases (all forms) and 714 000 new smear-positive cases of tuberculosis may occur annually. About a third of the total tuberculosis burden of India is borne by the urban conglomerations consisting mainly of towns, cities, and their suburbs.

Notifications. Based on the average case notification from districts with existing tuberculosis programmes (with about 83% of the population of the country), NTI estimated more than 1.5 million newly registered cases of pulmonary tuberculosis in 1991, 21% of them were smear-positive. The trend in notification, presented in Figure 1, reflects the increase in the number of districts integrated in the tuberculosis programme from 320 in 1980 to 387 in 1991, and also an increased proportion of cases not confirmed by smear examination. The proportion of smear-positive cases has decreased from 25% in 1980 to about 20% in the late eighties. Relapses, failures and partially treated patients are often inappropiately included in these notifications.

Figure 1. India: Notifications of cases of tuberculosis, 1980-1991



Extra-pulmonary cases are not reported
Source: NTI, 1992

Age and sex distribution. The majority of tuberculosis cases in India occur below the age of 45 years, with about 75% of the diagnosed cases between 15 and 44 years old. Age-specific estimates of incidence from 1974 applied to the 1992 population, would imply that about 58% of all cases today occur between 15 and 44 years old. Two thirds of the cases are estimated to occur among males but tuberculosis takes a proportionally much larger toll on young females than among young males. More than 50% of female cases occur before age 34.

Mortality. Total mortality due to TB is uncertain but by any estimate poses a huge economic burden for India. Tuberculosis mortality is estimated by NTI to have been 69 to 95/100 000 in 1961-68 and 41/100 000 in 1977-81, or over 350 000 tuberculosis deaths annually (Table 2). Data from the Survey of Cause of Deaths yield a more recent parameter by which to estimate current mortality, resulting in 400 000 deaths, about 75 000 deaths in the 15-24 age group, 95 000 in the 25-34 age group and about 160 000 deaths in the 35-44 age group. Using the 1955 Sample Survey estimates of incidence, if all cases were diagnosed and at the present treatment completion rate of 30%, there would be about 657 000 annual deaths of tuberculosis. A large proportion of these deaths occur among women and it has been estimated that maternal mortality and tuberculosis claim approximately the same number of lives. For the decade of the 1990's, any of these estimates implyes a staggering cumulative burden for the disease.

Table 2. India: Estimates of probable tuberculosis mortality

Source & year	Estimated mortality per 100 000	Annual deaths	Approximate (1) cumulative deaths 1990-2000
NTI			
77-81	41.0	346 000	3 460 000
Causes of deaths survey			
92	50.0	422 000	4 220 000
Sample Survey incidence estimates (2)			
55-58	77.8	657 000	6 570 000
"Styblo model" of incidence with 1.5% RI (2)			
92	50.1	432 000	4 320 000

(1) Mortality rates from surveys applied to 1992 population structure and cumulative burden not adjusted for age structure within the decade.

(2) Assuming no improvement from the current treatment completion rate of 30% and assuming 100% coverage of new cases.

Using the number of cases of tuberculosis currently notified by the NTP, the reported completion rate (30%), a case fatality of 10% among patients who complete treatment, 48% among smear positive-patients who did not complete treatment and 24% among smear-negative patients, it can be estimated that about 345 000 tuberculosis patients today diagnosed in the programme die. Almost all of these deaths are preventable. Increasing the treatment completion rate to only 85% would prevent close to 200 000 deaths annually, a 57% decrease in mortality.

Table 3. India: Number of Tuberculosis deaths which could be expected among cases officially reported in 1991 at different rates of treatment completion and potential reduction in mortality.

Completion rate	Expected deaths among		Reduction in mortality (all cases)	
	Smear positive	Total cases*	Lives saved	Percentage reduction
30% (current)	121 000	345 000	Base line	-
40%	109 000	309 000	36 000	10%
70%	71 000	202 000	143 000	41%
85%	52 000	148 000	197 000	57%

* Pulmonary. As extra-pulmonary cases are not reported, they are not included in this calculation

Cumulative mortality during the decade to the year 2000 will probably exceed 3.5 million deaths, an enormous burden for society. A large share of these premature deaths can be avoided with a well-functioning programme. Given the ages at which deaths from tuberculosis are now occurring and the low costs for tuberculosis programme inputs in India, it is probable that the discounted cost per healthy year of life gained as a result of a well-functioning tuberculosis control programme will be well under US $10, making tuberculosis control one of the highest priority interventions for the State and central governments.

AIDS and tuberculosis. HIV began to spread in India only in the latter part of the 1980s and there is no evidence yet that HIV infections are having an impact on the tuberculosis situation. Only recently HIV testing has become more common in a few research and academic institutions. A survey conducted among all newly diagnosed smear-positive tuberculosis patients in 1990 in Madras found 15 confirmed positive HIV cases among 2165 patients tested (0.7%). In Vellore, there were 16 confirmed HIV positives among 906 patients newly diagnosed with pulmonary tuberculosis (1.8%). In 1992, 12 of 183 (6.3%) tuberculosis patients admitted to a hospital in Bombay were HIV-infected. In a follow-up study of 220 HIV infected individuals conducted in Madras, 115 (52%) had radiological evidence of tuberculosis and 34 (15%) were culture positive. Other studies of HIV-prevalence in the general adult population have revealed prevalence varying between 0.1% in Calcutta to 1% in Bombay. The AIDS programme estimates that currently there are 750 000 persons infected with HIV in the country and that there will be 5 million in the year 2000. Assuming half of these people are also infected with tuberculosis, and that the breakdown rate from tuberculosis infection to disease among dually infected individuals is 10% per year, more than 35 000 HIV-related tuberculosis cases will occur in 1992. There may be as many as 250 000 HIV-related tuberculosis cases annually at the end of the decade. Virtually all of these cases will be in addition to the expected incidence. As important as these cases will be, they will continue to represent only a fraction of the cumulative cases of tuberculosis during the decade.

Tuberculosis drug resistance. Only a few laboratories can conduct drug sensitivity testing in India. Although data on drug resistance is scarce and resistance is not systematically monitored, available information (Table 4) is cause for concern. The very high rate of secondary resistance to both rifampicin and isoniazid is particularly serious, with long term implications as these patients will transmit a virtually incurable form of disease within the community.

Table 4: India: Primary and Acquired Drug Resistance in selected areas.

Type of patient and sample size		% Resistance to S	H	R	HR	SHR
Failure						
81	Delhi Centre (1)	-	50.7	-	33.3	-
354	Delhi Suburbs (1)	-	78.8	-	61.5	-
560	North Arcot (2)	30.0	65.0	16.0	6.0	9.0
Previously Treated						
37	Madras (2)	35.0	62.0	13.5	5.4	8.1
111	Raichur (2)	11.7	52.7	17.1	5.4	11.7
New cases by history						
241	Madras (2)	7.3	12.6	1.6	0.8	0.8
244	Raichur (2)	11.0	19.1	3.2	2.0	1.2
324	Delhi (1)	-	18.5	-	0.6	-

(1) : Ind. J. Tub. Vol.39 No.2 pp 121-124
(2) : TRC Annual Report and M. Datta, personal communication

Conclusions:

The burden of tuberculosis in India is staggering by any measure. About 1.5 million cases are notified every year, more than half of the adult population is infected, and there are at least 300 000 tuberculosis deaths annually. Social and economic consequences of tuberculosis for individuals and for the society are enormous in human suffering, economic loss, and decreased productivity. Recent trends are discouraging, indicating a programme which does not have any measurable impact and which appears to function far below its potential. While further study and improved analysis are needed to rigorously document the epidemiological situation, it will not change the broad conclusion that tuberculosis is one of India's most serious and still neglected health problems.

5. ORGANIZATION OF THE PROGRAMME

1. National Level. The Ministry of Health and Family Welfare (MOH/FW) is divided into an administrative arm headed by the Secretary of Health and a technical arm headed by the Director General of Health Services (DGHS). The Secretary of Health is assisted by Additional Secretaries and the DGHS by Additional DGHSs and several Deputy DGHSs. One of these Deputy DGHS supervises the NTP as well as several other programmes. The responsible officer for the TB programme is an Assistant DGHS (TB). The NTP is located within the technical arm of the MOH/FW and on the administrative side, it is coordinated by a Joint Secretary who is responsible for its financial and administrative control.

National Tuberculosis Programme Policies. The long term objective of the NTP is to reduce tuberculosis in the country to the level where it ceases to be a public health problem. To accomplish this objective, the NTP focuses on 1) the BCG vaccination of infants, 2) the detection of the maximum number of tuberculosis patients among out-patients attending health institutions, and 3) the efficient treatment of identified tuberculosis patients, all as an integral part of India's general health services.

Central Structure of the NTP. The Central Unit of the NTP has a staff of about 10 people. In addition to the Director, there are two physicians and 6 administrative officers for drug procurement, international assistance, monitoring of monthly reports, annual planning and coordination with the National Tuberculosis Institute (NTI)[4]. Currently, the post of programme director (Assistant DGHS-TB) and one of the two medical officer posts are vacant. The level of the programme director is lower than that of other programme directors (EPI, Leprosy) and below the level of the director of NTI. This, plus the fact that two out the three central level posts are vacant reflect the low priority given to the NTP and show the absence of strong national leadership. This situation, if maintained, would jeopardize any attempts to revitalize the programme.

The Central Unit is responsible for drugs forecasting, purchase and allocation, the annual planning and participation in the discussions of the MOH/FW with the planning commission to determine the annual and 5-yearly "plan budget" of the NTP, and for liaison with international agencies (WHO, SIDA), with NTI, and with state TB programmes. The central unit does not play any significant role with respect to tuberculosis control technical policy, training and manual preparation, monitoring and supervision. These responsibilities have been progressively taken by NTI. NTI management, however, is virtually independent of the NTP. Additionally, State Tuberculosis Officers are State employees, and they are not accountable in practice to the ADGHS (TB).

NTP budget. The MOH/FW budget is composed of a "non-plan budget" used for personnel, salaries, hospitals, etc and a "plan budget", allocated by the Planning Commission for future investments or creation of new posts. The "non-plan budget" is not controlled by the NTP and fluctuates minimally from year to year. No detailed information could be made available to the review team about the proportion of the NTP budget corresponding to the "non-plan" budget nor a breakdown by States of the NTP budget and its trend. The 1992 (March 92 - February 93) plan-budget of the NTP is R 145 million (US$ 5.3 million) of which R 110 million - more than 75% - are used to purchase drugs and 25 million for other expenses such as X-ray units and films, microscopes, vehicles, etc. Anti-tuberculosis drug costs are shared on the average on a 50:50 basis between Central and State governments. Within the overall NTP budget, the Central government also provides anti-tuberculosis drugs to voluntary organizations, and supplies, equipment, and drugs to the Union Territories.

Other resources. The Swedish International Development Agency (SIDA) has provided funds through WHO. These funds have been used to purchase x-ray units with Odelca cameras, miniature x-ray film rolls, vehicles, anti-tuberculosis drugs and microscopes. Occasionally, District and State tuberculosis associations provide anti-tuberculosis drugs, materials and equipment to specific district programmes or local tuberculosis facilities.

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[4] National Tuberculosis Institute (NTI). The National Tuberculosis Institute (NTI), located in Bangalore, is responsible for training NTP personnel, monitoring the programme and conducting operational research studies. Each year, NTI organizes two 10-week courses. In 1991, for example, 166 health professionals were trained. Apart from training DTC teams, the NTI also provides refresher courses for persons working for district tuberculosis control programmes and reorientation/retraining seminars for senior health administrators and teachers from medical colleges, etc. Lastly, the NTI collaborates with the World Health Organzation (WHO) for international training efforts.

2. State level. India is administratively divided into 25 States and 7 Union Territories. In the State MOH/FW, the NTP is under the Director of Medical Services, Health and Family Welfare and the Director of National Programmes. All States have a State Tuberculosis Officer (STO), usually assisted by a staff of 6 to 10. The vast majority of STOs have been trained at the NTI. In principle, there is a meeting of all STOs at the central level once a year.

Responsibilities of the State Tuberculosis Officer (STO). The STO is responsible for negotiating for the State the amount of drugs provided by the central government and monitoring drug distribution to the Districts. He is responsible for the overall supervision of District Tuberculosis Officers (DTO) and through them of Peripheral Health Institutions (PHI). Lastly, he should organize and coordinate training activities at the State level, in conjunction with the State Tuberculosis Training and Demonstration Centres and with NTI.

State tuberculosis demonstration and training centre (STDTC). Seventeen states have training and demonstration centres. These centres were created in the early sixties to supplement NTI. They have an average staff of 100 people with about 30 professionals. In addition to training, they have responsibilities in diagnosing and treating patients and have, in some instances, research activities. In practice, however, the vast majority of these centres do not have an organized training programme or research activities and operate solely as District Tuberculosis Centres (DTC).

3. District level. The District is the basic demographic, economic, administrative and political unit in India. The District is further divided into Taluks and Community Development Blocks. One District encompasses 1,800 to 2,000 villages, has an average population of about 1.5 million, and a land area of 10,000 square kilometres. Health institutions in the District generally include:

1. One district hospital in the headquarters town.
2. Community Health Centres (CHC). Usually one in each Taluk, with several doctors and specialized services (about 10 CHC per district).
3. Primary Health Centres (PHC). In principle, one in each community development block (about 40 per district).
4. Varying number of sub-centres (180), other peripheral health institutions, dispensaries, maternity and child welfare centres, employee dispensaries, and private hospitals.
5. Specialized tuberculosis institutions. Tuberculosis clinic, DTC where the DTC has been implemented, sanatorium (about 100 beds per district).

With one CHC per 100 000 population and one PHC per 30 000 population, an average district may have about 10 to 15 CHCs and 50 PHCs. The country is covered by a network of 21 805 PHCs and 137 683 sub-centres (Figure 2).

Figure 2

ADMINISTRATIVE ORGANIZATION AND HEALTH SERVICES

ORGANIZATIONAL LEVEL - Number - Average Population	HEALTH SERVICES
National - 850 000 000	Institutes
State - 25 - 34 000 000	Hospitals Sanatoria State TB Centre (STTDC)
District - 438 - 1 500 000 - 2 000 000	District Hospital District TB Centre (DTC)
Taluk - appr. 15 per district - 100 000	Community Health Centre (CHC) Central Hospital
Community Development Blok - appr. 40 per district - 30 000 - 40 000	Primary Health Centre (PHC) Maternal and Child Welfare Centres Employee and Panchayat Union Dispensaries
Villages - 1800 - 2000 per district - 700 - 800	Subcentres (each 4-5 villages) with Multipurpose Health Workers

In addition to these services, it is estimated that there are 330 tuberculosis clinics in operation in urban areas to provide services for the local residents. Approximately 47,000 hospital beds are available in the country for the in-patient care of seriously ill tuberculosis patients.

In the district, curative medical services and hospitals are managed by the District Medical Officer (DMO) and preventive services and primary health care by the District Public Health Officer. Although the District Tuberculosis Officer (DTO) works under the authority of the DMO, he has no formal control or authority over the district hospital and specialized institutions. Conversely, he controls and supervises tuberculosis activities in PHIs although these institutions are under the administrative authority of the District Public Health Officer. This situation means that the DTO cannot exercise leadership to improve the quality and coordination of tuberculosis control activities in hospitals and does not have the line of authority required to properly manage control activities in peripheral institutions.

District Tuberculosis Programme (DTP). In 1991, District Tuberculosis Programmes were in existence in 378 districts out of 438 districts in the country (86%). In a district, all health institutions which undertake case-finding and treatment for tuberculosis are considered as participating units of the DTP. These institutions are classified as either DTCs or PHIs. Each district participating in the DTP has one DTC. Sub centres do not have medical officers and are not considered as part of the DTP network.

District Tuberculosis Centre. DTCs maintain the patient case registers, manage the recording and reporting system and are responsible for supervising the TB activities of the PHIs. The DTCs also serve as referral centres to PHIs for X-ray examinations. They have X-ray units, microscopes and vehicles. They receive funds for drugs, gasoline, car maintenance, etc. from the State. Anti-tuberculosis drugs are supplied by the national Central Unit to all districts including those where the NTP has not yet been implemented. Most DTCs receive additional drugs directly from the State. DTCs have a staff of 15 to 20 persons including the District Tuberculosis Officer (DTO), one to three tuberculosis medical officers, one radiology technician, one laboratory technician, one to five treatment organizers, one statistical assistant, one pharmacist, and one or two drivers.

Peripheral Health Institutions (PHI). In the District, most CHCs and a number of PHCs staffed with at least one doctor are selected as PHI to implement the NTP and conduct diagnosis and treatment of tuberculosis. There are 3 types of PHIs:

1. X-ray centres, offering X-ray and microscopy
2. Microscopy centres, offering microscopy only
3. Referring centres, preparing sputum smear for or referring patients to the nearest microscopy centre.

No special staff is posted at PHIs and the Medical Officer in charge is responsible for tuberculosis activities. In some instances, one of the health workers of the centre (microscopist, X-ray technician) takes responsibility for tuberculosis patient management.

Multipurpose Health Workers (MPHW). In all PHIs there are multipurpose health workers who represent the most peripheral level of health care. The are usually based in subcentres, in pairs. With respect to tuberculosis, they are to maintain a list of all patients on treatment, to visit them regularly and to refer symptomatic patients to the nearest PHI or the DTC. They are not currently responsible for distributing or administering anti-tuberculosis drugs.

Urban tuberculosis control. There are a multiplicity of urban organizations and institutions involved in tuberculosis control activities, both public and private. These organizations, however, rarely coordinate their efforts and often work in isolation and/or overlap activities. Consequently, areas and/or population pockets needing tuberculosis services may be overlooked and manpower and financial resources are not well utilized. Since 1975, city tuberculosis programmes are to be organized in a similar fashion to DTPs, with the stipulation that each city programme would be tailored to the administrative, operational and social conditions of the specific city. Currently, however, only a few large urban areas have well-functioning tuberculosis programmes. Voluntary organizations and tuberculosis associations have been able to augment city tuberculosis programmes in many instances by providing technical and financial support, health education, and community outreach.

Conclusions:

The NTP has a very weak central structure, which for a long time has not provided leadership in establishing and updating policy and technical procedures and assuming programme direction. As a result, programme procedures have stagnated and the original philosophy of the NTP has not been fully implemented, or revised to make full use of the development of PHC. The functions and resources of the State level, in particular training, have not been developed and properly utilized. In most large urban centers the coordination of activities among diffrent institutions, under the guidance of the STO and STDTC, have not yet been implemented. In a similar way, the curative services (hospitals, etc.) and preventive services (PHIs) are not coordinated at District level in a single network for TB control, and the lines of authority of the DTO are not clearly established. The extension of TB diagnosis and treatment activities to the community through the MPHW has been slow, and that valuable human resource is not sufficiently utilized to enhance access to care and patient compliance to recommended therapies. There is no technical and policy advisory body to lend credibility and promote visibility of the programme to government agencies and potential donors and to provide support to the national team in the preparation and periodic updating of national policies, technical and administrative procedures, and monitoring and evaluation of the programme.

6. CASE FINDING AND DIAGNOSIS

Diagnostic services provided by the NTP are free of charge for the patients. A major stated objective of the NTP is to detect the maximum number of tuberculosis patients in the community and among outpatients attending health institutions with symptoms suggestive of tuberculosis, giving priority to sputum positive patients. According to NTI manuals, the principal approach of case finding should be routine screening by sputum smear examination of chest symptomatic patients attending health centres, and symptomatic patients be referred for x-ray only after a negative sputum examination has been repeated. In practice, however, this policy is not followed.

Patients with respiratory symptoms attending a public outpatient facility are investigated with chest x-ray and generally one sputum smear examination. Patients who have to come back a few days after their initial exams are not routinely requested to bring an overnight sputum sample. Often diagnostic smears are not done or the results are not recorded on the treatment card. PHIs without x-ray facilities refer sputum negative patients to a peripheral x-ray centre or to the DTC. Looking for better care or because of public transport facilities, which directly link to urban centres, many patients bypass the microscopy centre and go directly to an x-ray centre or hospital, adding to their workload and increasing the proportion of cases diagnosed through x-rays.

Most facilities with X-rays diagnose the patients and initiate TB treatment on radiological evidence, in spite of a negative smear examination. Very few facilities indicate further sputum examinations, or treat smear negative tuberculosis suspects with non-specific antibiotics and follow-up the patient's clinical and radiological evolution prior to initiating anti-TB therapy, suggesting overdiagnosis based on x-rays. Overall, approximately 20% of patients diagnosed with tuberculosis have at least one positive smear, a very low proportion compared to the expected capacity of smear examination of diagnosing 40-60% of all TB cases. The practice of doing generally only one diagnostic smear examination is probably resulting in infectious cases being treated as noninfectious (with inadequate regimens and supervision) or not diagnosed at all. Official data published for one state tuberculosis programme showed that between 1969 and 1987 the total number of tuberculosis cases almost doubled whereas the proportion of smear positive cases decreased from 61% to 28%, suggesting that clinical practice is relying less on bacteriology and further separating from the policies recommended by the NTP.

Unfortunatelly, outpatient facilities run by non-government organizations (NGOs) generally follow the same routines. Moreover, NGO institutions and municipal health facilities were found to charge registration fees for each visit. In private practice, patients have to pay for consultations, smear examinations by private laboratories and the prescribed medication.

It is estimated that up to 50% of tuberculosis patients are identified and at least partially treated by private practitioners. These patients do not initially enter the NTP and are not registered. Many patients then move to the public sector because of the cost of care and drugs. Thus, a large proportion of patients attending a health service facility have previously been seen by a private practitioner.

Due to the high number of PHIs in the district, the maintenance of an updated cross indexing system at DTC is complex. Patients may not be able to provide a complete address due to illiteracy or type of dwelling or because TB has a social stigma and the patient does not want to receive mail from the DTC or visits from DTC staff. Unless they present an identity card issued by a public institution, patients previously treated outside the public system or which are not found in the DTC cross index are diagnosed, registered and notified as "new" cases. This practice correctly incorporates new cases initially detected outside the public system, but duplicates notifications if the patient was detected by a public institution outside the District.

A more serious problem is that the clasification in "new" or "old" bears no relation to the previous treatment history and is not useful to decide on patient therapy. If the patient is not found to have been previously indexed in the DTC, he is considered "new" and is given a regimen for new cases. The insufficient definition of "new" and previously treated patient leads to the prescription of wrong regimens. A significant proportion of previously incompletely treated cases is known to have acquired resistance to isoniazid and streptomycin. The efficacy of "conventional" chemotherapy for such cases, who are most likely still symptomatic and smear-positive, is very low.

Laboratory facilities

Most laboratories visited were equipped with monocular, rather than binocular, microscopes without an electric light attachment. Some of the microscopes were in poor condition and the light source appeared to be inadequate. The quality of slides varied and some slides were found to be uneven and poorly stained. Acid fast bacilli could not always be found in smears read as positive. An ocular magnification ratio of five or six was routinely used rather than the usual 10 ratio. As definitions for data entry

are irregular, laboratory registers do not permit determination of the proportion of new cases, retreatment cases and follow-up examinations. Sputum smears are not routinely used for monitoring of treatment outcome.

Many laboratory technicians working in peripheral microscopy centres have been trained for the malaria control programme and are not familiar with sputum smear examinations. Malaria smears are often given a higher priority and may constitute a high case load. The number of sputum smears to be read by one technician per day is usually considerably less than 20 except in larger institutions such as DTCs and major hospitals. The rate of positive smears varies between 1 and 10%. These low positivity rates may be partly a result of poor selection of symptomatics, poor quality of the samples, low quality microscopes, weak laboratory practices, inadequate training and an excessively limited exposure to tuberculosis smear slides due to a small catchment area. The supply of chemicals was adequate and no shortages were reported. Slides with negative smear results are often reused, as indicated in the NTI manual, with a risk of false positive results.

Quarterly or semi-annual supervisory visits are made by the DTC team to assess the performance of the laboratory staff. The supervisors check usually only all the positive slides, retained at the microscopy centre for reading. Notes on the supervisory observations made, such as the proportion of false positive and false negative readings, were not available for scrutiny. There is no system of quality control through sending slides to the DTC or to a State reference laboratory. Laboratory staff are often in need of re-training and staining is of varying quality. Few States have functioning reference laboratories to train District staff, supervise DTC laboratories, carry out sistematic quality control of smears and do sputum culture and sensitivity testing when necessary. In one State it was observed that the STDTC laboratory had different procedures for smear examination that those recommended by the NTI manuals and utilized by the DTC laboratories in the State.

X-ray practices

With very few exceptions, diagnosis in clinical practice is based on the chest x-ray. Even with one negative smear or no smear result, tuberculosis treatment is initiated if the x-ray appears suggestive of active pulmonary tuberculosis. The x-rays taken in referral centres are usually kept at these facilities. The referring PHI only receives a note with the x-ray result. The standard equipment in most x-ray units is an ODELCA camera with 70 or 100 mm films. In some hospitals, standard size films are used. Chest clinics at the district level use both small and standard size x-ray films. Most of the technicians are sufficiently trained and the chest films are of a good quality, but complaints were expressed about the quality of the domestic films. X-ray centers had well functioning x-ray units and usually sufficient film to handle the tuberculosis caseload within the centers, although temporary shortages of x-ray films are commonly experienced by PHIs. 93% of x-ray machines were in working order at the DTCs as of 1991 (13). Assessment by an inexperienced reader of the small size x-ray films widely used for diagnostic x-rays or use of slightly inferior quality films can lead to an increase in overdiagnosis.

Conclusions:

The NTP has an infrastructure of microscopy and x-ray centres, integrated into the primary health care system and staff are available to perform case finding activities down to the village level of health care delivery. Major weaknesses of the NTP with regard to case finding are that usually only one or no sputum smear is obtained before a tuberculosis diagnosis is made, and that diagnosis is primarily based on the results of a

chest x-ray. This practice results in significant underdiagnosis of smear positive cases by smear examination and in treatment of infectious patients as smear negative cases with inappropiate regimens, and discourages monitoring of treatment outcome by sputum smear results. Patients with respiratory symptoms are often inadequately assessed and treated before the diagnosis of smear negative tuberculosis is made. The lack of vigorous procedures for patient management increases the tendency to rely on x-ray examinations resulting in the overdiagnosis of smear negative tuberculosis. Inadequate case history and the impractical case registers result in multiple diagnosis of defaulters and overnotification.

The primary aim in case finding should be the identification of sputum smear positive cases. Before the diagnosis of tuberculosis and decision to treat are made, the results of at least two sputum smears should be available. The role of the sputum smear examination in tuberculosis diagnosis should be greatly emphasized and the role of radiological examinations should be reconsidered. For differential diagnosis, the ODELCA cameras and miniature films for diagnostic chest x-rays may be phased out and replaced with equipment based on the specifications for the WHO Basic Radiological System, after carefully working out the cost considerations. For screening of symptomatic attendees in hospitals of large urban areas to select patients for bacteriology, small size X-rays may be useful.

The NTI laboratory manual should be revised, used for training at State level and distributed as a reference to the laboratory staff of PHIs. Wall posters with the basic procedures for microscopy, as were seen in one of the States visited, should be made available to all peripheral microscopy centres. Supervision of DTC laboratories should be undertaken by State reference laboratories. Supervision at State and at District levels should include a system of quality control whereby samples of positive and negative smears are systematically sent to a reference laboratory for confirmation. Acceptable quality binocular microscopes should be made available. All diagnostic centres, including those outside the State health services, must adhere to uniform programme guidelines.

7. TREATMENT

The manuals for the District Tuberculosis Programme (NTI, 1990) include the current national policies for the treatment of tuberculosis. The Introduction Manual states that free chemotherapy should be provided to self referred tuberculosis patients. The highest priority is given to treatment of sputum positive cases to reduce the transmission of infection in the community. Five regimens of "conventional chemotherapy" of 12-18 months duration for all forms of tuberculosis are recommended. In a phased manner, two short course regimens of 6-8 months duration are to be provided for sputum positive cases. Patients are "allowed to collect drugs from the nearest PHI and are motivated to consume drugs for prescribed duration regularly".

In Annex 4.1 the regimens found to be most frequently used in the DTP are presented according to the currently recognized category of patient and priority given if drugs are available. The categorization used in the following sections of this report corresponds to that used in the WHO Guidelines for Treatment of Tuberculosis in NTPs. However, in the India NTP manuals, the seven recommended regimens do not always refer to the specific category of tuberculosis patients and the choices of regimens are not prioritized.

Treatment practices.

Patients are mostly treated by "conventional" regimens on an ambulatory basis and oral drugs are self administered by the patient. In some States (mostly in the South of the country) the regimen of HT is rarely utilized due to the reported high frequency of side effects. There, most patients are treated with HE for 18 months or SH twice a week. In some States of the North where thiacetazone is well tolerated, the drug is not supplied in sufficient quantity because of shortages in the national market attributed to the low profit margin on the drug for the pharmaceutical companies.

SCC regimens for pulmonary smear-positive patients are theoretically implemented in approximately fifty percent of the districts in the country, but in reality only a minority of patients are treated with SCC so far. SCC is being implemented slowly, mainly because the expansion of SCC has not been given high priority in the NTP. The selection of patients eligible for SCC observed during the review is quite strict, probably because the medical officers of the DTP have doubts about the compliance of patients in self-administration of the SCC regimens. SCC drugs are often kept at the DTC or selected PHIs and patients living far away cannot come twice a month for the drug collections.

The treatment is usually prescribed by a medical officer of the DTC or PHI, and provided free of charge. Anti-tuberculosis drugs for the recommended regimens, in particular for SCC, are periodically out of stock, reducing the motivation of the patient to regularly attend the institution and contributing to the prescription of a non standardized regimen. Patients attending private clinics are required to pay for their medications. They may go to governmental institutions when they are unable to continue to pay for treatment, but do so only when they are very sick. In a limited number of situations, treatment may be supported by voluntary organizations. Often when there is a shortage of one or more drugs in the health centre, patients are required to buy the missing drugs. In one State, streptomycin, part of the "conventional" regimen, was presently missing in most centres visited by the review team due to a 50% budget reduction from the previous year's budget.

Patients with severe forms of tuberculosis (e.g. meningitis), those with complications of tuberculosis (e.g. pneumothorax, hemoptysis), those with tuberculosis complicated by other diseases and failure of an initial regimen requiring retreatment are hospitalized. Places of hospitalization are referral hospitals including sanatoria and medical colleges. Seldom are tuberculosis patients hospitalized in CHCs or district hospitals. Hospitalized patients frequently receive "conventional" chemotherapy that has low efficacy for critically ill and retreatment cases. Existing hospital beds for tuberculosis are utilized for advanced disease and not fully utilized to prevent treatment failure. Hospitalized patients often receive weak regimens and the beds are therefore not utilized in a cost-effective manner.

In the DTC, drug collection is done once a month for "conventional" therapy and twice a month for SCC regimens. The frequency of drug collections by the patient is similar during the initial and the intensive phase of chemotherapy. Streptomycin is administered in the health institution nearest to the patient home or by a private nurse. Usually the patient does not see the medical officer during the follow-up. He may be asked to see the MO if he has drug side effects. The monitoring of side effects is not systematic and there is little information regarding the percentage of patients who may have experienced major side effects.

Guidelines for changing regimens during chemotherapy or for prolongation of the duration of a regimen have not been issued by the NTP, creating confusion, particularly for MOs in the PHIs. Unnecessarily long conventional regimens are a burden for the patient, causes an unnecessary workload for the staff, and results in drug wastage. The decision to discharge from treatment is made by the MO on the basis of the treatment card and on the clinical condition of the patient. Criteria for discharge from chemotherapy are not clearly specified in the NTP manuals. The patient is permitted to stop chemotherapy when he has completed 80% of his prescribed regimen. If he has not completed such a course, he has to continue the treatment for the duration of time for which he has not collected drugs. Due to the high incidence of defaulting, most patients receive unnecessarily long regimens. In addition, the definition of treatment failure is not clearly specified nor is practice uniform among MOs working in the PHC centres with regards to how to manage a failure case.

After treatment completion and discharge, the patient is instructed to return every 3-6 months for follow-up. This practice is unnecessary and results in wasting of effort for both the patient and health staff.

Treatment organization.

Smear examinations are not repeated during conventional chemotherapy, to confirm that the patient is really sputum negative or to determine sputum conversion in smear positive patients. For SCC regimens, NTI recommendations do not require sputum examination at the end of the intensive phase of chemotherapy nor are criteria specified for prolongation of the 2 months initial intensive phase if the patients remain smear-positive. Smear examination after the initial intensive phase of SCC is required in some centres participating in the Tuberculosis Research Centre operational trial, but is done in approximately 20% of the patients only. The insufficient monitoring by sputum examination during chemotherapy does not allow for evaluation of the outcome of the initial intensive phase of SCC chemotherapy. Patients who are still smear-positive at the end of the initial phase should receive special supervision by the DTP staff because they may not have strictly adhered to the prescribed medications. These patients may still be cured by the same regimen for new cases if the drugs of the initial intensive phase are continued for an extra month and the staff fully supervises the patient.

National policies require that pulmonary patients be monitored by x-ray examination after six months and at the end of conventional chemotherapy. This requirement is not necessary in smear-positive patients and is not cost-effective in smear-negative patients. In practice, only a fraction of pulmonary cases are followed up by chest x-ray films in the DTP. Extrapulmonary tuberculosis patients are monitored by physical examination and by appropriate clinical tests.

The decentralization of the treatment of tuberculosis patients to PHIs, as recommended by the NTP, is not fully utilized for the administration of SCC regimens. The lack of decentralization results in a high percentage of dropouts. A significant percentage of patients diagnosed in DTCs are defaulting the first drug collection. The treatment card is not opened nor are the name and address of the identified smear positive cases in the community communicated to the PHI closest to the patient's home to retrieve the patient. Name and address of patients under treatment by the DTC or other institutions are also not routinely communicated to the PHI.

In PHCs, the MO at the beginning of treatment and the pharmacist during follow-up should provide patient motivation. At present, the same effort is made for all categories of patients, without sufficient focus for smear-

positive cases of TB that are the priority for cure. In DTCs, the DTO and MOs should provide motivation at the beginning of treatment and the treatment organizer should do so during the follow-up. Sometimes, in training and demonstration centres, health education and motivation is provided to small groups of patients. There is no formal monitoring of the effectiveness of such practices. There is no special effort to re-motivate patients who are still smear-positive at the end of the initial phase of SCC, when there is still a high probability of smear conversion and cure if the drugs are taken regularly. Effectiveness of health education practices among the patients and among the community are seldom evaluated and health education material is rarely available among patients, family members and health staff. Not enough emphasis is put on informing the patient and the health staff about the importance of sputum examination.

Follow up of defaulters is not practical because the staff is required to take action for a large number of patients, without focusing on those who remain smear-positive during chemotherapy. The current guidelines recommend that priority be given to sputum positive patients, leaving to the DTO the decision of excluding sputum negative patients from defaulter action. If home visits cannot be done, guidelines require that letters be mailed twice: after three days of defaulting and after 11 days if the patient is still delinquent. During the review it was found that letters are the most common action to retrieve defaulters. However, a large number of patients provide incomplete addresses and therefore reminder letters cannot reach them. In the PHC, the multipurpose health staff are sometimes asked to retrieve the patients, but such action is probably not stressed enough by the medical superintendent and Chief Medical Officer. The village health worker is often not informed about the TB patient(s) living in the village. The PHC is also not systematically informed by the DTC about new patients diagnosed and remaining under treatment by the DTC or hospitals.

The reasons for defaulting are well identified by the tuberculosis programme staff. Among the most important is the fact that the patient loses interest once he becomes asymptomatic. Disruption of drugs stock, incomplete provision of the first line drugs for "conventional" and SCC, long waiting time, inability of the system to adjust to the patient needs, distance of DTC or hospitals from the patient's home are the other most common reasons for defaulting. Some patients go to a health institution different from where they are registered with the hope of receiving better care. This increases default as well as making it more difficult to retrieve them. The DTC and other specialized institutions do not use auxiliary staff (MPHW) to retrieve defaulters and do not inform PHC of the existence of patients on treatment from that area.

Among defaulters, approximately 30% to 50% miss drug collections before the fourth month of chemotherapy. 5% of patients default after diagnosis is made and before therapy is initiated. In some instances, the patient is not informed that he has tuberculosis and should be treated. Lack of motivation of staff, weak leadership of the medical officer and little accountability to the chief medical officer for tuberculosis have been identified by the supervisory teams as additional reasons for patient defaulting.

In the policies of the NTP there is no target for treatment completion and cure of pulmonary smear-positive patients. In such patients the fatality rate is known to be high and irregular chemotherapy leads to drug resistance. The present policies and practices are insufficient to reduce the spread of the infection, particularly of drug resistant mycobacteria, and the mortality due to tuberculosis. The observation of the assessment teams show that the TB programme objectives are not efficiently prioritized. The existing health infrastructure and resources available are not fully utilized to sterilize smear-positive patients as quickly as possible. In a significant proportion

of the sources of infection diagnosed by the DTP, the chemotherapy is not started, and a large percentage of smear-positive patients put under treatment drop out during chemotherapy.

The decentralization of the programme is not achieved. Guidelines for patient management are not present at the level of peripheral health institutions (PHC and CHC for a population of 100.000 to 200.000) where most of the patients could benefit from the existing health services. Medical officers working in PHCs and CHCs are generally not trained for the proper management of the tuberculosis patient. Supervisory visits to PHI from DTC and chief medical office are not targeted to improve treatment outcomes.

Conclusions:

NTP policies and procedures on treatment do not reflect the WHO recommended emphasis on short course chemotherapy and patient registration systems which facilitate the monitoring of completion and cure rates of patients on anti-tuberculosis treatment. The tuberculosis programme at the delivery level does not adequately emphasize the importance of treatment completion as the main index for programme evaluation. During the programme review, the teams observed that DTP practices depart from what should be done to effectively treat tuberculosis patients. Service delivery focuses on case finding activities and not on treatment completion and cure. Tuberculosis staff are not optimally utilized to enhance treatment completion activities. Additionally, there is no good system to evaluate treatment results. NTP policies and procedures should be revised to ensure that the most efficacious and current treatment regimens are recommended, including fewer regimens and short course regimens where appropriate. Registration systems should solicit data to monitor completion and cure rates, with particular focus on smear-positive tuberculosis patients. The main goal of the NTP should be to ensure that patient completion of anti-tuberculosis treatment and cure be reflected in all policies and procedures and that such be carried out in the current integrated health care delivery system. Guidelines for treatment organization are attached in Annex 4.2.

8. PROGRAMME MANAGEMENT

8.1 CASE NOTIFICATION

Tools for programme monitoring are the treatment card, the laboratory register, the master book of treatment cards (MBTC), the cross index card, the patient identity card and the report on treatment results. The use of register books and report forms is in accordance with the NTP guidelines in DTCs where the statistical assistant is in position and has been trained at NTI. However, training courses have been rarely repeated and trained staff have been transferred to other programmes within the district. The format of the treatment registers is not always standard, as they are copied by hand and not printed, and the content does not include all the data required to analize the results of treatment. The card is sent from the PHI to the DTC when the patient completes treatment, defaults or dies, so the MBTC is the only source of data on treatment left at PHI level.

The usefulness of the recording and reporting system does not appear to be well known at all levels of the system. Consequently, evaluation of programme outcome and actions are missing, and the evaluation by cohort analysis of results of treatment is often not done. Cross checking of patients registered in the laboratory register, the treatment card, and registrations in the MBTC is not operating efficiently. Therefore no action is taken for smear positive patients registered in the laboratory register who default from the first drug collection, data on initial defaulters are not available and the information in the cards and MBTC is not complete.

Conclusions:

The current reporting and recording system for the NTP is cumbersome and does not address the main WHO recommended objective of the programme, i.e. the monitoring of the cure rate among smear-positive cases of tuberculosis. Cohort analysis does not cover all smear-positive cases diagnosed and is not done at the PHI level. The current NTP system of registration and notification should be revised to facilitate recording of essential data, such as previous history of TB treatment, and emphasize the collection and cohort analysis of treatment results as the main indicator of programme effectiveness.

A printed copy of the laboratory register and patient register books should be made available to each PHI implemented to provide tuberculosis care. These registers should be kept by a PHI staff trained in record keeping and should be supervised at least every two months by the DTC supervisor. Supervisors should cross check the records in the registers to assess the consistency of the data. Standardized reports on the indicators of programme performance should be filled out at the end of each quarter and forwarded to the DTC. The DTC will consolidate the reports from the PHIs and forward them to the state TB Office. DTC team supervisory visits to PHIs should be prioritized on the basis of performance.

8.2 SUPPLIES AND TRANSPORT.

Anti-tuberculosis drugs

Anti-tuberculosis drugs used by the NTP are manufactured or compounded by pharmaceutical companies within the country. In principle, 50% of the anti-tuberculosis drugs for the NTP are purchased by the national government and 50% by the States. The national government negotiates with the states its financial contribution for drugs based on the capacity of the State to complement the central government contribution. The amount of drugs needed by each state is determined annually by the central unit from the number of patients reported the previous year, the population, and the requests received from districts. These requests are initially scrutinized at the state level. The central unit negotiates the purchase of drugs with the pharmaceutical industry but it must buy from semi-public corporations as long as the drug price is no more that 20% higher than the price of private companies. The distribution of drugs to the districts is the responsibility of the Medical Store Organization.

The State portion of the anti-TB drug supply is generally purchased by the District from manufacturers selected in State bids, using allotted State funds and sent to the District directly by the drug manufacturer. Monitoring of stock supply, reserve stock, and usage is left to the District. Although the districts send notification of supplies on hand, usage, and drug projections to the STO, it is unclear whether analysis of usage patterns is regularly undertaken at the State level. Facilities are likewise unaware of drug supplies available in neighboring facilities or institutions.

At the district level, the DTO usually estimates the needs of anti-tuberculosis drugs on the basis of the previous year's consumption. He receives the drugs purchased directly by the central government and the budget allotted by the state through the chief medical officer. In some situations, the budget obtained from the State to purchase anti-tuberculosis drugs was sufficient for only a fraction of the needs, due to increases in drugs costs (approximately 20% compared to the previous year). In some districts, the funds were sufficient, and if additional funds were necessary, they could be requested from the state. In some instances, shortages were corrected by using funds from TB associations, Interrupted supply of some

anti-tuberculosis drugs at district level were noted as being due to late or incomplete supply by the production laboratories of approved orders or due to the absence of reserve stocks at the state level. The state does not purchase or receive drugs directly nor does it maintain a buffer stock.

The rifampicin used by the NTP is not a combination capsule. Fixed dose combinations of rifampicin with isoniazid, and with isoniazid and pyrazinamide are however available in the market. The quality of such single drugs and combination drugs is not currently being monitored by the NTP.

Conclusions:

Ensuring an uninterrupted supply of anti-TB drugs to the tuberculosis patient should be a key function of the national and State tuberculosis programmes. Shortfalls in funding and delay of drug supplies from the pharmaceutical industries can be compensated by 1) closer monitoring of usage patterns, drug purchase projections and stocks by the STO and 2) establishing a buffer stock at the State level sufficient to ensure at least a 6 month supply of uninterrupted drug distribution to the districts. Similarly, districts and PHIs should maintain internal buffer stocks of three months as an additional preventive measure. Estimations of the amount of buffer stock should be based on the number of patients reported during the previous year. In addition, drug quality should be monitored by the National Unit and the States through a selected scientific institution.

Transport

The non-availability of road worthy vehicles and poor budget allocations for fuel have been cited as reasons for limiting the number of supervisory visits by the DTC team to PHIs. At District level, fuel quotas were clearly insufficient, in view of the increased number of PHIs to supervise and distances to cover. As a result, supervision of PHIs is not done with the frequency required, or several PHIs are supervised in the same trip with insufficient time allotted to each one. Adequate provision of fuel should be provided to the DTC for supervision, and transport should be provided to district supervisors based at subdivisional level to reduce milage and fuel costs.

8.3 SUPERVISION, MONITORING AND EVALUATION

According to NTP policy, the District Tuberculosis Officer and his team of laboratory technician, x-ray technician, and treatment officer, etc. are responsible for the supervision of all personnel within their District involved in tuberculosis activities. The team is expected to visit each of their PHIs on a quarterly basis. They are to evaluate diagnostic and treatment procedures, validate laboratory results, monitor record keeping activities, check on defaulter actions taken, and monitor anti-tuberculosis drug supplies and support equipment. In addition to their supervisory duties, the team is expected to do on-the-spot training and/or retraining of staff, collaborate with other disease control programmes on topics of mutual interest, and offer continuing education to the general public. Supervisory checklists have been provided by the NTP to guide the supervision of DTCs and PHIs. At PHI level, Medical Officers have been made responsible for the supervision of laboratory technicians and multipurpose health workers.

When the NTP was operationalized in 1962, the District demographic unit was designated as the basic unit for the NTP. All NTP activities were conceived and organized at the District level. In the three intervening decades, the District has grown in population, and the number of government health services has grown at least in proportion to the population growth.

It is increasingly difficult for the DTC team to operate under the organization conceived thirty years ago, to feasibly supervise and manage at the District level. In one District visited, with a population of 4 million, 119 out of 148 Peripheral health institutions have implemented the DTP. The DTC staff would have to make 20 visits per month, supervising 2 facilities per trip in order to provide quarterly coverage for its implemented centers. This schedule of activities does not include the general hospitals, voluntary organizations, etc. which also treat tuberculosis patients and should benefit from regular supervision.

The assessment team noted that the District Tuberculosis team did make visits to PHIs. The quality of the visits was difficult to assess, and the frequency and regularity of the visits were difficult to validate, as supervisory reports were not available for scrutiny. Records were not in order at facilities where recent supervisory visits were noted.

Alarmingly, there has been a steady decline in the proportion of PHIs supervised by the DTC team, from 51% in 1983 to 41% in 1991. In 1987 only 84% of functioning DTPs sent quarterly reports. Of these only 72% (60% of functioning DTPs) gave information on supervisory visits. Of the 60% of DTPs giving information, they had supervised only 45% of their PHIs. Thus only 27% of the PHIs have been reportedly supervised. The quality of the supervision is not known (5).

Currently, supervisory visits are primarily used to evaluate record maintenance, laboratory performance, assess defaulter retrieval activities, and monitor the supply of anti-tuberculosis drugs and other equipment. Not only are the supervisory objectives poorly fullfilled, but very little time is devoted to the evaluation and supervision of programme performance with regard to the accuracy of case-finding and to patient completion of treatment.

The National Tuberculosis Institute (NTI) has been responsible for the monitoring of the National Tuberculosis Programme since 1978. Information on DTP activities is recorded through a system of records kept at the facilities and periodic reports sent to the NTI. Peripheral health institutions report case finding and treatment activities on a monthly basis to the DTP. The DTP prepares quarterly and annual reports for the NTI, inclusive of data received from the PHIs involved in tuberculosis activities.

Programme monitoring and evaluation has been largely limited to review and analysis of notification data and regularity of reports. The current information system does not provide for the monitoring of treatment outcome or programme outcome indicators. Management indicators and monitoring procedures focus attention on case finding but exhibit very little emphasis on case treatment and cohort analysis. Additionally, patients who are hospitalized in the more than 40,000 tuberculosis hospital beds are not registered in the NTI information system. Likewise, the large number of patients receiving initial care through the private sector are not registered with NTI. Consequently, it is estimated that less than 57% of all cases of identified tuberculosis are registered with the NTI (1).

In 1991, only 378 districts out of 438 with DTPs had registration in place (86.3%). Of those with DTPs, only 278 out of 378 sent reports (74%). Of the DTPs which reported to the NTI, they only received reports from 8502 out of 12,338 PHIs. Results from the 1987 "In Depth study on the NTP of India" (1) showed a general lack of awareness among tuberculosis staff of the importance of records and reports. Very few officers have readily made use of them. Data in the reports was not useful for programmme management activities. Supervising officials rarely checked records and reports or gave guidance regarding their proper maintenance. Reports were very often

incomplete and unreliable. Although on site evaluation of case management is reported, it is acknowledged by supervisors that the monthly and quarterly reports sent to the DTC are not analyzed nor are the sending institutions given any feedback as to performance as reflected in the written reports.

Conclusions:

There needs to be a clear emphasis placed on supervision if the NTP programme is going to succeed. Tuberculosis programme personnel need to be retrained about supervisory methodologies as well as supervisory content which emphasizes programme performance parameters. In order to address the increase in population and health care facilities at the periphery, a medical officer or treatment organizer and a laboratory supervisor should be added to the District Tuberculosis team at the sub-divisional level (about 500,000 population) in order to facilitate decentralization of supervision, staff training, monitoring and evaluation, and management of tuberculosis programme activities at the level of PHIs. To reduce travel time and cost, these staff should be based in a hospital or X-ray centre and they should be provided with transportation.

Monitoring of case finding and treatment results has not been prioritized, is still centralized and is not used at health facilities to evaluate the quality of programme delivery and implement corrective actions when necessary. PHIs management staff should be retrained on monitoring and evaluation methodologies. They should be taught to analyze their own facilities performance indicators and to take corrective action promptly. DTC, State and national staff should analyze the quarterly and annual reports received and provide feedback to the health facilities on the priority indicators of programme efficacy.

8.4 EDUCATION AND TRAINING

Since 1962, the National Tuberculosis Institute (NTI) at Bangalore, India has been the main training institution for tuberculosis programme staff. The various members of the District Tuberculosis Center (DTC) team (medical officers, x-ray technicians, laboratory technicians, pharmacists/treatment organizers, and statistical assistants) undergo a 10 week training program at the facility, with special emphasis on their areas of responsibility. The NTI also conducts seminars for state tuberculosis officers, university faculty, and district medical officers, as well as refresher courses for DTC staff.

In theory, in addition to NTI, the State Tuberculosis Training and Demonstration Centers (STTDC) are responsible for training BCG supervisors, orientation training of health visitors, and training of medical students and ancillary health care providers on the clinical aspects tuberculosis control. Continuing education for the private physician is often undertaken with assistance from the Indian Medical Association and voluntary organizations.

The review teams found, however, that the training given by STTDCs was neither comprehensive nor consistent with NTI policies and procedures with regards to diagnosis and treatment recommendations, i.e., x-ray reading, procedures for procuring and preparing sputum for smear microscopy, treatment regimen recommendations, etc. Training materials were not available for scrutiny. Instruction in the STTDC is provided on the basis of observations of clinical procedures, focusing on clinical aspects rather than programme operations.

Since the emphasis on primary health care and the push for integration of health services, medical officers and MPHWs have, in principle, become part of the tuberculosis control effort. The training and orientation of these health personnel in NTP policies and procedures varies widely. In some districts, the DTO and his staff provide systematic, but brief (two-day) training to medical officers and MPHWs using NTI training materials. In other areas, the training has been delegated to institutes of Public Health which provide general courses ranging from one year to eighteen months for health workers and one month for medical officers, where the tuberculosis content is a component of the course curricula. Medical officers of PHCs are also expected to train their staff in tuberculosis activities. Many of them, however, have yet to be trained themselves. The majority of medical officers interviewed in the field stated that they did not carry out any training activities for their staff.

Since 1962, over 4,800 team personnel or roughly 900 full teams have been trained by NTI staff. However, as the number of districts implemented has increased, and as senior personnel are promoted or attain superannuation, not all of the district teams currently have a full complement of trained persons. As of 1991, only 24% of DTCs had a fully trained team, while 66% had the services of a trained district tuberculosis officer (DTO), 76% had trained x-ray technicians, 78% had trained laboratory technicians, 88% had trained treatment organizers, and 59% had trained statistical assistants (13).

Conclusions:

Training is vital to the successful implementation of the review team's recommendations for the NTP. Training materials must be developed to reflect the proposed changes in programme policies and procedures. The needs for training of tuberculosis personnel for DTCs, PHIs and other health institutions exceeds the present training capacity of the NTI. The current NTP training should be descentralized by utilizing the existing state training facilities, medical colleges, public health institutes and tuberculosis-oriented voluntary agencies to augment training efforts. These institutions should receive NTP training materials and "train the trainer" courses to maintain standardization of training efforts. International and national training opportunities should be made available for the different levels of tuberculosis programme staff.

The NTP manuals should be revised to reflect the recommendations of the Review, and standardized educational materials should be developed by NTP for different categories of personnel involved in tuberculosis control activities (including medical students, general practitioners, etc. in private practice) and for patient motivation.

9. PRIVATE SECTOR

According to a study of 102 private doctors practicing in Bombay, 60% to 70% of patients bypass the public health system and seek care by private physicians when they become chest symptomatics (6). Review team field observations suggested that the proportion of patients seeking care in the private sector was slightly lower than evidenced in the Bombay study, but still represent about probably half of the new TB cases. Although many of those patients later move to the public sector, private practicioners have a major role and their management of TB cases influences also the results of the NTP. It appears that private physicians do not adhere to any set regimen for TB care. As in the public sector, dependence on x-ray diagnosis was evidenced. Case finding methodology and treatment regimens for tuberculosis patients vary widely and are usually more costly than regimens recommended by the NTP. Patients are usually given a prescription and sent to a pharmacy

for drug purchase, with very little monitoring of patient compliance. Defaulter action is rarely taken.

The training of general practitioners is currently not adequate and has not been updated to incorporate recent advances in knowledge and strategies of the NTP. The capacity and organization of medical associations (IMA, Anti-tuberculosis associations) have not been tapped to provide continuing education and programme awareness to the private sector. Interviewed members of the Indian Medical Association (IMA) at State and District level showed strong support for the NTP efforts. IMA members seemed well aware of the issues and challenges facing tuberculosis control and were willing to utilize the organization to promote tuberculosis health education efforts and distribute educational materials to its members on the topic of TB case finding and management. The use of health education messages targeted towards both the private physician and the consumer regarding correct treatment regimens and the importance of completing treatment should be tested as a method to standardize care provided by the private sector.

Conclusions:

A large share of the provision of health services in the country, including tuberculosis diagnosis and treatment, is done by private practitioners. They are, however, not currently included in the NTP system, either for notification of patients or standardization of diagnostic and treatment procedures. The role of the private sector in the care of the tuberculosis patient needs to be further clarified by the NTP. If indeed it is found that a large share of tuberculosis patients seek care in the private sector, improved training in medical schools and education of private practicioners must be implemented to ensure proper diagnosis and treatment and augment cure rates for patients under private care.

10. RESEARCH

India has a long history of tuberculosis research to improve programme delivery and treatment efficacy, and much of the information and experience obtained has been applied successfully in other countries. The research institutions can be utilized to analyze the functioning of the programme and to test alternatives to improve programme results, in particular organizati of treatment delivery to increase the cure rate. To ensure that the studies provide relevant information for programme improvement, and that this information is opportune and utilized, this research should be planned and supported as an integral part of the NTP. Some operational research projects have already been discussed before the Review mission. Two major institutions currently involved in TB research are briefly described below.

The Tuberculosis Research Centre (TRC) in Madras was established in 1956, under the joint auspices of the Government of Tamil Nadu, the Indian Council of Medical Research, the British Medical Research Council and the World Health Organization, for studying initially the efficacy of domiciliary chemotherapy, in comparison with conventional sanatorium treatment. The centre was taken over by the Indian Council of Medical Research in 1965 and made a permanent research establishment. It established that a well-organised domiciliary chemotherapy with a daily regimen of isoniazid plus PAS produced results closely approaching those obtained in sanatorium with the same regimen; a satellite study established that there was no extra risk to the close family contacts from the infectious case after the start of treatment. Subsequently, the Centre investigated various regimens of chemotherapy in controlled clinical trials, backed up by in-depth laboratory investigations and solid statistical methodology. Clinical trials of various regimens of shortcourse chemotherapy that would be suited to Indian conditions were carried out, and more recently a study on implementation of

shortcourse chemotherapy under programme conditions in 18 districts selected from different parts of the country was initiated. In recent years, a strong department of immunology and cardiopulmonary function have been added to the Centre. Finally, the epidemiological unit that undertook a large trial of BCG vaccine in South India has now been integrated with the Centre. The Tuberculosis Research Centre has the capacity for undertaking training programmes that could complement the efforts of the National Tuberculosis Institute in Bangalore.

The National Tuberculosis Institute was established in Bangalore in 1960 with the objective of developing a suitable programme for tuberculosis based on operational research studies, training medical and paramedical workers for the District Tuberculosis Programme and monitoring the Programme through periodic reports received from the Districts. Based on studies on awareness of symptoms and action taken and on the Madras TRC studies demonstrating the efficiency of domiciliary chemotherapy, the NTP was evolved and launched at the NTI. In subsequent years, operational studies were undertaken on methods to improve case-finding, techniques for enhancing patient motivation and thereby enhance case-holding efficiency, and programme organization. Concurrently, large-scale field studies were initiated to provide information on epidemiological indicators such as prevalence and incidence of disease, fate of newly-diagnosed cases under programme conditions, and on the prevalence of tuberculous infection and infection with other atypical mycobacteria. Thereafter, and in view of conflicting reports about the efficacy of BCG vaccine, the largest BCG trial ever undertaken was launched in Chingleput, South India, to determine the efficacy of two strains of BCG vaccine at two different strengths.

Conclusions:

As a step towards the reorganization of India National Tuberculosis Programme activities, the research potential of the various research institutions should be evaluated in light of the findings and recommendations of this review and needs of the NTP for operational research studies. Operational research to test the feasibility and results of different technical and organizational strategies to be adopted by the tuberculosis programme should be an integral part of the revised tuberculosis programme.

11. SITUATION ANALYSIS

Even after three decades of National Programme activities, the tuberculosis burden on Indian society remains enormous - something on the order of five million premature deaths in a decade, half of which are among women, mainly in the reproductive age. This mortality must affect at least twice that number of Indians with consequent lowered productivity, disability and perpetuation of poverty. Excellence in research, early successes proving the advantages of some modern treatments, availability of powerful and effective antibiotics, a well established TB structure at the State level and, in the last two decades, extensive development of the institutional structure for primary health care in the rural areas, have not yielded the progress against the disease which India could have expected. Decline in the annual risk of infection (and in incidence) has been agonizingly slow in many areas. Well over half the population is infected with TB and the risk of infection is far too high at between 1 and 2% per year. An aging population structure, increasing HIV prevalence and apparently rising levels of drug resistance mean that without a reoriented and vitalized public TB control effort the disease will pose an increasingly serious health and developmental constraint for several decades to come.

The main factors to be addressed in making real progress against TB fall in four main categories - organizational, managerial, technical and developmental. Elements of the present health care system, and many parts of the current TB control programme provide the basis for implementation of major improvements. Strengthening and reorientation of policy and program execution in each of the problem areas offer sound prospects of improvement in curing TB patients in numbers which will result in 8-10% annual decline in the risk of infection and effectively halve the tuberculosis burden in about a decade while ensuring much lower disease and infection rates for decades into the future.

The state TB control programs are well structured and have direct intervention capabilities at the district level and below in about three quarters of the country. In contrast, the national TB control programme has languished with ineffective terms of authority and budgets and an exceptionally low executive position within the Ministry of Health for such an important disease. Monitoring, critically examining and adjusting national policy for effective state performance has consequently atrophied.

In the absence of a strong central Ministry unit, power for TB policie. has been ceded to the National TB institute (NTI) in Bangalore. The NTI has had preeminence in training and some types of research for TB but now suffers serious institutional weaknesses. Budget shortfalls, unfocussed direction of research, training program content which is not replicated at state level and lack of experience with making and implementing policy have left a gap in national TB leadership. The absence of a national policy body for TB at central level, supported by a strong executive TB unit within the Ministry, has meant that no revision of policy has been made in spite of repeated evaluation showing poor results, and therefore NTI has not changed or developed alternative TB Program procedures.

Further, the content of their training has stagnated in relation to recent TB control success elsewhere. In the absence of a strong central program, NTI has been forced to assume program management and standard-setting functions which are inappropriate for a training/research institution. This is particularly true as NTI does not have the staff and executive authority to monitor and enforce compliance of the states with policy.

Below the State level, TB has been indicated as a priority for integration into the key health services. However, the TB program's effective cooperation with health service providers at the primary level and willingness of the providers, under current policies, to devote substantial attention to TB, remains doubtful at best. The ambivalence resides both in lack of strong and focussed national program direction and in the absence of policies responsive to the legitimate interest at the local level for a clearcut, standard, easy to follow program which is effective for cure. Strong direction, some decentralization below the district level, training, increased funding and a comprehensive policy package are needed.

Technical problems confronting the NTP are both historical and the result of some isolation. There remains traditional emphasis on case-finding activities when only a minority of discovered cases are being cured. Technical practices emphasize radiographic methods which are sensitive, but not specific, rather than concentrating on high-quality microscopy which with a good quality control system can be both specific and sensitive. Too frequently, one sputum smear is examined rather than several, leading to inappropriate treatment of infectious cases. Microscopes are often monocular and of poor quality, training is uneven and quality assurance systems seldom function. Protocols for appropriate use of radiography and clinical diagnostic methods need to be prepared and disseminated.

Treatment for diagnosed patients is chosen from too many regimens and adequate short-course chemotherapy is yet infrequently used and is completed in only a minority of cases. Repeated sputum smears during the course of treatment are not regularly taken to monitor effectiveness of therapy. Provision of services is often too remote or inconvenient to encourage patient compliance, and providers lack adequate motivation and training for patient supervision. Improved treatment protocols, training, adequate supplies of only SCC drugs, and adaptation of practices to provide some degree of supervised initial chemotherapy, whenever feasible, are needed.

Recording and reporting procedures do not permit rigorous supervision of the system as a whole or at the institutional level. Case definitions are not adequate. Criteria for completion of treatment and discharge do not exist. Laboratory registers and patient treatment registers do not contain the information necessary to perform cross checking or to monitor the performance of states, districts, blocks or individuals providers. Conversion status of smear positive patients cannot be documented. Cohort analysis to ensure and measure program effectiveness cannot be satisfactorily done with present registry formats and procedures. Therefore, adaptation of existing TB Program policies and resources to implement and improve recording and reporting system is required.

Developmental constraints include both institutional and financial issues. Operational research to test and improve on program performance is not currently an integral part of the TB program. Training materials and objectives are in need of revision to support a revitalized program and pedagogical content may need improvement. Medical college curricula need additions to provide both theoretical and practical exposure to the elements of TB control as doctors graduating now will continue to see TB throughout their working careers. Present private medical practitioners need to be educated about modern treatment and policies of the program. This can be done through existing NGOs. To do this, strengthening of the NTI, of the state level training centre, and studies and technical assistance at both the national and state levels will be needed. Opportunities for overseas training and experience will accelerate adoption of effective new experience in TB control elsewhere.

The government has recently decided to increase funding for TB control and is for now continuing to provide for the treatment of all TB patients diagnosed in the public system. The present high number of overdiagnosis and treatment of patients which now appears to be occurring offer scope for savings in an improved program. Overall though, financial resources for TB appear to have declined in real terms in recent years because of inflation and rising import costs, despite the government's recognition of the trend and efforts to counteract it. Moreover, only a fraction of patients today requiring treatment receive it in full.

A strengthened program will require increased resource allocations at both the central and local levels for drugs, supervision (including transport), training and operating cost. Given the demonstrated cost-effectiveness of TB control programs compared to other health sector interventions, revision and expansion of India's TB program with external financial assistance would appear to be fully justified.

12. RECOMMENDATIONS

1. The structure of the National Tuberculosis Programme should be strengthened by 1) establishing an apex policy making authority and an executive task force with managerial functions to implement programme reorganization, and 2) upgrading the central tuberculosis control unit in the Directorate to provide strong leadership and enhance the efficiency and effectiveness of the National Tuberculosis Programme.

2. The quality of patient diagnosis should be improved by 1) using three smear examinations to detect infectious cases among symptomatics before deciding on patient treatment, 2) ensuring the quality of microscopy with adequate equipment, training and quality control, and 3) establishing criteria for diagnosis by radiological and clinical methods.

3. National and state tuberculosis programme resources should be directed to ensuring cure of tuberculosis patients, giving priority to infectious cases of tuberculosis by 1) adopting short-course chemotherapy, 2) establishing criteria for treatment completion, cure and discharge from medical care, and 3) ensuring an uninterrupted supply of drugs of good quality.

4. The current NTP system of registration and notification should be revised to emphasize the cohort analysis of treatment results (completion and cure, transfers, defaulters, died, treatment failures) as the main indicator of programme effectiveness.

5. Policies should be developed to ensure decentralization of treatment services closer to the community level to enhance access to care and patient compliance to recommended therapies.

6. Pilot projects should be implemented at block level to test the feasibility and results of different technical and organizational strategies to be adopted by the tuberculosis programme -- i.e., to test the capacity to implement recommendations 2-5 above.

7. A medical officer or treatment organizer and a laboratory supervisor, with the necessary transport, should be added to the existing administrative structure at the sub-district level (about 500,000 population) to strengthen tuberculosis programme management and to facilitate decentralization of supervision.

8. Training materials must be developed to reflect the proposed changes in programme policies and procedures. The current training infrastructure will need to broaden the scope of its training capabilities by utilizing state training facilities, medical colleges, public health institutes and tuberculosis-oriented voluntary agencies to augment training efforts. International and national training opportunities should be made available for the different levels of tuberculosis programme staff.

9. Operational research must be carried out as an integral part of the revised tuberculosis programme to evaluate programme performance, improve delivery of services, problem solving and obtain baseline epidemiological information to measure reduction in the risk of infection.

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S. Radhakrishna

TUBERCULOSIS PROGRAMME REVIEW

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TUBERCULOSIS PROGRAMME REVIEW - INDIA, 1992

1. EXECUTIVE SUMMARY

The Government of India, recognizing the magnitude of the problem of tuberculosis, the limited progress achieved by previous control activities and the expected increase in incidence as a consequence of the HIV epidemic has decided to give priority to tuberculosis control. In support of this decision the Government requested WHO to carry out a joint programme review together with other interested parties. A Steering Group was designated to coordinate the evaluation of the programme, as a first step to formulating a project for possible external assistance.

The review of the national tuberculosis programme (NTP) of India was carried out by a team representing the Government of India (GOI), the World Health Organization and the Swedish International Development Agency (SIDA). The purpose of the review was to evaluate present policies and practices, analyze their adequacy to reduce the tuberculosis problem and recommend organizational, technical and administrative measures to improve the programme.

The review team analyzed the available documents including epidemiological data and reports of previous evaluations of the programme, discussed with officers of major institutions involved in disease control and in training, and made field visits in three States (Gujarat, Uttar Pradesh and Tamil Nadu) to assess the programme at the State, District and peripheral levels.

The burden of tuberculosis in India is staggering by any measure. More thaN half of the adult population is infected. About 1.5 million cases are notified every year and there are probably well over 500 000 tuberculosis deaths annually. Recent trends show that the programme is not having a measurable impact on transmission and appears to function far below its potential.

The Government of India formulated the NTP in 1962. The major objectives were to prevent tuberculosis through BCG vaccination; to diagnose tuberculosis cases among symptomatics and provide efficient treatment, giving priority to sputum positive patients; and to implement these activities as an integral part of general health services. The District was the basic unit for the NTP organization.

At present, organization of the general health system has been extended to reach the community level with primary health services. The tuberculosis programme is integrated into the general health services, and treatment services are provided at the levels where medical staff is available. However, the population growth and the proliferation of public health services has made many Districts unwieldy for supervision by the tuberculosis team which is based in a single District Tuberculosis Center. Further, monitoring and training are mainly under the responsibility of the National Tuberculosis Institute (NTI), the State TB officers playing only a minor role in these important areas.

Human and financial resources are provided by GOI and the States to cover most of the needs of the programme and current policy is to provide free diagnosis and treatment. Currently available data do not allow analysis of the adequacy or efficiency with which these resources are applied, but preliminary indications and overall TB programme performance point to the need for substantial improvements. If the programme is to operate as intended and begin to make a significant impact on the disease, increased funding will be necessary, emphasizing the need for improvements in programme effectiveness and efficiency.

The present management structure at national level requires strengthening to assume leadership in redefining policies, effectively assisting States and supervising programme implementation, retraining staff involved in TB activities, administering funds, and procuring supplies. The States, which provide health services, need also to assume their responsibility in TB programme management, and will require reorganization and training of the public and non government health institutions involved in TB control.

There is little coordination between hospitals and primary health institutions in rural areas, and between the different services providing tuberculosis care in most urban areas, to ensure the management of tuberculosis patients until cure.

Improvements in the methods and management of case finding must take place. In spite of the recognized priority of bacteriological diagnosis and cure of sputum positive cases to reduce the problem of tuberculosis, a large proportion of human and financial resources is currently used to treat cases diagnosed only on clinical and radiological evidence. This practice is common both to the NTP and to private practitioners and is reflected in medical college curricula. Bacteriology is not sufficiently used to confirm medical diagnosis and criteria for initiating treatment in sputum negative cases are not well defined. As a result of not identifying correctly smear-positive and smear-negative cases, and newly diagnosed and previously treated patients, some patients may be treated with inadequate regimens. Sputum microscopy examinations are carried out with insufficient standards and microscopy laboratories are inadequately equipped. A TB laboratory network assuring equipment, training and quality control is not in place.

Rationalization of treatment is required. There are currently too many alternative treatment regimens and the conventional regimens are of unnecessary long duration and low effectiveness. Short course chemotherapy regimens of higher cost-effectiveness are slowly being implemented but insufficient priority has been given to ensuring effective treatment of infectious patients, particularly during the initial intensive phase of chemotherapy.

The present system of recording and monitoring patient identification and progress during treatment to ensure health service concentration on achievir cure of infectious cases is seriously deficient. The present system does not allow the systematic evaluation of the results of treatment at health facility or block level. Neither does the registration system permit the use of cohort analysis of patients to assess cure rate as the main indicator of programme efficacy.

Drug supplies are occasionally interrupted by lack of timely funding and of buffer stocks. Additionally, the quality of the drugs supplied is not controlled. The extensive network of multipurpose health workers (MPHW) has not been sufficiently utilized at the community level to prevent defaulting and achieve treatment completion.

The present training system relies mainly on the National Tuberculosis Institute (NTI) courses. The state-level demonstration and training centres do not function. District Tuberculosis Centres (DTCs) are not adequately prepared to provide in-service training for dissemination of policy and standards. It does not make adequate use of training institutions and NGOs at the State level to transmit current policies and procedures. The curricula at medical colleges do not stress the basic principles of TB control and there is no systematic continuing education for medical practitioners.

In spite of extensive national experience in both operational and basic TB research, alternative methods to correct the extremely low proportion of cases diagnosed with bacteriological confirmation and of patients completing the prescribed treatment and cured have seldom been implemented. The findings of previous programme evaluations have not always been applied to improve existing programme procedures, nor has adequate use of the results of research and programme evaluation been made.

Nonetheless, the basic strengths of the India TB programme are considerable. The objectives on which the programme was established thirty years ago - integration, decentralization, free services, priority to treatment of infectious cases - are still valid today. They provide a sound basis for revitalization of the national TB strategy. In addition, the tuberculosis control programme can relatively easily build on its strengths: a well defined structure which provides services within general health care in an integrated manner; a basic managerial unit at District level with Central and State Governments providing support for diagnosis and treatment; experienced training and research institutions; and, a general health care system extended to the community through multipurpose health workers. An updated and strengthened programme can expect to reduce the magnitude of the problem by about half in each 10-15 years with the consequent savings in lives, human suffering and more effective use of financial resources. This will require a political commitment, initial investment and strong leadership, plus the rapid development of an efficient national model to serve as training ground and provide operational experience to programme managers at all levels.

RECOMMENDATIONS

1. The structure of the National Tuberculosis Programme should be strengthened by 1) establishing an apex policy making authority and an executive task force with managerial functions to implement programme reorganization, and 2) upgrading the central tuberculosis control unit in the Directorate to provide strong leadership and enhance the efficiency and effectiveness of the National Tuberculosis Programme.

2. The quality of patient diagnosis should be improved by 1) using three smear examinations to detect infectious cases among symptomatics before deciding on patient treatment, 2) ensuring the quality of microscopy with adequate equipment, training and quality control, and 3) establishing criteria for diagnosis by radiological and clinical methods.

3. National and state tuberculosis programme resources should be directed to ensuring cure of tuberculosis patients, giving priority to infectious cases of tuberculosis by 1) adopting short-course chemotherapy, 2) establishing criteria for treatment completion, cure and discharge from medical care, and 3) ensuring an uninterrupted supply of drugs of good quality.

4. The current NTP system of registration and notification should be revised to emphasize the cohort analysis of treatment results (completion and cure, transfers, defaulters, died, treatment failures) as the main indicator of programme effectiveness.

5. Policies should be developed to ensure decentralization of treatment services closer to the community level to enhance access to care and patient compliance to recommended therapies.

6. Pilot projects should be implemented at block level to test the feasibility and results of different technical and organizational

strategies to be adopted by the tuberculosis programme -- i.e., to test the capacity to implement recommendations 2-5 above.

7. A medical officer or treatment organizer and a laboratory supervisor, with the necessary transport, should be added to the existing administrative structure at the sub-district level (about 500,000 population) to strengthen tuberculosis programme management and to facilitate decentralization of supervision.

8. Training materials must be developed to reflect the proposed changes in programme policies and procedures. The current training infrastructure will need to broaden the scope of its training capabilities by utilizing state training facilities, medical colleges, public health institutes and tuberculosis-oriented voluntary agencies to augment training efforts. International and national training opportunities should be made available for the different levels of tuberculosis programme staff.

9. Operational research must be carried out as an integral part of the revised tuberculosis programme to evaluate programme performance, improve delivery of services, problem solving and obtain baseline epidemiological information to measure reduction in the risk of infection.

INDIA - TUBERCULOSIS PROGRAMME REVIEW 1992

2. INTRODUCTION.

A review of the national tuberculosis programme was carried out from 9/1/92 to 9/17/92 as a collaborative effort of the Government of India (GOI), the World Health Organization (WHO) and the Swedish International Development Agency (SIDA). The purpose of the review was to evaluate present policies and practices, analyze their adequacy to reduce the tuberculosis problem and recommend organizational, technical, and administrative measures to improve the programme. The assessment included:

1. An overall description of the current programme achievements and problems,
2. An analysis of the tuberculosis burden, the programme resources and the programme structure,
3. Specific discussion of the leading issues facing the programme and their underlying causes, and
4. Recommendations for the next steps to improve the programme.

At the central level the team reviewed information relating to the magnitude of the tuberculosis problem in the country and epidemiological trends, programme structure, policies, technical norms and procedures relating to tuberculosis diagnosis and treatment, drug supply and logistics, supervision, monitoring and evaluation, education and training, coordination with other programmes and research. Meetings were held with the Ministry of Health, major referral facilities in New Delhi and voluntary organizations.

Following the review at the central level, the review participants divided into three teams to assess tuberculosis control activities at the State and District levels through facility visits and interviews with responsible staff in three selected States (Tamil Nadu, Gujarat, and Uttar Pradesh). Then the teams reconvened in Delhi for discussion of the review findings, conclusions and development of principal recommendations for submission to the Government of India. A draft summary of the conclusions and main recommendations was presented to the Secretary of Health at the end of the review.

A list of participants is attached in Annex 1, and a list of persons contacted and institutions visited as part of the review is in Annex 2.

This document summarizes the findings of the review. Background information on India can be found in Annex 3.1.

3. LIST OF ABBREVIATIONS

ADGHS	-	ASSISTANT DIRECTOR GENERAL OF HEALTH SERVICES
BCG	-	BACILLI CALMETTE & GUERIN
CHC	-	COMMUNITY HEALTH CENTRE
DGHS	-	DIRECTOR GENERAL OF HEALTH SERVICES
DHO	-	DISTRICT HEALTH (MEDICAL) OFFICER
DOT	-	DIRECTLY OBSERVED TREATMENT
DTC	-	DISTRICT TUBERCULOSIS PROGRAMME
DTO	-	DISTRICT TUBERCULOSIS OFFICER
DTP	-	DISTRICT TUBERCULOSIS PROGRAMME
EPI	-	EXPANDED PROGRAMME OF IMMUNIZATION
GH	-	GENERAL HOSPITAL
GNP	-	GROSS NATIONAL PRODUCT
GOI	-	GOVERNMENT OF INDIA
GP	-	GENERAL PRACTITIONER
H	-	ISONIAZID
ICMR	-	INDIAN COUNCIL OF MEDICAL RESEARCH
IMA	-	INDIAN MEDICAL ASSOCIATION
IMR	-	INFANT MORTALITY RATE
MBTC	-	MASTER BOOK OF TREATMENT CARDS
MC	-	MYCROSCOPY CENTRE
MCH	-	MATERNAL AND CHILD HEALTH
MO	-	MEDICAL OFFICER
MOH/FW	-	MINISTRY OF HEALTH AND FAMILY WELFARE
MPHW	-	MULTI-PURPOSE HEALTH WORKER
NGO	-	NON-GOVERNMENTAL ORGANIZATION
NRR	-	NET REPRODUCTIVE RATE
NTI	-	NATIONAL TUBERCULOSIS INSTITUTE
NTP	-	NATIONAL TUBERCULOSIS PROGRAMME
PHC	-	PRIMARY HEALTH CENTRE
PHI	-	PERIPHERAL HEALTH INSTITUTIONS
PPD	-	PURIFIED PROTEIN DERIVATIVE
R	-	RIFAMPICIN
RC	-	REFERAL CENTRE
RI	-	RISK OF INFECTION
RS	-	RUPEES
S	-	STREPTOMYCIN
SCC	-	SHORT COURSE CHEMOTHERAPY
SIDA	-	SWEDISH INTERNATIONAL DEVELOPMENT AGENCY
STO	-	STATE TUBERCULOSIS OFFICER
STTDC	-	STATE TUBERCULOSIS TRAINING AND DEMONSTRATION CENTRE
T	-	THIOACETAZONE
TAI	-	TUBERCULOSIS ASSOCIATION OF INDIA
TRC	-	TUBERCULOSIS RESEARCH CENTRE
VHAI	-	VOLUNTARY HEALTH ASSOCIATION OF INDIA
XC	-	X-RAY CENTRE

4. TUBERCULOSIS IN INDIA

Prevalence of infection. A number of studies over the past 30 years, mainly in rural southern India, have shown the prevalence of infection among children 0-9 years old to be between 3.1% and 11.2% (Table 1). In the early 1960s, more than 50% of the population 20 years and older was infected with M. tuberculosis and most infections occurred before 15 years of age. By the late 1960s there was no evidence of change in this pattern. Since that time, there is no clear evidence of substantial changes in prevalence of infection among children beyond that which might have been expected from secular trends.

Table 1. India: Prevalence of tuberculosis infection among un-vaccinated children 0 to 9 years old and estimated annual Risk of Infection (RI)

Prevalence of infection	RI	Year	Location	Source
4.9%	1.0%	1961	Tumkur	NTI
9.6%	2.0%	1969	Tiruvallore	TRC
10.1%	2.1%	1983	Bangalore	NTI
10.4%	2.2%	1984	Dharmapuri	NTI
3.1%	0.6%	1985	Bangalore	NTI
9.0%	1.9%	1989	Kadambatmur	TRC
11.2%	2.3%	1989	Thiruvelangadu	TRC
6.7%	1.4%	1989	North Arcot	TRC

Annual risk of infection. The intensity of disease transmission in the community is best reflected by the annual Risk of Infection (RI) which represents the probability of a previously uninfected individual becoming infected with tuberculosis during a one year period.

RIs calculated from prevalence studies presented in Table 1 range from 0.6% to 2.3%. These data are difficult to interpret because methods vary among surveys but they clearly indicate wide variation within limited geographical areas and provide no clear evidence of a substantial decrease of the risk of infection over the last 30 years. This stagnant situation is substantiated by two recently published studies conducted in rural areas of Southern India. One showed that the RI decreased from 1.0% in 1961 to 0.61% in 1985, equivalent to an average decline of 3.2% per year. The other study showed no decrease in the risk of infection between 1969 and 1984 (RI of 1.7% in both years). These results would be consistent with a poorly functioning programme which would be creating chronic cases of tuberculosis and drug resistance.

Because most adults were infected in their youth, a small decrease of the RI would not have any rapid impact on the prevalence of infection in the adult population. It is safe to estimate that at least 50% of the population above the age of 20 years is infected and will remain at risk of disease and death from tuberculosis for their lifetime. A conservative estimate is that, currently, the RI for India is still between 1% and 2%.

Disease prevalence. The Sample Survey of tuberculosis conducted between 1955-58 remains the major source of information used by the NTP to anticipate

the tuberculosis situation in the country. The survey showed wide variations in prevalence of disease among persons aged 5 years or more (sputum-positive tuberculosis by smear or culture), ranging from a low of 229/100,000 to a high of 813/100,000. The overall prevalence was 398/100,000.

In 1960-61 and in 1972-73 surveys conducted by NTI showed the prevalence of radiological disease to be 1900 and 1100 per 100,000 respectively. In 1990, in an area near Madras, the rate was estimated to be 1700/100,000. In the first of these studies, the prevalence of sputum-positive tuberculosis was 410/100,000 and in others studies conducted by NTI between 1961 and 1968 in the Bangalore area the prevalence of bacteriologically confirmed tuberculosis (smear or culture-positive) ranged from 337 to 406/100,000 over the age of 5 years. About half of these cases (45% to 52%) were smear-positive. In a number of surveys and studies since that time, there is no evidence of a significant decrease in TB during the last three decades and there remains a very wide range of prevalence of TB in India. In the 1972-73 follow up of the 1960-61 study, the prevalence of bacteriologically confirmed disease was 440/100,000. Two studies conducted in 1989 and 1990 in two areas near Madras in the population above the age of 15 years found prevalence of bacteriologically confirmed disease of 1090 and of 430/100,000 (58% and 69% of confirmed cases were smear-positive).

The only clear exception to this stagnant situation is recent data from the Tuberculosis Prevention Trial[1], in which a 350 000 population of South India is being followed prospectively. This study indicates a decrease in prevalence and incidence of both radiologically active and sputum-positive tuberculosis between 1968 and 1985. Most of the decrease, however, occurred during the first few years of the study. Data from 1978 to 1985 show stagnation with a prevalence about 1700/100 000 above the age of 10 years old (by X-ray or culture) and an incidence of about 450/100 000 over the age of 10 years (X-ray or culture). During the same period, 50% of all cases had bacteriologically confirmed (culture-positive) tuberculosis.

Among the many factors influencing prevalence of disease, the effectiveness of treatment is important. Poor treatment completion significantly increases the prevalence of disease. A recent retrospective cohort study conducted under programme conditions by the Tuberculosis Research Centre (TRC), Madras, illustrates the potential impact of poor treatment completion. It showed that among patients on short course chemotherapy who collected less than 50%, 50% to 79% and 80% or more of their drugs, 44%, 37% and 21% respectively were still sputum smear-positive after the end of treatment[2].

Low effectiveness of the treatment programme explains much of the stagnation in disease trends over the last three decades. Further, with the current treatment completion rate it is probable that chronic and partially treated patients represent a large proportion of patients diagnosed by the programme.

Current tuberculosis rates. Age specific incidence rates (NTI, 1974) estimates suggest that about 870 000 new smear-positive cases of tuberculosis may have occurred in 1992. This number is very similar to the 850 000 estimate obtained on the basis of incidence data from the Tuberculosis Prevention Trial[3]. If the current average annual risk of infection is 1.7%,

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[1] S.P. Tripathy, personal communication, 1992

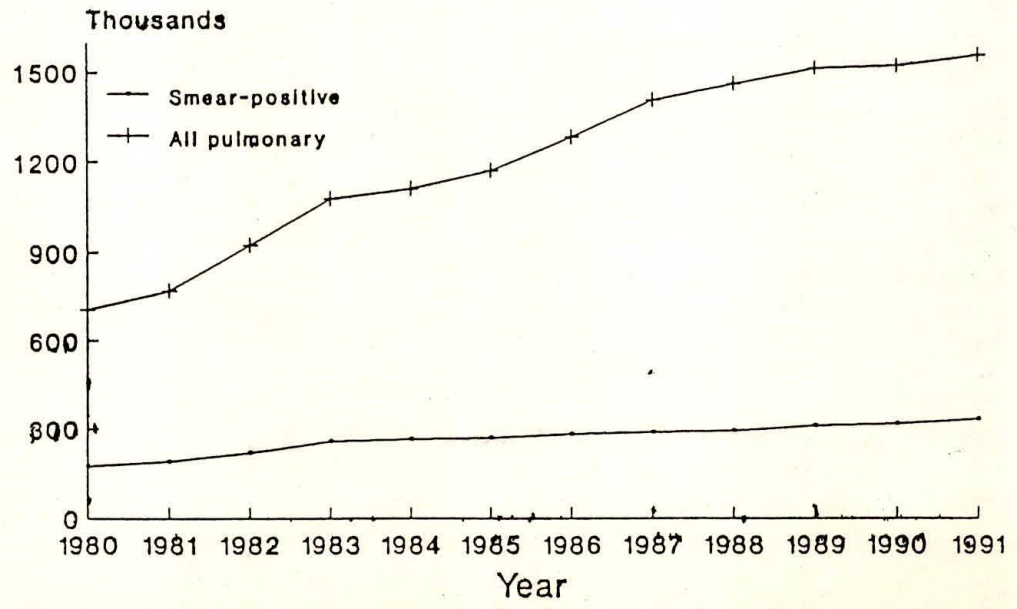
[2] TRC Annual Report, 1990

[3] S.P. Tripathy, personal communication, 1992

1.6 million new cases (all forms) and 714 000 new smear-positive cases of tuberculosis may occur annually. About a third of the total tuberculosis burden of India is borne by the urban conglomerations consisting mainly of towns, cities, and their suburbs.

Notifications. Based on the average case notification from districts with existing tuberculosis programmes (with about 83% of the population of the country), NTI estimated more than 1.5 million newly registered cases of pulmonary tuberculosis in 1991, 21% of them were smear-positive. The trend in notification, presented in Figure 1, reflects the increase in the number of districts integrated in the tuberculosis programme from 320 in 1980 to 387 in 1991, and also an increased proportion of cases not confirmed by smear examination. The proportion of smear-positive cases has decreased from 25% in 1980 to about 20% in the late eighties. Relapses, failures and partially treated patients are often inappropiately included in these notifications.

Figure 1. India: Notifications of cases of tuberculosis, 1980-1991



Extra-pulmonary cases are not reported
Source: NTI, 1992

Age and sex distribution. The majority of tuberculosis cases in India occur below the age of 45 years, with about 75% of the diagnosed cases between 15 and 44 years old. Age-specific estimates of incidence from 1974 applied to the 1992 population, would imply that about 58% of all cases today occur between 15 and 44 years old. Two thirds of the cases are estimated to occur among males but tuberculosis takes a proportionally much larger toll on young females than among young males. More than 50% of female cases occur before age 34.

Mortality. Total mortality due to TB is uncertain but by any estimate poses a huge economic burden for India. Tuberculosis mortality is estimated by NTI to have been 69 to 95/100 000 in 1961-68 and 41/100 000 in 1977-81, or over 350 000 tuberculosis deaths annually (Table 2). Data from the Survey of Cause of Deaths yield a more recent parameter by which to estimate current mortality, resulting in 400 000 deaths, about 75 000 deaths in the 15-24 age group, 95 000 in the 25-34 age group and about 160 000 deaths in the 35-44 age group. Using the 1955 Sample Survey estimates of incidence, if all cases were diagnosed and at the present treatment completion rate of 30%, there would be about 657 000 annual deaths of tuberculosis. A large proportion of these deaths occur among women and it has been estimated that maternal mortality and tuberculosis claim approximately the same number of lives. For the decade of the 1990's, any of these estimates implyes a staggering cumulative burden for the disease.

Table 2. India: Estimates of probable tuberculosis mortality

Source & year	Estimated mortality per 100 000	Annual deaths	Approximate (1) cumulative deaths 1990-2000
NTI			
77-81	41.0	346 000	3 460 000
Causes of deaths survey			
92	50.0	422 000	4 220 000
Sample Survey incidence estimates (2)			
55-58	77.8	657 000	6 570 000
"Styblo model" of incidence with 1.5% RI (2)			
92	50.1	432 000	4 320 000

(1) Mortality rates from surveys applied to 1992 population structure and cumulative burden not adjusted for age structure within the decade.

(2) Assuming no improvement from the current treatment completion rate of 30% and assuming 100% coverage of new cases.

Using the number of cases of tuberculosis currently notified by the NTP, the reported completion rate (30%), a case fatality of 10% among patients who complete treatment, 48% among smear positive-patients who did not complete treatment and 24% among smear-negative patients, it can be estimated that about 345 000 tuberculosis patients today diagnosed in the programme die. Almost all of these deaths are preventable. Increasing the treatment completion rate to only 85% would prevent close to 200 000 deaths annually, a 57% decrease in mortality.

Table 3. India: Number of Tuberculosis deaths which could be expected among cases officially reported in 1991 at different rates of treatment completion and potential reduction in mortality.

Completion rate	Expected deaths among		Reduction in mortality (all cases)	
	Smear positive	Total cases*	Lives saved	Percentage reduction
30% (current)	121 000	345 000	Base line	-
40%	109 000	309 000	36 000	10%
70%	71 000	202 000	143 000	41%
85%	52 000	148 000	197 000	57%

* Pulmonary. As extra-pulmonary cases are not reported, they are not included in this calculation

Cumulative mortality during the decade to the year 2000 will probably exceed 3.5 million deaths, an enormous burden for society. A large share of these premature deaths can be avoided with a well-functioning programme. Given the ages at which deaths from tuberculosis are now occurring and the low costs for tuberculosis programme inputs in India, it is probable that the discounted cost per healthy year of life gained as a result of a well-functioning tuberculosis control programme will be well under US $10, making tuberculosis control one of the highest priority interventions for the State and central governments.

AIDS and tuberculosis. HIV began to spread in India only in the latter part of the 1980s and there is no evidence yet that HIV infections are having an impact on the tuberculosis situation. Only recently HIV testing has become more common in a few research and academic institutions. A survey conducted among all newly diagnosed smear-positive tuberculosis patients in 1990 in Madras found 15 confirmed positive HIV cases among 2165 patients tested (0.7%). In Vellore, there were 16 confirmed HIV positives among 906 patients newly diagnosed with pulmonary tuberculosis (1.8%). In 1992, 12 of 183 (6.3%) tuberculosis patients admitted to a hospital in Bombay were HIV-infected. In a follow-up study of 220 HIV infected individuals conducted in Madras, 115 (52%) had radiological evidence of tuberculosis and 34 (15%) were culture positive. Other studies of HIV-prevalence in the general adult population have revealed prevalence varying between 0.1% in Calcutta to 1% in Bombay. The AIDS programme estimates that currently there are 750 000 persons infected with HIV in the country and that there will be 5 million in the year 2000. Assuming half of these people are also infected with tuberculosis, and that the breakdown rate from tuberculosis infection to disease among dually infected individuals is 10% per year, more than 35 000 HIV-related tuberculosis cases will occur in 1992. There may be as many as 250 000 HIV-related tuberculosis cases annually at the end of the decade. Virtually all of these cases will be in addition to the expected incidence. As important as these cases will be, they will continue to represent only a fraction of the cumulative cases of tuberculosis during the decade.

Tuberculosis drug resistance. Only a few laboratories can conduct drug sensitivity testing in India. Although data on drug resistance is scarce and resistance is not systematically monitored, available information (Table 4) is cause for concern. The very high rate of secondary resistance to both rifampicin and isoniazid is particularly serious, with long term implications as these patients will transmit a virtually incurable form of disease within the community.

Table 4: India: Primary and Acquired Drug Resistance in selected areas.

Type of patient and sample size		% Resistance to S	H	R	HR	SHR
Failure						
81	Delhi Centre (1)	-	50.7	-	33.3	-
354	Delhi Suburbs (1)	-	78.8	-	61.5	-
560	North Arcot (2)	30.0	65.0	16.0	6.0	9.0
Previously Treated						
37	Madras (2)	35.0	62.0	13.5	5.4	8.1
111	Raichur (2)	11.7	52.7	17.1	5.4	11.7
New cases by history						
241	Madras (2)	7.3	12.6	1.6	0.8	0.8
244	Raichur (2)	11.0	19.1	3.2	2.0	1.2
324	Delhi (1)	-	18.5	-	0.6	-

(1) : Ind. J. Tub. Vol.39 No.2 pp 121-124
(2) : TRC Annual Report and M. Datta, personal communication

Conclusions:

The burden of tuberculosis in India is staggering by any measure. About 1.5 million cases are notified every year, more than half of the adult population is infected, and there are at least 300 000 tuberculosis deaths annually. Social and economic consequences of tuberculosis for individuals and for the society are enormous in human suffering, economic loss, and decreased productivity. Recent trends are discouraging, indicating a programme which does not have any measurable impact and which appears to function far below its potential. While further study and improved analysis are needed to rigorously document the epidemiological situation, it will not change the broad conclusion that tuberculosis is one of India's most serious and still neglected health problems.

5. ORGANIZATION OF THE PROGRAMME

1. National Level. The Ministry of Health and Family Welfare (MOH/FW) is divided into an administrative arm headed by the Secretary of Health and a technical arm headed by the Director General of Health Services (DGHS). The Secretary of Health is assisted by Additional Secretaries and the DGHS by Additional DGHSs and several Deputy DGHSs. One of these Deputy DGHS supervises the NTP as well as several other programmes. The responsible officer for the TB programme is an Assistant DGHS (TB). The NTP is located within the technical arm of the MOH/FW and on the administrative side, it is coordinated by a Joint Secretary who is responsible for its financial and administrative control.

National Tuberculosis Programme Policies. The long term objective of the NTP is to reduce tuberculosis in the country to the level where it ceases to be a public health problem. To accomplish this objective, the NTP focuses on 1) the BCG vaccination of infants, 2) the detection of the maximum number of tuberculosis patients among out-patients attending health institutions, and 3) the efficient treatment of identified tuberculosis patients, all as an integral part of India's general health services.

Central Structure of the NTP. The Central Unit of the NTP has a staff of about 10 people. In addition to the Director, there are two physicians and 6 administrative officers for drug procurement, international assistance, monitoring of monthly reports, annual planning and coordination with the National Tuberculosis Institute (NTI)[4]. Currently, the post of programme director (Assistant DGHS-TB) and one of the two medical officer posts are vacant. The level of the programme director is lower than that of other programme directors (EPI, Leprosy) and below the level of the director of NTI. This, plus the fact that two out the three central level posts are vacant reflect the low priority given to the NTP and show the absence of strong national leadership. This situation, if maintained, would jeopardize any attempts to revitalize the programme.

The Central Unit is responsible for drugs forecasting, purchase and allocation, the annual planning and participation in the discussions of the MOH/FW with the planning commission to determine the annual and 5-yearly "plan budget" of the NTP, and for liaison with international agencies (WHO, SIDA), with NTI, and with state TB programmes. The central unit does not play any significant role with respect to tuberculosis control technical policy, training and manual preparation, monitoring and supervision. These responsibilities have been progressively taken by NTI. NTI management, however, is virtually independent of the NTP. Additionally, State Tuberculosis Officers are State employees, and they are not accountable in practice to the ADGHS (TB).

NTP budget. The MOH/FW budget is composed of a "non-plan budget" used for personnel, salaries, hospitals, etc and a "plan budget", allocated by the Planning Commission for future investments or creation of new posts. The "non-plan budget" is not controlled by the NTP and fluctuates minimally from year to year. No detailed information could be made available to the review team about the proportion of the NTP budget corresponding to the "non-plan" budget nor a breakdown by States of the NTP budget and its trend. The 1992 (March 92 - February 93) plan-budget of the NTP is R 145 million (US$ 5.3 million) of which R 110 million - more than 75% - are used to purchase drugs and 25 million for other expenses such as X-ray units and films, microscopes, vehicles, etc. Anti-tuberculosis drug costs are shared on the average on a 50:50 basis between Central and State governments. Within the overall NTP budget, the Central government also provides anti-tuberculosis drugs to voluntary organizations, and supplies, equipment, and drugs to the Union Territories.

Other resources. The Swedish International Development Agency (SIDA) has provided funds through WHO. These funds have been used to purchase x-ray units with Odelca cameras, miniature x-ray film rolls, vehicles, anti-tuberculosis drugs and microscopes. Occasionally, District and State tuberculosis associations provide anti-tuberculosis drugs, materials and equipment to specific district programmes or local tuberculosis facilities.

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[4] National Tuberculosis Institute (NTI). The National Tuberculosis Institute (NTI), located in Bangalore, is responsible for training NTP personnel, monitoring the programme and conducting operational research studies. Each year, NTI organizes two 10-week courses. In 1991, for example, 166 health professionals were trained. Apart from training DTC teams, the NTI also provides refresher courses for persons working for district tuberculosis control programmes and reorientation/retraining seminars for senior health administrators and teachers from medical colleges, etc. Lastly, the NTI collaborates with the World Health Organzation (WHO) for international training efforts.

2. State level. India is administratively divided into 25 States and 7 Union Territories. In the State MOH/FW, the NTP is under the Director of Medical Services, Health and Family Welfare and the Director of National Programmes. All States have a State Tuberculosis Officer (STO), usually assisted by a staff of 6 to 10. The vast majority of STOs have been trained at the NTI. In principle, there is a meeting of all STOs at the central level once a year.

Responsibilities of the State Tuberculosis Officer (STO). The STO is responsible for negotiating for the State the amount of drugs provided by the central government and monitoring drug distribution to the Districts. He is responsible for the overall supervision of District Tuberculosis Officers (DTO) and through them of Peripheral Health Institutions (PHI). Lastly, he should organize and coordinate training activities at the State level, in conjunction with the State Tuberculosis Training and Demonstration Centres and with NTI.

State tuberculosis demonstration and training centre (STDTC). Seventeen states have training and demonstration centres. These centres were created in the early sixties to supplement NTI. They have an average staff of 100 people with about 30 professionals. In addition to training, they have responsibilities in diagnosing and treating patients and have, in some instances, research activities. In practice, however, the vast majority of these centres do not have an organized training programme or research activities and operate solely as District Tuberculosis Centres (DTC).

3. District level. The District is the basic demographic, economic, administrative and political unit in India. The District is further divided into Taluks and Community Development Blocks. One District encompasses 1,800 to 2,000 villages, has an average population of about 1.5 million, and a land area of 10,000 square kilometres. Health institutions in the District generally include:

1. One district hospital in the headquarters town.
2. Community Health Centres (CHC). Usually one in each Taluk, with several doctors and specialized services (about 10 CHC per district).
3. Primary Health Centres (PHC). In principle, one in each community development block (about 40 per district).
4. Varying number of sub-centres (180), other peripheral health institutions, dispensaries, maternity and child welfare centres, employee dispensaries, and private hospitals.
5. Specialized tuberculosis institutions. Tuberculosis clinic, DTC where the DTC has been implemented, sanatorium (about 100 beds per district).

With one CHC per 100 000 population and one PHC per 30 000 population, an average district may have about 10 to 15 CHCs and 50 PHCs. The country is covered by a network of 21 805 PHCs and 137 683 sub-centres (Figure 2).

Figure 2

ADMINISTRATIVE ORGANIZATION AND HEALTH SERVICES

ORGANIZATIONAL LEVEL - Number - Average Population	HEALTH SERVICES
National - 850 000 000	Institutes
State - 25 - 34 000 000	Hospitals Sanatoria State TB Centre (STTDC)
District - 438 - 1 500 000 - 2 000 000	District Hospital District TB Centre (DTC)
Taluk - appr. 15 per district - 100 000	Community Health Centre (CHC) Central Hospital
Community Development Blok - appr. 40 per district - 30 000 - 40 000	Primary Health Centre (PHC) Maternal and Child Welfare Centres Employee and Panchayat Union Dispensaries
Villages - 1800 - 2000 per district - 700 - 800	Subcentres (each 4-5 villages) with Multipurpose Health Workers

In addition to these services, it is estimated that there are 330 tuberculosis clinics in operation in urban areas to provide services for the local residents. Approximately 47,000 hospital beds are available in the country for the in-patient care of seriously ill tuberculosis patients.

In the district, curative medical services and hospitals are managed by the District Medical Officer (DMO) and preventive services and primary health care by the District Public Health Officer. Although the District Tuberculosis Officer (DTO) works under the authority of the DMO, he has no formal control or authority over the district hospital and specialized institutions. Conversely, he controls and supervises tuberculosis activities in PHIs although these institutions are under the administrative authority of the District Public Health Officer. This situation means that the DTO cannot exercise leadership to improve the quality and coordination of tuberculosis control activities in hospitals and does not have the line of authority required to properly manage control activities in peripheral institutions.

District Tuberculosis Programme (DTP). In 1991, District Tuberculosis Programmes were in existence in 378 districts out of 438 districts in the country (86%). In a district, all health institutions which undertake case-finding and treatment for tuberculosis are considered as participating units of the DTP. These institutions are classified as either DTCs or PHIs. Each district participating in the DTP has one DTC. Sub centres do not have medical officers and are not considered as part of the DTP network.

District Tuberculosis Centre. DTCs maintain the patient case registers, manage the recording and reporting system and are responsible for supervising the TB activities of the PHIs. The DTCs also serve as referral centres to PHIs for X-ray examinations. They have X-ray units, microscopes and vehicles. They receive funds for drugs, gasoline, car maintenance, etc. from the State. Anti-tuberculosis drugs are supplied by the national Central Unit to all districts including those where the NTP has not yet been implemented. Most DTCs receive additional drugs directly from the State. DTCs have a staff of 15 to 20 persons including the District Tuberculosis Officer (DTO), one to three tuberculosis medical officers, one radiology technician, one laboratory technician, one to five treatment organizers, one statistical assistant, one pharmacist, and one or two drivers.

Peripheral Health Institutions (PHI). In the District, most CHCs and a number of PHCs staffed with at least one doctor are selected as PHI to implement the NTP and conduct diagnosis and treatment of tuberculosis. There are 3 types of PHIs:

1. X-ray centres, offering X-ray and microscopy
2. Microscopy centres, offering microscopy only
3. Referring centres, preparing sputum smear for or referring patients to the nearest microscopy centre.

No special staff is posted at PHIs and the Medical Officer in charge is responsible for tuberculosis activities. In some instances, one of the health workers of the centre (microscopist, X-ray technician) takes responsibility for tuberculosis patient management.

Multipurpose Health Workers (MPHW). In all PHIs there are multipurpose health workers who represent the most peripheral level of health care. The are usually based in subcentres, in pairs. With respect to tuberculosis, they are to maintain a list of all patients on treatment, to visit them regularly and to refer symptomatic patients to the nearest PHI or the DTC. They are not currently responsible for distributing or administering anti-tuberculosis drugs.

Urban tuberculosis control. There are a multiplicity of urban organizations and institutions involved in tuberculosis control activities, both public and private. These organizations, however, rarely coordinate their efforts and often work in isolation and/or overlap activities. Consequently, areas and/or population pockets needing tuberculosis services may be overlooked and manpower and financial resources are not well utilized. Since 1975, city tuberculosis programmes are to be organized in a similar fashion to DTPs, with the stipulation that each city programme would be tailored to the administrative, operational and social conditions of the specific city. Currently, however, only a few large urban areas have well-functioning tuberculosis programmes. Voluntary organizations and tuberculosis associations have been able to augment city tuberculosis programmes in many instances by providing technical and financial support, health education, and community outreach.

Conclusions:

The NTP has a very weak central structure, which for a long time has not provided leadership in establishing and updating policy and technical procedures and assuming programme direction. As a result, programme procedures have stagnated and the original philosophy of the NTP has not been fully implemented, or revised to make full use of the development of PHC. The functions and resources of the State level, in particular training, have not been developed and properly utilized. In most large urban centers the coordination of activities among diffrent institutions, under the guidance of the STO and STDTC, have not yet been implemented. In a similar way, the curative services (hospitals, etc.) and preventive services (PHIs) are not coordinated at District level in a single network for TB control, and the lines of authority of the DTO are not clearly established. The extension of TB diagnosis and treatment activities to the community through the MPHW has been slow, and that valuable human resource is not sufficiently utilized to enhance access to care and patient compliance to recommended therapies. There is no technical and policy advisory body to lend credibility and promote visibility of the programme to government agencies and potential donors and to provide support to the national team in the preparation and periodic updating of national policies, technical and administrative procedures, and monitoring and evaluation of the programme.

6. CASE FINDING AND DIAGNOSIS

Diagnostic services provided by the NTP are free of charge for the patients. A major stated objective of the NTP is to detect the maximum number of tuberculosis patients in the community and among outpatients attending health institutions with symptoms suggestive of tuberculosis, giving priority to sputum positive patients. According to NTI manuals, the principal approach of case finding should be routine screening by sputum smear examination of chest symptomatic patients attending health centres, and symptomatic patients be referred for x-ray only after a negative sputum examination has been repeated. In practice, however, this policy is not followed.

Patients with respiratory symptoms attending a public outpatient facility are investigated with chest x-ray and generally one sputum smear examination. Patients who have to come back a few days after their initial exams are not routinely requested to bring an overnight sputum sample. Often diagnostic smears are not done or the results are not recorded on the treatment card. PHIs without x-ray facilities refer sputum negative patients to a peripheral x-ray centre or to the DTC. Looking for better care or because of public transport facilities, which directly link to urban centres, many patients bypass the microscopy centre and go directly to an x-ray centre or hospital, adding to their workload and increasing the proportion of cases diagnosed through x-rays.

Most facilities with X-rays diagnose the patients and initiate TB treatment on radiological evidence, in spite of a negative smear examination. Very few facilities indicate further sputum examinations, or treat smear negative tuberculosis suspects with non-specific antibiotics and follow-up the patient's clinical and radiological evolution prior to initiating anti-TB therapy, suggesting overdiagnosis based on x-rays. Overall, approximately 20% of patients diagnosed with tuberculosis have at least one positive smear, a very low proportion compared to the expected capacity of smear examination of diagnosing 40-60% of all TB cases. The practice of doing generally only one diagnostic smear examination is probably resulting in infectious cases being treated as noninfectious (with inadequate regimens and supervision) or not diagnosed at all. Official data published for one state tuberculosis programme showed that between 1969 and 1987 the total number of tuberculosis cases almost doubled whereas the proportion of smear positive cases decreased from 61% to 28%, suggesting that clinical practice is relying less on bacteriology and further separating from the policies recommended by the NTP.

Unfortunatelly, outpatient facilities run by non-government organizations (NGOs) generally follow the same routines. Moreover, NGO institutions and municipal health facilities were found to charge registration fees for each visit. In private practice, patients have to pay for consultations, smear examinations by private laboratories and the prescribed medication.

It is estimated that up to 50% of tuberculosis patients are identified and at least partially treated by private practitioners. These patients do not initially enter the NTP and are not registered. Many patients then move to the public sector because of the cost of care and drugs. Thus, a large proportion of patients attending a health service facility have previously been seen by a private practitioner.

Due to the high number of PHIs in the district, the maintenance of an updated cross indexing system at DTC is complex. Patients may not be able to provide a complete address due to illiteracy or type of dwelling or because TB has a social stigma and the patient does not want to receive mail from the DTC or visits from DTC staff. Unless they present an identity card issued by a public institution, patients previously treated outside the public system or which are not found in the DTC cross index are diagnosed, registered and notified as "new" cases. This practice correctly incorporates new cases initially detected outside the public system, but duplicates notifications if the patient was detected by a public institution outside the District.

A more serious problem is that the clasification in "new" or "old" bears no relation to the previous treatment history and is not useful to decide on patient therapy. If the patient is not found to have been previously indexed in the DTC, he is considered "new" and is given a regimen for new cases. The insufficient definition of "new" and previously treated patient leads to the prescription of wrong regimens. A significant proportion of previously incompletely treated cases is known to have acquired resistance to isoniazid and streptomycin. The efficacy of "conventional" chemotherapy for such cases, who are most likely still symptomatic and smear-positive, is very low.

Laboratory facilities

Most laboratories visited were equipped with monocular, rather than binocular, microscopes without an electric light attachment. Some of the microscopes were in poor condition and the light source appeared to be inadequate. The quality of slides varied and some slides were found to be uneven and poorly stained. Acid fast bacilli could not always be found in smears read as positive. An ocular magnification ratio of five or six was routinely used rather than the usual 10 ratio. As definitions for data entry

are irregular, laboratory registers do not permit determination of the proportion of new cases, retreatment cases and follow-up examinations. Sputum smears are not routinely used for monitoring of treatment outcome.

Many laboratory technicians working in peripheral microscopy centres have been trained for the malaria control programme and are not familiar with sputum smear examinations. Malaria smears are often given a higher priority and may constitute a high case load. The number of sputum smears to be read by one technician per day is usually considerably less than 20 except in larger institutions such as DTCs and major hospitals. The rate of positive smears varies between 1 and 10%. These low positivity rates may be partly a result of poor selection of symptomatics, poor quality of the samples, low quality microscopes, weak laboratory practices, inadequate training and an excessively limited exposure to tuberculosis smear slides due to a small catchment area. The supply of chemicals was adequate and no shortages were reported. Slides with negative smear results are often reused, as indicated in the NTI manual, with a risk of false positive results.

Quarterly or semi-annual supervisory visits are made by the DTC team to assess the performance of the laboratory staff. The supervisors check usually only all the positive slides, retained at the microscopy centre for reading. Notes on the supervisory observations made, such as the proportion of false positive and false negative readings, were not available for scrutiny. There is no system of quality control through sending slides to the DTC or to a State reference laboratory. Laboratory staff are often in need of re-training and staining is of varying quality. Few States have functioning reference laboratories to train District staff, supervise DTC laboratories, carry out sistematic quality control of smears and do sputum culture and sensitivity testing when necessary. In one State it was observed that the STDTC laboratory had different procedures for smear examination that those recommended by the NTI manuals and utilized by the DTC laboratories in the State.

X-ray practices

With very few exceptions, diagnosis in clinical practice is based on the chest x-ray. Even with one negative smear or no smear result, tuberculosis treatment is initiated if the x-ray appears suggestive of active pulmonary tuberculosis. The x-rays taken in referral centres are usually kept at these facilities. The referring PHI only receives a note with the x-ray result. The standard equipment in most x-ray units is an ODELCA camera with 70 or 100 mm films. In some hospitals, standard size films are used. Chest clinics at the district level use both small and standard size x-ray films. Most of the technicians are sufficiently trained and the chest films are of a good quality, but complaints were expressed about the quality of the domestic films. X-ray centers had well functioning x-ray units and usually sufficient film to handle the tuberculosis caseload within the centers, although temporary shortages of x-ray films are commonly experienced by PHIs. 93% of x-ray machines were in working order at the DTCs as of 1991 (13). Assessment by an inexperienced reader of the small size x-ray films widely used for diagnostic x-rays or use of slightly inferior quality films can lead to an increase in overdiagnosis.

Conclusions:

The NTP has an infrastructure of microscopy and x-ray centres, integrated into the primary health care system and staff are available to perform case finding activities down to the village level of health care delivery. Major weaknesses of the NTP with regard to case finding are that usually only one or no sputum smear is obtained before a tuberculosis diagnosis is made, and that diagnosis is primarily based on the results of a

chest x-ray. This practice results in significant underdiagnosis of smear positive cases by smear examination and in treatment of infectious patients as smear negative cases with inappropiate regimens, and discourages monitoring of treatment outcome by sputum smear results. Patients with respiratory symptoms are often inadequately assessed and treated before the diagnosis of smear negative tuberculosis is made. The lack of vigorous procedures for patient management increases the tendency to rely on x-ray examinations resulting in the overdiagnosis of smear negative tuberculosis. Inadequate case history and the impractical case registers result in multiple diagnosis of defaulters and overnotification.

The primary aim in case finding should be the identification of sputum smear positive cases. Before the diagnosis of tuberculosis and decision to treat are made, the results of at least two sputum smears should be available. The role of the sputum smear examination in tuberculosis diagnosis should be greatly emphasized and the role of radiological examinations should be reconsidered. For differential diagnosis, the ODELCA cameras and miniature films for diagnostic chest x-rays may be phased out and replaced with equipment based on the specifications for the WHO Basic Radiological System, after carefully working out the cost considerations. For screening of symptomatic attendees in hospitals of large urban areas to select patients for bacteriology, small size X-rays may be useful.

The NTI laboratory manual should be revised, used for training at State level and distributed as a reference to the laboratory staff of PHIs. Wall posters with the basic procedures for microscopy, as were seen in one of the States visited, should be made available to all peripheral microscopy centres. Supervision of DTC laboratories should be undertaken by State reference laboratories. Supervision at State and at District levels should include a system of quality control whereby samples of positive and negative smears are systematically sent to a reference laboratory for confirmation. Acceptable quality binocular microscopes should be made available. All diagnostic centres, including those outside the State health services, must adhere to uniform programme guidelines.

7. TREATMENT

The manuals for the District Tuberculosis Programme (NTI, 1990) include the current national policies for the treatment of tuberculosis. The Introduction Manual states that free chemotherapy should be provided to self referred tuberculosis patients. The highest priority is given to treatment of sputum positive cases to reduce the transmission of infection in the community. Five regimens of "conventional chemotherapy" of 12-18 months duration for all forms of tuberculosis are recommended. In a phased manner, two short course regimens of 6-8 months duration are to be provided for sputum positive cases. Patients are "allowed to collect drugs from the nearest PHI and are motivated to consume drugs for prescribed duration regularly".

In Annex 4.1 the regimens found to be most frequently used in the DTP are presented according to the currently recognized category of patient and priority given if drugs are available. The categorization used in the following sections of this report corresponds to that used in the WHO Guidelines for Treatment of Tuberculosis in NTPs. However, in the India NTP manuals, the seven recommended regimens do not always refer to the specific category of tuberculosis patients and the choices of regimens are not prioritized.

Treatment practices.

Patients are mostly treated by "conventional" regimens on an ambulatory basis and oral drugs are self administered by the patient. In some States (mostly in the South of the country) the regimen of HT is rarely utilized due to the reported high frequency of side effects. There, most patients are treated with HE for 18 months or SH twice a week. In some States of the North where thiacetazone is well tolerated, the drug is not supplied in sufficient quantity because of shortages in the national market attributed to the low profit margin on the drug for the pharmaceutical companies.

SCC regimens for pulmonary smear-positive patients are theoretically implemented in approximately fifty percent of the districts in the country, but in reality only a minority of patients are treated with SCC so far. SCC is being implemented slowly, mainly because the expansion of SCC has not been given high priority in the NTP. The selection of patients eligible for SCC observed during the review is quite strict, probably because the medical officers of the DTP have doubts about the compliance of patients in self-administration of the SCC regimens. SCC drugs are often kept at the DTC or selected PHIs and patients living far away cannot come twice a month for the drug collections.

The treatment is usually prescribed by a medical officer of the DTC or PHI, and provided free of charge. Anti-tuberculosis drugs for the recommended regimens, in particular for SCC, are periodically out of stock, reducing the motivation of the patient to regularly attend the institution and contributing to the prescription of a non standardized regimen. Patients attending private clinics are required to pay for their medications. They may go to governmental institutions when they are unable to continue to pay for treatment, but do so only when they are very sick. In a limited number of situations, treatment may be supported by voluntary organizations. Often when there is a shortage of one or more drugs in the health centre, patients are required to buy the missing drugs. In one State, streptomycin, part of the "conventional" regimen, was presently missing in most centres visited by the review team due to a 50% budget reduction from the previous year's budget.

Patients with severe forms of tuberculosis (e.g. meningitis), those with complications of tuberculosis (e.g. pneumothorax, hemoptysis), those with tuberculosis complicated by other diseases and failure of an initial regimen requiring retreatment are hospitalized. Places of hospitalization are referral hospitals including sanatoria and medical colleges. Seldom are tuberculosis patients hospitalized in CHCs or district hospitals. Hospitalized patients frequently receive "conventional" chemotherapy that has low efficacy for critically ill and retreatment cases. Existing hospital beds for tuberculosis are utilized for advanced disease and not fully utilized to prevent treatment failure. Hospitalized patients often receive weak regimens and the beds are therefore not utilized in a cost-effective manner.

In the DTC, drug collection is done once a month for "conventional" therapy and twice a month for SCC regimens. The frequency of drug collections by the patient is similar during the initial and the intensive phase of chemotherapy. Streptomycin is administered in the health institution nearest to the patient home or by a private nurse. Usually the patient does not see the medical officer during the follow-up. He may be asked to see the MO if he has drug side effects. The monitoring of side effects is not systematic and there is little information regarding the percentage of patients who may have experienced major side effects.

Guidelines for changing regimens during chemotherapy or for prolongation of the duration of a regimen have not been issued by the NTP, creating confusion, particularly for MOs in the PHIs. Unnecessarily long conventional regimens are a burden for the patient, causes an unnecessary workload for the staff, and results in drug wastage. The decision to discharge from treatment is made by the MO on the basis of the treatment card and on the clinical condition of the patient. Criteria for discharge from chemotherapy are not clearly specified in the NTP manuals. The patient is permitted to stop chemotherapy when he has completed 80% of his prescribed regimen. If he has not completed such a course, he has to continue the treatment for the duration of time for which he has not collected drugs. Due to the high incidence of defaulting, most patients receive unnecessarily long regimens. In addition, the definition of treatment failure is not clearly specified nor is practice uniform among MOs working in the PHC centres with regards to how to manage a failure case.

After treatment completion and discharge, the patient is instructed to return every 3-6 months for follow-up. This practice is unnecessary and results in wasting of effort for both the patient and health staff.

Treatment organization.

Smear examinations are not repeated during conventional chemotherapy, to confirm that the patient is really sputum negative or to determine sputum conversion in smear positive patients. For SCC regimens, NTI recommendations do not require sputum examination at the end of the intensive phase of chemotherapy nor are criteria specified for prolongation of the 2 months initial intensive phase if the patients remain smear-positive. Smear examination after the initial intensive phase of SCC is required in some centres participating in the Tuberculosis Research Centre operational trial, but is done in approximately 20% of the patients only. The insufficient monitoring by sputum examination during chemotherapy does not allow for evaluation of the outcome of the initial intensive phase of SCC chemotherapy. Patients who are still smear-positive at the end of the initial phase should receive special supervision by the DTP staff because they may not have strictly adhered to the prescribed medications. These patients may still be cured by the same regimen for new cases if the drugs of the initial intensive phase are continued for an extra month and the staff fully supervises the patient.

National policies require that pulmonary patients be monitored by x-ray examination after six months and at the end of conventional chemotherapy. This requirement is not necessary in smear-positive patients and is not cost-effective in smear-negative patients. In practice, only a fraction of pulmonary cases are followed up by chest x-ray films in the DTP. Extrapulmonary tuberculosis patients are monitored by physical examination and by appropriate clinical tests.

The decentralization of the treatment of tuberculosis patients to PHIs, as recommended by the NTP, is not fully utilized for the administration of SCC regimens. The lack of decentralization results in a high percentage of dropouts. A significant percentage of patients diagnosed in DTCs are defaulting the first drug collection. The treatment card is not opened nor are the name and address of the identified smear positive cases in the community communicated to the PHI closest to the patient's home to retrieve the patient. Name and address of patients under treatment by the DTC or other institutions are also not routinely communicated to the PHI.

In PHCs, the MO at the beginning of treatment and the pharmacist during follow-up should provide patient motivation. At present, the same effort is made for all categories of patients, without sufficient focus for smear-

positive cases of TB that are the priority for cure. In DTCs, the DTO and MOs should provide motivation at the beginning of treatment and the treatment organizer should do so during the follow-up. Sometimes, in training and demonstration centres, health education and motivation is provided to small groups of patients. There is no formal monitoring of the effectiveness of such practices. There is no special effort to re-motivate patients who are still smear-positive at the end of the initial phase of SCC, when there is still a high probability of smear conversion and cure if the drugs are taken regularly. Effectiveness of health education practices among the patients and among the community are seldom evaluated and health education material is rarely available among patients, family members and health staff. Not enough emphasis is put on informing the patient and the health staff about the importance of sputum examination.

Follow up of defaulters is not practical because the staff is required to take action for a large number of patients, without focusing on those who remain smear-positive during chemotherapy. The current guidelines recommend that priority be given to sputum positive patients, leaving to the DTO the decision of excluding sputum negative patients from defaulter action. If home visits cannot be done, guidelines require that letters be mailed twice: after three days of defaulting and after 11 days if the patient is still delinquent. During the review it was found that letters are the most common action to retrieve defaulters. However, a large number of patients provide incomplete addresses and therefore reminder letters cannot reach them. In the PHC, the multipurpose health staff are sometimes asked to retrieve the patients, but such action is probably not stressed enough by the medical superintendent and Chief Medical Officer. The village health worker is often not informed about the TB patient(s) living in the village. The PHC is also not systematically informed by the DTC about new patients diagnosed and remaining under treatment by the DTC or hospitals.

The reasons for defaulting are well identified by the tuberculosis programme staff. Among the most important is the fact that the patient loses interest once he becomes asymptomatic. Disruption of drugs stock, incomplete provision of the first line drugs for "conventional" and SCC, long waiting time, inability of the system to adjust to the patient needs, distance of DTC or hospitals from the patient's home are the other most common reasons for defaulting. Some patients go to a health institution different from where they are registered with the hope of receiving better care. This increases default as well as making it more difficult to retrieve them. The DTC and other specialized institutions do not use auxiliary staff (MPHW) to retrieve defaulters and do not inform PHC of the existence of patients on treatment from that area.

Among defaulters, approximately 30% to 50% miss drug collections before the fourth month of chemotherapy. 5% of patients default after diagnosis is made and before therapy is initiated. In some instances, the patient is not informed that he has tuberculosis and should be treated. Lack of motivation of staff, weak leadership of the medical officer and little accountability to the chief medical officer for tuberculosis have been identified by the supervisory teams as additional reasons for patient defaulting.

In the policies of the NTP there is no target for treatment completion and cure of pulmonary smear-positive patients. In such patients the fatality rate is known to be high and irregular chemotherapy leads to drug resistance. The present policies and practices are insufficient to reduce the spread of the infection, particularly of drug resistant mycobacteria, and the mortality due to tuberculosis. The observation of the assessment teams show that the TB programme objectives are not efficiently prioritized. The existing health infrastructure and resources available are not fully utilized to sterilize smear-positive patients as quickly as possible. In a significant proportion

of the sources of infection diagnosed by the DTP, the chemotherapy is not started, and a large percentage of smear-positive patients put under treatment drop out during chemotherapy.

The decentralization of the programme is not achieved. Guidelines for patient management are not present at the level of peripheral health institutions (PHC and CHC for a population of 100.000 to 200.000) where most of the patients could benefit from the existing health services. Medical officers working in PHCs and CHCs are generally not trained for the proper management of the tuberculosis patient. Supervisory visits to PHI from DTC and chief medical office are not targeted to improve treatment outcomes.

Conclusions:

NTP policies and procedures on treatment do not reflect the WHO recommended emphasis on short course chemotherapy and patient registration systems which facilitate the monitoring of completion and cure rates of patients on anti-tuberculosis treatment. The tuberculosis programme at the delivery level does not adequately emphasize the importance of treatment completion as the main index for programme evaluation. During the programme review, the teams observed that DTP practices depart from what should be done to effectively treat tuberculosis patients. Service delivery focuses on case finding activities and not on treatment completion and cure. Tuberculosis staff are not optimally utilized to enhance treatment completion activities. Additionally, there is no good system to evaluate treatment results. NTP policies and procedures should be revised to ensure that the most efficacious and current treatment regimens are recommended, including fewer regimens and short course regimens where appropriate. Registration systems should solicit data to monitor completion and cure rates, with particular focus on smear-positive tuberculosis patients. The main goal of the NTP should be to ensure that patient completion of anti-tuberculosis treatment and cure be reflected in all policies and procedures and that such be carried out in the current integrated health care delivery system. Guidelines for treatment organization are attached in Annex 4.2.

8. PROGRAMME MANAGEMENT

8.1 CASE NOTIFICATION

Tools for programme monitoring are the treatment card, the laboratory register, the master book of treatment cards (MBTC), the cross index card, the patient identity card and the report on treatment results. The use of register books and report forms is in accordance with the NTP guidelines in DTCs where the statistical assistant is in position and has been trained at NTI. However, training courses have been rarely repeated and trained staff have been transferred to other programmes within the district. The format of the treatment registers is not always standard, as they are copied by hand and not printed, and the content does not include all the data required to analize the results of treatment. The card is sent from the PHI to the DTC when the patient completes treatment, defaults or dies, so the MBTC is the only source of data on treatment left at PHI level.

The usefulness of the recording and reporting system does not appear to be well known at all levels of the system. Consequently, evaluation of programme outcome and actions are missing, and the evaluation by cohort analysis of results of treatment is often not done. Cross checking of patients registered in the laboratory register, the treatment card, and registrations in the MBTC is not operating efficiently. Therefore no action is taken for smear positive patients registered in the laboratory register who default from the first drug collection, data on initial defaulters are not available and the information in the cards and MBTC is not complete.

Conclusions:

The current reporting and recording system for the NTP is cumbersome and does not address the main WHO recommended objective of the programme, i.e. the monitoring of the cure rate among smear-positive cases of tuberculosis. Cohort analysis does not cover all smear-positive cases diagnosed and is not done at the PHI level. The current NTP system of registration and notification should be revised to facilitate recording of essential data, such as previous history of TB treatment, and emphasize the collection and cohort analysis of treatment results as the main indicator of programme effectiveness.

A printed copy of the laboratory register and patient register books should be made available to each PHI implemented to provide tuberculosis care. These registers should be kept by a PHI staff trained in record keeping and should be supervised at least every two months by the DTC supervisor. Supervisors should cross check the records in the registers to assess the consistency of the data. Standardized reports on the indicators of programme performance should be filled out at the end of each quarter and forwarded to the DTC. The DTC will consolidate the reports from the PHIs and forward them to the state TB Office. DTC team supervisory visits to PHIs should be prioritized on the basis of performance.

8.2 SUPPLIES AND TRANSPORT.

Anti-tuberculosis drugs

Anti-tuberculosis drugs used by the NTP are manufactured or compounded by pharmaceutical companies within the country. In principle, 50% of the anti-tuberculosis drugs for the NTP are purchased by the national government and 50% by the States. The national government negotiates with the states its financial contribution for drugs based on the capacity of the State to complement the central government contribution. The amount of drugs needed by each state is determined annually by the central unit from the number of patients reported the previous year, the population, and the requests received from districts. These requests are initially scrutinized at the state level. The central unit negotiates the purchase of drugs with the pharmaceutical industry but it must buy from semi-public corporations as long as the drug price is no more that 20% higher than the price of private companies. The distribution of drugs to the districts is the responsibility of the Medical Store Organization.

The State portion of the anti-TB drug supply is generally purchased by the District from manufacturers selected in State bids, using allotted State funds and sent to the District directly by the drug manufacturer. Monitoring of stock supply, reserve stock, and usage is left to the District. Although the districts send notification of supplies on hand, usage, and drug projections to the STO, it is unclear whether analysis of usage patterns is regularly undertaken at the State level. Facilities are likewise unaware of drug supplies available in neighboring facilities or institutions.

At the district level, the DTO usually estimates the needs of anti-tuberculosis drugs on the basis of the previous year's consumption. He receives the drugs purchased directly by the central government and the budget allotted by the state through the chief medical officer. In some situations, the budget obtained from the State to purchase anti-tuberculosis drugs was sufficient for only a fraction of the needs, due to increases in drugs costs (approximately 20% compared to the previous year). In some districts, the funds were sufficient, and if additional funds were necessary, they could be requested from the state. In some instances, shortages were corrected by using funds from TB associations, Interrupted supply of some

anti-tuberculosis drugs at district level were noted as being due to late or incomplete supply by the production laboratories of approved orders or due to the absence of reserve stocks at the state level. The state does not purchase or receive drugs directly nor does it maintain a buffer stock.

The rifampicin used by the NTP is not a combination capsule. Fixed dose combinations of rifampicin with isoniazid, and with isoniazid and pyrazinamide are however available in the market. The quality of such single drugs and combination drugs is not currently being monitored by the NTP.

Conclusions:

Ensuring an uninterrupted supply of anti-TB drugs to the tuberculosis patient should be a key function of the national and State tuberculosis programmes. Shortfalls in funding and delay of drug supplies from the pharmaceutical industries can be compensated by 1) closer monitoring of usage patterns, drug purchase projections and stocks by the STO and 2) establishing a buffer stock at the State level sufficient to ensure at least a 6 month supply of uninterrupted drug distribution to the districts. Similarly, districts and PHIs should maintain internal buffer stocks of three months as an additional preventive measure. Estimations of the amount of buffer stock should be based on the number of patients reported during the previous year. In addition, drug quality should be monitored by the National Unit and the States through a selected scientific institution.

Transport

The non-availability of road worthy vehicles and poor budget allocations for fuel have been cited as reasons for limiting the number of supervisory visits by the DTC team to PHIs. At District level, fuel quotas were clearly insufficient, in view of the increased number of PHIs to supervise and distances to cover. As a result, supervision of PHIs is not done with the frequency required, or several PHIs are supervised in the same trip with insufficient time allotted to each one. Adequate provision of fuel should be provided to the DTC for supervision, and transport should be provided to district supervisors based at subdivisional level to reduce milage and fuel costs.

8.3 SUPERVISION, MONITORING AND EVALUATION

According to NTP policy, the District Tuberculosis Officer and his team of laboratory technician, x-ray technician, and treatment officer, etc. are responsible for the supervision of all personnel within their District involved in tuberculosis activities. The team is expected to visit each of their PHIs on a quarterly basis. They are to evaluate diagnostic and treatment procedures, validate laboratory results, monitor record keeping activities, check on defaulter actions taken, and monitor anti-tuberculosis drug supplies and support equipment. In addition to their supervisory duties, the team is expected to do on-the-spot training and/or retraining of staff, collaborate with other disease control programmes on topics of mutual interest, and offer continuing education to the general public. Supervisory checklists have been provided by the NTP to guide the supervision of DTCs and PHIs. At PHI level, Medical Officers have been made responsible for the supervision of laboratory technicians and multipurpose health workers.

When the NTP was operationalized in 1962, the District demographic unit was designated as the basic unit for the NTP. All NTP activities were conceived and organized at the District level. In the three intervening decades, the District has grown in population, and the number of government health services has grown at least in proportion to the population growth.

It is increasingly difficult for the DTC team to operate under the organization conceived thirty years ago, to feasibly supervise and manage at the District level. In one District visited, with a population of 4 million, 119 out of 148 Peripheral health institutions have implemented the DTP. The DTC staff would have to make 20 visits per month, supervising 2 facilities per trip in order to provide quarterly coverage for its implemented centers. This schedule of activities does not include the general hospitals, voluntary organizations, etc. which also treat tuberculosis patients and should benefit from regular supervision.

The assessment team noted that the District Tuberculosis team did make visits to PHIs. The quality of the visits was difficult to assess, and the frequency and regularity of the visits were difficult to validate, as supervisory reports were not available for scrutiny. Records were not in order at facilities where recent supervisory visits were noted.

Alarmingly, there has been a steady decline in the proportion of PHIs supervised by the DTC team, from 51% in 1983 to 41% in 1991. In 1987 only 84% of functioning DTPs sent quarterly reports. Of these only 72% (60% of functioning DTPs) gave information on supervisory visits. Of the 60% of DTPs giving information, they had supervised only 45% of their PHIs. Thus only 27% of the PHIs have been reportedly supervised. The quality of the supervision is not known (5).

Currently, supervisory visits are primarily used to evaluate record maintenance, laboratory performance, assess defaulter retrieval activities, and monitor the supply of anti-tuberculosis drugs and other equipment. Not only are the supervisory objectives poorly fullfilled, but very little time is devoted to the evaluation and supervision of programme performance with regard to the accuracy of case-finding and to patient completion of treatment.

The National Tuberculosis Institute (NTI) has been responsible for the monitoring of the National Tuberculosis Programme since 1978. Information on DTP activities is recorded through a system of records kept at the facilities and periodic reports sent to the NTI. Peripheral health institutions report case finding and treatment activities on a monthly basis to the DTP. The DTP prepares quarterly and annual reports for the NTI, inclusive of data received from the PHIs involved in tuberculosis activities.

Programme monitoring and evaluation has been largely limited to review and analysis of notification data and regularity of reports. The current information system does not provide for the monitoring of treatment outcome or programme outcome indicators. Management indicators and monitoring procedures focus attention on case finding but exhibit very little emphasis on case treatment and cohort analysis. Additionally, patients who are hospitalized in the more than 40,000 tuberculosis hospital beds are not registered in the NTI information system. Likewise, the large number of patients receiving initial care through the private sector are not registered with NTI. Consequently, it is estimated that less than 57% of all cases of identified tuberculosis are registered with the NTI (1).

In 1991, only 378 districts out of 438 with DTPs had registration in place (86.3%). Of those with DTPs, only 278 out of 378 sent reports (74%). Of the DTPs which reported to the NTI, they only received reports from 8502 out of 12,338 PHIs. Results from the 1987 "In Depth study on the NTP of India" (1) showed a general lack of awareness among tuberculosis staff of the importance of records and reports. Very few officers have readily made use of them. Data in the reports was not useful for programmme management activities. Supervising officials rarely checked records and reports or gave guidance regarding their proper maintenance. Reports were very often

incomplete and unreliable. Although on site evaluation of case management is reported, it is acknowledged by supervisors that the monthly and quarterly reports sent to the DTC are not analyzed nor are the sending institutions given any feedback as to performance as reflected in the written reports.

Conclusions:

There needs to be a clear emphasis placed on supervision if the NTP programme is going to succeed. Tuberculosis programme personnel need to be retrained about supervisory methodologies as well as supervisory content which emphasizes programme performance parameters. In order to address the increase in population and health care facilities at the periphery, a medical officer or treatment organizer and a laboratory supervisor should be added to the District Tuberculosis team at the sub-divisional level (about 500,000 population) in order to facilitate decentralization of supervision, staff training, monitoring and evaluation, and management of tuberculosis programme activities at the level of PHIs. To reduce travel time and cost, these staff should be based in a hospital or X-ray centre and they should be provided with transportation.

Monitoring of case finding and treatment results has not been prioritized, is still centralized and is not used at health facilities to evaluate the quality of programme delivery and implement corrective actions when necessary. PHIs management staff should be retrained on monitoring and evaluation methodologies. They should be taught to analyze their own facilities performance indicators and to take corrective action promptly. DTC, State and national staff should analyze the quarterly and annual reports received and provide feedback to the health facilities on the priority indicators of programme efficacy.

8.4 EDUCATION AND TRAINING

Since 1962, the National Tuberculosis Institute (NTI) at Bangalore, India has been the main training institution for tuberculosis programme staff. The various members of the District Tuberculosis Center (DTC) team (medical officers, x-ray technicians, laboratory technicians, pharmacists/treatment organizers, and statistical assistants) undergo a 10 week training program at the facility, with special emphasis on their areas of responsibility. The NTI also conducts seminars for state tuberculosis officers, university faculty, and district medical officers, as well as refresher courses for DTC staff.

In theory, in addition to NTI, the State Tuberculosis Training and Demonstration Centers (STTDC) are responsible for training BCG supervisors, orientation training of health visitors, and training of medical students and ancillary health care providers on the clinical aspects tuberculosis control. Continuing education for the private physician is often undertaken with assistance from the Indian Medical Association and voluntary organizations.

The review teams found, however, that the training given by STTDCs was neither comprehensive nor consistent with NTI policies and procedures with regards to diagnosis and treatment recommendations, i.e., x-ray reading, procedures for procuring and preparing sputum for smear microscopy, treatment regimen recommendations, etc. Training materials were not available for scrutiny. Instruction in the STTDC is provided on the basis of observations of clinical procedures, focusing on clinical aspects rather than programme operations.

Since the emphasis on primary health care and the push for integration of health services, medical officers and MPHWs have, in principle, become part of the tuberculosis control effort. The training and orientation of these health personnel in NTP policies and procedures varies widely. In some districts, the DTO and his staff provide systematic, but brief (two-day) training to medical officers and MPHWs using NTI training materials. In other areas, the training has been delegated to institutes of Public Health which provide general courses ranging from one year to eighteen months for health workers and one month for medical officers, where the tuberculosis content is a component of the course curricula. Medical officers of PHCs are also expected to train their staff in tuberculosis activities. Many of them, however, have yet to be trained themselves. The majority of medical officers interviewed in the field stated that they did not carry out any training activities for their staff.

Since 1962, over 4,800 team personnel or roughly 900 full teams have been trained by NTI staff. However, as the number of districts implemented has increased, and as senior personnel are promoted or attain superannuation, not all of the district teams currently have a full complement of trained persons. As of 1991, only 24% of DTCs had a fully trained team, while 66% had the services of a trained district tuberculosis officer (DTO), 76% had trained x-ray technicians, 78% had trained laboratory technicians, 88% had trained treatment organizers, and 59% had trained statistical assistants (13).

Conclusions:

Training is vital to the successful implementation of the review team's recommendations for the NTP. Training materials must be developed to reflect the proposed changes in programme policies and procedures. The needs for training of tuberculosis personnel for DTCs, PHIs and other health institutions exceeds the present training capacity of the NTI. The current NTP training should be descentralized by utilizing the existing state training facilities, medical colleges, public health institutes and tuberculosis-oriented voluntary agencies to augment training efforts. These institutions should receive NTP training materials and "train the trainer" courses to maintain standardization of training efforts. International and national training opportunities should be made available for the different levels of tuberculosis programme staff.

The NTP manuals should be revised to reflect the recommendations of the Review, and standardized educational materials should be developed by NTP for different categories of personnel involved in tuberculosis control activities (including medical students, general practitioners, etc. in private practice) and for patient motivation.

9. PRIVATE SECTOR

According to a study of 102 private doctors practicing in Bombay, 60% to 70% of patients bypass the public health system and seek care by private physicians when they become chest symptomatics (6). Review team field observations suggested that the proportion of patients seeking care in the private sector was slightly lower than evidenced in the Bombay study, but still represent about probably half of the new TB cases. Although many of those patients later move to the public sector, private practicioners have a major role and their management of TB cases influences also the results of the NTP. It appears that private physicians do not adhere to any set regimen for TB care. As in the public sector, dependence on x-ray diagnosis was evidenced. Case finding methodology and treatment regimens for tuberculosis patients vary widely and are usually more costly than regimens recommended by the NTP. Patients are usually given a prescription and sent to a pharmacy

for drug purchase, with very little monitoring of patient compliance. Defaulter action is rarely taken.

The training of general practitioners is currently not adequate and has not been updated to incorporate recent advances in knowledge and strategies of the NTP. The capacity and organization of medical associations (IMA, Anti-tuberculosis associations) have not been tapped to provide continuing education and programme awareness to the private sector. Interviewed members of the Indian Medical Association (IMA) at State and District level showed strong support for the NTP efforts. IMA members seemed well aware of the issues and challenges facing tuberculosis control and were willing to utilize the organization to promote tuberculosis health education efforts and distribute educational materials to its members on the topic of TB case finding and management. The use of health education messages targeted towards both the private physician and the consumer regarding correct treatment regimens and the importance of completing treatment should be tested as a method to standardize care provided by the private sector.

Conclusions:

A large share of the provision of health services in the country, including tuberculosis diagnosis and treatment, is done by private practitioners. They are, however, not currently included in the NTP system, either for notification of patients or standardization of diagnostic and treatment procedures. The role of the private sector in the care of the tuberculosis patient needs to be further clarified by the NTP. If indeed it is found that a large share of tuberculosis patients seek care in the private sector, improved training in medical schools and education of private practicioners must be implemented to ensure proper diagnosis and treatment and augment cure rates for patients under private care.

10. RESEARCH

India has a long history of tuberculosis research to improve programme delivery and treatment efficacy, and much of the information and experience obtained has been applied successfully in other countries. The research institutions can be utilized to analyze the functioning of the programme and to test alternatives to improve programme results, in particular organization of treatment delivery to increase the cure rate. To ensure that the studies provide relevant information for programme improvement, and that this information is opportune and utilized, this research should be planned and supported as an integral part of the NTP. Some operational research projects have already been discussed before the Review mission. Two major institutions currently involved in TB research are briefly described below.

The Tuberculosis Research Centre (TRC) in Madras was established in 1956, under the joint auspices of the Government of Tamil Nadu, the Indian Council of Medical Research, the British Medical Research Council and the World Health Organization, for studying initially the efficacy of domiciliary chemotherapy, in comparison with conventional sanatorium treatment. The centre was taken over by the Indian Council of Medical Research in 1965 and made a permanent research establishment. It established that a well-organised domiciliary chemotherapy with a daily regimen of isoniazid plus PAS produced results closely approaching those obtained in sanatorium with the same regimen; a satellite study established that there was no extra risk to the close family contacts from the infectious case after the start of treatment. Subsequently, the Centre investigated various regimens of chemotherapy in controlled clinical trials, backed up by in-depth laboratory investigations and solid statistical methodology. Clinical trials of various regimens of shortcourse chemotherapy that would be suited to Indian conditions were carried out, and more recently a study on implementation of

shortcourse chemotherapy under programme conditions in 18 districts selected from different parts of the country was initiated. In recent years, a strong department of immunology and cardiopulmonary function have been added to the Centre. Finally, the epidemiological unit that undertook a large trial of BCG vaccine in South India has now been integrated with the Centre. The Tuberculosis Research Centre has the capacity for undertaking training programmes that could complement the efforts of the National Tuberculosis Institute in Bangalore.

The National Tuberculosis Institute was established in Bangalore in 1960 with the objective of developing a suitable programme for tuberculosis based on operational research studies, training medical and paramedical workers for the District Tuberculosis Programme and monitoring the Programme through periodic reports received from the Districts. Based on studies on awareness of symptoms and action taken and on the Madras TRC studies demonstrating the efficiency of domiciliary chemotherapy, the NTP was evolved and launched at the NTI. In subsequent years, operational studies were undertaken on methods to improve case-finding, techniques for enhancing patient motivation and thereby enhance case-holding efficiency, and programme organization. Concurrently, large-scale field studies were initiated to provide information on epidemiological indicators such as prevalence and incidence of disease, fate of newly-diagnosed cases under programme conditions, and on the prevalence of tuberculous infection and infection with other atypical mycobacteria. Thereafter, and in view of conflicting reports about the efficacy of BCG vaccine, the largest BCG trial ever undertaken was launched in Chingleput, South India, to determine the efficacy of two strains of BCG vaccine at two different strengths.

Conclusions:

As a step towards the reorganization of India National Tuberculosis Programme activities, the research potential of the various research institutions should be evaluated in light of the findings and recommendations of this review and needs of the NTP for operational research studies. Operational research to test the feasibility and results of different technical and organizational strategies to be adopted by the tuberculosis programme should be an integral part of the revised tuberculosis programme.

11. SITUATION ANALYSIS

Even after three decades of National Programme activities, the tuberculosis burden on Indian society remains enormous - something on the order of five million premature deaths in a decade, half of which are among women, mainly in the reproductive age. This mortality must affect at least twice that number of Indians with consequent lowered productivity, disability and perpetuation of poverty. Excellence in research, early successes proving the advantages of some modern treatments, availability of powerful and effective antibiotics, a well established TB structure at the State level and, in the last two decades, extensive development of the institutional structure for primary health care in the rural areas, have not yielded the progress against the disease which India could have expected. Decline in the annual risk of infection (and in incidence) has been agonizingly slow in many areas. Well over half the population is infected with TB and the risk of infection is far too high at between 1 and 2% per year. An aging population structure, increasing HIV prevalence and apparently rising levels of drug resistance mean that without a reoriented and vitalized public TB control effort the disease will pose an increasingly serious health and developmental constraint for several decades to come.

The main factors to be addressed in making real progress against TB fall in four main categories - organizational, managerial, technical and developmental. Elements of the present health care system, and many parts of the current TB control programme provide the basis for implementation of major improvements. Strengthening and reorientation of policy and program execution in each of the problem areas offer sound prospects of improvement in curing TB patients in numbers which will result in 8-10% annual decline in the risk of infection and effectively halve the tuberculosis burden in about a decade while ensuring much lower disease and infection rates for decades into the future.

The state TB control programs are well structured and have direct intervention capabilities at the district level and below in about three quarters of the country. In contrast, the national TB control programme has languished with ineffective terms of authority and budgets and an exceptionally low executive position within the Ministry of Health for such an important disease. Monitoring, critically examining and adjusting national policy for effective state performance has consequently atrophied.

In the absence of a strong central Ministry unit, power for TB policies has been ceded to the National TB institute (NTI) in Bangalore. The NTI has had preeminence in training and some types of research for TB but now suffers serious institutional weaknesses. Budget shortfalls, unfocussed direction of research, training program content which is not replicated at state level and lack of experience with making and implementing policy have left a gap in national TB leadership. The absence of a national policy body for TB at central level, supported by a strong executive TB unit within the Ministry, has meant that no revision of policy has been made in spite of repeated evaluation showing poor results, and therefore NTI has not changed or developed alternative TB Program procedures.

Further, the content of their training has stagnated in relation to recent TB control success elsewhere. In the absence of a strong central program, NTI has been forced to assume program management and standard-setting functions which are inappropriate for a training/research institution. This is particularly true as NTI does not have the staff and executive authority to monitor and enforce compliance of the states with policy.

Below the State level, TB has been indicated as a priority for integration into the key health services. However, the TB program's effective cooperation with health service providers at the primary level and willingness of the providers, under current policies, to devote substantial attention to TB, remains doubtful at best. The ambivalence resides both in lack of strong and focussed national program direction and in the absence of policies responsive to the legitimate interest at the local level for a clearcut, standard, easy to follow program which is effective for cure. Strong direction, some decentralization below the district level, training, increased funding and a comprehensive policy package are needed.

Technical problems confronting the NTP are both historical and the result of some isolation. There remains traditional emphasis on case-finding activities when only a minority of discovered cases are being cured. Technical practices emphasize radiographic methods which are sensitive, but not specific, rather than concentrating on high-quality microscopy which with a good quality control system can be both specific and sensitive. Too frequently, one sputum smear is examined rather than several, leading to inappropriate treatment of infectious cases. Microscopes are often monocular and of poor quality, training is uneven and quality assurance systems seldom function. Protocols for appropriate use of radiography and clinical diagnostic methods need to be prepared and disseminated.

Treatment for diagnosed patients is chosen from too many regimens and adequate short-course chemotherapy is yet infrequently used and is completed in only a minority of cases. Repeated sputum smears during the course of treatment are not regularly taken to monitor effectiveness of therapy. Provision of services is often too remote or inconvenient to encourage patient compliance, and providers lack adequate motivation and training for patient supervision. Improved treatment protocols, training, adequate supplies of only SCC drugs, and adaptation of practices to provide some degree of supervised initial chemotherapy, whenever feasible, are needed.

Recording and reporting procedures do not permit rigorous supervision of the system as a whole or at the institutional level. Case definitions are not adequate. Criteria for completion of treatment and discharge do not exist. Laboratory registers and patient treatment registers do not contain the information necessary to perform cross checking or to monitor the performance of states, districts, blocks or individuals providers. Conversion status of smear positive patients cannot be documented. Cohort analysis to ensure and measure program effectiveness cannot be satisfactorily done with present registry formats and procedures. Therefore, adaptation of existing TB Program policies and resources to implement and improve recording and reporting system is required.

Developmental constraints include both institutional and financial issues. Operational research to test and improve on program performance is not currently an integral part of the TB program. Training materials and objectives are in need of revision to support a revitalized program and pedagogical content may need improvement. Medical college curricula need additions to provide both theoretical and practical exposure to the elements of TB control as doctors graduating now will continue to see TB throughout their working careers. Present private medical practitioners need to be educated about modern treatment and policies of the program. This can be done through existing NGOs. To do this, strengthening of the NTI, of the state level training centre, and studies and technical assistance at both the national and state levels will be needed. Opportunities for overseas training and experience will accelerate adoption of effective new experience in TB control elsewhere.

The government has recently decided to increase funding for TB control and is for now continuing to provide for the treatment of all TB patients diagnosed in the public system. The present high number of overdiagnosis and treatment of patients which now appears to be occurring offer scope for savings in an improved program. Overall though, financial resources for TB appear to have declined in real terms in recent years because of inflation and rising import costs, despite the government's recognition of the trend and efforts to counteract it. Moreover, only a fraction of patients today requiring treatment receive it in full.

A strengthened program will require increased resource allocations at both the central and local levels for drugs, supervision (including transport), training and operating cost. Given the demonstrated cost-effectiveness of TB control programs compared to other health sector interventions, revision and expansion of India's TB program with external financial assistance would appear to be fully justified.

12. RECOMMENDATIONS

1. The structure of the National Tuberculosis Programme should be strengthened by 1) establishing an apex policy making authority and an executive task force with managerial functions to implement programme reorganization, and 2) upgrading the central tuberculosis control unit in the Directorate to provide strong leadership and enhance the efficiency and effectiveness of the National Tuberculosis Programme.

2. The quality of patient diagnosis should be improved by 1) using three smear examinations to detect infectious cases among symptomatics before deciding on patient treatment, 2) ensuring the quality of microscopy with adequate equipment, training and quality control, and 3) establishing criteria for diagnosis by radiological and clinical methods.

3. National and state tuberculosis programme resources should be directed to ensuring cure of tuberculosis patients, giving priority to infectious cases of tuberculosis by 1) adopting short-course chemotherapy, 2) establishing criteria for treatment completion, cure and discharge from medical care, and 3) ensuring an uninterrupted supply of drugs of good quality.

4. The current NTP system of registration and notification should be revised to emphasize the cohort analysis of treatment results (completion and cure, transfers, defaulters, died, treatment failures) as the main indicator of programme effectiveness.

5. Policies should be developed to ensure decentralization of treatment services closer to the community level to enhance access to care and patient compliance to recommended therapies.

6. Pilot projects should be implemented at block level to test the feasibility and results of different technical and organizational strategies to be adopted by the tuberculosis programme -- i.e., to test the capacity to implement recommendations 2-5 above.

7. A medical officer or treatment organizer and a laboratory supervisor, with the necessary transport, should be added to the existing administrative structure at the sub-district level (about 500,000 population) to strengthen tuberculosis programme management and to facilitate decentralization of supervision.

8. Training materials must be developed to reflect the proposed changes in programme policies and procedures. The current training infrastructure will need to broaden the scope of its training capabilities by utilizing state training facilities, medical colleges, public health institutes and tuberculosis-oriented voluntary agencies to augment training efforts. International and national training opportunities should be made available for the different levels of tuberculosis programme staff.

9. Operational research must be carried out as an integral part of the revised tuberculosis programme to evaluate programme performance, improve delivery of services, problem solving and obtain baseline epidemiological information to measure reduction in the risk of infection.

DIS 5.3

TUBERCULOSIS IN INDIA

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TUBERCULOSIS IN INDIA

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DIRECTORATE GENERAL OF HEALTH SERVICES
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CONTENTS

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FOREWORD

This book is a comprehensive presentation of the facts about development of tuberculosis movement in the country and the details of the various aspects of the Tuberculosis Control Programme.

The activities taken up by the Government in the various plan periods, the concept and organisation of the National Tuberculosis Programme and the various significant research studies conducted in India that have contributed new knowledge in the field of tuberculosis control and have formed the basis of our community wide Tuberculosis Control Programme. also have been highlighted.

Tuberculosis is a major public health problem in the country. The tools for diagnosis of the cases, effective medicine for their treatment and BCG vaccination for protection of infants and children are available and have been provided freely in the National Tuberculosis Control Programme. It is only with the concerted efforts of the Government, the voluntary organisations and the community that the programme can succeed and the problem of tuberculosis can be tackled.

I hope the readers will find this book interesting and useful in having an insight to the problem and the efforts being made to deal with it under the National Tuberculosis Programme.

New Delhi
28-1-77.

Dr. P. P. GOEL
Director General of Health Services

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INTRODUCTION

TUBERCULOSIS has been known to mankind since the dawn of history. From the mummified bodies, engravings and paintings in Egypt, scriptures and literatures from Babylonia and China, literatures from the ancient civilisations of Greece, Persia and Macedonia and the Vedas and other Sanskrit literatures of India. it is evident that these ancient civilisations knew tuberculosis as a health hazard even 4000 to 5000 years before the birth of Christ. A hymn is consecrated to the cure of 'Yakshma' in Rig Veda which is dated as about 2000 B.C. Charak and Susruta in 600 B.C. referred to tuberculosis as very difficult to cure. Hipprocrates (460-377 B.C.), the father of modern medicine opined that attention to the tuberculosis patients was a waste of time and that they were a burden to the State.

However, till about the beginning of the 19th century, nothing much was known about the cause or cure of the disease. Tuberculosis was known as consumption, white plague, King's evil and phthisis. It was mostly considered as an incurable disease.

From the beginning of the 19th century, new knowledge started to gather. Laennec, himself a consumptive, invented stethescope in 1819 and described 'auscultation' by use of the stethescope. Villemin in 1868 demonstrated that tuberculosis had to be due to a specific agent, but it was Robert Koch who made the epoch making discovery of the tubercle bacillus in 1882. X-rays were discovered in 1895 by Prof. Roentgen which became available for clinical use in 1904. Von Perquet in 1907 described *intra dermal* tuberculin skin test. Calmette and Guerine in 1922 discovered BCG vaccine which is now extensively used as a protective measure.

However, specific treatment for tuberculosis by drugs that could kill or inhibit the tubercle bacilli was not known till the new era of chemotherapy in tuberculosis began in 1944, with the discovery of Streptomycin by Bugie and Walksman. This was followed by discovery of other potent anti-TB drugs like para-amino salicylic acid by Lehmann in 1946 and isonicotinic acid hydrazide by Grunberg *et al* in 1951. Several very potent anti-TB drugs became available by about the

middle of the present century and thus effective treatment of tuberculosis became possible revolutionising the whole concept of treatment and care of the tuberculosis.

Tuberculosis is a peculiar disease in the sense that it is of a chronic nature, the causative germ is more or less ubiquitous and easily infects most of the people and yet a few suffer from the disease. Symptoms may simulate many other diseases. Diagnosis of a case requires special techniques and treatment of a patient requires special drugs for a long duration. Like any other infectious disease, tuberculosis also comes in epidemics but unlike other diseases, the secular epidemic curve in tuberculosis lasts for decades if not centuries.

However, we have the knowledge and the means to detect tuberculosis cases and to treat them effectively. It is possible to cure a patient of tuberculosis. It is also possible to prevent spread of the disease and to protect the uninfected from infection by TB germs. Tuberculosis control programmes have, therefore, been organised in all parts of the world and many developed countries have been able to bring down the problem considerably.

In India as in other countries, fight against tuberculosis has been a very long battle. Several eminent scientists, philanthropists, private individuals, non-official organisations apart from the government have contributed largely in the battle against tuberculosis in India.

Several important studies in the field of tuberculosis epidemiology, control and treatment have been undertaken in India, the findings of which have been widely acclaimed all over the world. Based on these findings, a scientifically sound and operationally feasible tuberculosis control programme which is within our resources has been evolved and is being implemented in our country.

The purpose of this book is to give an idea of the nature and magnitude of the problem of tuberculosis in the country and to review the work done so far for tackling the problem.

CHAPTER I

THE PROBLEM

TUBERCULOSIS in India began to engage attention as a public health problem from the early years of this century.

In 1910, Sir Pardey Lukis, the then Director-General of Indian Medical Services pointed out to the Government of India that Tuberculosis was fast spreading and it called for concerted countrywide control measures.

The conferences of sanitary officials of India in the North and in the South in 1912 and 1914 expressed the need for proper investigation about the spread of tuberculosis in urban areas and from there to the rural areas.

As a result, the Government of India appointed Dr. Lankaster in 1914 to make an enquiry into the Tuberculosis problem in the country. After his enquiry during 1914-16, he came to the conclusion that the prevalence of tuberculosis was alarmingly high in the country, that during the preceding forty years even in areas that were considered as virgin soil, the population has become considerably infected by tuberculosis and that with development of commerce and industry and establishment of communication, the prevalence was increasing in the towns and cities and spreading to the villages.

However, apart from a general impression as was formed by Dr. Lankaster after his investigation and that of many other specialists working in the field of tuberculosis, the exact size and extent of the problem of tuberculosis in India was not known as reliable statistics were not available.

The main methods by which the size and extent of the problem of tuberculosis could be ascertained are:—

(1) Deaths from tuberculosis.

(2) Prevalence of the disease *i.e.* patients suffering from the disease as ascertained by morbidity surveys.

(3) Infection rate *i.e.*, persons who have been infected by tubercle bacilli and therefore are likely to fall a prey to the disease.

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Deaths from Tuberculosis

No reliable information about deaths from tuberculosis was available as vital statistical information even in towns and cities was not complete. Mostly information about deaths from various diseases had to come from inexperienced Government officials, who in their turn relied on the neighbours or relations of the deceased. Causes of death were grouped under a few broad groups like fevers, dysentery and diarrhoea, respiratory diseases and other causes, and tuberculosis could have been included in any of these broad groups according to the predominant symptom which the patient presented.

Sir Leonard Rodgers in an investigation estimated that 9% of those classified as dying of fever died of tuberculosis. A similar analysis of the figures for Cossipore near Calcutta showed a mortality (from tuberculosis) of 2.68 per thousand. Of the total deaths, 7.9% were due to tuberculosis. At about the time of the First World War, Sir Leonard Rodgers analysed the post-mortem figures for Calcutta for over 22 years and found that no fewer than 17% of the total deaths had been due to tuberculosis. Since at about that time (1911—1921), the crude mortality was 47 per 1000, the tuberculosis morbidity could be computed at eight per 1000. Vital statistical information from cities collected by Dr. Lankaster for his book *Tuberculosis in India* (1920) showed that tuberculosis deaths in Calcutta were 2.1; Bombay, 2.83; Madras, 2.5; and Ahmedabad 5.9 per thousand in 1919. He thought that actual rate was 4 per thousand or more in most cities. However, most often these were under-estimates because in a large number of cases, the cause of death as tuberculosis could not be established.

Frimodt-Moller (1949) and Mc. Dougal (1950) estimated TB deaths in India as 263 and 200 per 100,000 with rigorus control measures applied to the study population. Frimodt-Moller reported death from tuberculosis to be 64.1/100,000 in 1952 and 21.1 in 1955. Recent estimate of the longitudinal survey of the National TB Institute (1968) is 100 per 100,000 in an area where no control measures have been applied.

All these findings give an idea that the death rate due to tuberculosis was very high some decades back and continues to be high even now, though it is progressively going down in recent years.

Morbidity Surveys

In the earlier part only small studies limited to small population groups in different areas were undertaken by different workers. Dr. Benjamin in 1938 found 2.6% to be the prevalence rate of tuberculosis in the suburbs of Madras. Dr. Lal in 1944 calculated a morbidity of 7% in West Bengal. Dr. Sikand and Dr. Raj Narain in 1952 found 1.8%, Dr. Phillip in Madras in 1952 found 2.5% and Dr. Hertzberg in Trivandrum found 1.8% to be the morbidity rate for tuberculosis. Dr. Sikand and Dr. Raj Narain in 1952 indicated 1.36% to be the morbidity rate of tuberculosis among displaced persons in Faridabad. In Madanapalle, a survey by Dr. Frimodt-Moller showed a morbidity of 1.6% in the town and 0.42% in the adjoining villages in 1949. During 1952-53, an X-ray survey of the Government of India employees in Delhi showed a morbidity of 0.77%. The Sample Survey in 1955 in a small population in Ambur in South India showed a morbidity of 1.4%.

All these small surveys gave an impression that millions would be suffering from the disease in both urban and rural areas and it was felt necessary to have a precise estimate of the morbidity of the disease in the country as a whole.

The National Sample Survey was, therefore, conducted during 1955-58 which showed a morbidity of 1.3% to 2.5% X-ray cases and 0.4% bacteriologically confirmed cases and this prevalence was found to be uniform in cities, towns and villages. The findings of this Survey, which for the first time gave reliable and more or less precise information about the size and extent of the problem, on the basis of which a National policy for control of tuberculosis in the country could be built, has been discussed in the next Chapter. Subsequent surveys in Delhi (1960), Tumkur (1960) and Bangalore (1961-68) have also confirmed the findings of the National Sample Survey.

Tuberculin Test

Some information about the prevalence of infection can be obtained from the various tuberculin test surveys conducted in the country. Tuberculin tests done by Dr. Gill in 1930 in several areas in Bengal, Madras, Assam and Bihar showed the infection rate varying from 11.4% to 33.3% upto 15 years of age and 69.9% above that age. Benjamin in 1938 in a survey in rural South India noted tuberculin positive reaction to be 8.2% in villages and 11.6% in small towns among those under

15 years of age and in a suburb of Madras he found a positive reaction in 41.2% below 15 years of age and 69.8% above 15 years. Dr. Lal in 1944 in Bengal found infection rate to be as high as 88% in urban areas and 32% in rural areas.

Tuberculin testing conducted in connection with the mass BCG Campaign in the earlier phase of the programme showed infection rate to be in the range of 19% in 0-6 years age-group, 39% in the 7-15 years age-group, 63% in the 15-24 age-group and 83% in the age-group above 25 years. The average for all ages was about 54%. Contrary to our belief that tuberculosis was a major problem in the cities and towns rather than in the villages, the tuberculin test results of the mass BCG campaign showed that infection rate was more or less of the same order in cities, towns and villages which indicated that tuberculosis disease was perhaps equally prevalent in both urban and rural areas. This presumption was later confirmed by the findings of the National Sample Survey.

Estimated size of the problem

From the recent studies and observations it can be estimated that a little over half the total population of the country consists of reactors to tuberculin apparently because of infection by tubercle bacilli. At the rate of 1.8% there should be about nine million persons having radiologically active tuberculosis disease and about a quarter of them *i.e.*, about two million, are infectious, excreting tubercle bacilli in their sputum and most of them have symptoms. The death rate from tuberculosis is estimated to be about 80 to 100 per 100,000 population per year.

CHAPTER II

EARLY ATTEMPTS

WITH THE gradually increasing awareness of the seriousness of tuberculosis in the country, attempts also began to be made to deal with the problem from the beginning of the present century. In the earlier stages, however, the measures were not organised and the progress was slow. This was mainly because the exact size and nature of the problem was not known and no preventive or really effective treatment measures were yet known to the profession. Open air treatment had been gaining popularity in the West but this was mainly for early cases. Little could be done for advanced cases. With very limited bed accommodation in hospitals in India for tuberculosis, it was not possible to take advanced cases of tuberculosis patients who might occupy the beds for a long time and in the end might succumb to the disease.

Attention was gradually diverted to establishment of tuberculosis dispensaries for treatment of the tuberculous and organisation of societies and associations mainly to promote health education about the causes of tuberculosis and its prevention and to organise care of the sick.

A. OPEN AIR SANATORIA

I. Private Enterprise

Most of the early efforts to provide treatment for tuberculosis were made by philanthropic societies and individuals on compassionate grounds. It was realised also that isolation of infective cases of tuberculosis was a form of prevention. Other forms of prevention were not in the public mind as yet. In several instances, it was the discovery of tuberculosis among young people in educational institutions which led to the provision of special facilities to deal with them. No small help in starting anti-tuberculosis work was rendered by individuals who themselves had the misfortune to get the disease. In this, India shared the experience of other countries.

(i) Christian Missions: The first open-air sanatorium for isolation and treatment of tuberculosis patients was founded in 1906 in Tilaunia, near Ajmer, by a Christian

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Mission. It was intended mainly for girls from schools and orphanages connected with this mission in North India. An institution in Almora in the Himalayas for tuberculous women was also started by a Christian Mission in 1908 and about the same time a small sanatorium for women and girls at Pendra Road in the Central Provinces (now Madhya Pradesh) was also started.

In South India, Dr. Louisa Hart, a Missionary working in Madanapalle was treating a number of tuberculosis patients in temporary buildings in her general hospital for a number of years. After the Union Mission Tuberculosis Sanatorium was founded in Madanapalle in 1912, this sanatorium took over the patients of Dr. Hart and had them transferred to the permanent buildings at Arogyavaram in 1915.

(*ii*) *Private Societies*: The first Sanatorium outside Christian auspices was opened in 1909 at Dharampore in Simla Hills, due to the benefactions of some Bombay philanthropists, mainly Parsis, and under the management of the Consumptives Homes Society of Bombay.

II. Under Government Supervision

The first sanatorium started under Government supervision was the King Edward Sanatorium at Bhowali, Uttar Pradesh opened in 1912, with money collected in that province in memory of King Edward VII.

III. Individual Effort

An instance of a sanatorium established by a private individual is one which was opened in 1912 by Dr. R. B. Billimoria in Poona and which two years later moved to its present site in Panchgani, Maharashtra State.

Other sanatoria started about this time were the "Turner" Sanatorium in Bombay—Dr. Turner was Medical Officer of Health, Bombay—and a Sanatorium at Deolai built from a bequest by a private individual, Seth Bhagwandas Narotamdas.

B. Tuberculosis Dispensaries

The opening of tuberculosis dispensaries on the lines of Sir Robert Phillip, which had a large part in the campaign against the disease in the West, started somewhat later. The

first one opened was in Bombay in connection with the Bombay Anti-Tuberculosis League. In Madras, the King Edward Memorial Institute (now called the Tuberculosis Institute) was established in 1917 by the efforts of the late Dr. P. S. Chandrasekara Aiyar.

C. Prevention and Health Education

(*i*) *Anti-Tuberculosis Leagues*: A number of anti-tuberculosis societies were formed in Bombay, Lucknow and Ajmer about the time of the First World War. The main object of these societies was educative propaganda about the causes and prevention of tuberculosis.

(*ii*) *The Bengal Tuberculosis Association*: Through the inspiration and pioneering efforts of some Missionary groups in Bengal, the Tuberculosis Association of Bengal was established in Calcutta in 1929. This organisation carried out fairly extensive propaganda in favour of concerned action against tuberculosis.

In spite of the growing attention paid to the tuberculosis problem, by 1935 there were only about 6,000 beds available in the whole of India, which then included what are now Bangladesh and Pakistan, for the treatment of tuberculosis patients.

(*iii*) *Tuberculosis Association of India*: As a result of public opinion gathering strength demanding action to deal with the increasing menace of tuberculosis, the first concerted effort was made through the organisation of the King George V Thanksgiving Fund in 1929. With the funds raised by this organisation, the Tuberculosis Association of India was established in February, 1939. Its organisation and activities are discussed in the next chapter.

(*iv*) *Methods of Treatment in early stages*: The main line of treatment advocated was open air and dry climate and good food. Patients who were not too sick to move about were usually advised to go to a dry climate and take plenty of exericse for improving their appetite; feeding or overfeeding of patients was the general rule.

Tuberculin was extensively used between the years 1910 and 1920. Sodium Morrhuate which was being advocated for leprosy was also extensively used in India for tuberculosis.

From 1925 onwards Sanocrysin and other gold preparations came into vogue. Artificial pneumothorax was introduced in 1921 by Dr. Johannes Gravesen of Denmark who was associated with the Union Mission Tuberculosis Sanatorium. Thoracoscopy and cauterisation of adhesions were started in the same Institution in 1931 and gradually these operations became very popular. Thoracoplasty in its modern form, however, came to be increasingly used since 1932 in some of the institutions. Lung-resection for tuberculosis was started for the first time in India in 1948.

At that stage, it was assumed that all infectious tuberculosis patients would need hospitalisation, as hospitalisation was the only recognised form of treatment. Hospitalisation alone of all infectious patients would have cost about Rs. 360 crores, in addition to the enormous capital outlay involved in the construction of buildings for hospitals and sanatoria, yet it was realised that this could touch only a fringe of the problem. A new vision and an entirely new strategy was called for.

CHAPTER III

TUBERCULOSIS ASSOCIATION OF INDIA

In 1937, Lady Linlithgow, wife of the then Viceroy of India, after an appraisal of the Tuberculosis problem in India issued an appeal for funds to establish an anti-tuberculosis association in India. The Association was to consist of a central body supported by provincial and State organisations as affiliates of the Central body. In response to her appeal, a sum of Rs. 85 lakhs was collected. After returning 95% to States and provinces for maintenance of clinics and where possible of sanatoria and after-care settlements, the balance was retained for the Tuberculosis Association of India. To this was added direct donations and the corpus of the King George Thanksgiving Fund and the Tuberculosis Association of India was established in Delhi under the Societies Registration Act of 1860 on 23 February, 1939.

The main activities of the Association are summarised below:

New Delhi TB Centre

To serve as a model institution for "organised home treatment" of tuberculosis, the Association established with the help of Government of India, the New Delhi TB Clinic in 1940. Simultaneously, a few voluntary Care and After-care Committees were formed to assist the New Delhi TB Clinic in meeting the social requirements of patients. The New Delhi TB Clinic was upgraded in 1951 as a Training & Demonstration Centre with the help of the Government of India, WHO and UNICEF. Subsequently, the activities of the Centre multiplied manifold and today this Centre is reputed as one of the most efficient institutions in the country.

TB Sanatorium at Kasauli

In 1941, the Association established a sanatorium at Kasauli near Simla Hills. The sanatorium known as Lady Linlithgow Sanatorium had 250 beds and was one of the premier TB sanatoria in the country. For want of enough paying patients, this institution was closed down recently.

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TB Directory

The Association collected information regarding tuberculosis institutions in the country and published the first directory in 1943. This was revised periodically and the last (6th) edition was published in 1964. This is a useful document in respect of information about the facilities available in tuberculosis institutions in the country.

TB Hospital at Delhi

With the donations from a Delhi philanthropist, Lala Ramsarup Khanna and grants from the Government of India, the Association established the Lala Ramsarup TB Hospital at Mehrauli, Delhi with 306 beds which started functioning from 1953. It is one of the good hospitals in the country with all facilities including thoracic surgery.

Other Services

Apart from establishment of institutions and compilation of Directory, the Association had undertaken several other services. The Tuberculosis Hermitage at Sangrur was maintained by the Association for five years with Government of India grants and treated over 550 refugee TB patients upto March 1955. Thereafter, the hospital was handed over to the State Government.

With a grant received from the former Viceroy's War Purposes Fund, the Association selected 14 sanatoria all over India and treated over 450 Tuberculosis ex-servicemen.

The Consumptives Home Society, a charitable organisation of Bombay, had established one of the oldest TB sanatoria (K. E. Sanatorium) in Dharampur, Himachal Pradesh. The Society handed it over to the Tuberculosis Association of India in 1954. The Association maintained this Sanatorium for nearly 15 years but had to return it to the Consumptives Home Society because of financial difficulty.

Technical Committee

The Tuberculosis Association of India established a Technical Committee in 1948. This Committee consists of reputed Tuberculosis workers drawn from various parts of India to advise the Association on matters relating to control of tuberculosis.

Research

The institutions of the Association have also undertaken several research projects approved by the Indian Council of Medical Research pertaining to tuberculosis. The Ministry of Health also had provided grants to the Association to carry out surveys in urban and rural areas of Delhi by its institutions.

The Association has a Research Committee. On the recommendations of this Committee, a research programme has been instituted to find out if the period of treatment of tuberculosis could be shortened. A preliminary report of this study was presented recently to the International Tuberculosis Conference at Mexico.

Conference

A regular programme of the Association calculated to bring together those working in the anti-tuberculosis field and to involve tuberculosis workers in the anti-tuberculosis movement is the organisation annually of a conference of tuberculosis and chest diseases workers from different parts of the country. This conference deals with various aspects of tuberculosis control work and useful discussions are held.

Health Education

The Association has been carrying out regular programme of health education activities since its inception. These include broadcast talks, preparation and distribution of pamphlets and posters on various aspects of tuberculosis control measures, newspaper advertisements, etc. The Association prepares and distributes propaganda material to its affiliates and the latter bring these out in regional languages.

The Association has also brought out a blue print which deals with different aspects of tuberculosis control. The second edition of this blue print has been brought out recently.

Journal

The Association started the *Indian Journal of Tuberculosis* in September 1953. This is a quarterly journal devoted to the different aspects of tuberculosis control. Its editorial board consists of well-known tuberculosis specialists.

Textbook

A significant event for the Association was the publication of a textbook on Tuberculosis in 1970. This book deals with all aspects of tuberculosis. The problems of tuberculosis that are common to most of the developing countries in Asia and Africa have also been discussed in this book. The second edition of the textbook on Tuberculosis is now under preparation.

Training of workers

The different institutions of the Association like New Delhi TB Centre. Lala Ramsarup TB Hospital and the Lady Linlithgow Sanatorium take active part in the training of doctors and other personnel in tuberculosis. The New Delhi TB Centre conducts a regular course in training of TB Health Visitors. The Association played a vital role in persuading the Indian Universities to institute diploma courses in tuberculosis.

The Technical Committee has been reviewing questions relating to the teaching of tuberculosis at various stages of medical education and has been making important recommendations from time to time.

Affiliated Associations

There are 23 State Tuberculosis Associations which are affiliated to the Tuberculosis Association of India. Most of them have established district organisations and carry out educational activities. They organise conferences, camps, care committees and refresher courses. Many Associations also maintain certain TB institutions like TB clinic, TB laboratory, etc. They also give financial assistance to indigent TB patients.

Seal Sale Campaign

The Association started the seal sale campaign in 1939. Starting on 2 October, Mahatma Gandhi's birthday, it terminates on 26 January, the Republic Day every year. The campaign is usually inaugurated in the Capital by the President of India and in the States by Governors or other dignitaries. During the past 25 years, this special programme has helped focus attention on the tuberculosis problem and generated an appreciable amount of interest in the programme.

International contacts

Since its inception, the Tuberculosis Association of India has been an affiliate of the International Union Against Tuberculosis. It has maintained cordial relations with National Associations all over the world. It organised the XIV National Conference in New Delhi in 1957. Its representatives have participated in most of the international conferences after 1947.

The Association is also an active member of the Eastern Regional Organisation. The Tuberculosis Association of India hosted the IX Conference of the Region in New Delhi alongwith its 29th National Conference on Tuberculosis & Chest Diseases in 1974.

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CHAPTER IV

BHORE COMMITTEE'S ASSESSMENT AND RECOMMENDATIONS

THE GOVERNMENT of India appointed in 1944 a Health Survey and Development Committee, popularly known as the "Bhore Committee" to study the health problems of the country and suggest plans for the development of health programmes.

On the basis of data then available, the Bhore Committee estimated that there could easily be about 2.5 million active cases of tuberculosis in the country, of whom perhaps about 0.5 million were dying every year. The recommendations of this Committee were in line with the anti-tuberculosis measures carried out in Western countries even though there were certain modifications to suit Indian conditions. The Committee's recommendations briefly were:

(*a*) Establishment of TB clinics, one for every district town. They emphasised the part domiciliary service had to play in tuberculosis control. They also recommended services of mobile clinics to cover the rural areas.

(*b*) Establishment of TB hospitals. They accepted the usual standard of one bed per annual TB death but recommended 2,17,300 beds as the minimum requirement. These were to be established in primary unit hospitals, secondary unit hospitals and district headquarter hospitals. Since provision of such a large number of beds would take many years, they recommended that in the first five years, 200 beds should be provided for every 10 million population.

(*c*) Provision of homes for incurables and establishment of after-care colonies. They suggested that non-official organisations interested in social welfare should help in this venture and the Government should meet a substantial part of the expenditure through generous grants.

(*d*) Development of facilities for training of tuberculosis workers was considered very urgent.

(*e*) Undertaking tuberculosis surveys for providing baseline information regarding incidence of the disease and for effective planning of tuberculosis.

(*f*) Creation of a Section for Tuberculosis in the Directorate-General of Health Services with an expert in Tuberculosis to advice, coordinate and further anti-tuberculosis work in the country as a whole.

(*g*) Encouragement of non-official efforts to supplement government work.

One of the first steps taken by the Government was to implement the Bhore Committee's recommendation in regard to the creation of a separate Section for Tuberculosis in the Directorate-General of Health Services with a senior expert as its Adviser. The other recommendations were taken up gradually.

Health Association of India
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CHAPTER V

POSITION AT THE TIME OF INDEPENDENCE

With the attainment of Independence in 1947, the National Government naturally devoted considerable thought and funds for social welfare in India and gave high priority to tuberculosis as it happened to be the most serious public health problem in the country, next only to Malaria. This also coincided with the increasing interest which the international organisations like the World Health Organisation, the UNICEF and the International Tuberculosis Campaign were taking in tuberculosis as a world problem. However, the events that followed Independence made the tuberculosis problem even more serious and difficult than were visualised by the Bhore Committee. Partition of India brought in as its aftermath a large number of displaced persons to India. Most of them had to live in crowded areas with extremely poor hygienic conditions. There was also the problem of malnutrition. These accentuated the already bad tuberculosis problem in the country.

Though the urgency of taking up a large scale control measure for such a big and serious problem was fully realised, it was not possible for the government to immediately implement all the recommendations of the Bhore Committee, because for providing even the minimum requirements suggested in that report, a substantially large sum was necessary. The number of beds available at that time for tuberculosis patients in India was only about 6,000 and the number of clinics about 85 whereas the estimated number of patients was about 2.5 million. It was estimated that for controlling the problem of tuberculosis of such a magnitude, India would require some 3,000 to 4,000 TB clinics and some five lakh beds according to the usual standards obtaining in the Western countries at that time. The cost of these was estimated to be over 5,000 million rupees. It was obvious that from the point of view of men, material and resources, introduction of such a programme was impossible within a reasonable period of time. Attention was, therefore, directed towards prevention. Since BCG had proved to be efficacious in the prevention of tuberculosis in many of the Western countries and could be applied quickly, easily and at a comparatively low cost, the chief method chosen for

prevention of the disease was BCG vaccination. It was planned that the vulnerable population should be protected by BCG vaccination within a period of 10 to 12 years and in the meantime resources and knowledge should be mobilised to adopt other measures for effective control of tuberculosis.

BCG vaccination was started as a pilot project at first in 1948 in Madanappalle in South India and thereafter it was extended as a school vaccination programme in all the States during 1949 to 1951 with the help of the International Tuberculosis Campaign. At the same time, the Government of India set up a BCG Production Laboratory at Guindy, Madras in 1948 for production of BCG and tuberculin for the country's programme.

About the same time arrangements were made to establish with the help of the World Health Organisation and the UNICEF, TB Training & Demonstration Centres at Delhi, Patna and Trivandrum to serve as model for TB clinics and also as Centres for training of personnel for the country's TB control programme. A number of fellowships for tuberculosis workers for training abroad were also given.

CHAPTER VI

FIRST FIVE YEAR PLAN

In 1951, the First Five Year Plan of the Government of India was started, and tuberculosis was given a prominent place therein. A scheme for control of tuberculosis in the country as a whole was drawn up by a Technical Committee consisting of experts from different parts of the country. This scheme was accepted by the Planning Commission. It included:

(i) Expansion of BCG vaccination on a mass-scale.

(ii) Establishment of TB clinics and expansion of domiciliary services.

(iii) Establishment of more Training & Demonstration Centres.

(iv) Provision of beds for isolation and treatment of those TB patients living in crowded and unhygienic areas.

(v) Rehabilitation of ex-patients.

(vi) Research.

As health is a 'State' subject, the National Government had to depend largely on the State Governments for implementation of most of the schemes. A sum of Rs. 46.3 million was provided in the Plan, of which Rs. 38.0 million was in the State sector.

During the First Plan period, BCG vaccination programme was expanded on a mass-scale to cover the population below the age of 25, approximately 170 million. The BCG Vaccine Laboratory in Guindy was expanded so as to produce adequate quantity of vaccine necessary for the expanded programme. The target for BCG vaccination in the First Plan was testing and vaccination of a total of 87 million persons. The actual achievement was, however, 71.5 million tuberculin tests and 24.5 million BCG vaccinations.

Priority was given to establishment of TB clinics because it was thought that it was one of the practical methods for arranging domiciliary treatment for tuberculosis which could

be introduced very quickly and because provision of a very large number of beds required for treatment of TB cases as recommended by the Bhore Committee was found impracticable due to paucity of funds. The discovery of new anti-bacterial drugs for treatment of tuberculosis and their effectiveness in domiciliary service provided further justification for giving top priority to the establishment of TB clinics. Fifty five new clinics could be established in the First Plan but it was noted that most of the clinics in the country were not run satisfactorily. Majority of the clinics did not have adequate diagnostic facilities nor did they have adequate staff to carry out an effective domiciliary service. This fact was taken note of while recommendations were made for the Second Five Year Plan.

It was suggested that about 10,000 beds should be provided for tuberculosis in the First Five Year Plan specially for isolation of infective patients living in crowded and unhygienic homes in cities and towns. About 5,000 beds were added during the Plan in the various States against the target of 10,000 but these were mostly added in existing sanatoria and hospitals. In addition, two special hospitals for tuberculosis children were established during the first Plan period, one in the North at Mehrauli in Delhi and the other in the South at the UMT Sanatorium, Madanapalle. The three training centres for tuberculosis at Delhi, Patna and Trivandrum were completed. Establishment of work centres for rehabilitation of ex-TB patients was also contemplated but no progress could be made.

Investigations on use of newly available anti-bacterial drugs for treatment of tuberculosis were undertaken at Madanapalle Sanatorium, Kasauli Sanatorium and also in other institutions under the Indian Council of Medical Research. An important research during the First Plan was the community tuberculosis control programme by the TB Sanatorium in Madanapalle where methods of TB control including isolation of infective cases and BCG vaccination were introduced in a rural community around Madanapalle.

Two main landmarks in respect of research that were of vital importance for subsequent development of a National TB Control Programme were the start of the National Sample Tuberculosis Survey and the establishment of the Chemotherapy Research Centre at Madras by the end of the First Five Year Plan in 1956. Till then, though it was realised that

the problem of tuberculosis in the country was very large, its precise extent, prevalence and incidence in different areas, communities and age-groups and the two sexes were not known and this was a big handicap in organising a mass control programme and fixing rational priorities.

The Tuberculosis Chemotherapy Centre was established in Madras in 1956 by the ICMR with the cooperation of the World Health Organisation, the British Medical Research Council and the Government of Madras. The main object of this project was to determine the . efficiency of domiciliary chemotherapy *vis-a-vis* hospital treatment and other problems connected with treating patients in their homes. The other objective was to work out appropriate drug regimens specially for domiciliary chemotherapy.

CHAPTER VII

SECOND FIVE YEAR PLAN

THE PRIORITIES in the Second Plan were about the same as in the First Plan. The difficulties and pitfalls encountered in the implementation of the First Plan schemes were taken note of and steps were taken to rectify these.

The First Plan schemes were to be implemented solely by the States except BCG vaccination programme and research. As a result, TB clinics were established without proper equipment and staff and TB beds were added mostly in hospitals and sanatoria that were not useful for infective cases in crowded areas. One of the important changes made in the Second Plan was, therefore, to undertake certain of the TB control schemes as national programme and the Central Government to give a subsidy to the State Governments for their implementation.

The target set for BCG vaccination in the Second Plan was to complete the mass vaccination programme to cover 170 million young people. For intensifying activities, certain subsidies were provided by the Central Government to the States. As a result of expansion, 91.7 million tuberculin tests and 37.5 million BCG vaccinations were performed in the Second Plan period. New building and plant, for the manufacture of freeze dried BCG vaccine were made available at the BCG Laboratory and some freeze dried vaccine was manufactured on an experimental basis.

In the Second Plan, the Government of India agreed to supply X-ray and laboratory equipments to the newly established or upgraded TB clinics for expansion of domiciliary treatment service. The target was to establish and upgrade 180 TB clinics. As against this target, 80 new TB clinics were established, of which 60 were equipped with funds provided by the Government of India.

A target of establishment of 10 TB Training & Demonstration Centres in association with the Medical Colleges in different States was fixed. However, three Training & Demonstration Centres could only be established at Nagpur, Madras and Hyderabad.

4,000 TB isolation beds were established during the Second Plan period for which the Government of India gave a subsidy of Rs. 1,250 per bed.

Establishment of after-care work centres in association with large clinics in the country for training of TB and ex-TB patients and their family members in different handicrafts was also taken up in the Second Plan. Six such rehabilitation centres could be established in the Second Plan period as against a target of eight.

The National Sample Survey started in 1956 was completed in 1958. The report was published by the Indian Council of Medical Research which gave precise information for the first time about the size and nature of the problem in the country.

The community Field Research Programme in Madanapalle was further expanded under auspices of the Indian Council of Medical Research and the W.H.O. The study population was increased from 50,000 to 2,00,000 and the scope of the study was expanded to include effect of domiciliary treatment in a community by repeated examinations of the patients and their contacts and periodical surveys of the population in that community.

The studies conducted by the Chemotherapy Centre, Madras showed that the results of home treatment with anti-TB drugs as carried out at the Centre in Madras were as good as the results of sanatorium treatment and that bed rest or good diet did not play any major role in the treatment of tuberculosis.

One very significant event of the Second Plan was the establishment of the National Tuberculosis Institute at Bangalore in 1959. This was inaugurated by the late Prime Minister, Pt. Jawaharlal Nehru on the 16 September, 1960. This Institute was planned to serve as a centre to evolve and work out tuberculosis control methods best suited to a country like India where tuberculosis problem is large and the resources are meagre and to train the staff required to implement the tuberculosis programme in the country. The Institute was established by the Government of India in the premises then made available by the Government of Mysore and with the help of the World Health Organisation and the UNICEF.

The activities of these two institutions are discussed in a subsequent Chapter.

CHAPTER VIII

THIRD FIVE YEAR PLAN

THE Third Five Year Plan from 1961-66 was continued for two more years in 1967-68 and 1968-69 till the start of the Fourth Five Year Plan in 1969-70.

In 1962 the Health Survey and Planning Committee (Mudaliar Committee) reassessed the problem of tuberculosis and recommended measures essential to deal with it. This Committee recommended that BCG vaccination should be further intensified, domiciliary treatment for tuberculosis should be further expanded and mobile X-rays for rural areas should be provided. The Committee recommended one TB clinic for each one million population, one lakh additional TB beds in the Third Plan and a full time State TB Officer (A.D.P.H., TB) in each State.

During the Third Plan period, the schemes for mass BCG vaccination and establishment of TB clinics, Training & Demonstration Centres and TB beds were therefore continued and their expansion provided for. A new scheme for establishment of mobile X-ray clinics was taken up with a view to catering to the needs of the vast majority of patients living in the rural areas since most of the TB institutions and clinics, etc., established so far were located only in urban areas. Simultaneously, the National Tuberculosis Institute was engaged in their attempt at evolving suitable methods by which anti-TB measures could be integrated with the community development service in the rural areas with a view to providing tuberculosis services in the periphery.

The National Tuberculosis Institute within a short period after its establishment, was able to introduce a major change in the strategy and concept of National Tuberculosis Programme by evolving a community control programme for tuberculosis. On the basis of the findings of the National Sample Survey that the prevalence of tuberculosis was almost equal in both rural and urban areas in India, it was considered essential to plan a programme for providing diagnostic treatment and prevention facilities in the rural areas where 80% of the country's population lives. Operation research conducted by the National Tuberculosis Institute proved the feasibility of

organising a programme aimed at providing measures for diagnosis, treatment and prevention of tuberculosis on a community basis. Based on the findings of the various social, organisational and operational research studies in community approach, a district TB control programme was evolved in 1962. The concept, methodology and organisation of the District Tuberculosis Programme is discussed in a subsequent Chapter under National Tuberculosis Programme. The main activity of the National TB Programmes since then has been establishment of District TB Centres for organising control measures through all the peripheral health facilities in the district.

The strategy of the BCG vaccination programme was also changed. It will be realised that the Plan at the time of inception of the BCG vaccination programme was to cover the entire susceptible population in its first round and thereafter integrate BCG with the appropriate agency of the general health service to be able to cover the newly added young population. However, since a large backlog of the susceptible population was still available and neither the school health service nor the maternity and child welfare service was sufficiently organised to be able to take full responsibility of providing BCG immunization to the entire young population, it was proposed to continue the BCG programme but it was decided to integrate the BCG teams with the District TB Control Programmes that were taken up as a Plan scheme in the Third Plan. As BCG vaccination without preliminary tuberculin test was found to be safe and simple, direct BCG vaccination was introduced and vaccination was limited to the younger age group of 0-14 years. Newborn vaccination was also introduced starting with the maternity hospitals and other maternity institutions in urban areas. A total of 95.7 million tuberculin tests and 55.9 million BCG vaccinations were performed during the period from 1961—68.

District TB Centres under the District TB Control Programme were established in 119 districts and many of the TB clinics in the district headquarters established in the previous Plans were upgraded to function as District TB Centres by organising TB control programme for the entire district. Thus, the total number of upgraded District TB Centres that were to function as headquarter of the managerial team of a district programme and as a referral centre for the entire programme came upto 170 by 1968.

A target was fixed for establishment of five more State Training & Demonstration Centres at State level for training of personnel. As against this target, eight were established during the Plan period. Thus, the total number of State Training & Demonstration Centres came to 15.

Against the target of establishment of 25 mobile X-ray clinics, five were developed and in the meantime the need for such clinics was no longer considered urgent after the District TB control concept for rural areas was evolved by the National Tuberculosis Institute.

A target for establishment of 5,000 TB isolation beds was fixed. However, priority was given to establishment of District TB Centres through which bulk of the patients could be treated rather than to establishment of isolation beds. A total of 1,571 beds were only established during the Plan period.

Certain advance actions for implementation of the scheme proposed for the Fourth Plan were also taken up during the course of the Third Plan period. These were:—

(1) *Establishment of regional organisations*: To guide implement, supervise and assess the work of the district TB programme in the States and to coordinate their activities, six regional Centres were originally proposed for the Fourth Plan and two of these were established in the Third Plan itself in Bangalore for the Southern districts and in New Delhi for some of the Northern districts.

(2) *Supply of anti-TB drugs*: The most important event in the Third Five Year Plan was the start of a scheme for supply of anti-TB drugs to State TB clinics as well as to TB clinics run by voluntary organisations for domiciliary treatment. 237 TB clinics under the State Governments and 45 TB clinics under voluntary organisations took advantage of this scheme immediately after it was started in the Third Five Year Plan. Anti-TB drugs worth more than Rs. 16 million were supplied during the Third Plan period.

CHAPTER IX

FOURTH FIVE YEAR PLAN

In the Fourth Plan, all the schemes of the Third Plan were continued. However, it was observed during the previous Plans that in spite of all the guidance and assistance given by the Central Government, implementation of the programme by the States was poor. It was, therefore, felt that to be able to develop the required organisation for tuberculosis control in the entire country the Government of India should take the responsibility of bearing the cost of the entire programme in the Fourth Plan period. All the schemes under the TB Control Programme in the Fourth Plan were therefore made Centrally sponsored schemes with 100% Central assistance. This meant that whereas in the previous Plans, the Government of India assisted the States in the establishment of District TB Centres and isolation beds by bearing a portion of the recurring and non-recurring expenditure, in the Fourth Plan, the Government of India undertook the responsibility of bearing the entire cost of establishment and maintenance of these institutions and of anti-TB drugs and BCG vaccine required for the programme.

The number of districts at that time was 330. 170 of these were already covered under District TB Control Programme upto the end of the Third Five Year Plan. It was therefore proposed to cover the rest of the 160 districts during the course of the Fourth Plan so that by the end of the Plan period, all the districts of the country would have been covered by the District TB Control Programmes. A target of 160 District TB Centres was, therefore, fixed for the Fourth Plan.

The need for a minimum number of beds as adjunct to domiciliary service for problem cases of District TB Programmes in the districts was considered essential. There were several districts where there was no TB bed at all. A target of establishment of 2500 TB isolation beds was therefore fixed for the Fourth Plan. States were advised to establish such beds as additional TB wards in district hospitals where no TB bed was available. In the meantime because of the popularity of domiciliary service, many of the TB beds maintained by voluntary organisations were at the point of being closed down

for want of paying patients and resources. It was, therefore, suggested to the States that in any area without TB beds if there was a TB hospital or sanatorium run by a voluntary organisation within a radius of 250 miles, they should rather reserve beds in such voluntary organisations instead of establishing new beds and the Government of India was prepared to pay the cost of reservation within the stipulated pattern of assistance to State Governments.

At the end of the Third Plan, there were still two major States *viz.*, Madhya Pradesh and Assam not having a training & Demonstration Centre. For the other smaller States like Nagaland, Tripura, Manipur, etc., and the Union Territories, it was not considered necessary to have separate Training & Demonstration Centres as they could take advantage of the Training & Demonstration Centres of the adjacent States. A target for establishment of two Training & Demonstration Centres at Assam and Madhya Pradesh was therefore fixed.

Regarding supply of BCG vaccine, it was decided that money required for purchase of BCG vaccine, tuberculin, etc., from the BCG Vaccine Laboratory will be paid by the Government of India to the States. So far as supply of anti-TB drugs to TB clinics run by State Governments and voluntary organisations for domiciliary treatment of TB patients is concerned, it was decided to continue free supply of these drugs by the Government of India as hitherto.

During the course of the Fourth Plan, 114 more TB clinics were added as against the target of 160. The two Training & Demonstration Centres as targetted were established and 1571 isolation beds were established against the target of 2500. In the meantime, BCG vaccination programme of the country was further expanded through other agencies like the railways, armed forces, voluntary organisations, etc.

A new Central scheme for expansion of production of freeze-dried BCG vaccine was taken up in the Fourth Plan. Production of freeze-dried BCG vaccine in the BCG Laboratory which was only about 5 million doses in 1969-70 was enhanced to about 30 million doses by 1973-74. By the end of the Plan period use of liquid vaccine in the entire programme was stopped and only freeze-dried vaccine was used. A total of 60 million direct vaccinations were performed in Plan period. BCG vaccine and tuberculin worth about Rs. 4.5 million were supplied to the States.

Anti-TB drugs worth about Rs. 33 million were supplied to more than 300 TB clinics run by the State Governments and about 60 TB clinics run by voluntary organisations for free supply to the TB patients on domiciliary treatment.

In the meantime, the project: Tuberculosis Prevention Trial, which started with a feasibility study in 1964 and as a regular project in 1968 was continued for assessing the value of BCG in the prevention of tuberculosis in the circumstances prevailing in our country. The first phase of the work which included initial examination of the population comprising about 3,67,000 was completed by March, 1971.

CHAPTER X

FIFTH FIVE YEAR PLAN

THE Fifth Five Year Plan which started from 1974 would continue till 1979. During the Fifth Five Year Plan, it has been decided to continue the schemes for supply of anti-TB drugs to State TB clinics as well as to voluntary TB clinics and supply of BCG vaccine and tuberculin to the States as Centrally sponsored schemes with 100% Central assistance. So far as establishment of District TB Centres and Isolation beds are concerned, these are included in the State sector for which funds are being provided in the State budget.

The provision for the different schemes under the National TB Control Programme for the Fifth Plan are:

I. Centrally sponsored schemes		
(i) Supply of anti-TB drugs to State TB Clinics		Rs. 575 lakhs
(ii) Supply of anti-TB drugs to voluntary organisation-run TB clinics		Rs. 100 lakhs
(iii) Supply of BCG vaccine to States		Rs. 150 lakhs
II. State schemes	*Target*	
(i) Establishment of District TB Centres	75 Centres	Rs. 335 lakh,
(ii) Establishment of TB Isolation Beds	3500 beds	Rs. 506.60,
(iii) Equipment for State/ District TB Centres	75 sets	Rs. 90.00.

With the establishment of 284 District TB Centres upto the end of Fourth Plan, it was estimated that another 75 districts were to be provided with a District TB Centre in each, taking into consideration also the new districts that were created in the meantime. So far, the United Nations Children's

Fund was supplying X-ray, Laboratory equipment and vehicles for these District TB Centres. In the Fifth Plan UNICEF aid is not available. It is, therefore, necessary for the States to establish and equip the 75 Centres during the course of the Fifth Plan. The phasing suggested for establishments of these 75 District TB Centres in the Fifth Plan should enable us to cover the entire country by District TB Programme by the end of the Plan period.

3500 more TB Isolation beds are to be established by the States in the Fifth Plan as adjunct to domiciliary service programme of the District TB Programmes. These are to be added as wards in existing general and tuberculosis hospitals. With the establishment of these beds, the total number of TB beds in the country will come to a little over 44,000.

BCG vaccination of newborns and infants in an integrated approach to immunization of children in rural areas with BCG, smallpox and DPT by the peripheral health workers of the Primary Health Centres is being organised in the Fifth Plan. In each P.H.C. area there are 20 to 24 workers in the periphery like ANMs, BHWs, Vaccinators, etc. The population of the N.E.S. Block are to be divided among them at 4500 to 5000 per worker and the children in this population are to be vaccinated by them with the three vaccines during the course of their normal work. These persons are being trained and will be supervised by the existing BCG teams that will continue to cover the school-age group. To meet the increased requirement of BCG vaccine, production of freeze-dried BCG is being enhanced to 60 million doses in the next few years for which a sum of Rs. 50 lakhs has been provided. Necessary major equipment for freeze-drying of vaccine and automatic sealing of ampoules, etc., is being procured and the testing and quality control laboratory is being expanded, so that, if required, production of freeze-dried BCG can be further enhanced in the Fifth Plan itself.

Anti-TB drugs as usual are being procured by the Government of India and are being supplied directly to the TB clinics. Miniature X-ray films are also being procured centrally for supply to District TB Centres. BCG vaccine is being supplied from the BCG Vaccine Laboratory, Madras. Tuberculin for diagnostic use is also supplied from the same Laboratory. A sum of Rs. 13.5 million was utilised for supply of drugs and BCG in 1975-76 and about Rs. 15 million was likely to be utilised in 1976-77.

CHAPTER XI

NATIONAL TUBERCULOSIS PROGRAMME

THE TUBERCULOSIS Programme of the country has been evolved takng into consideration the following facts:

(a) That the nine million or so cases of active tuberculosis in the country are evenly distributed in the towns and villages, that is, 82% of the cases are in the villages where no special facility for tuberculosis exists.

(b) That the pool of infectors are the sputum positive cases totalling about two million in the country, most of whom have also symptoms and therefore have a felt need for taking action, and in fact, are already seeking relief for their suffering from the general hospitals, health centres and dispensaries in their areas.

(c) That domiciliary treatment is most suited for treatment of tuberculosis and institutional treatment becomes necessary only for a small percentage of problem cases.

(d) That the programme for tuberculosis control must cover the entire country, be well within the available resources in men, money and material and provide sizeable benefit to the community in the foreseeable future.

(e) That by organising tuberculosis control on a community basis through the existing health facilities which provides a permanent programme and is easy of implementation, it is possible to bring under treatment a large proportion of the infectious cases in community in a reasonably short period of time.

(f) That BCG vaccination is an effective and reliable preventive measure and can be integrated with the general health services as a regular features.

(g) That tuberculosis is a chronic infectious disease of ubiquitous distribution and about half the total population of the country is infected by tuberculosis germs that constitute the main source of future patients for

several decades. High birth rate adds to the susceptible population every year needing a regular BCG vaccination programme all the time. Therefore, the programme has got to be countrywide, of a permanent nature and should be integrated with general health service.

The fundamentals of control programmes are:

(i) Prevention of development of tuberculosis infection and disease among those who are not infected.

(ii) Detection and treatment of as large a number of infectious cases as possible with a view to rendering them non-infectious.

To achieve these objectives, the main emphasis in the National Tuberculosis Programme has been on the organisation of District TB programme by establishing a fully equipped and staffed District TB Centre in each of the districts and developing tuberculosis case-finding, treatment and BCG vaccination activities in the entire district through the existing health facilities.

CHAPTER XII

DISTRICT TUBERCULOSIS PROGRAMME

AN AVERAGE district in India has a population of about 1.5 million. It is divided into about ten taluks with a taluk headquarter town in each, of which the largest is generally the district headquarter. There are about 1800 villages which are grouped into 20 blocks, each provided with a Primary Health Centre. In addition to the Primary Health Centres, there are another about 30 small hospitals, dispensaries, *etc.*, thus having about 50 health institutions, each under the charge of a qualified medical officer.

On an average there are about 20,000 patients in a district of whom about 5,000 are infectious. These 5,000 cases are the ones that are sources of infection and most of whom also have symptoms. They are given priority in the district TB control programme, both with a view to providing relief of symptoms and 'sterilizing' the infectious pool. The rate at which new cases (*i.e.*, diseases incidence) are added every year to the pool of cases can be estimated to be about one-third to one-fourth of the prevalence cases. This means that about 1250 to 1500 infectious cases are added to the pool of 5,000 every year and similar number of cases either die or recover from the disease, thus keeping the infectious pool more or less constant at about 5,000 cases. On a rough estimate, on the basis of the drugs consumed or budget provided for anti-TB drugs in any district where District TB Control Programme has not been organised, it is estimated that not more than 100 to 200 cases could be under active treatment.

In a district TB control programme, the District TB Centre established at the district headquarter and staffed by personnel trained in the concept of community approach to the problem of tuberculosis at the National Tuberculosis Institute, functions as a referral centre for the entire district and as the headquarter of the managerial team responsible for organising the programme in the entire district. The actual activity of case-finding mainly by sputum examination and of rendering anti-TB drug treatment on domiciliary basis takes place in the 50 and odd peripheral health institutions where the district tuberculosis team is to organise the programme. Thus, each patient in the periphery is offered the diagnostic as well as

treatment facility throughout the whole period of his treatment which is generally a minimum of one year, in the health facility near his home. Case index card for each patient is maintained at the District TB Centre and only treatment cards for the patients receiving treatment are maintained in the respective peripheral health institutions.

To start with, a patient suffering from tuberculosis may not be aware about it. Gradually he develops certain symptoms like cough, fever, weakness, loss of appetite, haemoptysis, etc., and goes to his nearest health institution seeking redressal of his symptoms. It has been found that in areas not having any regular tuberculosis programme, almost all the sputum positive cases (infectious) were aware about their symptoms and half of them had visited practitioners of modern medicine in search of treatment. Simple sputum examination can pick up about 82% of the infectious cases reporting to these health centres.

Thus, the bulk of the infectious cases having symptoms and seeking redressal at the peripheral health centres can be diagnosed by sputum microscopy and be offered regular treatment. For the other 18% it may be necessary to observe them and after necessary investigation, send them to the District TB Centre or other nearer X-ray facility for X-ray and further investigation. Priority is given to sputum examination because it has been found that only about 8% to 15% of the suspects (X-ray cases with negative sputum) breakdown into sputum positive status over a period of one to two years.

In such an organisation, the peripheral health institutions having sputum microscopy facility function as microscopy centres and the others not having microscopes can refer their patients to the nearest microscopy centre for sputum examination and therefrom to the nearest X-ray facility for X-ray examination.

Such activity of the District TB Control Programme does not really increase the workload enormously in any of the peripheral health institutions since in actual practice, the workload is not more than three or four sputum examinations per day. A minimum of recording and reporting is provided for to make it easy and simple. If a District TB Centre along with its 50 or more peripheral health institutions can diagnose and put under treatment about 1500 sputum positive cases per year, such a programme is likely to reduce the problem or tuberculosis. Prior to recommending this programme for the entire

country, it was tried as pilot project in some districts and it was found that such a coverage is possible without much additional inputs.

BCG vaccination also forms an integral part of the activities of the District TB Control Programme. For this a BCG team is posted in each district TB programme for systematic and regular coverage of the susceptible population in the entire district. The six technicians of the team cover the school children in all the schools and the pre-school and non-school going children from house to house. For newborn and infant vaccination, the staff of the existing maternity and other health institutions and the peripheral health workers are trained to build up a permanent organisation for this purpose.

TB Beds

The TB beds available in the district are used as adjunct to the domiciliary service of the District TB Control Programme. Hospitalisation is arranged for emergencies like haemoptysis, spontaneous pneumothorax, etc., or for cases where surgery is contemplated, for patients who are desperately ill, for those TB patients who are resistant to the standard anti-TB drugs and are therefore required to be treated with second-line drugs under observation or for those who do not have a place to live in.

State TB Centres

These are otherwise known as State TB Training & Demonstration Centres. One such Centre is provided in each of the major States of the country. The State TB Centre organises a model District TB Control Programme in the district including an urban programme in the city or town where it is located for demonstration, purposes. It undertakes training and re-orientation of the personnel engaged in the TB control programme of the country. It also organises seminars and re-orientation training courses for general health service personnel, private practitioners, etc. It conducts epidemiological and laboratory studies essential for the TB control programme. These centres are planned to be developed as State TB Centres, also for assessment and monitoring of the TB Control Programme of the State.

CHAPTER XIII

PRESENT STATUS OF THE PROGRAMME

THE PROGRESS of the different schemes of the National TB Control Programme are briefly discussed below:

District TB Centres

There are at present about 600 TB clinics in the country of which about 300 are District Centres organising District TB Programme in 300 districts. Each of these District TB Centres is staffed with a team of personnel trained at the National TB Institute, Bangalore. About 250 of these have been provided by the UNICEF or the Government of India with full set of X-ray and laboratory equipments and vehicles. Each District TB Centre on an average has about 25 peripheral health institutions participating in the programmes and about 2800 patients are under treatment of a District Programme.

There are only about 17 districts in the country that still have no TB clinic. In the remaining districts not yet covered by regular District TB Programme, it is possible to organise TB control programme with a little effort, since the TB clinics as the nucleus of the District TB Centre already exist and trained personnel are either available in the State or can be easily trained at National TB Institute. The main activity of a District TB Programme is to organise case-finding and treatment through the existing peripheral health institutions of a district.

BCG Programme

There are at present 308 BCG teams. These have been mostly integrated with District TB Programmes. 290 teams have been posted in or integrated with District TB Centres so far. These teams are mostly covering children in schools and the pre-school age children by house to house visits. A total of about 253 million persons have been tuberculin tested and about 195 million have been vaccinated since the inception of the campaign. On an average about 13 million infants and children are offered vaccination per year, which, however, includes only

about a million new borns and infants below one year of age. Training of paramedical personnel of the rural health service for newborn and infant vaccination is in progress. Production of freeze dried BCG vaccine in our BCG Vaccine Production Laboratory is being expanded.

TB Beds

The total number of TB beds available in the country today is about 41,500. A little less than a third of these beds are run by voluntary organisations and the rest are under control of State Governments, other governmental agencies, municipalities, etc.

Training & Demonstration Centres

There are at present 17 Training & Demonstration Centres, which are in varying stages of development. Most of these centres are running a model District TB Programme and are having training activity for medical and paramedical personnel, medical college students, private practitioners, etc., apart from conducting certain epidemiological studies. A brief note on the activities of some of these centres is given towards the end.

Regional TB Organisations

Two Regional TB Organisations are functioning at present, one in the North located at the New Delhi TB Centre and the other in the South located at the National Tuberculosis Institute, Bangalore. These organisations are responsible for assisting the States in developing District TB Control Programmes in their respective zones, briefing medical and paramedical personnel both in the District TB Centres and peripheral institutions and for providing expert advice and guidance.

Supply of Drugs to State TB Clinics

This scheme has been in operation since 1964. Under this scheme there are more than 300 TB clinics undertaking domiciliary treatment of TB cases that are being supplied standard anti-TB drugs directly by the Government of India. A little over 7,00,000 TB patients are estimated to be under domiciliary treatment at any point of time under this scheme through these 300 TB clinics and about 5000 sub-centres of the District TB Centres.

Supply of Drugs to Voluntary Organisations

This scheme has been in operation since 1966. Under this scheme, standard anti-TB drugs are supplied free of cost by the Government of India for domiciliary treatment only. The purpose is to encourage voluntary organisations to organise domiciliary treatment, to help them bring in more TB cases under domiciliary care and to enable them to supply drugs free of cost to indigent TB patients. There are about 55 TB clinics/TB institutions run by voluntary organisations that are taking advantage of this scheme and about 75,000 patients are under treatment in these clinics under this scheme at any time.

Supply of BCG Vaccine

Under this scheme BCG vaccine is supplied free to the States for use by BCG teams and other TB, Paediatric or M.C.H. institutions, etc., participating in the programme. Tuberculin for diagnostic use is also supplied to certain TB, paediatric and other medical institutions.

Training of Key Personnel

This activity is carried out mainly at the Government of India's National TB Institute at Bangalore. So far, about 420 district TB Teams comprising 2961 medical and paramedical personnel from different States have been trained in 32 courses for running the District TB Programmes. Apart from these, a number of State TB Centre personnel have also been trained and many Administrative Medical Officers of States, teachers of medical colleges, District Health Officers, Medical Officers from various organisations, etc., have participated in the seminars conducted regularly every year.

Several key personnel of the State TB Programmes have also been got trained abroad with fellowships under WHO/Colombo Plan, etc., in Tuberculosis Control.

CHAPTER XIV

RESEARCH

IN THE field of research in Tuberculosis, India is in the forefront today. Many of our research findings have contributed to the world knowledge about tuberculosis and its control and have been useful in evolving a sound programme for control of tuberculosis in India and in many other developing countries.

In this Chapter, an attempt is made to summarize the findings of some of the important research studies conducted in India, on the basis of which our National Tuberculosis Programme has been developed. Readers may also find the answers to some of the questions that normally come to their mind in respect of the present concept of tuberculosis control, home treatment of tuberculosis, the role of food and rest in treatment, risk if any, from a patient under treatment at home to his contacts, protective value of BCG, whether tuberculosis in our country is increasing or decreasing etc., from the summary of findings of these studies.

NATIONAL TUBERCULOSIS SURVEY

The National Tuberculosis Sample Survey (1955-58) was conducted by the Tuberculosis Sub-Committee of the Indian Council of Medical Research. The survey was limited to investigations of Pulmonary Tuberculosis, one of the most important forms from epidemiological and public health points of view. Various types of population in selected cities, towns and villages in the States of West Bengal, Bihar, U.P., Delhi, Punjab, Andhra Pradesh, Mysore, Madras, Maharashtra and Kerala were covered by the survey. About three lakh persons were examined in six cities, 30 towns and 151 villages. The Groups included in the survey were chosen in accordance with the statistical principles so that the findings may be of general application. Six institutions were entrusted with the survey work. These were the Tuberculosis Centres in New Delhi, Patna, Hyderabad and Trivandrum, the All India Institute of Hygiene and Public Health, Calcutta and the Union Mission Tuberculosis Sanatoriam, Madanapalle in Andhra Pradesh. The entire population excluding children under

five years of age in the areas selected for survey was subjected to mass miniature radiography and those suspected to be suffering from the disease on the basis of X-ray were subjected to further bacteriological tests.

The main findings of this National Survey were:

1. Prevalence rate for 'active' and 'probably active' tuberculosis varied from 13 to 25 per 1,000 population in cities, towns and villages in the different zones.
2. The rate of bacteriologically positive cases for 1,000 population in these areas varied from 2 to 8.
3. Prevalence rates in cities, towns and villages were generally of the same order.
4. Prevalence rates were lower for females than for males, specially in age-groups above 35 years.
5. In general, the prevalence rate showed a continuous increase with age.
6. In the cities the higher prevalence among persons living in *kucha* houses as compared to those in *pucca* houses indicated the possible effect of economic and sanitary conditions.
7. A large majority of the 'active' and 'probably active' cases had moderately advanced disease.
8. Definite cavitation was observed in 4 to 33 per cent of the 'active' and 'probably active' cases, this percentage being generally smaller in the cities.

The survey also showed that there may be areas in a city where the prevalence of tuberculosis may be as high as four or five per cent and that these areas were generally inhabited by the poorest in the population, often living in extremely insanitary conditions.

COMPARISON OF HOME AND SANATORIUM TREATMENT

This study was undertaken by the Tuberculosis Chemotherapy Centre, Madras, as a controlled comparison of home and sanatorium treatment for one year and subsequently for another four years to study the emergence of relapse cases in these two groups.

163 newly diagnosed and previously untreated sputum positive patients of pulmonary tuberculosis from poor sections of the community in Madras City were randomly treated at sanatorium or home with the same chemotherapy *i.e.*, INH 200 mg. and PAS 10 gm. in two divided doses per day. Patients of the home series were given weekly supply of drugs to be administered by themselves at home with monthly supervision of their progress at the clinic and were visited at home by a Health Visitor every fortnight. The patients in the sanatorium series had bed rest, good accommodation, balanced diet and nursing care. Thus, this was a comparison of treatment of patients in best sanatorium conditions with those in usual day-to-day home conditions of the poor sections of the community.

At the end of one year, 86% of the patients treated at home converted to sputum negative and remained so (bacteriologically quiescent) as against 92% in the sanatorium patients. Improvement in X-ray and closure of cavity were also of the same order in both the groups.

Follow-up: After one year, the sanatorium patients returned to their homes and the patients of both the series were closely followed up for another four years to study the long-term results. Considering the overall relapse rate of the disease in the two groups, it was found that seven per cent of the patients in home series and ten per cent patients in sanatorium series had bacteriological relapse over a four-year period of follow-up.

It was thus conclusively proved that effect of treatment of patients at home is as good as of treatment in an institution both in respect of immediate recovery and subsequent prevention of relapse and that good food, nursing care and bed rest, etc., do not play any useful role in the treatment of tuberculosis. Domiciliary treatment has the added advantage of not causing any dislocation in the family during the period of the patient's treatment for tuberculosis.

TB ATTACK RATE AMONG CLOSE FAMILY CONTACTS

This study was planned by the Tuberculosis Chemotherapy Centre to determine the relative risks for contacts of patients treated at home and in the sanatorium.

256 close family contacts of patients treated in homes and 272 similar contacts of patients treated in sanatorium were intensively followed up by X-ray and bacteriological examination for five years. In each family, there was just one infectious case and the contacts in the two series were similar in all other aspects. Effect of isolation of the index cases could be best studied by comparing attack rate in the two series in the first year when the index case of the sanatorium series was isolated in the hospital.

In the first year, 4.9% of the contacts in home series developed tuberculosis compared with 7.6% of the contacts of sanatorium patients. Over the whole period of five years, 9.8% of the contacts of patients treated at home developed tuberculosis as against 14.4% of the contacts of patients treated in sanatorium. There was no difference in the attack rate in the two groups even when the initially tuberculin negatives and initially tuberculin positives were analysed separately.

An interesting observation of the study was that the majority of cases in contacts occurred in children below five years and were detected within three months of diagnosis of the index case and there was suggestive evidence that in most of them the infection occurred before the index case was diagnosed.

From this study, it can be concluded that there is no special risk to the contacts of patients treated at home with effective chemotherapy, the main risk to them being before treatment has begun.

Effective treatment of an infectious patient, whether at home or in a sanatorium, rapidly kills the tubercle bacilli and makes the patient non-infectious in a short time. The purpose of isolation is therefore best achieved by putting the patient on treatment immediately after diagnosis and ensuring regular introduction of the medicine prescribed.

Sociological Study of Awareness of Symptoms Among Persons With Pulmonary Tuberculosis

About 2,000 persons having evidence of inactive, probably active and active tuberculosis disease in their X-rays whose sputum results were also available (experimental groups) were age/sex matched with an equal number of persons with normal X-ray (control group) in 34 villages and four towns in Tumkur district in Karnataka. These persons

were interviewed at random by social investigators for symptoms. Only such symptoms that were associated with Pulmonary tuberculosis were taken into consideration. Of these, pain in chest, haemoptysis or combination of these four symptoms were analysed statistically. 79% of the experimental group and 83% of the control group were satisfactorily interviewed.

Cough was found to be the most important single symptom. 69% of the sputum positives and 46% of the X-ray positives had this symptom against only 9% of the normals.

69% of the sputum positives, 52% of the X-ray positives, 29% of the inactives and 15% of the controls had at least one of the above mentioned four symptoms.

Analysis of the material also showed that 95% of the bacteriologically positive cases were aware about their symptoms, 72% experienced awareness and were worried about their sypmtoms and 52% of them actually took action at the existing health facilities under pressure of their symptoms.

This study showed that half the infectious patients in a community are already knocking at the doors of the existing health service under pressure of their symptoms and if adequate facilities are provided, another one-fourth will immediately report to these health institutions. Thus, about a half to three-fourth of the infectious cases can be dealt with in a short period at the existing peripheral health institutions.

DISTRICT TB PROGRAMME PILOT PROJECT, ANANTAPUR

The District TB Control Programme was formulated by the National TB Institute on the basis of their knowledge gained from various case finding, treatment and methodological alternatives tried in Tumkur and Bangalore districts in 1960-61 and was implemented as a pilot project in Anantapur district of Andhra Pradesh to study the feasibility of the District TB Control Programme in 1961.

The district had a population of about 1.5 million. One District TB Centre equipped with an X-ray unit was established at Anantapur town. There were 14 Primary Health

Centres, ten health units and 30 rural dispensaries. Medical doctors were available in almost all health centres. Microscopes were provided in PHCs and other dispensaries. Sputum case-finding was organised with co-operation of all these institutions. Sputum specimens of all persons with cough were collected in all these centres throughout the year. These sputum smears were examined in the centres having microscopes. The centres not having any microscopes sent their smears to the institutions with microscopes, functioning as microscopy centres.

In this way, sputa from 17,000 symptomatics were examined and 1870 smear positive cases were found in one year. This comes to about 80 per cent of the total estimated infectious cases. The workload involved in each institution was collection of only two sputum smears per working day. It was also revealed that 99% of the sputum positive cases had cough for more than two weeks.

All the diagnosed patients were given ambulatory domiciliary treatment at the peripheral institutions nearest to their homes. The regularity of treatment was better when patients were treated at centres nearest to their residence.

It was found easily feasible and useful to organise such a case finding and treatment programme through the peripheral health institutions in an average Indian district. This method of case finding and treatment was found to be much cheaper than orthodox method by X-ray, much easier to implement and had the virtue of being available as a regular programme throughout the year.

FIVE YEAR STUDY OF EPIDEMIOLOGY OF TUBERCULOSIS IN A RURAL POPULATION IN SOUTH INDIA

This longitudinal study was carried out by the National Tuberculosis Institute to observe the natural history of pulmonary tuberculosis under the existing socio-economic conditions in an area before any TB control measures under the National TB Programme could be introduced. A randomly selected rural population of 65,000 in Bangalore district where the National TB control programme was not introduced was surveyed four times at an average interval of $1\frac{1}{2}$ years over a period of five years during 1961-68 by repeated tuberculin test, X-ray and sputum examination.

The salient findings of the survey are:

(1) The prevalence rate of infection was about 30%. It showed a steady decrease specially in the age-group 0—24 years.

(2) The average annual incidence of infection (rate of new infection by tuberculosis every year among uninfacted) was about one per cent. During the study period, the incidence rates showed a decline from 1.63% to 0.8% for all ages combined.

(3) Prevalence rate of disease in the study population gradually decreased from 406 cases per 100,000 population in the first survey to 337 cases in the third survey but slightly rose to 393 cases in the fourth survey probably due to drought in the study area. For the younger age-group of 5 to 34 years, however, the rates showed a continuous decrease during the entire study period.

(4) Annual incidence rates of disease also showed a downward trend as in case of prevalence, being 132 cases per 100,000 population between first and second surveys, 99 between second and third and 103 between third and fourth surveys. The younger age-group below 35 years showed a steady downward trend during the entire study period.

(5) Prevalence and incidence rates of the disease increased with age and female cases were much less (one-third of prevalence cases and half of incidence cases) than in males.

(6) Of the 126 cases found at the first survey and followed up for five years, 49.2% died, 32.5% were cured and 8.3% continued to remain sputum positive at the end of five years. In the incidence cases (new cases detected by survey) however, there was a sizable natural cure of 52.4% and 14.3% died. In the prevalence cases (cases available at any given time) followed up for the same period the death rate was 16.9%.

(7) Primary drug resistance did not show any increase in five years.

The study showed a gradual natural downward trend in the prevalence and incidence of the disease, specially in the younger age-group.

DELHI TUBERCULOSIS SURVEY

The New Delhi Tuberculosis Centre conducted a survey (1962—70) in Delhi to study the epidemiology of tuberculosis in an urban population with a TB control programme in operation. A randomly selected population of nearly 30,000 was under surveillance in one of the most congested localities of Delhi. A reasonably good domiciliary service for detection and treatment of tuberculosis cases was available in the area for the last more than 30 years. Four surveys were carried out at an interval of 30 months during the period of study.

The following were the important findings:—

(1) The prevalence of total active cases which was 1720 per hundred thousand population in the first survey in 1962 came down to 880 in the fourth survey in 1970. Total bacillary cases came down from 400 per hundred thousand population in 1962 to 210 in 1970. Thus, prevalence of active cases of tuberculosis was reduced by about half.

(2) The prevalence rate increased with age. There was, however, no difference in the prevalence rate among males and females upto 35 years of age though after 35 years there was a steep rise in the disease amongst males. This was perhaps because these surveys covered an urban population.

(3) The incidence rate of bacillary cases was about 90 per hundred thousand population per year and that of total active cases 340 per year. The incidence rate did not show any downward trend.

The study showed that in an urban population with a reasonably good domiciliary service programme, there is a reduction in the prevalence rate of tuberculosis in a reasonably short period of time.

MADANAPALLE TUBERCULOSIS RESEARCH PROJECT

The project was started in 1950 and comprised Madanapalle town and about 200 villages within a radius of 10 miles with a population of 50,000. This population increased to about 90,000 by the end of the study period. Seven surveys were conducted in the population above five years of age with tuberculin, X-ray and sputum examination during the period from 1950 to 1965. Case finding, treatment, both domiciliary and institutional, and BCG vaccination were provided to this entire population.

The following are the salient findings of the survey:

(1) The number of bacillary cases which was 410 per 100,000 population at the time of the first survey in 1950-51 came down to 320 in 1957-58 and was further reduced to 110 per 100,000 population in 1964-65.

(2) The number of cases in the male population was two to three times more than in the female population.

(3) The prevalence rate of infectious cases increased with age, the number of cases in males being much more than in the females specially above 20 years of age.

(4) The incidence rate of fresh tuberculosis cases was found to be 34 per 100,000 population and the incidence rate of active and inactive but abacillary (sputum negative) cases was found to be 207 per 100,000 population.

(5) The death rate which was about 250 per 100,000 population in 1949 in Madanapalle town came down to about 64.1 in 1951-53 and further reduced only to 21.1 per 100,000 population in the period 1954-55, thus showing a definte reduction in death rate in the study area.

The findings of this project showed that with a reasonably good TB control programme in rural areas providing facilities of case findings, treatment and BCG vaccination, the death rate goes down steeply and the rate of prevalence of infectious cases can be reduced substantially in a reasonable period of time.

STUDY ON DIRECT BCG VACCINATION BY THE NATIONAL TUBERCULOSIS INSTITUTE

Till 1964, the conventional procedure in BCG vaccination programme was to do a preliminary tuberculin test and offer BCG only to the tuberculin negatives. This involved two visits to each area and other technical and operational complications. Offering direct BCG vaccination would simplify the procedure and speed up coverage of the young population. This study was, therefore, taken up by the National Tuberculosis Institute to see if direct vaccination was safe, effective and acceptable.

First study: A rural population of 1891 was randomly divided into four groups: (1) tuberculin tested and vaccinated, (2) tested but not vaccinated, (3) not tested but vaccinated and (4) not tested, not vaccinated and these groups were followed up with periodical examination, tuberculin tests and X-ray for 90 days.

Results showed that local reaction at the site of vaccination and regional lesion at the lymph nodes in both the tuberculin non-reactors and reactors was of the same order. There was no evidence of existing tuberculosis disease being exacerbated or foci of tuberculosis flaring up.

Second study: 1186 persons were both simultaneously tuberculin tested and BCG vaccinated and were followed up for local reaction for a month.

Local reactions were found to be of the same order in both the reactors and non-reactors as in the first study.

Third study showed that local reactions after direct vaccination in one village did not affect the acceptability of direct vaccination in neighbouring villages.

STUDY OF NEW DELHI TB CENTRE

In a similar study conducted by the New Delhi TB Centre among primary school children also, it was found that direct vaccination of reactors was innocuous.

Direct BCG vaccination is a safe procedure as it does not cause any unusual inconvenience or danger to the reactors and the acceptability of the programme is also not affected in any way.

MADANAPALLE BCG TRIAL

This study was undertaken to assess the protective value of BCG vaccination against tuberculosis in Indian population as a part of the Madanapalle Research Project starting from 1950.

A total of about 21,500 persons were tested with tuberculin. About 10,000 were found to be tuberculin positive reactors and 11,500 non-reactors. The non-reactors were randomly divided into two groups. BCG was given to 5,069 and 5,808 were left as unvaccinated. Both the vaccinated and control groups were followed up by periodical tuberculin test, X-ray and sputum examination till 1967.

The findings of the study can be summarized as follows:

In the first five years after vaccination, BCG was responsible for reduction of incidence of tuberculosis in the vaccinated population to the extent of 60% compared to that in the control group.

In the next five years, the reduction in incidence of tuberculosis attributable to BCG vaccination was 56.5%.

But if the cases found within the first 1 to 1½ years of the trial that could have acquired the infection before entry into the trial are excluded, the reduction in cases attributable to BCG vaccination was 71.4%.

After another four years' follow up in 1968, it was found that in 14 years, BCG vaccination was responsible for 24% reduction of active cases and 33% reduction of bacillary (infectious) cases in the vaccinated group.

Thus, it was observed that the vaccination was most effective in the earlier period but gradually became less effective in the later period because of possible waning effect of vaccination. The suggestion was that BCG should be used mainly shortly before the population to be protected is exposed to

infection with tubercle bacilli and a second vaccination may be necessary before substantial waning effect of the first vaccination takes place.

Other BCG trials in the world have shown various levels of protection *e.g.*, 96% in Danish School children (Hyge, 1947); 82% in North American Indians (Aronson, 1958); 70% in English School leavers (B.M.R.C., 1963); 74% in Chicago infants (Rosenthal, 1961); 31% in Puero Rican children (Palmer etc., 1958); and 36% in seven years and only 14% in 14 years in an American population (Comstock and Palmer, 1966).

Since the study population of the Madanapalle trial was small and as the other studies have shown different levels of protection from very good to insignificant, a large scale BCG trial known as Tuberculosis Prevention Trial is being conducted in South India to get precise information about the protective value of BCG in Indian context.

CHAPTER XV

HEALTH EDUCATION

HEALTH EDUCATION has a pivotal role to speed up our march towards a healthier India. While much is known today about the etiology (causes and spread) of many of the diseases that afflict mankind, communication of this knowledge to the people in a language they understand best remains as much a problem as a challenge. The advances achieved in medical sciences, and the technological knowhow acquired in diagnosis and treatment procedures have to be brought to the notice of the people, and accepted and adopted by them to get adequate returns, investments on health programmes.

Tuberculosis continues to be one of the major public health problems in our country. Eight to nine million or so active TB cases of whom 2-3 million are infectous, are evenly distributed in towns and villages in India, *i.e.*, 80% of the cases are in the villages. TB being a communicable disease thrives on low living standards, poor housing conditions, overcrowding. insanitation and malnutrition. Late reporting and late detection of tuberculosis cases also cause delay in timely control of tuberculosis cases and early recovery of those afflicted.

The management of tuberculosis has been revolutionized during the last three decades. New drugs, which are remarkably effective, have been discovered. B.C.G. vaccination offers a high level of protection against tuberculosis. Domiciliary treatment with potent drugs is available to all at their doorsteps. The fundamentals that govern the National Tuberculosis Control Programme (NTCP) are: (i) prevention of development of tuberculosis among those who are not infected, and (ii) detection and treatment of as large a number of infectious cases as possible with a view to rendering them non-infectious.

These can be achieved only through a sustained educational campaign, so that factors such as ignorance, apathy, superstitions and neglect which contribute to spread the disease are overcome. Health education could play a vital role in arousing consciousness in the people that is needed to imbibe a positive attitude towards health *i.e.*, health not only as freedom from disease but as a status of general well-being. Much of the success of the domiciliary treatment of TB patients depends on their co-operation. People have to be made aware of early signs and

symptoms of tuberculosis, and on suspicion, come forward for an examination.

Role of Health Workers

The success of the domiciliary treatment depends, to a certain extent, also on the skill and competence of the peripheral health workers. As these workers have opportunities to move closely with patients, it should be easier for them to supervise self-administration of drugs by these patients and to take prompt measures when they fail to adhere to the prescribed treatment. The health workers, whether posted in specialized clinic in an urban area or working for a general agency in the rural area, can discharge their duties efficiently and effectively provided they possess the basic knowledge regarding factors that promote transmission of infection, causation, prevention and management of the disease. They need also to be well-versed in health education skills and techniques to prove to be effective communicators.

The multipurpose health worker's scheme also calls for strengthening the skill and the competence of Basic Health Workers and A.N.Ms. to educate the communities on preventive and promotive aspects of health services. With the organized development of tuberculosis control programme in our country and extension of case finding and treatment facilities right upto the periphery through the existing general health services, an elementary scientific knowledge of various aspects of the programme has to be provided to the health workers. A peripheral worker has to be properly trained and equipped to deal with individuals and groups.

The workers has to have the support of different media to make his message effective. At present, very little inputs are being made in producing educational materials for use by peripheral workers and for the lay public. There is, therefore, a great need of developing suitable educational materials on all aspects of the tuberculosis control programme.

With a view to meet the growing needs of educational materials, the Central and State level Health Education Bureaux are engaged in production of 'proto-type' materials, for use both by health workers and the lay public. With the growing literacy level in the country, printed materials and other communication channels like films and television hold great potential and would prove highly useful to health workers in functioning effectively.

CHAPTER XVI

SOME IMPORTANT TUBERCULOSIS INSTITUTIONS

National Tuberculosis Institute, Bangalore

The National Tuberculosis Institute was established in 1959 at Bangalore for the following three objectives:

(i) To formulate through research a practical, comprehensive and economically feasible tuberculosis programme that could be applied equally to rural as well as urban parts of the country.

(ii) To train medical and para-medical programme workers in the programme methodology so that they could effectively supervise and maintain the programme.

(iii) To undertake continuing research in order to further evolve the programme and outline a simple method for its assessment.

Though the objectives appear deceptively simple at first sight, in reality they meant extensive epidemiological, operational and community behavioural studies as well as a complete reorientation of the old ideas. Completely new concepts and appreciably altered emphasis on the other approaches have since been advocated by the Institute with regard to management of the tuberculosis problem in the country.

The Institute is functioning as a subordinate office of the Central Government under the Director General of Health Services. The staff strength consists of 220: Senior scientists 13, medical-8, non-medical-5 and 75 field research staff. It has full-fledged research, teaching, laboratory, data processing and transport facilities.

Activities of the Institute

The Institute undertakes:

(i) *Epidemiological studies* that have yielded basic parameters regarding prevalence and incidence rates of tuberculosis infection and disease, the fate of tuberculosis patients over varying time periods, formulation

of mathematical epidemetric models, longitudinal observations revealing the time-trend of tuberculosis, the extent of infection with atypical mycobacteria and simpler and more practical methods of epidemiological research.

(ii) *Operational studies* that have brought out the varying case-loads and case-yields in respect of casefinding, treatment and BCG vaccination activities, the cost factor, simultaneous smallpox and BCG vaccination as well as direct BCG vaccination, sputum microscopy and its operational implications, efficiency and effectivity of the programme, etc.

(iii) *Sociological and behavioural studies* throwing light on the awareness of symptoms, action taking, quantification of suffering, acceptability of the provided facilities and the drug regimens, reasons for drug default and response to defaulter actions, fate of cases treated under the programme, etc.

(iv) *Bacteriological studies* centered on the Ziehl-Neelsen technique of sputum microscopy, fluorescence microscopy, culture, cost of examinations, etc.

An animal house is under construction which will open up research possibilities in the field of disease caused by atypical mycobacteria.

(v) *BCG studies* concerned with the quality of vaccine, technique of vaccination, assessment of the BCG vaccination campaign, etc.

(vi) *Miscellaneous research* connected with radiological equipment, technique of radiography, training methods and the results achieved through programme training, PERT-CPM of programme implementation, monitoring and assessment of the programme, etc.

Apart from research, the Institute has full scale involvement in training of the programme workers as well as tuberculosis workers of other categories, from India as well as other countries. This activity comprises the following national as well as international training courses.

(i) Two national courses each of 13 weeks' duration every year for training of tuberculosis control teams in the programme management. Each team comprises a medical officer, laboratory technician, treatment organiser, BCG non-medical team leader, X-ray technician and statistical assistant. The participants are deputed by State Governments and sometimes by the WHO from developing countries of the Region.

(ii) Two national courses each of 4 weeks duration every year for training of District Public Health Nurses in District Tuberculosis Programmes. The nurses are deputed by the States and sometimes by the WHO, from some developing countries.

(iii) Two higher level Tuberculosis Control Seminars every year for District level health administrators, professors of tuberculosis and social and preventive medicine, senior tuberculosis workers, etc.

(iv) One course every year for the personnel of State Tuberculosis Centres.

(v) The participants of UNICEF sponsored international training course for paediatric teachers.

(vi) The participants of the WHO sponsored international training course for general epidemiologists.

(vii) The participants of the WHO/Japan international training on epidemiology/and control of tuberculosis.

(viii) Tuberculosis workers from other countries visiting the institute on WHO fellowship.

Besides regular training courses, the Institute is involved in the orientation of undergraduate students from several medical colleges, doctor-interns and post-graduate students preparing for diplomas or degrees.

Achievements

Formulation of District Tuberculosis Programme: In 1961, the District Tuberculosis Programme (DTP) was formulated and recommended to the government as the pivot of the national tuberculosis programme. Thereafter, on the basis of operations research and the feedback from the programme functioning in different areas, new research studies are being constantly undertaken to improve the Tuberculosis programme in the country.

Research: In the field of research, the Institute has already conducted over 130 studies on pulmonary tuberculosis, community suffering and behaviour, BCG vaccine and the cost aspect as well as utilisation of the provided services by the people, efficiency of the services, monitoring and assessment of programme objectives. Over 140 technical reports and papers have since been published in national and international journals and periodicals. Besides, technical innovations in the form of a portable vaccination kit, a daylight X-ray film loading and developing box, electric and electronic circuitary in X-ray units and simple staining techniques have been developed. The DTP work manuals evolved by the Institute are in great demand in the country as well as outside.

Training: In the 33 national training courses conducted so far, 433 tuberculosis control teams have been trained, comprising 527 medical officers, 524 laboratory technicians, 466 statistical assistants as well as 107 foreign programme workers. In the 13 training courses conducted for public health nurses 65 have been trained. The 12 seminars have attracted 230 participants so far. The training effort is generally considerably ahead of the programme needs, after taking care of the turn over due to retirement, etc., and the wastage.

Miscellaneous: The Institute faculty has functioned as WHO advisers in several countries of the world, as visiting professors on international training courses, as members on several national and international technical committees and as participants in the international conferences, in order to present research papers.

BCG Vaccine Laboratory, Guindy, Madras

The Government of India felt the necessity to sponsor a nation-wide BCG Vaccination Programme in 1948, and, to achieve this object, Madras was chosen to house a BCG Vaccine Laboratory, as a building constructed by the Government of India for the production of Yellow Fever Vaccine was available in the King Institute Campus. At the request of the Government of India, the WHO sent Dr. Poul Lind, a Danish BCG Expert, with all essential equipment to start the Vaccine Production Centre, and in August, 1948 the Laboratory was opened by the then Union Health Minister, the late Rajkumari Amrit Kaur.

The supply of BCG vaccine and tuberculin dilutions began in February, 1949. Subsequently, the laboratory was shifted to its own building near the King Institute and large-scale production of BCG vaccine and tuberculin dilutions was taken up. Apart from meeting the full requirement of the country's mass BCG programme, the laboratory also supplied the biologicals to many of its neighbouring countries. It is the world's largest BCG producing centre.

As the life of the liquid BCG Vaccine is limited and the vaccine has to be protected from heat and light, need for the preparation of freeze dried BCG Vaccine, which is heat stable and which can be kept for longer periods was acutely felt. With this object a freeze-drying plant capable of preparing 4000 ampoules of freeze-dried vaccine in one shift was procured in the year 1957. Three more plants each capable of drying 1000 ampoules at a time were added in November, 1964.

After getting satisfactory results from the experiments on the preparation of freeze-dried vaccine, it was planned to go into large-scale production of freeze-dried vaccine to replace liquid vaccine in the entire programme. Additional sterile air-conditioned accommodation was provided, a testing and quality control section was added and the required equipment was procured. The production of freeze-dried BCG was enhanced to about 5 million doses and was supplied for use in the mass campaign in 1969.

In the Fourth Plan "Expansion of the BCG Vaccine Laboratory for enhancement of production of freeze-dried BCG vaccine" was taken up as a plan scheme. A large number of technical and non-technical staff was added, equipment was procured and an independent testing and quality control laboratory for testing and certifying the vaccine was established at the National Institute of Communicable Diseases in Delhi. The production was enhanced to 30 million doses by the end of the Fourth Plan and liquid vaccine was entirely replaced by freeze-dried vaccine in the whole programme. Tuberculin dilutions were also prepared and supplied for diagnostic use in the country. The WHO and UNICEF have been taking active interest in the expansion of the laboratory so as to develop this laboratory as a regional laboratory for supply of freeze-dried BCG to the other countries of the region. The WHO has been providing several consultants and fellowships. The UNICEF have been

supplying equipment and necessary spare parts, etc. An automatic ampoule sealing machine procured by the UNICEF was installed in the Laboratory in 1973.

In the Fifth Plan, the target is to double the present production of the laboratory and further expand it if necessary. A large part of the vaccine will be supplied in small packings of 20 doses for use by rural health workers and institutions. For this, a semi-industrial type freeze drier with a capacity of 8,000 ampoules per run has been procured by the Government of India and has been installed in the Laboratory. The WHO and the UNICEF have been assisting with experts, equipments and material. The Laboratory is also participating in the quality control and assay of BCG vaccine produced in different Laboratories in the world under WHO auspices.

The Testing and Quality Control Laboratory at the National Institute of Communicable Diseases is also being further developed.

Tuberculosis Chemotherapy Centre

The Tuberculosis Chemotherapy Centre was established in Madras in 1956, under the joint auspices of the Indian Council of Medical Research, the World Health Organisation, the British Medical Research Council and the Government of Tamil Nadu as a temporary project to conduct controlled studies designed to provide information on domiciliary chemotherapy in the treatment of pulmonary tuberculosis.

The Centre has three main divisions: (*i*) Laboratory Division consisting of bacteriology and biochemistry sections. (*ii*) Statistical Division and a Clinical division consisting of outpatient department, and (*iii*) Radiographic section and a well organised domiciliary service. A W.H.O. Senior Medical Officer acted as the Director of this Centre from 1956 to 1964. In 1964, the National Director was appointed by the Indian Council of Medical Research, and the Centre was made a permanent establishment under the Indian Council of Medical Research. The World Health Organisation continues to maintain active interest in the Centre's research work and provides expertise and supplies not available in India.

Controlled studies carried out at the Tuberculosis Chemotherapy Centre have revealed that ambulatory chemotherapy for tuberculosis, based on a well-organised clinic service for a year, virtually equals sanatorium treatment with the same chemotherapy for the same period, not only in the immediate therapeutic response in terms of overall radiographic improvement, cavity closure and sputum conversion but also in the likelihood of relapse in a subsequent 4-year period of follow-up. Furthermore, the risk of contracting tuberculosis was no greater in close family contacts of patients treated at home than in those of patients treated in sanatorium; indeed, the main risk to the contacts was from the infectious patient before treatment had begun. Thus, these studies clearly showed that the traditionally held virtues of sanatorium treatment, namely, prolonged bedrest, good diet, good airy accommodation, nursing and isolation, were remarkably unimportant provided adequate chemotherapy was administered. Controlled studies conducted by several other investigators did not demonstrate any advantage either of sanatorium treatment over clinic treatment and of rest over ambulation. As a result of these findings ambulatory chemotherapy has become the accepted practice in the tuberculosis control programme in India and in many other developing countries of the world.

In daily oral regimens, reliance has to be placed on the co-operation of patients for self-administering the drugs at home—a practice known to result in serious irregularities in drug-intake. This limitation can be overcome by supervising the administration of drugs. Obviously, daily supervision, as a general policy, being impracticable under domiciliary conditions, it might be possible to organise supervised administration of drugs if the drugs are given at less frequent intervals *e.g.*, once or twice a week. A regimen of streptomycin plus high dosage isoniazid given together in a single dose, twice a week under supervision was found to be highly effective in the treatment of pulmonary tuberculosis. This regimen is inexpensive and has the advantage that the physician knows exactly how much chemotherapy the patient receives. This regimen, therefore, offers a practical method of supervised chemotherapy; indeed, the value of this regimen in the primary treatment of tuberculosis has been confirmed by successive studies in this Centre. Based on these studies, the Centre has projected supervised intermittent chemotherapy as an alternative system of chemotherapy, especially in the countries where the organisation of standard oral regimens has already failed in practice. Recently, the Centre undertook a series of studies with a slow-release preparation of isoniazid for evolving effective once-weekly regimens which would considerably simplify the organization of chemotherapy programme. Current research is directed towards evolving effective short-course regimens.

The Centre also undertook studies on other chemotherapeutic regimens for treatment of tuberculosis with different standard and reserve drugs and chemoprophylaxis studies. The clinical studies were all supported by bacteriological and biochemical investigations in depth. Notable among other studies conducted at the Centre are studies on metabolism of anti-tuberculosis drugs, tests for detection of anti-tuberculosis drugs in urine, biological characteristics of Indian strains of tubercle bacilli and the comparative studies on different measures of sensitivity of tubercle bacilli to various anti-tuberculosis drugs.

Many of the findings of the Centre have received a worldwide acknowledgement and indeed some of them have had a great impact on the formulation of tuberculosis control programmes in Asia, Africa, South America and some parts of Europe. Though the main aim of the studies at this Centre is to evolve practical and effective methods of treatment for tuberculosis patients in India, the logical sequence of the investigations undertaken, together with supporting laboratory investigations, has resulted in invaluable knowledge of the principles of chemotherapy. The Centre is recognised by the Inter University Board for Post-Graduate Study leading to Ph.D. degree in bacteriology and bio-chemistry.

The training activities of the Centre include lecture demonstrations to senior medical students, interns and post-graduate medical students from the National Tuberculosis Institute, Bangalore and for the International Course in Tuberculosis. In addition, two I.C.M.R. fellowships are awarded annually for training in the methodology of controlled clinical trials and laboratory methods.

Tuberculosis Prevention Trial

A number of controlled BCG trials have given very conflicting results. Developing countries are dependent to a very great extent on BCG vaccination for the control of tuberculosis, because of the shortfalls in diagnosis and treatment of tuberculosis. Hence, it has become essential to assess precisely the value of BCG vaccination in our own context. The Project Tuberculosis Trial was, therefore, started in 1964 under the auspices of the ICMR, the U.S. Public Health and the WHO.

After a preliminary feasibility study, the BCG trial was started in 1968 in Chingleput District, Tamil Nadu. A sample survey showed that this area had high prevalence on non-specific sensitivity as well as of pulmonary tuberculosis. The initial examination included complete census, tuberculin tests with PPD-S and PPD-B, vaccinations with BCG or an injection with a placebo, examination by X-ray of persons over 10 years of age and bacteriological examination of 2 specimens of sputum from persons with X-ray abnormality. This phase of the work was completed by the end of March 1971, covering 32 months. Of the 3,66,265 persons registered, 2,82,247 were vaccinated with BCG or placebo.

The entire population of the area including the population examined initially is under continuous surveillance. Tuberculosis patients diagnosed by the study teams are being treated on domiciliary basis.

About 2½ months after the vaccination a random sample of the vaccinated population was retested with tuberculin and was also examined for BCG scars. It was found that 0.4% and 6.0% of those vaccinated with the strong and weak doses of vaccine respectively had no scars and 2.7% of those injected with placebo had scars. Among children aged (1-14) years and reacting with induration measuring (0-7) mm to the tuberculin test the mean size of post-vaccination allergy was found to be 16.8 mm for the strong vaccine and 12.8 mm for the weak vaccine. In the same group the mean size of scar was 5.2 mm for the strong vaccine and 3.4 mm for the weak vaccine.

Other Activities of the Project

Tuberculin testing of samples of population in certain areas of North India with PPD-S and PPD-B, was done to assess prevalence of non-specific sensitivity. It has been found that only the hills of the Uttar Pradesh, Kashmir Valley and Himachal Pradesh have very much lower prevalence of non-specific sensitivity. It has been found that the Nilgiri hills also have a low prevalence of non-specific sensitivity. The study suggested that non-specific sensitivity was associated with altitude and not with the geographical location of the area.

Retesting of random samples of the TB Prevention Trial population with tuberculin was carried out at 2½ years and four years after the initial examination. It was observed that

post-vaccination allergy had waned from three months to 2½ years and that there was no further waning from 2½ years to 4 years.

The reason for or the significance of this waning is not clear.

The prevalence of infection does not seem to have gone down at four years.

A Trial for the value of BCG in the prevention of Leprosy was started from October, 1973. So far, about 2,52,000 persons have been registered and about 1,73,000 persons examined. About 9000 definite as well as suspicious cases of leprosy have been diagnosed so far.

The effect of BCG vaccination on tuberculosis patients and tuberculin positive children has been studied. Long term follow-up results over a period of 15 months in patients and over 2½ years in children have shown that BCG vaccination did not increase mortality among patients of pulmonary tuberculosis or among strong reactors to tuberculin in children or bacteriological breakdown rates of suspect cases. It can safely be concluded that the data studied do not suggest that BCG vaccination of patients or strong reactors among children did any harm of the kind considered possible when direct BCG vaccination was initiated.

Results of the Main Study

BCG can protect against tuberculosis only among those who are non-reactors to tuberculin. Of the total number of new culture positive cases of tuberculosis that have developed during the first 2½ years of the trial, only 3% are among this group. The study is being continued so that adequate cases are obtained from among the tuberculin negatives so that the protective effect of BCG can be studied.

State TB Training & Demonstration Centres

New Delhi TB Centre

The New Delhi Tuberculosis Centre, originally known as [illegible] established by the Tuberc[illegible] Association of India [illegible] State TB [illegible] the country to be upgraded as Training [illegible] Demonstration Centre in 1951 with assistance from the Government of India, the

W.H.O. and the UNICEF. Research, training and service to TB patients have been the main functions of the Centre. In its clinical section, patients belonging to its own domiciliary treatment area covering a population of about 8 lakhs and also patients from other areas as well as from neighbouring States avail of the services in large numbers. Care committees have been organised by the Centre in different localities in its operational area to look after the economic and social problems of patients.

Research in various aspects of tuberculosis, especially in respect of methods aiming to improve the efficiency of domiciliary management and case finding, has been one of the main functions of the Centre. Several studies in respect of epidemiology and time trend of tuberculosis, drug schedules, BCG vaccination, etc., have been undertaken by the Centre. The Centre has participated in several international cooperative studies in respect of various aspects of tuberculosis and in several other cooperative studies arranged by the I.C.M.R. More than 100 papers based on experience of this Centre on various aspects of tuberculosis have been presented at national and international conferences and published in medical journals.

Training of various categories of medical and paramedical personnel has been one of the main functions assigned to this Centre since its inception. These include students for D.T.C.D. course and under-graduate and postgradaute medical students. Para-medical workers include Tuberculosis Health Visitors, nurses, medical social workers, radiographers, laboratory technicians, BCG technicians, etc. A number of refresher courses are also organised by the Centre. The Centre is running three demonstration programmes in rural and semi-urban areas of Delhi on the lines of the District TB control programme in collaboration with the other teaching institutes of Delhi.

The Northern Regional TB Centre is located in this Centre and works under the technical guidance and supervision of the Director of the Centre.

The bulk of the running expenditure of th[illegible] New Delhi TB Centre is provided by the Government [illegible] Other agencies like Tuberculosis Association of India [illegible] State TB Association and certain statutory local bodi[illegible] voluntary organisation also contribute towards [illegible] the institutions.

State Training & Demonstration Centre, Trivandrum

The State Training and Demonstration Centre, Trivandrum established in 1951, is one of the first three institutions of the country run as Training and Demonstration Centres, jointly by the W.H.O., Government of India and the State Government. Several WHO experts were associated with this Centre in the early years. The routine activities of the Centre are case detection, organisation of domiciliary treatment, health education and participation in certain epidemiological studies. The Centre participated in the National Tuberculosis Sample Survey. It started working on lines of the National TB Control Programme from 1st of April, 1964. It runs a model district TB programme apart from arranging training for various medical and para-medical workers. From 2 April, 1968, the Training and Demonstration Centre was re-designated as the State TB Centre for Kerala State to discharge duties and responsibilities envisaged in the National TB programme.

TB Training & Demonstration Centre, Patna

The TB Training & Demonstration Centre, Patna was established in 1951 as a joint venture of the WHO, Government of India and the State Government of Bihar. In July, 1959, the Centre was upgraded as Training & Demonstration Centre for the State of Bihar and the Centre established several sub-centres to undertake the pilot project schemes for domiciliary treatment within the corporation area of Patna. This Centre has the following sections: Epidemiological Section comprising X-ray and BCG Section, Laboratory Section, Clinical Section, Domiciliary Section and Health Education and Rehabilitation Scheme. It has indoor beds a Chest Surgical Unit. It runs a model district TB programme in Patna district.

The Centre provides training to under-graduate and post-graduate students of Patna Medical College. Besides, the Centre also imparts training to para-medical staff, health visitors, laboratory technicians, X-ray technicians, BCG technicians and nurses.

The Centre participated in the National Sample Survey in 1955-58. It has been taking part in different research activities in respect of tuberculosis.

Lady Willingdon TB Training & Demonstration Centre, Bangalore

Starting as a Tuberculosis dispensary in 1936, the Lady Willingdon TB Training & Demonstration Centre, Bangalore was upgraded to a training and demonstration centre for Mysore (Karnataka State) in 1960. It runs a model district TB programme in the State. It has one mobile X-ray unit and culture and sensitivity testing facilities.

The trainees and participants of various courses and seminars of N.T.I. and students and trainees of other regular medical and para-medical institutions in Bangalore visit the Centre as a part of their training. It conducts refresher and training courses for BCG technicians and TB health visitors and participants in the research and field studies of the N.T.I.

The N.T.I. has also been undertaking a pilot project of urban TB programme in the city of Bangalore.

TB Training & Demonstration Centre, Ahmedabad

The TB Training & Demonstration Centre, Ahmedabad in Gujarat was established in 1961. Initially it functioned in a small building but in 1972 it was shifted to its new commodious building.

Training is given to BCG technicians, health visitors, sanitary inspectors, public health nurses, medical students, medical officers of the State Government health service, tuberculosis medical officers and students of post-graduate courses in tuberculosis.

It runs a model district TB programme for the State. It has a mobile X-ray unit and participates in research activities like periodical survey in textile workers, etc.

State TB Training & Demonstration Centre, Agra

The State TB Training & Demonstration Centre, Agra is meant for the State of Uttar Pradesh having a population of 90 million. It started functioning in 1963. It is one of the large Training & Demonstration Centres in the country. There are about 21 different sections and during the last 13 years, more than 3,00,000 persons have been taken up for investigations, diagnosis, treatment and follow-up.

Training in Tuberculosis is imparted to medical and para-medical personnel including interns and TB health visitors. The centre is recognised by the University of Agra for M.D. in Tuberculosis.

The centre has been participating in chemotherapy trials and has been conducting non-specific sensitivity and other surveys in the area. It has contributed several scientific papers in many international and national conferences.

Kamla Nehru State TB and Demonstration Centre, Ajmer

The Kamala Nehru State TB and Demonstration Centre, Ajmer, Rajasthan was established on 1 January, 1964. It runs a model district TB programme and has the following Sections: Statistical section, Treatment section, X-ray section, Laboratory section, BCG section and Training section.

Training is imparted to TB health visitors, BCG technicians and also interns and medical students from medical college. Mobile X-ray and sputum culture and sensitivity test facilities are available.

This centre has participated in the drug trials conducted by the I.C.M.R. in 1969-72 and is undertaking a study on the prevalence and incidence of Pulmonary Tuberculosis among mica mine workers of Rajasthan.

Training & Demonstration Centre, Cuttack

The Training & Demonstration Centre, Cuttack was developed by upgrading the Chest clinic of S.C.B. Medical College Hospital in Cuttack in July, 1964. It runs a Tuberculosis control programme for the Cuttack District and trains medical and para-medical personnel of the State. The following categories of persons are trained in the centre: Health Visitors, laboratory technicians, radiographers, under-graduate students of medical college, house surgeons, post-graduate students of both diploma and degree courses or TB and Chest diseases and post-graduate students of other departments like medicine, social and preventive medicine, pathology, etc. It has also TB beds and a thoracic surgery unit attached to it, and functions as a referral hospital for the entire State.

State TB & Demonstration Centre, Patiala

The State TB and Demonstration Centre, Patiala was established as a TB Clinic in 1953. It was upgraded to a Training & Demonstration Centre in 1966. It has epidemiological, laboratory, statistical, radiological, treatment and BCG sections apart from an out-patient department and in-door wards. It also has a surgical section. It runs a model district TB programme for the State. All necessary facilities being available, the Centre attracts patients from all around, including adjacent States.

Training is imparted to TB health visitors, medical interns, sanitary inspectors, nursing students, basic health workers, medical practitioners of other systems of medicine, laboratory technicians, etc., and the Centre organises refresher courses also. Under the intensive health scheme of the State Health Department, the Centre is organising several mass miniature radiographic camps.

The staff of the centre has contributed several scientific papers in national conferences.

TB Training & Demonstration Centre, Shri Nagar

The TB Training & Demonstration Centre, Srinagar was established as a TB clinic in 1969, which was later upgraded to a Training & Demonstration Centre for the State of Jammu & Kashmir. Facilities exist for X-ray, domiciliary treatment programme, laboratory services, culture and sensitivity test. It runs a District TB control programme in the district of Srinagar. It also undertakes training of medical students. Training is given to BCG technicians and other para-medical assistants and basic health workers. It also undertakes orientation course for medical officers of the State health services.

Assessment of District TB Programmes and certain research activities are also undertaken by the Centre.

Training & Demonstration Centre, Bhopal

The Training & Demonstration Centre, Bhopal was established in 1972 as a State TB Centre for Madhya Pradesh.

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The Centre is organising a model district TB programme for the State. Training for under-graduates and interns of medical colleges, TB health visitors, nurses, BCG technicians, etc., has been organised. Additional accommodation and more equipment for developing this Centre into a full-fledged State TB Centre are under way.

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TUBERCULOSIS IN INDIA

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FOREWORD

This book is a comprehensive presentation of the facts about development of tuberculosis movement in the country and the details of the various aspects of the Tuberculosis Control Programme.

The activities taken up by the Government in the various plan periods, the concept and organisation of the National Tuberculosis Programme and the various significant research studies conducted in India that have contributed new knowledge in the field of tuberculosis control and have formed the basis of our community wide Tuberculosis Control Programme. also have been highlighted.

Tuberculosis is a major public health problem in the country. The tools for diagnosis of the cases, effective medicine for their treatment and BCG vaccination for protection of infants and children are available and have been provided freely in the National Tuberculosis Control Programme. It is only with the concerted efforts of the Government, the voluntary organisations and the community that the programme can succeed and the problem of tuberculosis can be tackled.

I hope the readers will find this book interesting and useful in having an insight to the problem and the efforts being made to deal with it under the National Tuberculosis Programme.

New Delhi
28-1-77.

Dr. P. P. GOEL
Director General of Health Services

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INTRODUCTION

TUBERCULOSIS has been known to mankind since the dawn of history. From the mummified bodies, engravings and paintings in Egypt, scriptures and literatures from Babylonia and China, literatures from the ancient civilisations of Greece, Persia and Macedonia and the Vedas and other Sanskrit literatures of India, it is evident that these ancient civilisations knew tuberculosis as a health hazard even 4000 to 5000 years before the birth of Christ. A hymn is consecrated to the cure of 'Yakshma' in Rig Veda which is dated as about 2000 B.C. Charak and Susruta in 600 B.C. referred to tuberculosis as very difficult to cure. Hipprocrates (460-377 B.C.), the father of modern medicine opined that attention to the tuberculosis patients was a waste of time and that they were a burden to the State.

However, till about the beginning of the 19th century, nothing much was known about the cause or cure of the disease. Tuberculosis was known as consumption, white plague, King's evil and phthisis. It was mostly considered as an incurable disease.

From the beginning of the 19th century, new knowledge started to gather. Laennec, himself a consumptive, invented stethescope in 1819 and described 'auscultation' by use of the stethescope. Villemin in 1868 demonstrated that tuberculosis had to be due to a specific agent, but it was Robert Koch who made the epoch making discovery of the tubercle bacillus in 1882. X-rays were discovered in 1895 by Prof. Roentgen which became available for clinical use in 1904. Von Perquet in 1907 described *intra dermal* tuberculin skin test. Calmette and Guerine in 1922 discovered BCG vaccine which is now extensively used as a protective measure.

However, specific treatment for tuberculosis by drugs that could kill or inhibit the tubercle bacilli was not known till the new era of chemotherapy in tuberculosis began in 1944, with the discovery of Streptomycin by Bugie and Walksman. This was followed by discovery of other potent anti-TB drugs like para-amino salicylic acid by Lehmann in 1946 and isonicotinic acid hydrazide by Grunberg *et al* in 1951. Several very potent anti-TB drugs became available by about the

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middle of the present century and thus effective treatment of tuberculosis became possible revolutionising the whole concept of treatment and care of the tuberculosis.

Tuberculosis is a peculiar disease in the sense that it is of a chronic nature, the causative germ is more or less ubiquitous and easily infects most of the people and yet a few suffer from the disease. Symptoms may simulate many other diseases. Diagnosis of a case requires special techniques and treatment of a patient requires special drugs for a long duration. Like any other infectious disease, tuberculosis also comes in epidemics but unlike other diseases, the secular epidemic curve in tuberculosis lasts for decades if not centuries.

However, we have the knowledge and the means to detect tuberculosis cases and to treat them effectively. It is possible to cure a patient of tuberculosis. It is also possible to prevent spread of the disease and to protect the uninfected from infection by TB germs. Tuberculosis control programmes have, therefore, been organised in all parts of the world and many developed countries have been able to bring down the problem considerably.

In India as in other countries, fight against tuberculosis has been a very long battle. Several eminent scientists, philanthropists, private individuals, non-official organisations apart from the government have contributed largely in the battle against tuberculosis in India.

Several important studies in the field of tuberculosis epidemiology, control and treatment have been undertaken in India, the findings of which have been widely acclaimed all over the world. Based on these findings, a scientifically sound and operationally feasible tuberculosis control programme which is within our resources has been evolved and is being implemented in our country.

The purpose of this book is to give an idea of the nature and magnitude of the problem of tuberculosis in the country and to review the work done so far for tackling the problem.

CHAPTER I

THE PROBLEM

TUBERCULOSIS in India began to engage attention as a public health problem from the early years of this century.

In 1910, Sir Pardey Lukis, the then Director-General of Indian Medical Services pointed out to the Government of India that Tuberculosis was fast spreading and it called for concerted countrywide control measures.

The conferences of sanitary officials of India in the North and in the South in 1912 and 1914 expressed the need for proper investigation about the spread of tuberculosis in urban areas and from there to the rural areas.

As a result, the Government of India appointed Dr. Lankaster in 1914 to make an enquiry into the Tuberculosis problem in the country. After his enquiry during 1914-16, he came to the conclusion that the prevalence of tuberculosis was alarmingly high in the country, that during the preceding forty years even in areas that were considered as virgin soil, the population has become considerably infected by tuberculosis and that with development of commerce and industry and establishment of communication, the prevalence was increasing in the towns and cities and spreading to the villages.

However, apart from a general impression as was formed by Dr. Lankaster after his investigation and that of many other specialists working in the field of tuberculosis, the exact size and extent of the problem of tuberculosis in India was not known as reliable statistics were not available.

The main methods by which the size and extent of the problem of tuberculosis could be ascertained are:—

(1) Deaths from tuberculosis.

(2) Prevalence of the disease *i.e.* patients suffering from the disease as ascertained by morbidity surveys.

(3) Infection rate *i.e.*, persons who have been infected by tubercle bacilli and therefore are likely to fall a prey to the disease.

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Deaths from Tuberculosis

No reliable information about deaths from tuberculosis was available as vital statistical information even in towns and cities was not complete. Mostly information about deaths from various diseases had to come from inexperienced Government officials, who in their turn relied on the neighbours or relations of the deceased. Causes of death were grouped under a few broad groups like fevers, dysentery and diarrhoea, respiratory diseases and other causes, and tuberculosis could have been included in any of these broad groups according to the predominant symptom which the patient presented.

Sir Leonard Rodgers in an investigation estimated that 9% of those classified as dying of fever died of tuberculosis. A similar analysis of the figures for Cossipore near Calcutta showed a mortality (from tuberculosis) of 2.68 per thousand. Of the total deaths, 7.9% were due to tuberculosis. At about the time of the First World War, Sir Leonard Rodgers analysed the post-mortem figures for Calcutta for over 22 years and found that no fewer than 17% of the total deaths had been due to tuberculosis. Since at about that time (1911—1921), the crude mortality was 47 per 1000, the tuberculosis morbidity could be computed at eight per 1000. Vital statistical information from cities collected by Dr. Lankaster for his book *Tuberculosis in India* (1920) showed that tuberculosis deaths in Calcutta were 2.1; Bombay, 2.83; Madras, 2.5; and Ahmedabad 5.9 per thousand in 1919. He thought that actual rate was 4 per thousand or more in most cities. However, most often these were under-estimates because in a large number of cases, the cause of death as tuberculosis could not be established.

Frimodt-Moller (1949) and Mc. Dougal (1950) estimated TB deaths in India as 263 and 200 per 100,000 with rigorus control measures applied to the study population. Frimodt-Moller reported death from tuberculosis to be 64.1/100,000 in 1952 and 21.1 in 1955. Recent estimate of the longitudinal survey of the National TB Institute (1968) is 100 per 100,000 in an area where no control measures have been applied.

All these findings give an idea that the death rate due to tuberculosis was very high some decades back and continues to be high even now, though it is progressively going down in recent years.

Morbidity Surveys

In the earlier part only small studies limited to small population groups in different areas were undertaken by different workers. Dr. Benjamin in 1938 found 2.6% to be the prevalence rate of tuberculosis in the suburbs of Madras. Dr. Lal in 1944 calculated a morbidity of 7% in West Bengal. Dr. Sikand and Dr. Raj Narain in 1952 found 1.8%, Dr. Phillip in Madras in 1952 found 2.5% and Dr. Hertzberg in Trivandrum found 1.8% to be the morbidity rate for tuberculosis. Dr. Sikand and Dr. Raj Narain in 1952 indicated 1.36% to be the morbidity rate of tuberculosis among displaced persons in Faridabad. In Madanapalle, a survey by Dr. Frimodt-Moller showed a morbidity of 1.6% in the town and 0.42% in the adjoining villages in 1949. During 1952-53, an X-ray survey of the Government of India employees in Delhi showed a morbidity of 0.77%. The Sample Survey in 1955 in a small population in Ambur in South India showed a morbidity of 1.4%.

All these small surveys gave an impression that millions would be suffering from the disease in both urban and rural areas and it was felt necessary to have a precise estimate of the morbidity of the disease in the country as a whole.

The National Sample Survey was, therefore, conducted during 1955-58 which showed a morbidity of 1.3% to 2.5% X-ray cases and 0.4% bacteriologically confirmed cases and this prevalence was found to be uniform in cities, towns and villages. The findings of this Survey, which for the first time gave reliable and more or less precise information about the size and extent of the problem, on the basis of which a National policy for control of tuberculosis in the country could be built, has been discussed in the next Chapter. Subsequent surveys in Delhi (1960), Tumkur (1960) and Bangalore (1961-68) have also confirmed the findings of the National Sample Survey.

Tuberculin Test

Some information about the prevalence of infection can be obtained from the various tuberculin test surveys conducted in the country. Tuberculin tests done by Dr. Gill in 1930 in several areas in Bengal, Madras, Assam and Bihar showed the infection rate varying from 11.4% to 33.3% upto 15 years of age and 69.9% above that age. Benjamin in 1938 in a survey in rural South India noted tuberculin positive reaction to be 8.2% in villages and 11.6% in small towns among those under

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15 years of age and in a suburb of Madras he found a positive reaction in 41.2% below 15 years of age and 69.8% above 15 years. Dr. Lal in 1944 in Bengal found infection rate to be as high as 88% in urban areas and 32% in rural areas.

Tuberculin testing conducted in connection with the mass BCG Campaign in the earlier phase of the programme showed infection rate to be in the range of 19% in 0-6 years age-group, 39% in the 7-15 years age-group, 63% in the 15-24 age-group and 83% in the age-group above 25 years. The average for all ages was about 54%. Contrary to our belief that tuberculosis was a major problem in the cities and towns rather than in the villages, the tuberculin test results of the mass BCG campaign showed that infection rate was more or less of the same order in cities, towns and villages which indicated that tuberculosis disease was perhaps equally prevalent in both urban and rural areas. This presumption was later confirmed by the findings of the National Sample Survey.

Estimated size of the problem

From the recent studies and observations it can be estimated that a little over half the total population of the country consists of reactors to tuberculin apparently because of infection by tubercle bacilli. At the rate of 1.8% there should be about nine million persons having radiologically active tuberculosis disease and about a quarter of them *i.e.*, about two million, are infectious, excreting tubercle bacilli in their sputum and most of them have symptoms. The death rate from tuberculosis is estimated to be about 80 to 100 per 100,000 population per year.

CHAPTER II

EARLY ATTEMPTS

WITH THE gradually increasing awareness of the seriousness of tuberculosis in the country, attempts also began to be made to deal with the problem from the beginning of the present century. In the earlier stages, however, the measures were not organised and the progress was slow. This was mainly because the exact size and nature of the problem was not known and no preventive or really effective treatment measures were yet known to the profession. Open air treatment had been gaining popularity in the West but this was mainly for early cases. Little could be done for advanced cases. With very limited bed accommodation in hospitals in India for tuberculosis, it was not possible to take advanced cases of tuberculosis patients who might occupy the beds for a long time and in the end might succumb to the disease.

Attention was gradually diverted to establishment of tuberculosis dispensaries for treatment of the tuberculous and organisation of societies and associations mainly to promote health education about the causes of tuberculosis and its prevention and to organise care of the sick.

A. OPEN AIR SANATORIA

I. Private Enterprise

Most of the early efforts to provide treatment for tuberculosis were made by philanthropic societies and individuals on compassionate grounds. It was realised also that isolation of infective cases of tuberculosis was a form of prevention. Other forms of prevention were not in the public mind as yet. In several instances, it was the discovery of tuberculosis among young people in educational institutions which led to the provision of special facilities to deal with them. No small help in starting anti-tuberculosis work was rendered by individuals who themselves had the misfortune to get the disease. In this, India shared the experience of other countries.

(*i*) *Christian Missions*: The first open-air sanatorium for isolation and treatment of tuberculosis patients was founded in 1906 in Tilaunia, near Ajmer, by a Christian

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Mission. It was intended mainly for girls from schools and orphanages connected with this mission in North India. An institution in Almora in the Himalayas for tuberculous women was also started by a Christian Mission in 1908 and about the same time a small sanatorium for women and girls at Pendra Road in the Central Provinces (now Madhya Pradesh) was also started.

In South India, Dr. Louisa Hart, a Missionary working in Madanapalle was treating a number of tuberculosis patients in temporary buildings in her general hospital for a number of years. After the Union Mission Tuberculosis Sanatorium was founded in Madanapalle in 1912, this sanatorium took over the patients of Dr. Hart and had them transferred to the permanent buildings at Arogyavaram in 1915.

(*ii*) *Private Societies*: The first Sanatorium outside Christian auspices was opened in 1909 at Dharampore in Simla Hills, due to the benefactions of some Bombay philanthropists, mainly Parsis, and under the management of the Consumptives Homes Society of Bombay.

II. Under Government Supervision

The first sanatorium started under Government supervision was the King Edward Sanatorium at Bhowali, Uttar Pradesh opened in 1912, with money collected in that province in memory of King Edward VII.

III. Individual Effort

An instance of a sanatorium established by a private individual is one which was opened in 1912 by Dr. R. B. Billimoria in Poona and which two years later moved to its present site in Panchgani, Maharashtra State.

Other sanatoria started about this time were the "Turner" Sanatorium in Bombay—Dr. Turner was Medical Officer of Health, Bombay—and a Sanatorium at Deolai built from a bequest by a private individual, Seth Bhagwandas Narotamdas.

B. Tuberculosis Dispensaries

The opening of tuberculosis dispensaries on the lines of Sir Robert Phillip, which had a large part in the campaign against the disease in the West, started somewhat later. The

first one opened was in Bombay in connection with the Bombay Anti-Tuberculosis League. In Madras, the King Edward Memorial Institute (now called the Tuberculosis Institute) was established in 1917 by the efforts of the late Dr. P. S. Chandrasekara Aiyar.

C. Prevention and Health Education

(*i*) *Anti-Tuberculosis Leagues*: A number of anti-tuberculosis societies were formed in Bombay, Lucknow and Ajmer about the time of the First World War. The main object of these societies was educative propaganda about the causes and prevention of tuberculosis.

(*ii*) *The Bengal Tuberculosis Association*: Through the inspiration and pioneering efforts of some Missionary groups in Bengal, the Tuberculosis Association of Bengal was established in Calcutta in 1929. This organisation carried out fairly extensive propaganda in favour of concerned action against tuberculosis.

In spite of the growing attention paid to the tuberculosis problem, by 1935 there were only about 6,000 beds available in the whole of India, which then included what are now Bangladesh and Pakistan, for the treatment of tuberculosis patients.

(*iii*) *Tuberculosis Association of India*: As a result of public opinion gathering strength demanding action to deal with the increasing menace of tuberculosis, the first concerted effort was made through the organisation of the King George V Thanksgiving Fund in 1929. With the funds raised by this organisation, the Tuberculosis Association of India was established in February, 1939. Its organisation and activities are discussed in the next chapter.

(*iv*) *Methods of Treatment in early stages*: The main line of treatment advocated was open air and dry climate and good food. Patients who were not too sick to move about were usually advised to go to a dry climate and take plenty of exericse for improving their appetite; feeding or overfeeding of patients was the general rule.

Tuberculin was extensively used between the years 1910 and 1920. Sodium Morrhuate which was being advocated for leprosy was also extensively used in India for tuberculosis.

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From 1925 onwards Sanocrysin and other gold preparations came into vogue. Artificial pneumothorax was introduced in 1921 by Dr. Johannes Gravesen of Denmark who was associated with the Union Mission Tuberculosis Sanatorium. Thoracoscopy and cauterisation of adhesions were started in the same Institution in 1931 and gradually these operations became very popular. Thoracoplasty in its modern form, however, came to be increasingly used since 1932 in some of the institutions. Lung-resection for tuberculosis was started for the first time in India in 1948.

At that stage, it was assumed that all infectious tuberculosis patients would need hospitalisation, as hospitalisation was the only recognised form of treatment. Hospitalisation alone of all infectious patients would have cost about Rs. 360 crores, in addition to the enormous capital outlay involved in the construction of buildings for hospitals and sanatoria, yet it was realised that this could touch only a fringe of the problem. A new vision and an entirely new strategy was called for.

CHAPTER III

TUBERCULOSIS ASSOCIATION OF INDIA

In 1937, Lady Linlithgow, wife of the then Viceroy of India, after an appraisal of the Tuberculosis problem in India issued an appeal for funds to establish an anti-tuberculosis association in India. The Association was to consist of a central body supported by provincial and State organisations as affiliates of the Central body. In response to her appeal, a sum of Rs. 85 lakhs was collected. After returning 95% to States and provinces for maintenance of clinics and where possible of sanatoria and after-care settlements, the balance was retained for the Tuberculosis Association of India. To this was added direct donations and the corpus of the King George Thanksgiving Fund and the Tuberculosis Association of India was established in Delhi under the Societies Registration Act of 1860 on 23 February, 1939.

The main activities of the Association are summarised below:

New Delhi TB Centre

To serve as a model institution for "organised home treatment" of tuberculosis, the Association established with the help of Government of India, the New Delhi TB Clinic in 1940. Simultaneously, a few voluntary Care and After-care Committees were formed to assist the New Delhi TB Clinic in meeting the social requirements of patients. The New Delhi TB Clinic was upgraded in 1951 as a Training & Demonstration Centre with the help of the Government of India, WHO and UNICEF. Subsequently, the activities of the Centre multiplied manifold and today this Centre is reputed as one of the most efficient institutions in the country.

TB Sanatorium at Kasauli

In 1941, the Association established a sanatorium at Kasauli near Simla Hills. The sanatorium known as Lady Linlithgow Sanatorium had 250 beds and was one of the premier TB sanatoria in the country. For want of enough paying patients, this institution was closed down recently.

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TB Directory

The Association collected information regarding tuberculosis institutions in the country and published the first directory in 1943. This was revised periodically and the last (6th) edition was published in 1964. This is a useful document in respect of information about the facilities available in tuberculosis institutions in the country.

TB Hospital at Delhi

With the donations from a Delhi philanthropist, Lala Ramsarup Khanna and grants from the Government of India, the Association established the Lala Ramsarup TB Hospital at Mehrauli, Delhi with 306 beds which started functioning from 1953. It is one of the good hospitals in the country with all facilities including thoracic surgery.

Other Services

Apart from establishment of institutions and compilation of Directory, the Association had undertaken several other services. The Tuberculosis Hermitage at Sangrur was maintained by the Association for five years with Government of India grants and treated over 550 refugee TB patients upto March 1955. Thereafter, the hospital was handed over to the State Government.

With a grant received from the former Viceroy's War Purposes Fund, the Association selected 14 sanatoria all over India and treated over 450 Tuberculosis ex-servicemen.

The Consumptives Home Society, a charitable organisation of Bombay, had established one of the oldest TB sanatoria (K. E. Sanatorium) in Dharampur, Himachal Pradesh. The Society handed it over to the Tuberculosis Association of India in 1954. The Association maintained this Sanatorium for nearly 15 years but had to return it to the Consumptives Home Society because of financial difficulty.

Technical Committee

The Tuberculosis Association of India established a Technical Committee in 1948. This Committee consists of reputed Tuberculosis workers drawn from various parts of India to advise the Association on matters relating to control of tuberculosis.

Research

The institutions of the Association have also undertaken several research projects approved by the Indian Council of Medical Research pertaining to tuberculosis. The Ministry of Health also had provided grants to the Association to carry out surveys in urban and rural areas of Delhi by its institutions.

The Association has a Research Committee. On the recommendations of this Committee, a research programme has been instituted to find out if the period of treatment of tuberculosis could be shortened. A preliminary report of this study was presented recently to the International Tuberculosis Conference at Mexico.

Conference

A regular programme of the Association calculated to bring together those working in the anti-tuberculosis field and to involve tuberculosis workers in the anti-tuberculosis movement is the organisation annually of a conference of tuberculosis and chest diseases workers from different parts of the country. This conference deals with various aspects of tuberculosis control work and useful discussions are held.

Health Education

The Association has been carrying out regular programme of health education activities since its inception. These include broadcast talks, preparation and distribution of pamphlets and posters on various aspects of tuberculosis control measures, newspaper advertisements, etc. The Association prepares and distributes propaganda material to its affiliates and the latter bring these out in regional languages.

The Association has also brought out a blue print which deals with different aspects of tuberculosis control. The second edition of this blue print has been brought out recently.

Journal

The Association started the *Indian Journal of Tuberculosis* in September 1953. This is a quarterly journal devoted to the different aspects of tuberculosis control. Its editorial board consists of well-known tuberculosis specialists.

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Textbook

A significant event for the Association was the publication of a textbook on Tuberculosis in 1970. This book deals with all aspects of tuberculosis. The problems of tuberculosis that are common to most of the developing countries in Asia and Africa have also been discussed in this book. The second edition of the textbook on Tuberculosis is now under preparation.

Training of workers

The different institutions of the Association like New Delhi TB Centre, Lala Ramsarup TB Hospital and the Lady Linlithgow Sanatorium take active part in the training of doctors and other personnel in tuberculosis. The New Delhi TB Centre conducts a regular course in training of TB Health Visitors. The Association played a vital role in persuading the Indian Universities to institute diploma courses in tuberculosis.

The Technical Committee has been reviewing questions relating to the teaching of tuberculosis at various stages of medical education and has been making important recommendations from time to time.

Affiliated Associations

There are 23 State Tuberculosis Associations which are affiliated to the Tuberculosis Association of India. Most of them have established district organisations and carry out educational activities. They organise conferences, camps, care committees and refresher courses. Many Associations also maintain certain TB institutions like TB clinic, TB laboratory, etc. They also give financial assistance to indigent TB patients.

Seal Sale Campaign

The Association started the seal sale campaign in 1950. Starting on 2 October, Mahatma Gandhi's birthday, it terminates on 26 January, the Republic Day every year. The campaign is usually inaugurated in the Capital by the President of India and in the States by Governors or other dignitaries. During the past 25 years, this special programme has helped focus attention on the tuberculosis problem and generated an appreciable amount of interest in the programme.

International contacts

Since its inception, the Tuberculosis Association of India has been an affiliate of the International Union Against Tuberculosis. It has maintained cordial relations with National Associations all over the world. It organised the XIV National Conference in New Delhi in 1957. Its representatives have participated in most of the international conferences after 1947.

The Association is also an active member of the Eastern Regional Organisation. The Tuberculosis Association of India hosted the IX Conference of the Region in New Delhi alongwith its 29th National Conference on Tuberculosis & Chest Diseases in 1974.

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CHAPTER IV

BHORE COMMITTEE'S ASSESSMENT AND RECOMMENDATIONS

THE GOVERNMENT of India appointed in 1944 a Health Survey and Development Committee, popularly known as the "Bhore Committee" to study the health problems of the country and suggest plans for the development of health programmes.

On the basis of data then available, the Bhore Committee estimated that there could easily be about 2.5 million active cases of tuberculosis in the country, of whom perhaps about 0.5 million were dying every year. The recommendations of this Committee were in line with the anti-tuberculosis measures carried out in Western countries even though there were certain modifications to suit Indian conditions. The Committee's recommendations briefly were:

(*a*) Establishment of TB clinics, one for every district town. They emphasised the part domiciliary service had to play in tuberculosis control. They also recommended services of mobile clinics to cover the rural areas.

(*b*) Establishment of TB hospitals. They accepted the usual standard of one bed per annual TB death but recommended 2,17,500 beds as the minimum requirement. These were to be established in primary unit hospitals, secondary unit hospitals and district headquarter hospitals. Since provision of such a large number of beds would take many years, they recommended that in the first five years, 200 beds should be provided for every 10 million population.

(*c*) Provision of homes for incurables and establishment of after-care colonies. They suggested that non-official organisations interested in social welfare should help in this venture and the Government should meet a substantial part of the expenditure through generous grants.

(*d*) Development of facilities for training of tuberculosis workers was considered very urgent.

(*e*) Undertaking tuberculosis surveys for providing baseline information regarding incidence of the disease and for effective planning of tuberculosis.

(*f*) Creation of a Section for Tuberculosis in the Directorate-General of Health Services with an expert in Tuberculosis to advice, coordinate and further anti-tuberculosis work in the country as a whole.

(*g*) Encouragement of non-official efforts to supplement government work.

One of the first steps taken by the Government was to implement the Bhore Committee's recommendation in regard to the creation of a separate Section for Tuberculosis in the Directorate-General of Health Services with a senior expert as its Adviser. The other recommendations were taken up gradually.

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CHAPTER V

POSITION AT THE TIME OF INDEPENDENCE

WITH THE attainment of Independence in 1947, the National Government naturally devoted considerable thought and funds for social welfare in India and gave high priority to tuberculosis as it happened to be the most serious public health problem in the country, next only to Malaria. This also coincided with the increasing interest which the international organisations like the World Health Organisation, the UNICEF and the International Tuberculosis Campaign were taking in tuberculosis as a world problem. However, the events that followed Independence made the tuberculosis problem even more serious and difficult than were visualised by the Bhore Committee. Partition of India brought in as its aftermath a large number of displaced persons to India. Most of them had to live in crowded areas with extremely poor hygienic conditions. There was also the problem of malnutrition. These accentuated the already bad tuberculosis problem in the country.

Though the urgency of taking up a large scale control measure for such a big and serious problem was fully realised, it was not possible for the government to immediately implement all the recommendations of the Bhore Committee, because for providing even the minimum requirements suggested in that report, a substantially large sum was necessary. The number of beds available at that time for tuberculosis patients in India was only about 6,000 and the number of clinics about 85 whereas the estimated number of patients was about 2.5 million. It was estimated that for controlling the problem of tuberculosis of such a magnitude, India would require some 3,000 to 4,000 TB clinics and some five lakh beds according to the usual standards obtaining in the Western countries at that time. The cost of these was estimated to be over 5,000 million rupees. It was obvious that from the point of view of men, material and resources, introduction of such a programme was impossible within a reasonable period of time. Attention was, therefore, directed towards prevention. Since BCG had proved to be efficacious in the prevention of tuberculosis in many of the Western countries and could be applied quickly, easily and at a comparatively low cost, the chief method chosen for

prevention of the disease was BCG vaccination. It was planned that the vulnerable population should be protected by BCG vaccination within a period of 10 to 12 years and in the meantime resources and knowledge should be mobilised to adopt other measures for effective control of tuberculosis.

BCG vaccination was started as a pilot project at first in 1948 in Madanappalle in South India and thereafter it was extended as a school vaccination programme in all the States during 1949 to 1951 with the help of the International Tuberculosis Campaign. At the same time, the Government of India set up a BCG Production Laboratory at Guindy, Madras in 1948 for production of BCG and tuberculin for the country's programme.

About the same time arrangements were made to establish with the help of the World Health Organisation and the UNICEF, TB Training & Demonstration Centres at Delhi, Patna and Trivandrum to serve as model for TB clinics and also as Centres for training of personnel for the country's TB control programme. A number of fellowships for tuberculosis workers for training abroad were also given.

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CHAPTER VI

FIRST FIVE YEAR PLAN

In 1951, the First Five Year Plan of the Government of India was started, and tuberculosis was given a prominent place therein. A scheme for control of tuberculosis in the country as a whole was drawn up by a Technical Committee consisting of experts from different parts of the country. This scheme was accepted by the Planning Commission. It included:

(i) Expansion of BCG vaccination on a mass-scale.

(ii) Establishment of TB clinics and expansion of domiciliary services.

(iii) Establishment of more Training & Demonstration Centres.

(iv) Provision of beds for isolation and treatment of those TB patients living in crowded and unhygienic areas.

(v) Rehabilitation of ex-patients.

(vi) Research.

As health is a 'State' subject, the National Government had to depend largely on the State Governments for implementation of most of the schemes. A sum of Rs. 46.3 million was provided in the Plan, of which Rs. 38.0 million was in the State sector.

During the First Plan period, BCG vaccination programme was expanded on a mass-scale to cover the population below the age of 25, approximately 170 million. The BCG Vaccine Laboratory in Guindy was expanded so as to produce adequate quantity of vaccine necessary for the expanded programme. The target for BCG vaccination in the First Plan was testing and vaccination of a total of 87 million persons. The actual achievement was, however, 71.5 million tuberculin tests and 24.5 million BCG vaccinations.

Priority was given to establishment of TB clinics because it was thought that it was one of the practical methods for arranging domiciliary treatment for tuberculosis which could

be introduced very quickly and because provision of a very large number of beds required for treatment of TB cases as recommended by the Bhore Committee was found impracticable due to paucity of funds. The discovery of new anti-bacterial drugs for treatment of tuberculosis and their effectiveness in domiciliary service provided further justification for giving top priority to the establishment of TB clinics. Fifty five new clinics could be established in the First Plan but it was noted that most of the clinics in the country were not run satisfactorily. Majority of the clinics did not have adequate diagnostic facilities nor did they have adequate staff to carry out an effective domiciliary service. This fact was taken note of while recommendations were made for the Second Five Year Plan.

It was suggested that about 10,000 beds should be provided for tuberculosis in the First Five Year Plan specially for isolation of infective patients living in crowded and unhygienic homes in cities and towns. About 5,000 beds were added during the Plan in the various States against the target of 10,000 but these were mostly added in existing sanatoria and hospitals. In addition, two special hospitals for tuberculosis children were established during the first Plan period, one in the North at Mehrauli in Delhi and the other in the South at the UMT Sanatorium, Madanapalle. The three training centres for tuberculosis at Delhi, Patna and Trivandrum were completed. Establishment of work centres for rehabilitation of ex-TB patients was also contemplated but no progress could be made.

Investigations on use of newly available anti-bacterial drugs for treatment of tuberculosis were undertaken at Madanapalle Sanatorium, Kasauli Sanatorium and also in other institutions under the Indian Council of Medical Research. An important research during the First Plan was the community tuberculosis control programme by the TB Sanatorium in Madanapalle where methods of TB control including isolation of infective cases and BCG vaccination were introduced in a rural community around Madanapalle.

Two main landmarks in respect of research that were of vital importance for subsequent development of a National TB Control Programme were the start of the National Sample Tuberculosis Survey and the establishment of the Chemotherapy Research Centre at Madras by the end of the First Five Year Plan in 1956. Till then, though it was realised that

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the problem of tuberculosis in the country was very large, its precise extent, prevalence and incidence in different areas, communities and age-groups and the two sexes were not known and this was a big handicap in organising a mass control programme and fixing rational priorities.

The Tuberculosis Chemotherapy Centre was established in Madras in 1956 by the ICMR with the cooperation of the World Health Organisation, the British Medical Research Council and the Government of Madras. The main object of this project was to determine the efficiency of domiciliary chemotherapy *vis-a-vis* hospital treatment and other problems connected with treating patients in their homes. The other objective was to work out appropriate drug regimens specially for domiciliary chemotherapy.

CHAPTER VII

SECOND FIVE YEAR PLAN

THE PRIORITIES in the Second Plan were about the same as in the First Plan. The difficulties and pitfalls encountered in the implementation of the First Plan schemes were taken note of and steps were taken to rectify these.

The First Plan schemes were to be implemented solely by the States except BCG vaccination programme and research. As a result, TB clinics were established without proper equipment and staff and TB beds were added mostly in hospitals and sanatoria that were not useful for infective cases in crowded areas. One of the important changes made in the Second Plan was, therefore, to undertake certain of the TB control schemes as national programme and the Central Government to give a subsidy to the State Governments for their implementation.

The target set for BCG vaccination in the Second Plan was to complete the mass vaccination programme to cover 170 million young people. For intensifying activities, certain subsidies were provided by the Central Government to the States. As a result of expansion, 91.7 million tuberculin tests and 37.5 million BCG vaccinations were performed in the Second Plan period. New building and plant, for the manufacture of freeze dried BCG vaccine were made available at the BCG Laboratory and some freeze dried vaccine was manufactured on an experimental basis.

In the Second Plan, the Government of India agreed to supply X-ray and laboratory equipments to the newly established or upgraded TB clinics for expansion of domiciliary treatment service. The target was to establish and upgrade 180 TB clinics. As against this target, 80 new TB clinics were established, of which 60 were equipped with funds provided by the Government of India.

A target of establishment of 10 TB Training & Demonstration Centres in association with the Medical Colleges in different States was fixed. However, three Training & Demonstration Centres could only be established at Nagpur, Madras and Hyderabad.

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4,000 TB isolation beds were established during the Second Plan period for which the Government of India gave a subsidy of Rs. 1,250 per bed.

Establishment of after-care work centres in association with large clinics in the country for training of TB and ex-TB patients and their family members in different handicrafts was also taken up in the Second Plan. Six such rehabilitation centres could be established in the Second Plan period as against a target of eight.

The National Sample Survey started in 1956 was completed in 1958. The report was published by the Indian Council of Medical Research which gave precise information for the first time about the size and nature of the problem in the country.

The community Field Research Programme in Madanapalle was further expanded under auspices of the Indian Council of Medical Research and the W.H.O. The study population was increased from 50,000 to 2,00,000 and the scope of the study was expanded to include effect of domiciliary treatment in a community by repeated examinations of the patients and their contacts and periodical surveys of the population in that community.

The studies conducted by the Chemotherapy Centre, Madras showed that the results of home treatment with anti-TB drugs as carried out at the Centre in Madras were as good as the results of sanatorium treatment and that bed rest or good diet did not play any major role in the treatment of tuberculosis.

One very significant event of the Second Plan was the establishment of the National Tuberculosis Institute at Bangalore in 1959. This was inaugurated by the late Prime Minister, Pt. Jawaharlal Nehru on the 16 September, 1960. This Institute was planned to serve as a centre to evolve and work out tuberculosis control methods best suited to a country like India where tuberculosis problem is large and the resources are meagre and to train the staff required to implement the tuberculosis programme in the country. The Institute was established by the Government of India in the premises then made available by the Government of Mysore and with the help of the World Health Organisation and the UNICEF.

The activities of these two institutions are discussed in a subsequent Chapter.

CHAPTER VIII

THIRD FIVE YEAR PLAN

THE Third Five Year Plan from 1961-66 was continued for two more years in 1967-68 and 1968-69 till the start of the Fourth Five Year Plan in 1969-70.

In 1962 the Health Survey and Planning Committee (Mudaliar Committee) reassessed the problem of tuberculosis and recommended measures essential to deal with it. This Committee recommended that BCG vaccination should be further intensified, domiciliary treatment for tuberculosis should be further expanded and mobile X-rays for rural areas should be provided. The Committee recommended one TB clinic for each one million population, one lakh additional TB beds in the Third Plan and a full time State TB Officer (A.D.P.H., TB) in each State.

During the Third Plan period, the schemes for mass BCG vaccination and establishment of TB clinics, Training & Demonstration Centres and TB beds were therefore continued and their expansion provided for. A new scheme for establishment of mobile X-ray clinics was taken up with a view to catering to the needs of the vast majority of patients living in the rural areas since most of the TB institutions and clinics, etc., established so far were located only in urban areas. Simultaneously, the National Tuberculosis Institute was engaged in their attempt at evolving suitable methods by which anti-TB measures could be integrated with the community development service in the rural areas with a view to providing tuberculosis services in the periphery.

The National Tuberculosis Institute within a short period after its establishment, was able to introduce a major change in the strategy and concept of National Tuberculosis Programme by evolving a community control programme for tuberculosis. On the basis of the findings of the National Sample Survey that the prevalence of tuberculosis was almost equal in both rural and urban areas in India, it was considered essential to plan a programme for providing diagnostic treatment and prevention facilities in the rural areas where 80% of the country's population lives. Operation research conducted by the National Tuberculosis Institute proved the feasibility of

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organising a programme aimed at providing measures for diagnosis, treatment and prevention of tuberculosis on a community basis. Based on the findings of the various social, organisational and operational research studies in community approach, a district TB control programme was evolved in 1962. The concept, methodology and organisation of the District Tuberculosis Programme is discussed in a subsequent Chapter under National Tuberculosis Programme. The main activity of the National TB Programmes since then has been establishment of District TB Centres for organising control measures through all the peripheral health facilities in the district.

The strategy of the BCG vaccination programme was also changed. It will be realised that the Plan at the time of inception of the BCG vaccination programme was to cover the entire susceptible population in its first round and thereafter integrate BCG with the appropriate agency of the general health service to be able to cover the newly added young population. However, since a large backlog of the susceptible population was still available and neither the school health service nor the maternity and child welfare service was sufficiently organised to be able to take full responsibility of providing BCG immunization to the entire young population, it was proposed to continue the BCG programme but it was decided to integrate the BCG teams with the District TB Control Programmes that were taken up as a Plan scheme in the Third Plan. As BCG vaccination without preliminary tuberculin test was found to be safe and simple, direct BCG vaccination was introduced and vaccination was limited to the younger age group of 0-14 years. Newborn vaccination was also introduced starting with the maternity hospitals and other maternity institutions in urban areas. A total of 95.7 million tuberculin tests and 55.9 million BCG vaccinations were performed during the period from 1961—68.

District TB Centres under the District TB Control Programme were established in 119 districts and many of the TB clinics in the district headquarters established in the previous Plans were upgraded to function as District TB Centres by organising TB control programme for the entire district. Thus, the total number of upgraded District TB Centres that were to function as headquarter of the managerial team of a district programme and as a referral centre for the entire programme came upto 170 by 1968.

A target was fixed for establishment of five more State Training & Demonstration Centres at State level for training of personnel. As against this target, eight were established during the Plan period. Thus, the total number of State Training & Demonstration Centres came to 15.

Against the target of establishment of 25 mobile X-ray clinics, five were developed and in the meantime the need for such clinics was no longer considered urgent after the District TB control concept for rural areas was evolved by the National Tuberculosis Institute.

A target for establishment of 5,000 TB isolation beds was fixed. However, priority was given to establishment of District TB Centres through which bulk of the patients could be treated rather than to establishment of isolation beds. A total of 1,571 beds were only established during the Plan period.

Certain advance actions for implementation of the scheme proposed for the Fourth Plan were also taken up during the course of the Third Plan period. These were:—

(1) *Establishment of regional organisations*: To guide implement, supervise and assess the work of the district TB programme in the States and to coordinate their activities, six regional Centres were originally proposed for the Fourth Plan and two of these were established in the Third Plan itself in Bangalore for the Southern districts and in New Delhi for some of the Northern districts.

(2) *Supply of anti-TB drugs*: The most important event in the Third Five Year Plan was the start of a scheme for supply of anti-TB drugs to State TB clinics as well as to TB clinics run by voluntary organisations for domiciliary treatment. 237 TB clinics under the State Governments and 45 TB clinics under voluntary organisations took advantage of this scheme immediately after it was started in the Third Five Year Plan. Anti-TB drugs worth more than Rs. 16 million were supplied during the Third Plan period.

CHAPTER IX

FOURTH FIVE YEAR PLAN

In the Fourth Plan, all the schemes of the Third Plan were continued. However, it was observed during the previous Plans that in spite of all the guidance and assistance given by the Central Government, implementation of the programme by the States was poor. It was, therefore, felt that to be able to develop the required organisation for tuberculosis control in the entire country the Government of India should take the responsibility of bearing the cost of the entire programme in the Fourth Plan period. All the schemes under the TB Control Programme in the Fourth Plan were therefore made Centrally sponsored schemes with 100% Central assistance. This meant that whereas in the previous Plans, the Government of India assisted the States in the establishment of District TB Centres and isolation beds by bearing a portion of the recurring and non-recurring expenditure, in the Fourth Plan, the Government of India undertook the responsibility of bearing the entire cost of establishment and maintenance of these institutions and of anti-TB drugs and BCG vaccine required for the programme.

The number of districts at that time was 330. 170 of these were already covered under District TB Control Programme upto the end of the Third Five Year Plan. It was therefore proposed to cover the rest of the 160 districts during the course of the Fourth Plan so that by the end of the Plan period, all the districts of the country would have been covered by the District TB Control Programmes. A target of 160 District TB Centres was, therefore, fixed for the Fourth Plan.

The need for a minimum number of beds as adjunct to domiciliary service for problem cases of District TB Programmes in the districts was considered essential. There were several districts where there was no TB bed at all. A target of establishment of 2500 TB isolation beds was therefore fixed for the Fourth Plan. States were advised to establish such beds as additional TB wards in district hospitals where no TB bed was available. In the meantime because of the popularity of domiciliary service, many of the TB beds maintained by voluntary organisations were at the point of being closed down

for want of paying patients and resources. It was, therefore, suggested to the States that in any area without TB beds if there was a TB hospital or sanatorium run by a voluntary organisation within a radius of 250 miles, they should rather reserve beds in such voluntary organisations instead of establishing new beds and the Government of India was prepared to pay the cost of reservation within the stipulated pattern of assistance to State Governments.

At the end of the Third Plan, there were still two major States *viz.*, Madhya Pradesh and Assam not having a training & Demonstration Centre. For the other smaller States like Nagaland, Tripura, Manipur, etc., and the Union Territories, it was not considered necessary to have separate Training & Demonstration Centres as they could take advantage of the Training & Demonstration Centres of the adjacent States. A target for establishment of two Training & Demonstration Centres at Assam and Madhya Pradesh was therefore fixed.

Regarding supply of BCG vaccine, it was decided that money required for purchase of BCG vaccine, tuberculin, etc., from the BCG Vaccine Laboratory will be paid by the Government of India to the States. So far as supply of anti-TB drugs to TB clinics run by State Governments and voluntary organisations for domiciliary treatment of TB patients is concerned, it was decided to continue free supply of these drugs by the Government of India as hitherto.

During the course of the Fourth Plan, 114 more TB clinics were added as against the target of 160. The two Training & Demonstration Centres as targetted were established and 1571 isolation beds were established against the target of 2500. In the meantime, BCG vaccination programme of the country was further expanded through other agencies like the railways, armed forces, voluntary organisations, etc.

A new Central scheme for expansion of production of freeze-dried BCG vaccine was taken up in the Fourth Plan. Production of freeze-dried BCG vaccine in the BCG Laboratory which was only about 5 million doses in 1969-70 was enhanced to about 30 million doses by 1973-74. By the end of the Plan period use of liquid vaccine in the entire programme was stopped and only freeze-dried vaccine was used. A total of 60 million direct vaccinations were performed in Plan period. BCG vaccine and tuberculin worth about Rs. 4.5 million were supplied to the States.

Anti-TB drugs worth about Rs. 33 million were supplied to more than 300 TB clinics run by the State Governments and about 60 TB clinics run by voluntary organisations for free supply to the TB patients on domiciliary treatment.

In the meantime, the project: Tuberculosis Prevention Trial, which started with a feasibility study in 1964 and as a regular project in 1968 was continued for assessing the value of BCG in the prevention of tuberculosis in the circumstances prevailing in our country. The first phase of the work which included initial examination of the population comprising about 3,67,000 was completed by March, 1971.

CHAPTER X

FIFTH FIVE YEAR PLAN

THE Fifth Five Year Plan which started from 1974 would continue till 1979. During the Fifth Five Year Plan, it has been decided to continue the schemes for supply of anti-TB drugs to State TB clinics as well as to voluntary TB clinics and supply of BCG vaccine and tuberculin to the States as Centrally sponsored schemes with 100% Central assistance. So far as establishment of District TB Centres and Isolation beds are concerned, these are included in the State sector for which funds are being provided in the State budget.

The provision for the different schemes under the National TB Control Programme for the Fifth Plan are:

I. Centrally sponsored schemes

(i) Supply of anti-TB drugs to State TB Clinics	Rs. 575 lakhs
(ii) Supply of anti-TB drugs to voluntary organisation-run TB clinics	Rs. 100 lakhs
(iii) Supply of BCG vaccine to States	Rs. 150 lakhs

II. State schemes

	Target	
(i) Establishment of District TB Centres	75 Centres	Rs. 335 lakh,
(ii) Establishment of TB Isolation Beds	3500 beds	Rs. 506.60,
(iii) Equipment for State/ District TB Centres	75 sets	Rs. 90.00.

With the establishment of 284 District TB Centres upto the end of Fourth Plan, it was estimated that another 75 districts were to be provided with a District TB Centre in each, taking into consideration also the new districts that were created in the meantime. So far, the United Nations Children's

Fund was supplying X-ray, Laboratory equipment and vehicles for these District TB Centres. In the Fifth Plan UNICEF aid is not available. It is, therefore, necessary for the States to establish and equip the 75 Centres during the course of the Fifth Plan. The phasing suggested for establishments of these 75 District TB Centres in the Fifth Plan should enable us to cover the entire country by District TB Programme by the end of the Plan period.

3500 more TB Isolation beds are to be established by the States in the Fifth Plan as adjunct to domiciliary service programme of the District TB Programmes. These are to be added as wards in existing general and tuberculosis hospitals. With the establishment of these beds, the total number of TB beds in the country will come to a little over 44,000.

BCG vaccination of newborns and infants in an integrated approach to immunization of children in rural areas with BCG, smallpox and DPT by the peripheral health workers of the Primary Health Centres is being organised in the Fifth Plan. In each P.H.C. area there are 20 to 24 workers in the periphery like ANMs, BHWs, Vaccinators, etc. The population of the N.E.S. Block are to be divided among them at 4500 to 5000 per worker and the children in this population are to be vaccinated by them with the three vaccines during the course of their normal work. These persons are being trained and will be supervised by the existing BCG teams that will continue to cover the school-age group. To meet the increased requirement of BCG vaccine, production of freeze-dried BCG is being enhanced to 60 million doses in the next few years for which a sum of Rs. 50 lakhs has been provided. Necessary major equipment for freeze-drying of vaccine and automatic sealing of ampoules, etc., is being procured and the testing and quality control laboratory is being expanded, so that, if required, production of freeze-dried BCG can be further enhanced in the Fifth Plan itself.

Anti-TB drugs as usual are being procured by the Government of India and are being supplied directly to the TB clinics. Miniature X-ray films are also being procured centrally for supply to District TB Centres. BCG vaccine is being supplied from the BCG Vaccine Laboratory, Madras. Tuberculin for diagnostic use is also supplied from the same Laboratory. A sum of Rs. 13.5 million was utilised for supply of drugs and BCG in 1975-76 and about Rs. 15 million was likely to be utilised in 1976-77.

CHAPTER XI

NATIONAL TUBERCULOSIS PROGRAMME

THE TUBERCULOSIS Programme of the country has been evolved takng into consideration the following facts:

(a) That the nine million or so cases of active tuberculosis in the country are evenly distributed in the towns and villages, that is, 82% of the cases are in the villages where no special facility for tuberculosis exists.

(b) That the pool of infectors are the sputum positive cases totalling about two million in the country, most of whom have also symptoms and therefore have a felt need for taking action, and in fact, are already seeking relief for their suffering from the general hospitals, health centres and dispensaries in their areas.

(c) That domiciliary treatment is most suited for treatment of tuberculosis and institutional treatment becomes necessary only for a small percentage of problem cases.

(d) That the programme for tuberculosis control must cover the entire country, be well within the available resources in men, money and material and provide sizeable benefit to the community in the foreseeable future.

(e) That by organising tuberculosis control on a community basis through the existing health facilities which provides a permanent programme and is easy of implementation, it is possible to bring under treatment a large proportion of the infectious cases in community in a reasonably short period of time.

(f) That BCG vaccination is an effective and reliable preventive measure and can be easily integrated with the general health service as one of its regular features.

(g) That tuberculosis is a chronic infectious disease of ubiquitous distribution and about half the total population of the country is infected by tuberculosis germs that constitute the main source of future patients for

several decades. High birth rate adds to the susceptible population every year needing a regular BCG vaccination programme all the time. Therefore, the programme has got to be countrywide, of a permanent nature and should be integrated with general health service.

The fundamentals of control programmes are:

(i) Prevention of development of tuberculosis infection and disease among those who are not infected.

(ii) Detection and treatment of as large a number of infectious cases as possible with a view to rendering them non-infectious.

To achieve these objectives, the main emphasis in the National Tuberculosis Programme has been on the organisation of District TB programme by establishing a fully equipped and staffed District TB Centre in each of the districts and developing tuberculosis case-finding, treatment and BCG vaccination activities in the entire district through the existing health facilities.

CHAPTER XII

DISTRICT TUBERCULOSIS PROGRAMME

An Average district in India has a population of about 1.5 million. It is divided into about ten taluks with a taluk headquarter town in each, of which the largest is generally the district headquarter. There are about 1800 villages which are grouped into 20 blocks, each provided with a Primary Health Centre. In addition to the Primary Health Centres, there are another about 30 small hospitals, dispensaries, *etc.*, thus having about 50 health institutions, each under the charge of a qualified medical officer.

On an average there are about 20,000 patients in a district of whom about 5,000 are infectious. These 5,000 cases are the ones that are sources of infection and most of whom also have symptoms. They are given priority in the district TB control programme, both with a view to providing relief of symptoms and 'sterilizing' the infectious pool. The rate at which new cases (*i.e.*, diseases incidence) are added every year to the pool of cases can be estimated to be about one-third to one-fourth of the prevalence cases. This means that about 1250 to 1500 infectious cases are added to the pool of 5,000 every year and similar number of cases either die or recover from the disease, thus keeping the infectious pool more or less constant at about 5,000 cases. On a rough estimate, on the basis of the drugs consumed or budget provided for anti-TB drugs in any district where District TB Control Programme has not been organised, it is estimated that not more than 100 to 200 cases could be under active treatment.

In a district TB control programme, the District TB Centre established at the district headquarter and staffed by personnel trained in the concept of community approach to the problem of tuberculosis at the National Tuberculosis Institute, functions as a referral centre for the entire district and as the headquarter of the managerial team responsible for organising the programme in the entire district. The actual activity of case-finding mainly by sputum examination and of rendering anti-TB drug treatment on domiciliary basis takes place in the 50 and odd peripheral health institutions where the district tuberculosis team is to organise the programme. Thus, each patient in the periphery is offered the diagnostic as well as

treatment facility throughout the whole period of his treatment which is generally a minimum of one year, in the health facility near his home. Case index card for each patient is maintained at the District TB Centre and only treatment cards for the patients receiving treatment are maintained in the respective peripheral health institutions.

To start with, a patient suffering from tuberculosis may not be aware about it. Gradually he develops certain symptoms like cough, fever, weakness, loss of appetite, haemoptysis, etc., and goes to his nearest health institution seeking redressal of his symptoms. It has been found that in areas not having any regular tuberculosis programme, almost all the sputum positive cases (infectious) were aware about their symptoms and half of them had visited practitioners of modern medicine in search of treatment. Simple sputum examination can pick up about 82% of the infectious cases reporting to these health centres.

Thus, the bulk of the infectious cases having symptoms and seeking redressal at the peripheral health centres can be diagnosed by sputum microscopy and be offered regular treatment. For the other 18% it may be necessary to observe them and after necessary investigation, send them to the District TB Centre or other nearer X-ray facility for X-ray and further investigation. Priority is given to sputum examination because it has been found that only about 8% to 15% of the suspects (X-ray cases with negative sputum) breakdown into sputum positive status over a period of one to two years.

In such an organisation, the peripheral health institutions having sputum microscopy facility function as microscopy centres and the others not having microscopes can refer their patients to the nearest microscopy centre for sputum examination and therefrom to the nearest X-ray facility for X-ray examination.

Such activity of the District TB Control Programme does not really increase the workload enormously in any of the peripheral health institutions since in actual practice, the workload is not more than three or four sputum examinations per day. A minimum of recording and reporting is provided for to make it easy and simple. If a District TB Centre along with its 50 or more peripheral health institutions can diagnose and put under treatment about 1500 sputum positive cases per year, such a programme is likely to reduce the problem or tuberculosis. Prior to recommending this programme for the entire

country, it was tried as pilot project in some districts and it was found that such a coverage is possible without much additional inputs.

BCG vaccination also forms an integral part of the activities of the District TB Control Programme. For this a BCG team is posted in each district TB programme for systematic and regular coverage of the susceptible population in the entire district. The six technicians of the team cover the school children in all the schools and the pre-school and non-school going children from house to house. For newborn and infant vaccination, the staff of the existing maternity and other health institutions and the peripheral health workers are trained to build up a permanent organisation for this purpose.

TB Beds

The TB beds available in the district are used as adjunct to the domiciliary service of the District TB Control Programme. Hospitalisation is arranged for emergencies like haemoptysis, spontaneous pneumothorax, etc., or for cases where surgery is contemplated, for patients who are desperately ill, for those TB patients who are resistant to the standard anti-TB drugs and are therefore required to be treated with second-line drugs under observation or for those who do not have a place to live in.

State TB Centres

These are otherwise known as State TB Training & Demonstration Centres. One such Centre is provided in each of the major States of the country. The State TB Centre organises a model District TB Control Programme in the district including an urban programme in the city or town where it is located for demonstration, purposes. It undertakes training and re-orientation of the personnel engaged in the TB control programme of the country. It also organises seminars and re-orientation training courses for general health service personnel, private practitioners, etc. It conducts epidemiological and laboratory studies essential for the TB control programme. These centres are planned to be developed as State TB Centres, also for assessment and monitoring of the TB Control Programme of the State.

CHAPTER XIII

PRESENT STATUS OF THE PROGRAMME

THE PROGRESS of the different schemes of the National TB Control Programme are briefly discussed below:

District TB Centres

There are at present about 600 TB clinics in the country of which about 300 are District Centres organising District TB Programme in 300 districts. Each of these District TB Centres is staffed with a team of personnel trained at the National TB Institute, Bangalore. About 250 of these have been provided by the UNICEF or the Government of India with full set of X-ray and laboratory equipments and vehicles. Each District TB Centre on an average has about 25 peripheral health institutions participating in the programmes and about 2800 patients are under treatment of a District Programme.

There are only about 17 districts in the country that still have no TB clinic. In the remaining districts not yet covered by regular District TB Programme, it is possible to organise TB control programme with a little effort, since the TB clinics as the nucleus of the District TB Centre already exist and trained personnel are either available in the State or can be easily trained at National TB Institute. The main activity of a District TB Programme is to organise case-finding and treatment through the existing peripheral health institutions of a district.

BCG Programme

There are at present 308 BCG teams. These have been mostly integrated with District TB Programmes. 290 teams have been posted in or integrated with District TB Centres so far. These teams are mostly covering children in schools and the pre-school age children by house to house visits. A total of about 253 million persons have been tuberculin tested and about 195 million have been vaccinated since the inception of the campaign. On an average about 13 million infants and children are offered vaccination per year, which, however, includes only

about a million new borns and infants below one year of age. Training of paramedical personnel of the rural health service for newborn and infant vaccination is in progress. Production of freeze dried BCG vaccine in our BCG Vaccine Production Laboratory is being expanded.

TB Beds

The total number of TB beds available in the country today is about 41,500. A little less than a third of these beds are run by voluntary organisations and the rest are under control of State Governments, other governmental agencies, municipalities, etc.

Training & Demonstration Centres

There are at present 17 Training & Demonstration Centres, which are in varying stages of development. Most of these centres are running a model District TB Programme and are having training activity for medical and paramedical personnel, medical college students, private practitioners, etc., apart from conducting certain epidemiological studies. A brief note on the activities of some of these centres is given towards the end.

Regional TB Organisations

Two Regional TB Organisations are functioning at present, one in the North located at the New Delhi TB Centre and the other in the South located at the National Tuberculosis Institute, Bangalore. These organisations are responsible for assisting the States in developing District TB Control Programmes in their respective zones, briefing medical and paramedical personnel both in the District TB Centres and peripheral institutions and for providing expert advice and guidance.

Supply of Drugs to State TB Clinics

This scheme has been in operation since 1964. Under this scheme there are more than 300 TB clinics undertaking domiciliary treatment of TB cases that are being supplied standard anti-TB drugs directly by the Government of India. A little over 7,00,000 TB patients are estimated to be under domiciliary treatment at any point of time under this scheme through these 300 TB clinics and about 5000 sub-centres of the District TB Centres.

Supply of Drugs to Voluntary Organisations

This scheme has been in operation since 1966. Under this scheme, standard anti-TB drugs are supplied free of cost by the Government of India for domiciliary treatment only. The purpose is to encourage voluntary organisations to organise domiciliary treatment, to help them bring in more TB cases under domiciliary care and to enable them to supply drugs free of cost to indigent TB patients. There are about 55 TB clinics/TB institutions run by voluntary organisations that are taking advantage of this scheme and about 75,000 patients are under treatment in these clinics under this scheme at any time.

Supply of BCG Vaccine

Under this scheme BCG vaccine is supplied free to the States for use by BCG teams and other TB, Paediatric or M.C.H. institutions, etc., participating in the programme. Tuberculin for diagnostic use is also supplied to certain TB, paediatric and other medical institutions.

Training of Key Personnel

This activity is carried out mainly at the Government of India's National TB Institute at Bangalore. So far, about 420 district TB Teams comprising 2961 medical and paramedical personnel from different States have been trained in 32 courses for running the District TB Programmes. Apart from these, a number of State TB Centre personnel have also been trained and many Administrative Medical Officers of States, teachers of medical colleges, District Health Officers, Medical Officers from various organisations, etc., have participated in the seminars conducted regularly every year.

Several key personnel of the State TB Programmes have also been got trained abroad with fellowships under WHO/Colombo Plan, etc., in Tuberculosis Control.

CHAPTER XIV

RESEARCH

IN THE field of research in Tuberculosis, India is in the forefront today. Many of our research findings have contributed to the world knowledge about tuberculosis and its control and have been useful in evolving a sound programme for control of tuberculosis in India and in many other developing countries.

In this Chapter, an attempt is made to summarize the findings of some of the important research studies conducted in India, on the basis of which our National Tuberculosis Programme has been developed. Readers may also find the answers to some of the questions that normally come to their mind in respect of the present concept of tuberculosis control, home treatment of tuberculosis, the role of food and rest in treatment, risk if any, from a patient under treatment at home to his contacts, protective value of BCG, whether tuberculosis in our country is increasing or decreasing etc., from the summary of findings of these studies.

NATIONAL TUBERCULOSIS SURVEY

The National Tuberculosis Sample Survey (1955-58) was conducted by the Tuberculosis Sub-Committee of the Indian Council of Medical Research. The survey was limited to investigations of Pulmonary Tuberculosis, one of the most important forms from epidemiological and public health points of view. Various types of population in selected cities, towns and villages in the States of West Bengal, Bihar, U.P., Delhi, Punjab, Andhra Pradesh, Mysore, Madras, Maharashtra and Kerala were covered by the survey. About three lakh persons were examined in six cities, 30 towns and 151 villages. The Groups included in the survey were chosen in accordance with the statistical principles so that the findings may be of general application. Six institutions were entrusted with the survey work. These were the Tuberculosis Centres in New Delhi, Patna, Hyderabad and Trivandrum, the All India Institute of Hygiene and Public Health, Calcutta and the Union Mission Tuberculosis Sanatoriam, Madanapalle in Andhra Pradesh. The entire population excluding children under

five years of age in the areas selected for survey was subjected to mass miniature radiography and those suspected to be suffering from the disease on the basis of X-ray were subjected to further bacteriological tests.

The main findings of this National Survey were:

1. Prevalence rate for 'active' and 'probably active' tuberculosis varied from 13 to 25 per 1,000 population in cities, towns and villages in the different zones.
2. The rate of bacteriologically positive cases for 1,000 population in these areas varied from 2 to 8.
3. Prevalence rates in cities, towns and villages were generally of the same order.
4. Prevalence rates were lower for females than for males, specially in age-groups above 35 years.
5. In general, the prevalence rate showed a continuous increase with age.
6. In the cities the higher prevalence among persons living in *kucha* houses as compared to those in *pucca* houses indicated the possible effect of economic and sanitary conditions.
7. A large majority of the 'active' and 'probably active' cases had moderately advanced disease.
8. Definite cavitation was observed in 4 to 33 per cent of the 'active' and 'probably active' cases, this percentage being generally smaller in the cities.

The survey also showed that there may be areas in a city where the prevalence of tuberculosis may be as high as four or five per cent and that these areas were generally inhabited by the poorest in the population, often living in extremely insanitary conditions.

COMPARISON OF HOME AND SANATORIUM TREATMENT

This study was undertaken by the Tuberculosis Chemotherapy Centre, Madras, as a controlled comparison of home and sanatorium treatment for one year and subsequently for another four years to study the emergence of relapse cases in these two groups.

163 newly diagnosed and previously untreated sputum positive patients of pulmonary tuberculosis from poor sections of the community in Madras City were randomly treated at sanatorium or home with the same chemotherapy *i.e.*, INH 200 mg. and PAS 10 gm. in two divided doses per day. Patients of the home series were given weekly supply of drugs to be administered by themselves at home with monthly supervision of their progress at the clinic and were visited at home by a Health Visitor every fortnight. The patients in the sanatorium series had bed rest, good accommodation, balanced diet and nursing care. Thus, this was a comparison of treatment of patients in best sanatorium conditions with those in usual day-to-day home conditions of the poor sections of the community.

At the end of one year, 86% of the patients treated at home converted to sputum negative and remained so (bacteriologically quiescent) as against 92% in the sanatorium patients. Improvement in X-ray and closure of cavity were also of the same order in both the groups.

Follow-up: After one year, the sanatorium patients returned to their homes and the patients of both the series were closely followed up for another four years to study the long-term results. Considering the overall relapse rate of the disease in the two groups, it was found that seven per cent of the patients in home series and ten per cent patients in sanatorium series had bacteriological relapse over a four-year period of follow-up.

It was thus conclusively proved that effect of treatment of patients at home is as good as of treatment in an institution both in respect of immediate recovery and subsequent prevention of relapse and that good food, nursing care and bed rest, etc., do not play any useful role in the treatment of tuberculosis. Domiciliary treatment has the added advantage of not causing any dislocation in the family during the period of the patient's treatment for tuberculosis.

TB ATTACK RATE AMONG CLOSE FAMILY CONTACTS

This study was planned by the Tuberculosis Chemotherapy Centre to determine the relative risks for contacts of patients treated at home and in the sanatorium.

256 close family contacts of patients treated in homes and 272 similar contacts of patients treated in sanatorium were intensively followed up by X-ray and bacteriological examination for five years. In each family, there was just one infectious case and the contacts in the two series were similar in all other aspects. Effect of isolation of the index cases could be best studied by comparing attack rate in the two series in the first year when the index case of the sanatorium series was isolated in the hospital.

In the first year, 4.9% of the contacts in home series developed tuberculosis compared with 7.6% of the contacts of sanatorium patients. Over the whole period of five years, 9.8% of the contacts of patients treated at home developed tuberculosis as against 14.4% of the contacts of patients treated in sanatorium. There was no difference in the attack rate in the two groups even when the initially tuberculin negatives and initially tuberculin positives were analysed separately.

An interesting observation of the study was that the majority of cases in contacts occurred in children below five years and were detected within three months of diagnosis of the index case and there was suggestive evidence that in most of them the infection occurred before the index case was diagnosed.

From this study, it can be concluded that there is no special risk to the contacts of patients treated at home with effective chemotherapy, the main risk to them being before treatment has begun.

Effective treatment of an infectious patient, whether at home or in a sanatorium, rapidly kills the tubercle bacilli and makes the patient non-infectious in a short time. The purpose of isolation is therefore best achieved by putting the patient on treatment immediately after diagnosis and ensuring regular introduction of the medicine prescribed.

Sociological Study of Awareness of Symptoms Among Persons With Pulmonary Tuberculosis

About 2,000 persons having evidence of inactive, probably active and active tuberculosis disease in their X-rays whose sputum results were also available (experimental groups) were age/sex matched with an equal number of persons with normal X-ray (control group) in 34 villages and four towns in Tumkur district in Karnataka. These persons

were interviewed at random by social investigators for symptoms. Only such symptoms that were associated with Pulmonary tuberculosis were taken into consideration. Of these, pain in chest, haemoptysis or combination of these four symptoms were analysed statistically. 79% of the experimental group and 83% of the control group were satisfactorily interviewed.

Cough was found to be the most important single symptom. 69% of the sputum positives and 46% of the X-ray positives had this symptom against only 9% of the normals.

69% of the sputum positives, 52% of the X-ray positives, 29% of the inactives and 15% of the controls had at least one of the above mentioned four symptoms.

Analysis of the material also showed that 95% of the bacteriologically positive cases were aware about their symptoms, 72% experienced awareness and were worried about their sypmtoms and 52% of them actually took action at the existing health facilities under pressure of their symptoms.

This study showed that half the infectious patients in a community are already knocking at the doors of the existing health service under pressure of their symptoms and if adequate facilities are provided, another one-fourth will immediately report to these health institutions. Thus, about a half to three-fourth of the infectious cases can be dealt with in a short period at the existing peripheral health institutions.

DISTRICT TB PROGRAMME PILOT PROJECT, ANANTAPUR

The District TB Control Programme was formulated by the National TB Institute on the basis of their knowledge gained from various case finding, treatment and methodological alternatives tried in Tumkur and Bangalore districts in 1960-61 and was implemented as a pilot project in Anantapur district of Andhra Pradesh to study the feasibility of the District TB Control Programme in 1961.

The district had a population of about 1.5 million. One District TB Centre equipped with an X-ray unit was established at Anantapur town. There were 14 Primary Health

Centres, ten health units and 30 rural dispensaries. Medical doctors were available in almost all health centres. Microscopes were provided in PHCs and other dispensaries. Sputum case-finding was organised with co-operation of all these institutions. Sputum specimens of all persons with cough were collected in all these centres throughout the year. These sputum smears were examined in the centres having microscopes. The centres not having any microscopes sent their smears to the institutions with microscopes, functioning as microscopy centres.

In this way, sputa from 17,000 symptomatics were examined and 1870 smear positive cases were found in one year. This comes to about 80 per cent of the total estimated infectious cases. The workload involved in each institution was collection of only two sputum smears per working day. It was also revealed that 99% of the sputum positive cases had cough for more than two weeks.

All the diagnosed patients were given ambulatory domiciliary treatment at the peripheral institutions nearest to their homes. The regularity of treatment was better when patients were treated at centres nearest to their residence.

It was found easily feasible and useful to organise such a case finding and treatment programme through the peripheral health institutions in an average Indian district. This method of case finding and treatment was found to be much cheaper than orthodox method by X-ray, much easier to implement and had the virtue of being available as a regular programme throughout the year.

FIVE YEAR STUDY OF EPIDEMIOLOGY OF TUBERCULOSIS IN A RURAL POPULATION IN SOUTH INDIA

This longitudinal study was carried out by the National Tuberculosis Institute to observe the natural history of pulmonary tuberculosis under the existing socio-economic conditions in an area before any TB control measures under the National TB Programme could be introduced. A randomly selected rural population of 65,000 in Bangalore district where the National TB control programme was not introduced was surveyed four times at an average interval of 1½ years over a period of five years during 1961-68 by repeated tuberculin test, X-ray and sputum examination.

The salient findings of the survey are:

(1) The prevalence rate of infection was about 30%. It showed a steady decrease specially in the age-group 0—24 years.

(2) The average annual incidence of infection (rate of new infection by tuberculosis every year among uninfacted) was about one per cent. During the study period, the incidence rates showed a decline from 1.63% to 0.8% for all ages combined.

(3) Prevalence rate of disease in the study population gradually decreased from 406 cases per 100,000 population in the first survey to 337 cases in the third survey but slightly rose to 393 cases in the fourth survey probably due to drought in the study area. For the younger age-group of 5 to 34 years, however, the rates showed a continuous decrease during the entire study period.

(4) Annual incidence rates of disease also showed a downward trend as in case of prevalence, being 132 cases per 100,000 population between first and second surveys, 99 between second and third and 103 between third and fourth surveys. The younger age-group below 35 years showed a steady downward trend during the entire study period.

(5) Prevalence and incidence rates of the disease increased with age and female cases were much less (one-third of prevalence cases and half of incidence cases) than in males.

(6) Of the 126 cases found at the first survey and followed up for five years, 49.2% died, 32.5% were cured and 8.3% continued to remain sputum positive at the end of five years. In the incidence cases (new cases detected by survey) however, there was a sizable natural cure of 52.4% and 14.3% died. In the prevalence cases (cases available at any given time) followed up for the same period the death rate was 16.9%.

(7) Primary drug resistance did not show any increase in five years.

The study showed a gradual natural downward trend in the prevalence and incidence of the disease, specially in the younger age-group.

DELHI TUBERCULOSIS SURVEY

The New Delhi Tuberculosis Centre conducted a survey (1962—70) in Delhi to study the epidemiology of tuberculosis in an urban population with a TB control programme in operation. A randomly selected population of nearly 30,000 was under surveillance in one of the most congested localities of Delhi. A reasonably good domiciliary service for detection and treatment of tuberculosis cases was available in the area for the last more than 30 years. Four surveys were carried out at an interval of 30 months during the period of study.

The following were the important findings:—

(1) The prevalence of total active cases which was 1720 per hundred thousand population in the first survey in 1962 came down to 880 in the fourth survey in 1970. Total bacillary cases came down from 400 per hundred thousand population in 1962 to 210 in 1970. Thus, prevalence of active cases of tuberculosis was reduced by about half.

(2) The prevalence rate increased with age. There was, however, no difference in the prevalence rate among males and females upto 35 years of age though after 35 years there was a steep rise in the disease amongst males. This was perhaps because these surveys covered an urban population.

(3) The incidence rate of bacillary cases was about 90 per hundred thousand population per year and that of total active cases 340 per year. The incidence rate did not show any downward trend.

The study showed that in an urban population with a reasonably good domicilary service programme, there is a reduction in the prevalence rate of tuberculosis in a reasonably short period of time.

MADANAPALLE TUBERCULOSIS RESEARCH PROJECT

The project was started in 1950 and comprised Madanapalle town and about 200 villages within a radius of 10 miles with a population of 50,000. This population increased to about 90,000 by the end of the study period. Seven surveys were conducted in the population above five years of age with tuberculin, X-ray and sputum examination during the period from 1950 to 1965. Case finding, treatment, both domiciliary and institutional, and BCG vaccination were provided to this entire population.

The following are the salient findings of the survey:

(1) The number of bacillary cases which was 410 per 100,000 population at the time of the first survey in 1950-51 came down to 320 in 1957-58 and was further reduced to 110 per 100,000 population in 1964-65.

(2) The number of cases in the male population was two to three times more than in the female population.

(3) The prevalence rate of infectious cases increased with age, the number of cases in males being much more than in the females specially above 20 years of age.

(4) The incidence rate of fresh tuberculosis cases was found to be 34 per 100,000 population and the incidence rate of active and inactive but abacillary (sputum negative) cases was found to be 207 per 100,000 population.

(5) The death rate which was about 250 per 100,000 population in 1949 in Madanapalle town came down to about 64.1 in 1951-53 and further reduced only to 21.1 per 100,000 population in the period 1954-55, thus showing a definte reduction in death rate in the study area.

The findings of this project showed that with a reasonably good TB control programme in rural areas providing facilities of case findings, treatment and BCG vaccination, the death rate goes down steeply and the rate of prevalence of infectious cases can be reduced substantially in a reasonable period of time.

STUDY ON DIRECT BCG VACCINATION BY THE NATIONAL TUBERCULOSIS INSTITUTE

Till 1964, the conventional procedure in BCG vaccination programme was to do a preliminary tuberculin test and offer BCG only to the tuberculin negatives. This involved two visits to each area and other technical and operational complications. Offering direct BCG vaccination would simplify the procedure and speed up coverage of the young population. This study was, therefore, taken up by the National Tuberculosis Institute to see if direct vaccination was safe, effective and acceptable.

First study: A rural population of 1891 was randomly divided into four groups: (1) tuberculin tested and vaccinated, (2) tested but not vaccinated, (3) not tested but vaccinated and (4) not tested, not vaccinated and these groups were followed up with periodical examination, tuberculin tests and X-ray for 90 days.

Results showed that local reaction at the site of vaccination and regional lesion at the lymph nodes in both the tuberculin non-reactors and reactors was of the same order. There was no evidence of existing tuberculosis disease being exacerbated or foci of tuberculosis flaring up.

Second study: 1186 persons were both simultaneously tuberculin tested and BCG vaccinated and were followed up for local reaction for a month.

Local reactions were found to be of the same order in both the reactors and non-reactors as in the first study.

Third study showed that local reactions after direct vaccination in one village did not affect the acceptability of direct vaccination in neighbouring villages.

STUDY OF NEW DELHI TB CENTRE

In a similar study conducted by the New Delhi TB Centre among primary school children also, it was found that direct vaccination of reactors was innocuous.

Direct BCG vaccination is a safe procedure as it does not cause any unusual inconvenience or danger to the reactors and the acceptability of the programme is also not affected in any way.

MADANAPALLE BCG TRIAL

This study was undertaken to assess the protective value of BCG vaccination against tuberculosis in Indian population as a part of the Madanapalle Research Project starting from 1950.

A total of about 21,500 persons were tested with tuberculin. About 10,000 were found to be tuberculin positive reactors and 11,500 non-reactors. The non-reactors were randomly divided into two groups. BCG was given to 5,069 and 5,808 were left as unvaccinated. Both the vaccinated and control groups were followed up by periodical tuberculin test, X-ray and sputum examination till 1967.

The findings of the study can be summarized as follows:

In the first five years after vaccination, BCG was responsible for reduction of incidence of tuberculosis in the vaccinated population to the extent of 60% compared to that in the control group.

In the next five years, the reduction in incidence of tuberculosis attributable to BCG vaccination was 56.5%.

But if the cases found within the first 1 to 1½ years of the trial that could have acquired the infection before entry into the trial are excluded, the reduction in cases attributable to BCG vaccination was 71.4%.

After another four years' follow up in 1968, it was found that in 14 years, BCG vaccination was responsible for 24% reduction of active cases and 33% reduction of bacillary (infectious) cases in the vaccinated group.

Thus, it was observed that the vaccination was most effective in the earlier period but gradually became less effective in the later period because of possible waning effect of vaccination. The suggestion was that BCG should be used mainly shortly before the population to be protected is exposed to

infection with tubercle bacilli and a second vaccination may be necessary before substantial waning effect of the first vaccination takes place.

Other BCG trials in the world have shown various levels of protection *e.g.*, 96% in Danish School children (Hyge, 1947); 82% in North American Indians (Aronson, 1958); 70% in English School leavers (B.M.R.C., 1963); 74% in Chicago infants (Rosenthal, 1961); 31% in Puero Rican children (Palmer etc., 1958); and 36% in seven years and only 14% in 14 years in an American population (Comstock and Palmer, 1966).

Since the study population of the Madanapalle trial was small and as the other studies have shown different levels of protection from very good to insignificant, a large scale BCG trial known as Tuberculosis Prevention Trial is being conducted in South India to get precise information about the protective value of BCG in Indian context.

CHAPTER XV

HEALTH EDUCATION

HEALTH EDUCATION has a pivotal role to speed up our march towards a healthier India. While much is known today about the etiology (causes and spread) of many of the diseases that afflict mankind, communication of this knowledge to the people in a language they understand best remains as much a problem as a challenge. The advances achieved in medical sciences, and the technological knowhow acquired in diagnosis and treatment procedures have to be brought to the notice of the people, and accepted and adopted by them to get adequate returns, investments on health programmes.

Tuberculosis continues to be one of the major public health problems in our country. Eight to nine million or so active TB cases of whom 2-3 million are infectous, are evenly distributed in towns and villages in India, *i.e.*, 80% of the cases are in the villages. TB being a communicable disease thrives on low living standards, poor housing conditions, overcrowding, insanitation and malnutrition. Late reporting and late detection of tuberculosis cases also cause delay in timely control of tuberculosis cases and early recovery of those afflicted.

The management of tuberculosis has been revolutionized during the last three decades. New drugs, which are remarkably effective, have been discovered. B.C.G. vaccination offers a high level of protection against tuberculosis. Domiciliary treatment with potent drugs is available to all at their doorsteps. The fundamentals that govern the National Tuberculosis Control Programme (NTCP) are: (i) prevention of development of tuberculosis among those who are not infected, and (ii) detection and treatment of as large a number of infectious cases as possible with a view to rendering them non-infectious.

These can be achieved only through a sustained educational campaign, so that factors such as ignorance, apathy, superstitions and neglect which contribute to spread the disease are overcome. Health education could play a vital role in arousing consciousness in the people that is needed to imbibe a positive attitude towards health *i.e.*, health not only as freedom from disease but as a status of general well-being. Much of the success of the domiciliary treatment of TB patients depends on their co-operation. People have to be made aware of early signs and

symptoms of tuberculosis, and on suspicion, come forward for an examination.

Role of Health Workers

The success of the domiciliary treatment depends, to a certain extent, also on the skill and competence of the peripheral health workers. As these workers have opportunities to move closely with patients, it should be easier for them to supervise self-administration of drugs by these patients and to take prompt measures when they fail to adhere to the prescribed treatment. The health workers, whether posted in specialized clinic in an urban area or working for a general agency in the rural area, can discharge their duties efficiently and effectively provided they possess the basic knowledge regarding factors that promote transmission of infection, causation, prevention and management of the disease. They need also to be well-versed in health education skills and techniques to prove to be effective communicators.

The multipurpose health worker's scheme also calls for strengthening the skill and the competence of Basic Health Workers and A.N.Ms. to educate the communities on preventive and promotive aspects of health services. With the organized development of tuberculosis control programme in our country and extension of case finding and treatment facilities right upto the periphery through the existing general health services, an elementary scientific knowledge of various aspects of the programme has to be provided to the health workers. A peripheral worker has to be properly trained and equipped to deal with individuals and groups.

The workers has to have the support of different media to make his message effective. At present, very little inputs are being made in producing educational materials for use by peripheral workers and for the lay public. There is, therefore, a great need of developing suitable educational materials on all aspects of the tuberculosis control programme.

With a view to meet the growing needs of educational materials, the Central and State level Health Education Bureaux are engaged in production of 'proto-type' materials, for use both by health workers and the lay public. With the growing literacy level in the country, printed materials and other communication channels like films and television hold great potential and would prove highly useful to health workers in functioning effectively.

CHAPTER XVI

SOME IMPORTANT TUBERCULOSIS INSTITUTIONS

National Tuberculosis Institute, Bangalore

The National Tuberculosis Institute was established in 1959 at Bangalore for the following three objectives:

(i) To formulate through research a practical, comprehensive and economically feasible tuberculosis programme that could be applied equally to rural as well as urban parts of the country.

(ii) To train medical and para-medical programme workers in the programme methodology so that they could effectively supervise and maintain the programme.

(iii) To undertake continuing research in order to further evolve the programme and outline a simple method for its assessment.

Though the objectives appear deceptively simple at first sight, in reality they meant extensive epidemiological, operational and community behavioural studies as well as a complete reorientation of the old ideas. Completely new concepts and appreciably altered emphasis on the other approaches have since been advocated by the Institute with regard to management of the tuberculosis problem in the country.

The Institute is functioning as a subordinate office of the Central Government under the Director General of Health Services. The staff strength consists of 220: Senior scientists 13, medical-8, non-medical-5 and 75 field research staff. It has full-fledged research, teaching, laboratory, data processing and transport facilities.

Activities of the Institute

The Institute undertakes:

(i) *Epidemiological studies* that have yielded basic parameters regarding prevalence and incidence rates of tuberculosis infection and disease, the fate of tuberculosis patients over varying time periods, formulation

of mathematical epidemetric models, longitudinal observations revealing the time-trend of tuberculosis, the extent of infection with atypical mycobacteria and simpler and more practical methods of epidemiological research.

(ii) *Operational studies* that have brought out the varying case-loads and case-yields in respect of casefinding, treatment and BCG vaccination activities, the cost factor, simultaneous smallpox and BCG vaccination as well as direct BCG vaccination, sputum microscopy and its operational implications, efficiency and effectivity of the programme, etc.

(iii) *Sociological and behavioural studies* throwing light on the awareness of symptoms, action taking, quantification of suffering, acceptability of the provided facilities and the drug regimens, reasons for drug default and response to defaulter actions, fate of cases treated under the programme, etc.

(iv) *Bacteriological studies* centered on the Ziehl-Neelsen technique of sputum microscopy, fluorescence microscopy, culture, cost of examinations, etc.

An animal house is under construction which will open up research possibilities in the field of disease caused by atypical mycobacteria.

(v) *BCG studies* concerned with the quality of vaccine, technique of vaccination, assessment of the BCG vaccination campaign, etc.

(vi) *Miscellaneous research* connected with radiological equipment, technique of radiography, training methods and the results achieved through programme training, PERT-CPM of programme implementation, monitoring and assessment of the programme, etc.

Apart from research, the Institute has full scale involvement in training of the programme workers as well as tuberculosis workers of other categories, from India as well as other countries. This activity comprises the following national as well as international training courses.

(i) Two national courses each of 13 weeks' duration every year for training of tuberculosis control teams in the programme management. Each team comprises a medical officer, laboratory technician, treatment organiser, BCG non-medical team leader, X-ray technician and statistical assistant. The participants are deputed by State Governments and sometimes by the WHO from developing countries of the Region.

(ii) Two national courses each of 4 weeks duration every year for training of District Public Health Nurses in District Tuberculosis Programmes. The nurses are deputed by the States and sometimes by the WHO, from some developing countries.

(iii) Two higher level Tuberculosis Control Seminars every year for District level health administrators, professors of tuberculosis and social and preventive medicine, senior tuberculosis workers, etc.

(iv) One course every year for the personnel of State Tuberculosis Centres.

(v) The participants of UNICEF sponsored international training course for paediatric teachers.

(vi) The participants of the WHO sponsored international training course for general epidemiologists.

(vii) The participants of the WHO/Japan international training on epidemiology/and control of tuberculosis.

(viii) Tuberculosis workers from other countries visiting the institute on WHO fellowship.

Besides regular training courses, the Institute is involved in the orientation of undergraduate students from several medical colleges, doctor-interns and post-graduate students preparing for diplomas or degrees.

Achievements

Formulation of District Tuberculosis Programme: In 1961, the District Tuberculosis Programme (DTP) was formulated and recommended to the government as the pivot of the national tuberculosis programme. Thereafter, on the basis of operations research and the feedback from the programme functioning in different areas, new research studies are being constantly undertaken to improve the Tuberculosis programme in the country.

Research: In the field of research, the Institute has already conducted over 130 studies on pulmonary tuberculosis, community suffering and behaviour, BCG vaccine and the cost aspect as well as utilisation of the provided services by the people, efficiency of the services, monitoring and assessment of programme objectives. Over 140 technical reports and papers have since been published in national and international journals and periodicals. Besides, technical innovations in the form of a portable vaccination kit, a daylight X-ray film loading and developing box, electric and electronic circuitary in X-ray units and simple staining techniques have been developed. The DTP work manuals evolved by the Institute are in great demand in the country as well as outside.

Training: In the 33 national training courses conducted so far, 433 tuberculosis control teams have been trained, comprising 527 medical officers, 524 laboratory technicians, 466 statistical assistants as well as 107 foreign programme workers. In the 13 training courses conducted for public health nurses 65 have been trained. The 12 seminars have attracted 230 participants so far. The training effort is generally considerably ahead of the programme needs, after taking care of the turn over due to retirement, etc., and the wastage.

Miscellaneous: The Institute faculty has functioned as WHO advisers in several countries of the world, as visiting professors on international training courses, as members on several national and international technical committees and as participants in the international conferences, in order to present research papers.

BCG Vaccine Laboratory, Guindy, Madras

The Government of India felt the necessity to sponsor a nation-wide BCG Vaccination Programme in 1948, and, to achieve this object, Madras was chosen to house a BCG Vaccine Laboratory, as a building constructed by the Government of India for the production of Yellow Fever Vaccine was available in the King Institute Campus. At the request of the Government of India, the WHO sent Dr. Poul Lind, a Danish BCG Expert, with all essential equipment to start the Vaccine Production Centre, and in August, 1948 the Laboratory was opened by the then Union Health Minister, the late Rajkumari Amrit Kaur.

The supply of BCG vaccine and tuberculin dilutions began in February, 1949. Subsequently, the laboratory was shifted to its own building near the King Institute and large-scale production of BCG vaccine and tuberculin dilutions was taken up. Apart from meeting the full requirement of the country's mass BCG programme, the laboratory also supplied the biologicals to many of its neighbouring countries. It is the world's largest BCG producing centre.

As the life of the liquid BCG Vaccine is limited and the vaccine has to be protected from heat and light, need for the preparation of freeze dried BCG Vaccine, which is heat stable and which can be kept for longer periods was acutely felt. With this object a freeze-drying plant capable of preparing 4000 ampoules of freeze-dried vaccine in one shift was procured in the year 1957. Three more plants each capable of drying 1000 ampoules at a time were added in November, 1964.

After getting satisfactory results from the experiments on the preparation of freeze-dried vaccine, it was planned to go into large-scale production of freeze-dried vaccine to replace liquid vaccine in the entire programme. Additional sterile air-conditioned accommodation was provided, a testing and quality control section was added and the required equipment was procured. The production of freeze-dried BCG was enhanced to about 5 million doses and was supplied for use in the mass campaign in 1969.

In the Fourth Plan "Expansion of the BCG Vaccine Laboratory for enhancement of production of freeze-dried BCG vaccine" was taken up as a plan scheme. A large number of technical and non-technical staff was added, equipment was procured and an independent testing and quality control laboratory for testing and certifying the vaccine was established at the National Institute of Communicable Diseases in Delhi. The production was enhanced to 30 million doses by the end of the Fourth Plan and liquid vaccine was entirely replaced by freeze-dried vaccine in the whole programme. Tuberculin dilutions were also prepared and supplied for diagnostic use in the country. The WHO and UNICEF have been taking active interest in the expansion of the laboratory so as to develop this laboratory as a regional laboratory for supply of freeze-dried BCG to the other countries of the region. The WHO has been providing several consultants and fellowships. The UNICEF have been

supplying equipment and necessary spare parts, etc. An automatic ampoule sealing machine procured by the UNICEF was installed in the Laboratory in 1973.

In the Fifth Plan, the target is to double the present production of the laboratory and further expand it if necessary. A large part of the vaccine will be supplied in small packings of 20 doses for use by rural health workers and institutions. For this, a semi-industrial type freeze drier with a capacity of 8,000 ampoules per run has been procured by the Government of India and has been installed in the Laboratory. The WHO and the UNICEF have been assisting with experts, equipments and material. The Laboratory is also participating in the quality control and assay of BCG vaccine produced in different Laboratories in the world under WHO auspices.

The Testing and Quality Control Laboratory at the National Institute of Communicable Diseases is also being further developed.

Tuberculosis Chemotherapy Centre

The Tuberculosis Chemotherapy Centre was established in Madras in 1956, under the joint auspices of the Indian Council of Medical Research, the World Health Organisation, the British Medical Research Council and the Government of Tamil Nadu as a temporary project to conduct controlled studies designed to provide information on domiciliary chemotherapy in the treatment of pulmonary tuberculosis.

The Centre has three main divisions: (*i*) Laboratory Division consisting of bacteriology and biochemistry sections. (*ii*) Statistical Division and a Clinical division consisting of outpatient department, and (*iii*) Radiographic section and a well organised domiciliary service. A W.H.O. Senior Medical Officer acted as the Director of this Centre from 1956 to 1964. In 1964, the National Director was appointed by the Indian Council of Medical Research, and the Centre was made a permanent establishment under the Indian Council of Medical Research. The World Health Organisation continues to maintain active interest in the Centre's research work and provides expertise and supplies not available in India.

Controlled studies carried out at the Tuberculosis Chemotherapy Centre have revealed that ambulatory chemotherapy for tuberculosis, based on a well-organised clinic service for a year, virtually equals sanatorium treatment with the same chemotherapy for the same period, not only in the immediate therapeutic response in terms of overall radiographic improvement, cavity closure and sputum conversion but also in the likelihood of relapse in a subsequent 4-year period of follow-up. Furthermore, the risk of contracting tuberculosis was no greater in close family contacts of patients treated at home than in those of patients treated in sanatorium; indeed, the main risk to the contacts was from the infectious patient before treatment had begun. Thus, these studies clearly showed that the traditionally held virtues of sanatorium treatment, namely, prolonged bedrest, good diet, good airy accommodation, nursing and isolation, were remarkably unimportant provided adequate chemotherapy was administered. Controlled studies conducted by several other investigators did not demonstrate any advantage either of sanatorium treatment over clinic treatment and of rest over ambulation. As a result of these findings ambulatory chemotherapy has become the accepted practice in the tuberculosis control programme in India and in many other developing countries of the world.

In daily oral regimens, reliance has to be placed on the co-operation of patients for self-administering the drugs at home—a practice known to result in serious irregularities in drug-intake. This limitation can be overcome by supervising the administration of drugs. Obviously, daily supervision, as a general policy, being impracticable under domiciliary conditions, it might be possible to organise supervised administration of drugs if the drugs are given at less frequent intervals *e.g.*, once or twice a week. A regimen of streptomycin plus high dosage isoniazid given together in a single dose, twice a week under supervision was found to be highly effective in the treatment of pulmonary tuberculosis. This regimen is inexpensive and has the advantage that the physician knows exactly how much chemotherapy the patient receives. This regimen, therefore, offers a practical method of supervised chemotherapy; indeed, the value of this regimen in the primary treatment of tuberculosis has been confirmed by successive studies in this Centre. Based on these studies, the Centre has projected supervised intermittent chemotherapy as an alternative system of chemotherapy, especially in the countries where the organisation of standard oral regimens has already failed in practice. Recently, the Centre undertook a series of studies with a slow-release preparation of isoniazid for evolving effective once-weekly regimens which would considerably simplify the organization of chemotherapy programme. Current research is directed towards evolving effective short-course regimens.

The Centre also undertook studies on other chemotherapeutic regimens for treatment of tuberculosis with different standard and reserve drugs and chemoprophylaxis studies. The clinical studies were all supported by bacteriological and biochemical investigations in depth. Notable among other studies conducted at the Centre are studies on metabolism of anti-tuberculosis drugs, tests for detection of anti-tuberculosis drugs in urine, biological characteristics of Indian strains of tubercle bacilli and the comparative studies on different measures of sensitivity of tubercle bacilli to various anti-tuberculosis drugs.

Many of the findings of the Centre have received a worldwide acknowledgement and indeed some of them have had a great impact on the formulation of tuberculosis control programmes in Asia, Africa, South America and some parts of Europe. Though the main aim of the studies at this Centre is to evolve practical and effective methods of treatment for tuberculosis patients in India, the logical sequence of the investigations undertaken, together with supporting laboratory investigations, has resulted in invaluable knowledge of the principles of chemotherapy. The Centre is recognised by the Inter University Board for Post-Graduate Study leading to Ph.D. degree in bacteriology and bio-chemistry.

The training activities of the Centre include lecture demonstrations to senior medical students, interns and post-graduate medical students from the National Tuberculosis Institute, Bangalore and for the International Course in Tuberculosis. In addition, two I.C.M.R. fellowships are awarded annually for training in the methodology of controlled clinical trials and laboratory methods.

Tuberculosis Prevention Trial

A number of controlled BCG trials have given very conflicting results. Developing countries are dependent to a very great extent on BCG vaccination for the control of tuberculosis, because of the shortfalls in diagnosis and treatment of tuberculosis. Hence it has become essential to assess precisely the value of BCG vaccination in our own context. The Project Tuberculosis Trial was, therefore, started in 1964 under the auspices of the ICMR, the U.S. Public Health and the WHO.

After a preliminary feasibility study, the BCG trial was started in 1968 in Chingleput District, Tamil Nadu. A sample survey showed that this area had high prevalence on non-specific sensitivity as well as of pulmonary tuberculosis. The initial examination included complete census, tuberculin tests with PPD-S and PPD-B, vaccinations with BCG or an injection with a placebo, examination by X-ray of persons over 10 years of age and bacteriological examination of 2 specimens of sputum from persons with X-ray abnormality. This phase of the work was completed by the end of March 1971, covering 32 months. Of the 3,66,265 persons registered, 2,82,247 were vaccinated with BCG or placebo.

The entire population of the area including the population examined initially is under continuous surveillance. Tuberculosis patients diagnosed by the study teams are being treated on domiciliary basis.

About 2½ months after the vaccination a random sample of the vaccinated population was retested with tuberculin and was also examined for BCG scars. It was found that 0.4% and 6.0% of those vaccinated with the strong and weak doses of vaccine respectively had no scars and 2.7% of those injected with placebo had scars. Among children aged (1-14) years and reacting with induration measuring (0-7) mm to the tuberculin test the mean size of post-vaccination allergy was found to be 16.8 mm for the strong vaccine and 12.8 mm for the weak vaccine. In the same group the mean size of scar was 5.2 mm for the strong vaccine and 3.4 mm for the weak vaccine.

Other Activities of the Project

Tuberculin testing of samples of population in certain areas of North India with PPD-S and PPD-B, was done to assess prevalence of non-specific sensitivity. It has been found that only the hills of the Uttar Pradesh, Kashmir Valley and Himachal Pradesh have very much lower prevalence of non-specific sensitivity. It has been found that the Nilgiri hills also have a low prevalence of non-specific sensitivity. The study suggested that non-specific sensitivity was associated with altitude and not with the geographical location of the area.

Retesting of random samples of the TB Prevention Trial population with tuberculin was carried out at 2½ years and four years after the initial examination. It was observed that

post-vaccination allergy had waned from three months to 2½ years and that there was no further waning from 2½ years to 4 years.

The reason for or the significance of this waning is not clear.

The prevalence of infection does not seem to have gone down at four years.

A Trial for the value of BCG in the prevention of Leprosy was started from October, 1973. So far, about 2,52,000 persons have been registered and about 1,73,000 persons examined. About 9000 definite as well as suspicious cases of leprosy have been diagnosed so far.

The effect of BCG vaccination on tuberculosis patients and tuberculin positive children has been studied. Long term follow-up results over a period of 15 months in patients and over 2½ years in children have shown that BCG vaccination did not increase mortality among patients of pulmonary tuberculosis or among strong reactors to tuberculin in children or bacteriological breakdown rates of suspect cases. It can safely be concluded that the data studied do not suggest that BCG vaccination of patients or strong reactors among children did any harm of the kind considered possible when direct BCG vaccination was initiated.

Results of the Main Study

BCG can protect against tuberculosis only among those who are non-reactors to tuberculin. Of the total number of new culture positive cases of tuberculosis that have developed during the first 2½ years of the trial, only 3% are among this group. The study is being continued so that adequate cases are obtained from among the tuberculin negatives so that the protective effect of BCG can be studied.

State TB Training & Demonstration Centres

New Delhi TB Centre

The New Delhi Tuberculosis Centre, originally known as the [illegible] established by the Tuberculosis Association of India in 1941. It was [illegible] TB clinic in the country to be upgraded as Training and Demonstration Centre in 1951 with assistance from the Government of India, the

W.H.O. and the UNICEF. Research, training and service to TB patients have been the main functions of the Centre. In its clinical section, patients belonging to its own domiciliary treatment area covering a population of about 8 lakhs and also patients from other areas as well as from neighbouring States avail of the services in large numbers. Care committees have been organised by the Centre in different localities in its operational area to look after the economic and social problems of patients.

Research in various aspects of tuberculosis, especially in respect of methods aiming to improve the efficiency of domiciliary management and case finding, has been one of the main functions of the Centre. Several studies in respect of epidemiology and time trend of tuberculosis, drug schedules, BCG vaccination, etc., have been undertaken by the Centre. The Centre has participated in several international cooperative studies in respect of various aspects of tuberculosis and in several other cooperative studies arranged by the I.C.M.R. More than 100 papers based on experience of this Centre on various aspects of tuberculosis have been presented at national and international conferences and published in medical journals.

Training of various categories of medical and paramedical personnel has been one of the main functions assigned to this Centre since its inception. These include students for D.T.C.D. course and under-graduate and postgradaute medical students. Para-medical workers include Tuberculosis Health Visitors, nurses, medical social workers, radiographers, laboratory technicians, BCG technicians, etc. A number of refresher courses are also organised by the Centre. The Centre is running three demonstration programmes in rural and semi-urban areas of Delhi on the lines of the District TB control programme in collaboration with the other teaching institutes of Delhi.

The Northern Regional TB Centre is located in this Centre and works under the technical guidance and supervision of the Director of the Centre.

The bulk of the running expenditure of the New Delhi TB Centre is provided by the Government of India. Other agencies like Tuberculosis Association of India, [illegible] State TB Association and certain statutory local bodies and [illegible] tary organisation also contribute towards [illegible] the institutions.

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NATIONAL HEALTH PROGRAMMES SERIES

This series of publications is intended to promote the continuing education, dissemination of information as well as the study of health problems and major diseases in India for those who have concern for the health and well-being of the people. It is also intended to foster the development of an efficient system of health care service delivery in the country on the basis of such up-dated publications on the national programmes for the prevention and control of health problems. In this task, the practitioners and trainers/teachers of health systems, as also the policy-makers and those affected by their policy, must be brought together. The publications, issued in this series, will strive to bring them together in thought, so that they might work together in action.

NATIONAL HEALTH PROGRAMME SERIES 10

NATIONAL PROGRAMME FOR CONTROL OF TUBERCULOSIS

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CONTENTS

LIST OF ABBREVIATIONS

T.B.	Tuberculosis
N.T.P.	National Tuberculosis Programme
D.T.P.	District Tuberculosis Programme
N.T.I.	National Tuberculosis Institute
I.C.M.R.	Indian Council of Medical Research
B.M.R.C.	British Medical Research Council
P.H.I.	Peripheral Health Institute
P.H.C.	Primary Health Centre
D.T.C.	District Tuberculosis Centre
M.P.W.	Multipurpose Worker
A.F.B.	Acid Fast Bacilli
S.I.D.A.	Swedish International Development Agency
R1, R2, R3, etc.	Regimen No. 1, 2, 3, etc.
2 $S_2H_2R_2Z_2$	2 months regimen with Streptomycin, Sulphate, Isoniazid, Refampicin and Pyrazinamid on twice a twice a week.
2E.H.R.Z./ 6 T H or 6 E H	Ethambutol, Isoniazid, Refampicin and Pyrazinamid are given daily for 2 months followed by Thiacetazone and Isoniazid given daily for 6 months, or Ethambutol and Isoniazid given daily for 6 months.
S.C.C.	Short Course Chemotherapy
G.P.	General Practitioners
U.T.	Union Territory
S.T.O.	State TB Officer
A.N.M. Auxiliary	
A.N.M.	Auxiliary Nurse Midwife
E.P.I.	Expanded Programme on Immunization

FOREWORD

One of the cardinal factors for achieving Health for All by 2000 A.D. is the ability of the individual and the organisation to recognise and respond to changes in advancing technology for health maintenance and promotion, new pattern of disease, disability, etc. new social policies, expectations and programmes for better health services. Towards this end, the education of the people concerning prevailing health problems and methods of preventing and controlling them is the first requisite of Primary Health Care. This is more so in the case of public welfare personnel and professionals through whom the knowledge and skills should percolate to the grassroot level.

In adhering to the above perspective, the National Institute of Health and Family Welfare conducts nearly fifty training courses/workshops annually towards requirements of a system of continuing education for health administrators of States and Districts, teachers of medical college, and also the members of Indian Administrative Service. However, the problem of updating the knowledge and skills of these personnel, already on the job, still remains. It has proved arduous to have them re-trained at institutions. The snail-like pace of implementation reflects in many instances the fact that this is an area where most professionals feel unprepared. It is, therefore, essential to initiate a programme to get relevant information out to individual participant. As such, the development of self-learning resource materials to keep abreast of scientific advances in research as well as in programme strategies is an enviable task which the NIHFW has undertaken with large-scale efforts.

These resource material present an assiduous expatiation of various National Health Programmes and Schemes currently in operation in the health services system. Each of these expatiates the genesis, strategy, current status, and the outcome of the evaluation of individual programme. Thus, the primary aim of this ***Series*** would be to share and utilise the available resources to update the knowledge and skills of programme personnel at their own place.

I fervently hope that this publication will provide orientation on the use of such self-learning materials to learners/participants. I also wish to asseverate that these resource materials will be updated periodically and as such, I am sure, they should be a valuable aid in overcoming the lag.

Much of the positive value in this ***Series*** originated with one or another of our associates. sincerely thank these Programme Officers who had so kindly undertaken the onerous task of compilation and completion of these documents.

New Delhi
December, 1988

J.P. Gupta
Director

Series Editors

J.P. Gupta
S. Bhatnagar

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INTRODUCTION

Tuberculosis is a communicable, bacterial disease which results from infection with TB bacilli. The TB bacilli is a rod-shaped organism, discovered by Robert Koch in 1882. Tuberculosis can be traced back to the early history of mankind. In our country, it has been known since the Vedic ages, that is, about 5000 years ago. It is world-wide in distribution and strikes both the rich and poor, all races and both sexes. Tuberculosis affects all parts of the human body, but, most commonly, the lungs. The patient with lung TB excretes Tuberculosis bacilli with sputum through coughing, sneezing, etc. The germs, thus excreted, can enter, mainly with the help of air currents, another healthy human body while the person breathes in. On entering the lung, the bacilli generally get a foothold on the peripheral part of the lung and this process is called infection. The entry of the Tuberculosis germ into the body and its gaining a foothold does not always lead to disease, immediately or later. Only a few infected persons suffer with the disease process due to a number of factors which are both intrinsic and extraneous. The intrinsic factor is poor natural resistance or poor inborn immunity, which is a genetic one. Extraneous factors are many, like poor living conditions, low social and educational status, inadequate food or nourishment of the body, psychological and temperamental status of the person and affliction by some other diseases like diabetes, measles, cancer, etc. Today, Tuberculosis is treatable, curable and preventable.

MAGNITUDE OF THE PROBLEM

Improvements in diet, housing and living conditions in modern times have contributed to a decline in both TB mortality and new cases. The advent of chemotherapy during the last four decades has accelerated these trends. But Tuberculosis still ranks among the major health problems in the world, specially in the developing countries. There are about 15 to 20 million cases and three million deaths every year in the world due to Tuberculosis.

IN INDIA: The results of pre-tuberculine tests in mass BCG vaccination campaigns indicated, for the first time, that the problem of Tuberculosis was not limited to the urban areas only, in contrast to the earlier belief. The National Tuberculosis Survey during 1955-58 and subsequent limited surveys have confirmed these findings.

Tuberculosis is a major public health problem in India and number one killer among diseases. The National Tuberculosis Survey which was conducted by the ICMR in the year 1955-58, revealed that nearly 1.5 per cent of the total population above five years of age is estimated to be suffering from TB of the lungs, of whom one fourth, or 0.4 per cent are infectious. Subsequent limited surveys conducted in different parts of the country have confirmed these findings. As per the 1981 census the total population of the country was about 680 million and it was estimated that about 10 million people were suffering from radiologically active pulmonary Tuberculosis disease of the

lungs, out of which about 2.5 million people were infectious. Few lakhs of new Tuberculosis cases are added to the population every year but at the same time, an equal number of cases are removed, on account of death, spontaneous healing or treatment. This results in a state of near balance in the number of Tuberculosis patients from year to year. It is further estimated that nearly 50 per cent of the total population is infected with the TB bacilli, though they are apparently healthy. The annual infection rate (that is about 1.6 per cent) has remained almost constant for the last three decades.

Nearly 80 per cent of the people in our country live in about 6 lakh villages. It is estimated that at least 2-3 sputum positive cases can be found in each village of the country, and nearly 10-12 persons would be suffering from radiologically active Tuberculosis of the lung. In an average district with a population of 1.5 million, it is estimated that there will be about 5000 active pulmonary cases who are infectious and about 20,000 radiologically active pulmonary Tuberculosis cases. As per the recent study conducted by the NTI, Bangalore, in their field area, the mortality rate has come down to 53 per lakh population, and as per the study conducted by the New Delhi TB Centre, the mortality rate in their population area is around 40 per lakh population. Since the prevalence rate of pulmonary Tuberculosis cases is of the same order in the rural areas as in the urban ones, and nearly 80 per cent of the people of our country live in villages, the problem of Tuberculosis in our country is really a rural one.

AIM AND PRINCIPLES OF NATIONAL TB PROGRAMME (NTP) - BACKGROUND INFORMATION

The mass BCG vaccination campaign and the National TB survey conducted during 1955-58 led to the conclusion that Tuberculosis services had to be provided on a country-wide and long-term basis.

The NTP aims at the methods by which the systematic reduction of Tuberculosis in the community may be made within the available resources of the country and within a reasonable time. The method of treating the patients on a domiciliary basis was initially a compromise between the scientific idea for the few, and the economically and practically feasible one for the many. The short-term object of the programme is to diagnose and treat the patients at places nearest to their homes and also to give preventive services to the bulk of TB patients, specially those living in rural areas with the view of meeting their 'felt needs', and to reduce their suffering and prevent disability and deaths to the extent possible. The long-term objective of the programme is to reduce the problem gradually till it ceases to be a public health problem.

From the economic point of view, we have, at present, got a few thousand TB beds. To treat only the sputum positive cases, we need a few hundred crore rupees for constructing hospitals and another few hundred crore rupees as recurring expenditure annually. The money that would provide TB beds for

only 20-25 patients, can pay for the establishment of clinics which can handle 1000 to 1500 patients annually.

The cost of treating a Tuberculosis patient in a sanitorium for one year is equal to that of treating 15 patients on domiciliary basis. So, from the economic point of view, domiciliary treatment is the practical solution for tackling the Tuberculosis problem with limited resources.

From the scientific point of view regarding treatment of patients on domiciliary basis, it has been observed that the results of treating the patients in a hospital and at home are more or less the same. There is hardly any difference between the hospital patients and those treated at home, as regards the immediate therapeutic response in terms of radiological improvement, sputum conversion and closure of cavity at the end of one year, as also the danger of relapse in the future, and infection to the contacts, provided adequate chemotherapy is prescribed and taken regularly for the prescribed period by the patient.

It has already been mentioned that Tuberculosis is equally prevalent in rural and urban areas. For a developing country like India it would be a gigantic task to identify all the Tuberculosis cases living in hundreds and thousands of distant villages and to offer them regular treatment for a period of one to one and a half years.

The studies conducted by the NTI, Bangalore, have revealed that nearly 95 per cent of the infectious Tuberculosis patients are conscious of their symptoms and at least 50 per cent of them report to the nearest medical and health institutions to seek medical aid.

Another research study conducted by the ICMR (1955-56), conclusively proved that the Tuberculosis cases can be as effectively treated on domiciliary basis as in hospitals.

Based on the results of these two studies, the country-wide district Tuberculosis programme was evolved for the entire country by the NTI, Bangalore, in 1962. Under the programme, a district Tuberculosis centre is being established in every district of the country to organise a community-wide district Tuberculosis programme in association with all the existing medical and health institutions. In an average district of our country, there are about 50 such peripheral health institutions. The main aim of the programme is to detect as large a number of patients (sufferig from Tuberculosis) as possible, nearest to their homes and treat them effectively so that the infectious patients are rendered non-infectious and the active and non-infectious cases do not become infectious.

In doing so, priority is given to sputum positive Tuberculosis patients.

The patients are treated mostly on domiciliary basis because it is as effective as institutional treatment and more acceptable to TB patients since their domestic life lis not disrupted.

Each district Tuberculosis centre is staffed by a team of medical and paramedical personnel trained at the NTI, Bangalore, in X-ray and laboratory diagnosis, treatment organisation and community control of Tuberculosis, and is equipped with a static 100 M A X-ray unit fitted with an Odelca camera for miniature radiography, and laboratory equipment for direct smear miscroscopy.

The district Tuberculosis centre functions as a referral centre for the entire Tuberculosis control programme of the district. Its key personnel tour the existing peripheral medical and health institutions, including the primary health centres which cater to the health needs of the rural population, train the medical and paramedical personnel of such institutions in various essential activities under the Tuberculosis programme, supervise their working, ensure proper record keeping and reporting of the whole district and give advice also at the TB clinic in the town or city of its location.

Thus, the district TB centre serves as a base for carrying out the case finding and treatment programme throughout the district with the help of the network of general health services of the district, so that these facilities are brought nearer to the homes of the patients at minimum expenditure, and a permanent case finding and treatment programme is developed. The treatment is offered on an out-patient and mainly self-administered basis. The patients are encouraged to collect drugs from the PHCs nearest to their homes. The minimum duration of the uninterrupted chemotherapy is one year. The optimal duration of treatment is one to one and a half years and the extended period of treatment is upto a maximum of two years. All efforts are made to ensure that the patient receives uninterrupted treatment for at least 12 months. Defaulter actions are taken, both at the district Tuberculosis centre and at the peripheral health institutions, by way of letters to the individual patient, letters to the head of the village or by sending the health visitors/multipurpose health workers and village health guides, etc. In addition to this, under the NTP, additional district Tuberculosis centres are being established in those districts where the population is more than 2 million.

The additional district Tuberculosis centres are established in another sub-divisional town of the district. To cater to the needs of a small population of a district, a mini district TB centre is being established. It is not necessary to provide the full complement of key personnel at these mini district TB centres and these centres are not provided with any X-ray facilities. Instead, the X-ray facilities at the general hospital in the district are used.

INFRASTRUCTURE OF THE PROGRAMME

Out of the 434 districts in the country, the district TB programme has been implemented in 371 districts.

On an average, in a district there are about 50 implementable PHCs and other institutions (PHIs) and till now about 75 per cent of the PHIs have been brought under the National Tuberculosis Programme.

In addition, there are about 300 ordinary Tuberculosis clinics which are functioning in the country and are mostly located in big towns and cities. These are equipped with either static X-ray unit or Fluoroscopy and laboratory facilities and look after the needs of the local population living nearby.

There are about 46,000 TB beds available in the country to cater mainly to the needs of the selected group of patients, *i.e.* those who are seriously sick or suffering from some emergency or need surgical treatment or are social destitutes, etc. We are making efforts to establish sufficient numbers of Tuberculosis beds, as per the needs in every district of the country.

The Tuberculosis Institute, Bangalore, was established in 1959 with the aim of evolving nationally applicable methods of Tuberculosis control and training of key personnel for the Tuberculosis programme. Till now, about 4,600 key personnel of different categories have been trained. The Institute holds reorientation/training seminars for senior health administrators and professors of medical colleges, etc. Trainees from abroad also attend various international courses at the Institute. This Institute is also carrying out epidemiological, sociological, bacteriological and operational research connected with the Tuberculosis programme. It has also been selected to monitor the National Tuberculosis Programme on the basis of reports received from the DTCs and to provide suitable technical guidance to the district Tuberculosis centres to improve their performance.

This Institute is also carrying out short course chemotherapy regimen trials under operational conditions in the field area.

The Tuberculosis Research Centre, Madras, was established in 1956 for studying the feasibility and efficacy of domiciliary treatment of patients suffering from pulmonary Tuberculosis, and evaluation of inexpensive, effective chemotherapy regimens on mass application. The centre is at present engaged in conducting control clinical trials on chemotherapy in 18 districts of the country, clinical trials on Tuberculosis meningitis, Tuberculosis of the spine, etc. It has established a cardio-pulmonary physiology laboratory and epidemiology unit.

Seventeen Tuberculosis training and demonstration centres are functioning in the country to undertake the training of the medical and para-medical personnel required for manning the Tuberculosis centres; to give technical guidance to the district TB centres; to undertake the cultural and sensitivity tests; to give technical guidance to the complicated TB cases, etc. The State TB demonstration centre acts as a model TB centre for the State.

CONVENTIONAL DRUG REGIMENS RECOMMENDED UNDER THE PROGRAMME FOR SPUTUM POSITIVE PATIENTS (ADULTS)

Code No.	Drugs and Doses	Mode and Rhythm of administration	Instructions
R1	Isoniazid 300 mg + Thiacetazone 150 mg	Both drugs in a single dose or two divided doses, orally, daily	Self-administered at home after meals

R2	Bi-weekly regimen Inj. Streptomycin 0.75 gm/1 gm + Isoniazid 600 to 700 mgm (15 mgm/ kg body weight) with Pyridoxine	Intra-muscularly orally	Both drugs given at the same time under supervision of the treating physician twice weekly at intervals of 3 to 4 days
R3	Isoniazid 300 mg+ PAS 10 gms.	In a single dose in two divided doses both drugs orally, daily	Self-administered after meals
R4	Isoniazid 300 mg + Ethambutol 20 mg /kg body weight *i.e.* 800 mg per patients weight ∠50 kg and 1000 mg to 1200 mg >50 kg	Both drugs in a single dose; orally, daily	Self-administered at home after meals
R5	Biphasic regimen		
	a. *Intensive phase*	*For first two months*	
	Inj. Streptomycin 0.75 mg/1 gm + Isoniazid 300 mg +Thiacetazone 150 mgm or Ethambutol 200 mg per kg body weight *i.e.* 800 mg for patients ∠50 kg and 1000 to 1200 mg for those more than 50 kg or PAS 10 gms.	In a single dose, orally, daily, (PAS and Thiaceta-zone should be given in two divided doses)	Inj. given under supervision and rest to be self-administered at home
	b. *Continuation phase*		
	With R1, R2, R3 or R4	As per each regimen	As per each regimen

Remarks: Drug regimens comprising Inj. Streptomycine 0.75 gm/1 gm twice or even thrice a week + INH 200 mg or 300 mg daily is not sufficiently effective and, hence, not recommended.

For the Negative Tuberculosis Patients (Suspected Cases)

Tuberculosis paitents in whose sputum A F B are not seen, are advised Regimen R1; *i.e.* Isoniazid 300 mg + Thiacetazone 150 mgm in single dose orally, daily for one to one and a half years. Patients allergic to Thiacetazone can be treated with R4.

Note: The Drug PAS is gradually being withdrawn from the programme due to cost, non-availability, etc.

INTERNATIONAL ASSISTANCE TO THE TB PROGRAMME

By Swedish International Development Agency (SIDA): The Swedish International Development Agency has been supporting the case finding and treatment activities of the programme by supplying X-ray units with Odelca cameras, miniature X-ray film rolls, drugs needed for conducting the short course chemotherapy trial under pilot study, etc. since 1979. These X-ray machines with Odelca cameras are supplied to the unequipped district TB centres of the States/Union Territories, and as replacements to those district TB centres where the X-ray machines with Odelca cameras have outlived their utility. They are also are supplied to the additional TB centres, wherever created. The miniature X-ray film rolls are supplied to the district TB centres. Till now, the SIDA authorities have supplied about 175 X-ray machines with Odelca cameras. The short course chemotherapy trial under pilot study is being conducted in 18 districts of the country since 1983-84. The SIDA have also agreed to give additional assistance within June 1989 for supply of another 25 X-ray machines with Odelca cameras, miniature X-ray film rolls and 100 vehicles. These vehicles would be supplied to the different district TB centres of the country where either the vehicles have outlived their utility or to the newly created district TB centres for proper implementation and supervision of the programme by the DTCs. The SIDA is also helping the National Tuberculosis Institute, Bangalore, in various ways.

Assistance by the WHO: The WHO has been assisting the NTI, Bangalore, since its inception in 1959 and the TB Research Centre, Madras (ICMR) since 1956 by providing short-term consultants, fellowships, and essential supplies and equipment. They are also providing assistance to these two institutions for conducting short-term reorientation courses/seminars for senior health administrators of the States/Union Territories, teachers of medical colleges and refresher courses for the medical and paramedical personnel of the district TB centres.

EXPANSION OF THE PROGRAMME DURING THE VI AND VII PLANS

Expansion Under the 20-point Programme: A new thrust has been given to case finding activities of the NTP under the 20-point programme. Under the 20-point programme, targets for new TB case detection have been laid down

Institutional Area, South of IIT N.

since 1982-83 and these targets are being increased every year. The achievement of the targets of new TB case detection has been satisfactory from the beginning.

Prior to the laying down of targets, only about 7 lakh new TB cases under the programme had been detected, but at the present moment more than 1.4 million new Tuberculosis cases have been detected under the programme. To involve the primary health centres in more and more case finding activities in the rural areas, targets for new sputum examinations have been laid down since 1983-84. With this, the PHCs are being more actively involved than before in case finding activities, and a target for 600 new sputum examinations per year by each PHC has been laid down. Initially, the achievement of targets of new sputum examinations at PHCs was not very satisfactory but considerable improvements are being noticed gradually.

TARGETS AND ACHIEVEMENTS SINCE 1982-83 UNDER THE PROGRAMME

Year	Target for detection of new TB cases (in lakhs)	Achievements (in lakhs)	Target for conducting new sputum examinations at at PHCs (in lakhs)	Achievements (in lakhs)
82-83	10.00	10.80 (100%)	No target laid down	-
83-84	12.50	12.00 (96%)	34.00	12.00 (35%)
84-85	13.75	12.54 (91%)	34.00	17.31 (50.2%)
85-86	14.00	13.58 (97%)	34.00	20.3 (59.5%)
86-87	14.50	14.13 (97.5%)	34.00	21.69 (63.9%)
87-88	15.00	15.62 (104%)	34.00	24.11 (71%)
88-89	15.00	-	34.00	-

Expansion of the Programme in Rural Areas: To intensify the case finding and case holding activities under the programme in rural areas, it has been recommended that all the health workers of the peripheral health institutions are to be involved in case finding and domiciliary treatment of the Tuberculosis patients and also to be engaged in BCG vaccination of the newborns and infants. It has been recommended that the MPWs, during their

routine rounds in the villages, should identify the chest symptomatics suspected to be suffering from pulmonary Tuberculosis and motivate them to go to the nearest health institutions for necessary investigations, motivate the diagnosed Tuberculosis cases to continue the anti-TB drugs uninterruptedly for the prescribed period, and take defaulter action on the patients who have defaulted in continuing the drugs. The MPWs also involve themselves in health educational activities on TB amongst the villagers and TB patients. For conducting these activities, the MPWs in the PHCs and in the sub-centres are gradually trained in case finding, domiciliary treatment, BCG vaccination and also in health education activities.

The village health guides are also being involved in essential health educational activities under the programme including motivation of chest symptomatics to avail of all the diagnostic facilities of the health institutions, and in motivation of the Tuberculosis patients living in their areas to take the uninterrupted treatment for the prescribed period as per the advice of the treating physician.

To expand the treatment activities further for the rural people living in the far-flung villages, it has been recommended that all the sub-centres which have the necessary buildings for storage of drugs, and have the requisite staff, should be involved in the distribution of drugs to the Tuberculosis patients.

Expansion of the Programme in Urban Areas Under the City Tuberculosis Programme: The district Tuberculosis programme was planned mainly with rural India in mind. It has been observed that the problems in metropolitan and other big cities with a population over five lakhs are different and the district TB programme would not be able to serve the needs of these cities effectively. As such, it has been recommended that advantage should be taken of the newly created health posts in the big cities and towns with a population over five lakhs, for implementing the city TB programme, which is already functioning in some cities like Delhi, Bombay.

Extension of Short Course Chemotherapy Regimens (SCC): Under the clinical trial conditions, the conversion and relapse rates with the conventional drug regimens are 82 to 96 per cent and 7 to 15 per cent respectively, at the end of one year.

In a study conducted by the National Tuberculosis Institute, Bangalore, it was revealed that only 30 per cent of the cases completed treatment at the end of one year under programme conditions with the conventional regimens and the patients defaulted mostly after the first or second collection of drugs. It was further revealed that in spite of poor completion of treatment rate, the conversion rate of sputum was about 65 per cent at the end of one year.

But under the clinical trial conditions, there is about 100 per cent sputum conversion in six to eight weeks and the relapse rate is only around 2 per cent with the short course chemotherapy drug regimens. The duration of treatment

with these drugs is only six to eight months. The main handicap in using the short-term chemotherapy drugs was cost, but at the present moment, the cost of these drugs, specially of Refampicin has gone down considerably and it is expected that it will go down further.

The long duration of the treatment, for a period of one to two years, with the conventional anti-Tuberculosis drugs is believed to be one of the important causes for the irregularity and discontinuation of treatment. Hence, to cut short the duration of the treatment, achieve early conversion of the sputums, thereby, preventing the spread of the disease and also to lower the relapse rate etc., the short course chemotherapy drug regimens have been introduced on a pilot study basis since 1983-84 in 18 districts of the country to find out the feasibility of introducing these drugs under the programme conditions. With the encouraging results gained in the study, these regimens were introduced in another 101 districts by 1987-88 for the sputum positive newly detected Tuberculosis cases, excluding the 18 districts where these regimens were introduced under the pilot study. The short course chemotherapy regimens are going to be introduced in another 75 districts of the country during 1988-89. It is expected that the majority of the districts of our country would be covered with these regimens by the end of the VIIth Plan period.

It is hoped that by introducing these regimens, the defaulter rate of treatment will go down further.

SHORT COURSE CHEMOTHERAPY DRUG REGIMENS RECOMMENDED UNDER THE NATIONAL TUBERCULOSIS PROGRAMME

All sputum positive cases aged 15 years and above, irrespective of history and previous anti-TB treatment, are offered either of the following two drug regimens:

Drug Regimens

These regimens have two phases:

i. Intensive phase of the first two months with four drugs.
ii. Continuation phase of four to six months with two drugs.

Regimen A: Bi-weekly, intermittent supervised regimen

2S H R Z / 4 H R
2 2 2 2 2 2

Regimen containing

Streptomycin	(S 0.75 g)
Isoniazid	(H 600 mg)
Rifampicin	(R 600 mg)
Pyrazinamide	(Z 2 g)

In this regimen, the total duration of treatment is only six months. In the first two months (intensive phase), the patient is given Streptomycin, Isoniazid, Rifampicin and Pyrazinamide in the dosage mentioned above, twice a week. In the remaining four months (continuation phase), INH 600 mg, Rifampicin 600 mg are given twice a week. The patient has to report to the DTC/PHI and all drugs should be swallowed by the patient under the supervision of the doctor/health staff. In case of non-availability of SM or intolerance to Streptomycin, Ethambutol in the dosage of 12.6 gm (bi-weekly) may be substituted for Streptomycin.

Regimen B: Daily self-administered regimen

2EHRZ/6TH OR 6 EH

Ethambutol	(E 1 g)
Isoniazid	(H 300 mg)
Rifampicin	(R 450 mg)
Pyrazinamide	(Z 1.5 g)
Thiacetazone	(T 150 mg)

In this regimen, the total duration of treatment is eight months. During the eight months of treatment, the drugs have to be consumed daily by the patient. In the first two months (intensive phase), the patient is given Ethambutol, Isoniazid, Rifampicin and Pyrazinamide in the dosage mentioned above. During the remaining six months (continuation phase), INH 300 mg and Thiacetazone 150 mg daily have to be given. If the patient cannot tolerate Thiacetazone, Ethambutol 800 mg should be given daily.

Suitability of Patients for Appropriate Drug Regimen

The patients who reside near the centre, and who are willing to attend the centre twice a week for six months should be offered Regimen A.

The patients who express their inability to come to the centre twice a week or who repeatedly fail to come to the centre twice a week for one month for consumption of drugs are offered Regimen B, of eight months duration.

Patient 'Lost' from Treatment

A patient who does not come for drugs for one month from the due date even after two defaulter actions, is considered to be 'lost' from treatment. If the patient returns after becorning 'lost' he should be started on any one of the five standard drug regimens (R1 to R5). It is important to ensure that every patient put on short course regimens (either Regimen A or Regimen B) should have collected 75 per cent of the required doses of the intensive phase within three months from the start of treatment. Those patients who fail to complete this will not be eligible for the continuation phase and will be offered the standard drug regimen.

Compensatory Phase

Every effort has to be made to ensure that each patient put on SCC Regimen A or B, completes treatment within the stipulated period. However, due to unavoidable reasons, if any patient defaults, the compensatory phase may be allowed. For the intensive phase of chemotherapy, an extension of one month may be given to the patient to complete the required number of doses. That means that under drug Regimen A, 17 doses should be taken in two months. This may be allowed to be completed in three months. Under drug Regimen B, four fortnightly collections of drugs should be made in two months. This may be completed in three months.

Similarly, an extension of one month in the continuation phase may be allowed to compensate for the missing doses. However, the total duration of chemotherapy, including the compensatory phase, should not exceed eight months in drug Regimen A and ten months in drug Regimen B.

Termination of SCC

For any patient remaining sputum positive after six months from the time of initiating SCC on either of the regimens, the SCC is terminated and the treatment card is closed.

For such patients, a new treatment card is to be opened (prolonged treatment card) and the patient is put on INH and Thiacetazone (or Ethambutol) for one year. This is called prolonged treatment. Any patient remaining sputum positive after six months of prolonged treatment has to be referred to specialised institutions for management of treatment failure.

Follow-up Examination

Every patient should be followed up strictly with sputum smear examinations - once at the end of six months after starting treatment and another at the end of chemotherapy (inclusive of compensatory period, if any).

Completion of Treatment

A patient who has completed 75 per cent or more doses of the required number, during the intensive phase (including compensatory phase), is considered to have completed the intensive phase and is eligible to enter the continuation phase.

A patient who has completed 75 per cent or more of the required number of doses of the continuation phase is considered to have completed optimum treatment.

Expansion of Health Education Activities: Any health programme, specially the NTP, a programme of great magnitude, cannot succeed without the active involvement and cooperation of the community, village Panchayats,

Zilla Parishad, community leaders, youth leaders, etc. Ninety-five per cent of the infectious sputum positive cases are already conscious of their chest symptoms and a country-wide health education campaign must be carried out to educate this group of chest symptomatics so that they get themselves investigated and utilise the facilities available at the institutions nearest to their homes.

A vast majority of patients suffering from Tuberculosis either report first to the general practitioners or to the Government hospitals/dispensaries. As such, the active participation of these health institutions and general practitioners is a must for the success of the programme. The most important point is to create active interest in the minds of general practitioners/medical practitioners regarding the problem and the NTP and also to up-date their knowledge about the present philosophy, diagnosis and treatment of Tuberculosis through refresher courses. These courses are being conducted by the Tuberculosis Association of India.

Keeping this in mind, much stress has already been given to various health educational aspects of the Tuberculosis programme by bringing out TV spots, radio spots, advertisements in newspapers, material for medical practitioners and the general population, etc. under the programme during the VIIth Plan period.

The funds provided on health education activities till, now, during the VIIth Plan period, are as follows:

1985-86	Rs.10.00 lakhs
1986-87	Rs.40.00 lakhs
1987-88	Rs.60.00 lakhs
1988-89	Rs.50.00 lakhs

SCHEMES DURING THE VIITH PLAN PERIOD

As in the VIth Plan period, the schemes of establishment of more district Tuberculosis centres, TB beds, etc. have been included in the State plan sector.

Centrally Sponsored Sector: Under the Centrally sponsored sector, the following schemes are being implemented:

a. Supply of anti-TB drugs/equipment to the States on 50:50 sharing basis between the Centre and the States.

b. Supply of anti-TB drugs/equipment to the Union Territories as a 100 per cent Centrally sponsored scheme.

c. Supply of anti-TB drugs to the TB clinics run by voluntary bodies as a 100 per cent Centrally sponsored scheme.

d. Expenditure on health education activities as a 100 per cent Centrally sponsored scheme.

FINANCIAL OUTLAYS AND ACTUAL EXPENDITURE INCURRED DURING THE VITH AND VIITH PLAN PERIODS

VIth Plan Period

Against the actual allotment of Rs.700 lakhs, the actual expenditure was Rs.2040.00 lakhs.

VIIth Plan Period

Financial outlays Rs.5500.00 lakhs

Actual expenditure incurred during the first three years of the VIIth Plan:

1985-86	Rs.1112.00 lakhs
1986-87	Rs.1125.00 lakhs
1987-88	Rs.1415.00 lakhs

BCG Vaccine, Its Efficacy and Current Status NTP *vs* EPI

The BCG vaccination programme has been in operation since 1951. However, as the coverage of the susceptible population was not found to be very satisfactory, it was decided that instead of carrying out the campaign through BCG teams alone, the activity was to be integrated with the general health services so that the newborns and infants, specially in the vast rural areas, may be covered expeditiously under the EPI programme. The present BCG teams (available in the States and Union Territories) in addition to their current duties under the vaccination programme, are also engaged in proper training of the health workers in the technique of vaccination.

A study of the integration of the BCG vaccination programme with the general health services indicated that the services of Auxiliary Nurse Midwives (ANMs) who are now designated as Female Health Workers, could be utilised for BCG vaccination of infants without detriment to the ANMs' other functions. (Baily, Kulbhushan, etc. *Ind. J. Tub.* XX, 4, 155 (1973).

The Chingleput study on BCG vaccination clearly indicated that the BCG vaccination did not give any protections against the development of adult type TB. Several animal studies and several controlled trials (BMRC, 72, Rosenthal-61) had clearly shown that BCG vaccine almost always conferred a measurable degree of protection more closely to the childhood form of TB and its associate complications like meningeal and milliary type of TB. Hence, the present policy of BCG vaccination is to vaccinate the child soon after birth. In urban areas, the newborns are vaccinated just after birth in Maternity Hospitals and Child Welfare Clinics. In the rural areas, under the EPI programme, multipurpose health workers, vaccinate all the newborns before they are one year old alongwith other immunization.

Bovine Type of Bacilli and the Infection

A majority of the TB cases in the world are due to infection with human type of

bacilli except in the developed countries where a few cases of TB were due to the bovine type of infection. In India, the TB due to bovine type of infection is rare as milk is boiled before use. In the developed countries, TB due to the bovine type of infection has been controlled by pasteurising milk and other measures.

EVALUATION OF THE PROGRAMME

The programme was evaluated by the expert committee formed by the ICMR in the year 1975. The committee concluded that while the concept of the programme was sound, there was considerable scope for improvement in the implementation of the programme, specially at the peripheral health service levels. The committee made certain recommendations for further improvements which were then examined by an empowered committee appointed by the Ministry of Health and Family Welfare and the detailed guidelines for further improvement of the programme were given to the States for implementation.

From time to time, the experts of the Swedish International Development Agency (SIDA) evaluate the functioning of the programme before signing the agreement for aid to the programme and also during the agreement period. Recently, the programme has been evaluated by the expert team of the SIDA which has recognised the soundness of the programme and has also observed that the programme is working more or less satisfactorily and in the right direction.

They have, however, made some recommendations to improve upon the case detection and case holding activities of the programme, specially for the rural regions.

The NTI, Bangalore, has been entrusted with monitoring and evaluating the programme on the basis of the performance reports of the DTPs.

The programme is reviewed from time to time at the meetings of the Health Secretaries of the States/Union Territories and also during the meeting of the Central Council of Health, at the Central level.

The programme is also reviewed every month by the Ministry of Health and Family Welfare at the Central level and often at the levels of Health Secretaries/Ministry.

At the State level, the programme is reviewed and evaluated regularly at the State and district headquarters.

Recently, an independent organisation has been appointed by the Ministry of Health and Family Welfare to evaluate the programme independently.

RECOMMENDATIONS OF THE EVALUATION

A seminar held at the NTI, Bangalore, on 5th and 6th January, 1988, which was

attended by the health authorities of States/Union Territories, made some suggestions/recommendations for improvement of the programme. The salient recommendations/suggestions made by the ICMR committee and at the seminar held at Bangalore are as follows:

1. For the speedy expansion and intensification of the activities under the programme, the essential schemes which have a direct bearing on the expansions of the case finding activity and treatment programme should be taken up as a 100 per cent Centrally sponsored scheme. Due to financial constraints, the State/Union Territory health authorities are not able to provide sufficient funds for establishment of DTCs and for the procurement of anti-TB drugs, etc. out of their share. As such, it has been recommended that the scheme of establishment of DTCs in those districts where they are not available at all and the scheme of establishment of additional DTCs for the thickly populated districts be taken up as 100 per cent Centrally sponsored schemes and cash assistance be provided to the States/Union Territories for:

   a. provision of essential medical/paramedical staff;
   b. recurring expenditure for running of DTCs; and
   c. provision of essential equipment.

2. The performance under the programme should be reviewed regularly on a monthly basis at every level, just like the review of activities under the family welfare or MCH programme, etc.

3. Over half of the cases of PTB requiring treatment are sputum negative and cannot be diagnosed either due to non-availability of X-ray facilities at the PHCs or due to the distance of the PHCs and DTCs from the patients home. Under the minimum needs programme, it has been proposed to upgrade some of PHCs to community centres and rural dispensaries to health centres which would be equipped with general purpose X-ray units. The case finding activities under the TB programme can be substantially increased by the establishment of such equipped community health centres, etc. under the Minimum Needs Programme.

4. In about 30 per cent PHCs either no multipurpose laboratory technicians have been posted, or if posted, they are overloaded with work like malaria work, etc. It has been recommended that the admission capacity of the Laboratory Technicians Training School may be enlarged so that the existing PHCs and newly established PHCs are provided with multipurpose trained laboratory technicians.

5. Full-time NTI trained medical and paramedical personnel should be posted at the DTCs throughout the year for proper implementation and supervision of the programme.

6. A vehicle alongwith suitable POL charges should be provided in each district TB centre for proper implementation and supervision of the programme.

7. The MPWs and ANMs while receiving their basic training in the training institutes should be imparted the requisite training in the essential aspects of the TB programme.

8. Ever since the MPWs were entrusted the duty of collecting the sputum of the chest symptomatics in the field, making slides and sending them for examination through the microscopic centres, the quality of the work has deteriorated considerably. It has been recommended that the MPWs, instead of collecting sputums in the field during their home visits and preparing smear slides of such patients, may motivate the chest symptomatics to report to the nearest PHC for investigation. The group was of the view that MPWs should not be entrusted with the duty of supplying anti-TB drugs at the homes of the patients.

9. In a large number of PHCs, functioning microscopes are not available. It has been recommended that the microscopes may be supplied by the Government of India for the use of PHCs. It has been further recommended that oil immersion lenses may also be supplied by the Government to bring back into use the non-functioning microscopes available at the PHCs.

10. Additional district TB centres may be established in thickly populated districts or in those districts which are very large in area. It has been further recommended that the additional district TB centre should not be located in the city or town where a district TB centre is already functioning and it may be established in another town or city of the district so that the referral and supervision activities can be properly developed.

11. For improvement of case holding activities under the programme, the medical and paramedical personnel of the district TB centre and peripheral medical and health institutions have to play a vital role. Repeated motivation of the patients and members of their families would considerably reduce the defaulter rates. The multipurpose health workers should keep a list of TB patients living in their area so that during their visits to the field, the patients and their families are repeatedly educated about the need to take regular and uninterrupted treatment for the prescribed period of time, as advised by the medical attendant.

12. Voluntary organisations are playing an important role under the NTP. It has been recommended that existing provisions made for the supply of anti-TB drugs to such organisations be enhanced so that their total requirement of anti-TB drugs for domiciliary treatment can be met. It has been further recommended that those voluntary run TB institutions, which have already been provided with an X-ray unit with Odelca camera, may be supplied with miniature X-ray films for the expansion of case finding activities.

Requests for cash assistance for purchase of essential X-ray/laboratory equipment as well as for construction of buildings for TB institutions by such voluntary organisations should be suitably considered by the Government.

Section 35 CCA of the Income Tax Act may be amended to include donors for the establishment of TB hospitals and clinics.

13. The attitude and behaviour of the medical officers of the health institutions towards TB patients has to be more effective. Therefore, it has been recommended that continued medical education programmes from the grassroots to the State level for all medical and health personnel are essential. Medical colleges should be more actively involved in the implementation of the programme and undergraduate students may be sent for training at the DTCs.

14. The possibility of involving volunteers, Youth Clubs, Mahila Mandals for health education of the community should be explored.

15. The poor and the deserving indigent TB patients may be granted some cash assistance by the voluntary organisations to meet the expenses and other essential needs.

16. It has been recommended that in every major State, the posting of trained State TB officers alongwith requisite infrastructure is a MUST for improvement of the programme.

17. The drugs should be made available not only in the primary health centres, but also in the sub-centres where facilities of storage and distribution are available.

18. The TB clinic and demonstration centre/State TB centres should play a more active role in the implementation of the TB programme in the region. Besides running a district TB programme in the district, in which it is located, this training centre should also undertake the culture examination work and be a key referral centre for the entire State. The centre should also undertake the reorientation training of the CMO/DMO/Civil Surgeons of the State, conduct reorientation training of the X-ray technicians, laboratory technicians, etc. so that such functions which are being undertaken by the NTI, Bangalore, at present, can be transferred to the TB training and demonstration centre. It has been recommended that from 1.1.1990, the NTI may conduct only two regular training courses for the district medical and paramedical personnel.

19. It has been recommended that short course chemotherapy regimens may be extended to more districts in the country so that by the end of the VIIth Plan period, a majority of the districts can be covered by these regimens.

PRESENT POSITION OF NTP AND SHORTFALLS/PROBLEMS IN THE IMPLEMENTATION OF THE PROGRAMME

Since Independence, there have been considerable improvements in the developments of anti-TB measures, in our country. Prior to 1947, we had only about 85 ordinary TB clinics and about 6000 TB beds in the country. Against these, we have, at present, more than 600 TB clinics, which include district TB centres, and about 46,000 TB beds. A total of 371 districts have been covered under the district TB programme till now, out of the existing 434 districts of the

country, as we could not keep pace with the carving out of new districts out of bigger districts. At least 75 per cent of the implementable PHIs have been brought under the DTPs in the implemented DTPs. About 4600 key personnel have been trained by the NTI, Bangalore, for the uniform implementation and development of the programme throughout the country. With the inclusion of NTP under the 20-point programme, about 14 lakh new TB cases are being detected at the present moment as against about 7 lakh cases detected few years back. In addition to that, it is estimated that about 5 lakh new TB cases are being detected and treated by the GPs, voluntary organisations, general hospitals as well as by other agencies like Railways, ESI, Defence Services, etc. which usually do not notify the cases under their care to the district TB centres.

As a result of the active involvement of PHCs, the number of new sputum examinations are increasing year by year. To cut short the duration of treatment, short course chemotherapy drug regimens have already been introduced for the newly detected sputum positive Tuberculosis cases in 119 districts of the country and the same is going to be introduced in another 75 districts during 1988-89. There has been substantial augmentation of the financial allocation and expenditure as a Central share for the expansion of the activities of the programme. In spite of financial constraints, shortage of technical manpower, illiteracy, population explosion and poor socio-economic conditions etc., of the country, the achievements are by no means negligible.

But even with the extension of facilities and allocation of more and more funds, the programme has not progressed as expected earlier. The reasons for this are many and varied. In spite of more and more new sputum examinations being done at the PHCs, the quality of the sputum examinations has deteriorated. The achievements of case detection and case holdings have been below expectation.

The operational research study conducted by the NTI, Bangalore, on the POTENTIAL YIELD OF BACILLARY CASES IN NTP showed that each DTP can detect about 2000 bacillary cases annually, whereas actually, on an average, each DTP diagnosed only about 700 bacillary cases annually, that is, about 35 per cent of the potential yield. Irregularity of drug intake and inadequate duration of chemotherapy are the two major operational problems in the case holding activity of the programme. Only about 30 to 35 per cent cases complete the treatment with conventional regimens under the programme conditions.

In another study conducted by the NTI, Bangalore, investigating the efficacy of two standard regimens under programme conditions, the initial as well as subsequent motivation of the patients was done exactly according to the recommendation made in the programme which revealed similar completion rates at the end of one year. In all probability, the DTPs are not achieving results very close to the potentials.

But even with such defaulter rates, the conversion rate of sputums at the end of one year is about 65 per cent. Indeed, in the programme, neither the case finding nor the treatment activity are considered to be satisfactory. But there appears to be a much larger gap i the case finding achievements than in the treatment achievements.

From the operational study on DTP by the NTI, Bangalore, it is observed that there is enough scope for improvement in the case finding activities of the programme but this cannot possibly influence the treatment which could probably be improved by technical considerations and, to a certain extent, by modifying the operational conditions.

The reasons for the shortfall of the achievements of the NTP are many and varied. But the two major reasons are the poor and slow development of the general health services and poor socio-economic conditions/population explosion of the country.

The NTP has been rightly integrated with the general health services. Without the proper development of the general health services, the programme cannot improve and function in the right direction. Unfortunately, the primary health care facilities have not developed to the extent envisaged. In 1946, the Bhore Committee recommended that each PHC should cater to the needs of 30,000 population but due to the financial constraints, etc. this was not found to be feasible. So in the early 50s, it was initially planned to establish one PHC to cater to the needs of about 1,00,000 population, covering an area of about 200 to 900 sq. kms. The studies conducted by the National Institute of Health and Family Welfare and A.P. Jain's Committee report have indicated that the ACTIVE AREA OF INFLUENCE of a PHC does not go beyond the radius of 8 to 10 kms. Obviously, only the TB patients who are living close to these institutions have been availing of the facilities of the PHCs. This is an important reason for the poor performance of the programme due to the inadequate development of general health services.

Even before the advent of chemotherapy, the problem of TB could be controlled due to improved socio-economic conditions in the developed countries. It is estimated that about 35 per cent of the people in our country are living below the poverty line, which is one of the main hurdles to be faced.

Health being a State subject, the scheme of implementation and supervision of the NTP has been classified as a State Plan Activity and the following difficulties are often encountered in the States in the proper implementation and supervision of the programme:

1. Due to lack of financial resources, the State/Union Territory health authorities cannot implement and supervise the programme effectively.

2. In some of the States, there exist different administrative controls of the personnel working at the district TB centres and at the peripheral levels of the same district causing difficulty in the implementation and smooth running of the programme.

3. Equal priority has not been given to the TB programme as to the other programmes like Malaria, Family Planning, by the States/Union Territories health authorities.

4. The proper status has not been given to the district TB officers by many States/Union Territories authorities which hinders the proper implementation and supervision of the programme at the PHC level.

5. Non-availability of trained whole time State TB Officers in many of the major States is a big problem. A trained whole time STO is absolutely essential for the proper implementation and supervision of the DTP in the State.

6. The apathetic attitude of the medical and paramedical, personnel specially at the peripheral levels is another hurdle for the programme.

7. DTPs have to be implemented in about 66 districts of the country. Additional district TB centres are to be established in all the thickly populated districts. Twenty-five per cent of PHIs are yet to be brought under the ambit of the DTP.

8. In many of the district TB centres, trained key personnel and vehicles are not available throughout the year. This is a serious drawback since they are absolutely essential for the proper implementation and supervision of the programme.

9. In a good number of districts in some of the States either there are no TB bed or if there are, the number is less than ten.

10. In about 30 per cent of the PHCs either no NTI trained lab technician has been posted or if posted, the lone technician is overburdened with work like malaria work, etc. and findslittle time for sputum slide examinations.

11. The potentialities of the MPWs in case finding and case holding activities of the programme have not been fully exploited.

12. Great difficulties are often encountered in the case finding programme due to non-availability of essential materials and equipment like microscopes, glass slides, chemicals, etc. at the peripheral levels.

13. The potential of the case holding activities of the sub-centres that have sufficient staff and storage facilities for drugs, are not being fully exploited.

14. Poor development of health education activities on Tuberculosis.

Present Trends of Tuberculosis in India

In the opinion of many experienced clinicians in the country, the Tuberculosis disease has undergone a considerable change in its clinical presentation, specially over the last quarter of the century.

Many retrospective studies (TAI, 1958, 1968), despite their scientific weakness, have clearly brought out the gradual change in profile from a

prevalence of more acute and extensive disease among the young to a more chronic, or a less severe disease among the elderly people. The near consensus of these reports has been on a marked decrease of concomitant complications of pulmonary Tuberculosis as, for example, Enteritis, Laryngitis, Amyloid diseases, matted lymph glands with discharging sinuses, etc. It is very significant that very similar changes were noticed in countries where Tuberculosis has definitely declined.

Available epidemiological information signifies no change in the prevalence of bacillary Tuberculosis in the country, at least during the last three decades and that equal prevalence in urban and rural areas means that we are truly in the endemic phase of the disease and that there is a gradual but slow natural decline of Tuberculosis in the country. The reason for the slow and natural decline of Tuberculosis in the country, is probably the continued poverty, malnutrition, overcrowding, etc.

As already stated, the epidemiology indicates that TB situation is almost constant in India, and, if at all, shows a very slow downward trend. The downward trend is evidenced by the apparent shift in the age of first infection during the later decades of life and a gradual reduction in the incidence of the childhood form of Tuberculosis resulting from the first infection. Indications are also available that where the programme is functioning well, the problem, of Tuberculosis in the community does show a downward trend.

Prospects of TB Control in India

The present epidemic in India might have started in the 17th century and there is evidence to indicate that the epidemic has been declining since the turn of the 20th century. All available knowledge about the epidemiology indicates that the Tuberculosis situation is almost constant in our country and, if at all, shows a very slow downward decline.

At present, when the case finding activity is functioning at about 35 per cent of the potential, and treatment efficacy is about 65 per cent, it can be shown that per unit of investment in resources, improvement in case finding would give higher dividends than the improvement in the treatment activities.

The District TB Programme, even at the present level of efficacy, has the potential of enhancing the natural decline. Improved programme efficiency, specially under case finding, is likely to produce a quicker decline. Rapid socio-economic development and improved standards of living would lead to a more spectacular decline in Tuberculosis, but that would not fall strictly within the ambit of the control programme.

TB Programme for Urban Areas

The DTP was planned mainly with rural India in mind. However, the problems of metropolitan and other large cities with a population of over 5 lakhs are different and the DTP would not be able to serve the cities effectively. It is, therefore, imperative to have different programme for these cities. Such city

TB programmes are already functioning in Delhi and Bombay. The same programmes should be implemented in large towns with a population over 5 lakhs.

Since continued motivation and education of the masses in various aspects of the case finding, treatment and preventive activities under the programme is necessary to enlist their cooperation, an intensive health education campaign must be carried out and the necessary publicity material brought out periodically.

Mortality Trend

Tuberculosis is not a notifiable disease and the exact cause of death in each case cannot be ascertained. As such, it is not possible to spell out the exact number of deaths due to TB.

In a longitudinal study conducted by the NTI, Bangalore, in the Bangalore district, where no anti-TB services were conducted, the mortality rate during the period 1961 to 1968 was found to be 80 to 100 per lakh population. It has been found recently that the mortality rate has come down where the programme is functioning satisfactorily. As per the recent studies, conducted by the NTI, Bangalore, and the New Delhi TB Centre in their field areas, the mortality rates were found to be 53 and 40 per lakh population respectively.

SUMMARY

About 50 per cent of the people in our country are already infected with TB germs, and about 1.5 per cent of the people above five years of age are suffering from radiologically active pulmonary Tuberculosis; of these, 0.4 per cent are infectious. The mortality rate has come down from 80 to 100 per 100,000 population to 53 and 40 per 100,000 population in Bangalore and Delhi respectively where the programme is working satisfactorily. As 80 per cent of the people in our country are living in the rual areas; the Tuberculosis problem in this country is really a rural one.

The National Tuberculosis Programme, as envisaged by the National Tuberculosis Institute, Bangalore, has been functioning since 1962, and is a permanent country-wide programme, integrated with the general health services. It is based on epidemiological, sociological and economical conditions prevailing in the country. The objectives of the programme are to diagnose, treat and give preventive services to the bulk of the TB patients and to the community, nearest to their homes with a view to meet their 'felt needs' and also to reduce their suffering and prevent disability and death, with the ultimate objective of reducing the problem to such an extent that it ceases to be a public health problem.

Under the programme, a District TB Programme, is being implemented in every district of the country in association with all the existing general health institutions of the district. Emphasis has been laid mainly on microscopic

examination of sputum. Radiological examinations are restricted for patients whose sputum is repeatedly negative. Patients are treated primarily on domiciliary basis with the five regimens of conventional anti-TB drugs. To cut short the duration of the treatment, short course chemotherapy drug regimens have recently been introduced, or are going to be introduced, in 194 districts of the country by 1988-89. By the end of the VIIth Plan period, most districts will have been covered with these regimens. BCG vaccination is given only to infants below one year of age under the expanded programme of immunisation.

Multipurpose workers/village health guides are being involved in case finding and case holding activities. The drug delivery system is being expanded to the farthest corners of the districts by involving the sub-centres. Much stress has been laid on the health education activities. The programme is evaluated at various levels regularly.

Since independence, considerable improvements in anti-TB measures have been noticed. The major districts of the country have already been brought under the District Tuberculosis Programme. About 300 TB clinics and 46,000 TB beds are functioning, and about 76 per cent of the implementable PHIs have been brought under the DTP. About 4600 key personnel required to run the district TB centres have been trained.

The detection of new TB cases has more than doubled and the sputum examination of new cases in rural areas has increased considerably during the last few years. Considerable augmentation of funds to the programme as the Centre's share has been made during the VIth and VIIth Plan periods.

But in spite of extension of facilities and augmentation of funds, the progress has not been as expected.

The case finding efficiency of the District TB Programme is about 35 per cent of the potential. Studies conducted at the National Tuberculosis Institute, Bangalore, revealed that 82 per cent of the sputum positive cases can be diagnosed by examining the sputum twice. If the medical/paramedical personnel including the multipurpose workers are trained properly, effective supervision of their working is provided, additional laboratory technicians are posted wherever required and if a static miniature radiography equipment is provided to all big general hospitals, the case finding activities would improve considerably.

Similarly, the case holding efficiency of the programme is about 30 per cent of the expectation. The condition can improve considerably if the medical/paramedical personnel of the health institutions and also multi-purpose health workers are actively involved in repeated motivation of patients, their families and communities to take regular treatment for the prescribed period. The short course chemotherapy regimens already introduced in the programme, are likely to reduce the defaulter rate considerably.

The involvement of the general practitioners and voluntary organisations, and community participation in the programme is a MUST for the development of the programme. A health education campaign in the community should develop along with the proper functioning of our health and medical institutions. Rapid socio-economic developments and improved standards of living could lead to a more spectacular decline in Tuberculosis.

At present, our country is truly in the endemic phase of the disease and there is a gradual and slow natural decline of Tuberculosis.

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NATIONAL PROGRAMME FOR CONTROL OF TUBERCULOSIS

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CONTENTS

LIST OF ABBREVIATIONS

T.B.	Tuberculosis
N.T.P.	National Tuberculosis Programme
D.T.P.	District Tuberculosis Programme
N.T.I.	National Tuberculosis Institute
I.C.M.R.	Indian Council of Medical Research
B.M.R.C.	British Medical Research Council
P.H.I.	Peripheral Health Institute
P.H.C.	Primary Health Centre
D.T.C.	District Tuberculosis Centre
M.P.W.	Multipurpose Worker
A.F.B.	Acid Fast Bacilli
S.I.D.A.	Swedish International Development Agency
R1, R2, R3, etc.	Regimen No. 1, 2, 3, etc.
2 $S_2H_2R_2Z_2$	2 months regimen with Streptomycin, Sulphate, Isoniazid, Refampicin and Pyrazinamid on twice a twice a week.
2E.H.R.Z./ 6 T H or 6 E H	Ethambutol, Isoniazid, Refampicin and Pyrazinamid are given daily for 2 months followed by Thiacetazone and Isoniazid given daily for 6 months, or Ethambutol and Isoniazid given daily for 6 months.
S.C.C.	Short Course Chemotherapy
G.P.	General Practitioners
U.T.	Union Territory
S.T.O.	State TB Officer
A.N.M. Auxiliary	
A.N.M.	Auxiliary Nurse Midwife
E.P.I.	Expanded Programme on Immunization

FOREWORD

One of the cardinal factors for achieving Health for All by 2000 A.D. is the ability of the individual and the organisation to recognise and respond to changes in advancing technology for health maintenance and promotion, new pattern of disease, disability, etc. new social policies, expectations and programmes for better health services. Towards this end, the education of the people concerning prevailing health problems and methods of preventing and controlling them is the first requisite of Primary Health Care. This is more so in the case of public welfare personnel and professionals through whom the knowledge and skills should percolate to the grassroot level.

In adhering to the above perspective, the National Institute of Health and Family Welfare conducts nearly fifty training courses/workshops annually towards requirements of a system of continuing education for health administrators of States and Districts, teachers of medical college, and also the members of Indian Administrative Service. However, the problem of updating the knowledge and skills of these personnel, already on the job, still remains. It has proved arduous to have them re-trained at institutions. The snail-like pace of implementation reflects in many instances the fact that this is an area where most professionals feel unprepared. It is, therefore, essential to initiate a programme to get relevant information out to individual participant. As such, the development of self-learning resource materials to keep abreast of scientific advances in research as well as in programme strategies is an enviable task which the NIHFW has undertaken with large-scale efforts.

These resource material present an assiduous expatiation of various National Health Programmes and Schemes currently in operation in the health services system. Each of these expatiates the genesis, strategy, current status, and the outcome of the evaluation of individual programme. Thus, the primary aim of this *Series* would be to share and utilise the available resources to update the knowledge and skills of programme personnel at their own place.

I fervently hope that this publication will provide orientation on the use of such self-learning materials to learners/participants. I also wish to asseverate that these resource materials will be updated periodically and as such, I am sure, they should be a valuable aid in overcoming the lag.

Much of the positive value in this *Series* originated with one or another of our associates. sincerely thank these Programme Officers who had so kindly undertaken the onerous task of compilation and completion of these documents.

New Delhi
December, 1988

J.P. Gupta
Director

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INTRODUCTION

Tuberculosis is a communicable, bacterial disease which results from infection with TB bacilli. The TB bacilli is a rod-shaped organism, discovered by Robert Koch in 1882. Tuberculosis can be traced back to the early history of mankind. In our country, it has been known since the Vedic ages, that is, about 5000 years ago. It is world-wide in distribution and strikes both the rich and poor, all races and both sexes. Tuberculosis affects all parts of the human body, but, most commonly, the lungs. The patient with lung TB excretes Tuberculosis bacilli with sputum through coughing, sneezing, etc. The germs, thus excreted, can enter, mainly with the help of air currents, another healthy human body while the person breathes in. On entering the lung, the bacilli generally get a foothold on the peripheral part of the lung and this process is called infection. The entry of the Tuberculosis germ into the body and its gaining a foothold does not always lead to disease, immediately or later. Only a few infected persons suffer with the disease process due to a number of factors which are both intrinsic and extraneous. The intrinsic factor is poor natural resistance or poor inborn immunity, which is a genetic one. Extraneous factors are many, like poor living conditions, low social and educational status, inadequate food or nourishment of the body, psychological and temperamental status of the person and affliction by some other diseases like diabetes, measles, cancer, etc. Today, Tuberculosis is treatable, curable and preventable.

MAGNITUDE OF THE PROBLEM

Improvements in diet, housing and living conditions in modern times have contributed to a decline in both TB mortality and new cases. The advent of chemotherapy during the last four decades has accelerated these trends. But Tuberculosis still ranks among the major health problems in the world, specially in the developing countries. There are about 15 to 20 million cases and three million deaths every year in the world due to Tuberculosis.

IN INDIA: The results of pre-tuberculine tests in mass BCG vaccination campaigns indicated, for the first time, that the problem of Tuberculosis was not limited to the urban areas only, in contrast to the earlier belief. The National Tuberculosis Survey during 1955-58 and subsequent limited surveys have confirmed these findings.

Tuberculosis is a major public health problem in India and number one killer among diseases. The National Tuberculosis Survey which was conducted by the ICMR in the year 1955-58, revealed that nearly 1.5 per cent of the total population above five years of age is estimated to be suffering from TB of the lungs, of whom one fourth, or 0.4 per cent are infectious. Subsequent limited surveys conducted in different parts of the country have confirmed these findings. As per the 1981 census the total population of the country was about 680 million and it was estimated that about 10 million people were suffering from radiologically active pulmonary Tuberculosis disease of the

lungs, out of which about 2.5 million people were infectious. Few lakhs of new Tuberculosis cases are added to the population every year but at the same time, an equal number of cases are removed, on account of death, spontaneous healing or treatment. This results in a state of near balance in the number of Tuberculosis patients from year to year. It is further estimated that nearly 50 per cent of the total population is infected with the TB bacilli, though they are apparently healthy. The annual infection rate (that is about 1.6 per cent) has remained almost constant for the last three decades.

Nearly 80 per cent of the people in our country live in about 6 lakh villages. It is estimated that at least 2-3 sputum positive cases can be found in each village of the country, and nearly 10-12 persons would be suffering from radiologically active Tuberculosis of the lung. In an average district with a population of 1.5 million, it is estimated that there will be about 5000 active pulmonary cases who are infectious and about 20,000 radiologically active pulmonary Tuberculosis cases. As per the recent study conducted by the NTI, Bangalore, in their field area, the mortality rate has come down to 53 per lakh population, and as per the study conducted by the New Delhi TB Centre, the mortality rate in their population area is around 40 per lakh population. Since the prevalence rate of pulmonary Tuberculosis cases is of the same order in the rural areas as in the urban ones, and nearly 80 per cent of the people of our country live in villages, the problem of Tuberculosis in our country is really a rural one.

AIM AND PRINCIPLES OF NATIONAL TB PROGRAMME (NTP) - BACKGROUND INFORMATION

The mass BCG vaccination campaign and the National TB survey conducted during 1955-58 led to the conclusion that Tuberculosis services had to be provided on a country-wide and long-term basis.

The NTP aims at the methods by which the systematic reduction of Tuberculosis in the community may be made within the available resources of the country and within a reasonable time. The method of treating the patients on a domiciliary basis was initially a compromise between the scientific idea for the few, and the economically and practically feasible one for the many. The short-term object of the programme is to diagnose and treat the patients at places nearest to their homes and also to give preventive services to the bulk of TB patients, specially those living in rural areas with the view of meeting their 'felt needs', and to reduce their suffering and prevent disability and deaths to the extent possible. The long-term objective of the programme is to reduce the problem gradually till it ceases to be a public health problem.

From the economic point of view, we have, at present, got a few thousand TB beds. To treat only the sputum positive cases, we need a few hundred crore rupees for constructing hospitals and another few hundred crore rupees as recurring expenditure annually. The money that would provide TB beds for

only 20-25 patients, can pay for the establishment of clinics which can handle 1000 to 1500 patients annually.

The cost of treating a Tuberculosis patient in a sanitorium for one year is equal to that of treating 15 patients on domiciliary basis. So, from the economic point of view, domiciliary treatment is the practical solution for tackling the Tuberculosis problem with limited resources.

From the scientific point of view regarding treatment of patients on domiciliary basis, it has been observed that the results of treating the patients in a hospital and at home are more or less the same. There is hardly any difference between the hospital patients and those treated at home, as regards the immediate therapeutic response in terms of radiological improvement, sputum conversion and closure of cavity at the end of one year, as also the danger of relapse in the future, and infection to the contacts, provided adequate chemotherapy is prescribed and taken regularly for the prescribed period by the patient.

It has already been mentioned that Tuberculosis is equally prevalent in rural and urban areas. For a developing country like India it would be a gigantic task to identify all the Tuberculosis cases living in hundreds and thousands of distant villages and to offer them regular treatment for a period of one to one and a half years.

The studies conducted by the NTI, Bangalore, have revealed that nearly 95 per cent of the infectious Tuberculosis patients are conscious of their symptoms and at least 50 per cent of them report to the nearest medical and health institutions to seek medical aid.

Another research study conducted by the ICMR (1955-56), conclusively proved that the Tuberculosis cases can be as effectively treated on domiciliary basis as in hospitals.

Based on the results of these two studies, the country-wide district Tuberculosis programme was evolved for the entire country by the NTI, Bangalore, in 1962. Under the programme, a district Tuberculosis centre is being established in every district of the country to organise a community-wide district Tuberculosis programme in association with all the existing medical and health institutions. In an average district of our country, there are about 50 such peripheral health institutions. The main aim of the programme is to detect as large a number of patients (sufferig from Tuberculosis) as possible, nearest to their homes and treat them effectively so that the infectious patients are rendered non-infectious and the active and non-infectious cases do not become infectious.

In doing so, priority is given to sputum positive Tuberculosis patients.

The patients are treated mostly on domiciliary basis because it is as effective as institutional treatment and more acceptable to TB patients since their domestic life lis not disrupted.

Each district Tuberculosis centre is staffed by a team of medical and paramedical personnel trained at the NTI, Bangalore, in X-ray and laboratory diagnosis, treatment organisation and community control of Tuberculosis, and is equipped with a static 100 M A X-ray unit fitted with an Odelca camera for miniature radiography, and laboratory equipment for direct smear miscroscopy.

The district Tuberculosis centre functions as a referral centre for the entire Tuberculosis control programme of the district. Its key personnel tour the existing peripheral medical and health institutions, including the primary health centres which cater to the health needs of the rural population, train the medical and paramedical personnel of such institutions in various essential activities under the Tuberculosis programme, supervise their working, ensure proper record keeping and reporting of the whole district and give advice also at the TB clinic in the town or city of its location.

Thus, the district TB centre serves as a base for carrying out the case finding and treatment programme throughout the district with the help of the network of general health services of the district, so that these facilities are brought nearer to the homes of the patients at minimum expenditure, and a permanent case finding and treatment programme is developed. The treatment is offered on an out-patient and mainly self-administered basis. The patients are encouraged to collect drugs from the PHCs nearest to their homes. The minimum duration of the uninterrupted chemotherapy is one year. The optimal duration of treatment is one to one and a half years and the extended period of treatment is upto a maximum of two years. All efforts are made to ensure that the patient receives uninterrupted treatment for at least 12 months. Defaulter actions are taken, both at the district Tuberculosis centre and at the peripheral health institutions, by way of letters to the individual patient, letters to the head of the village or by sending the health visitors/multipurpose health workers and village health guides, etc. In addition to this, under the NTP, additional district Tuberculosis centres are being established in those districts where the population is more than 2 million.

The additional district Tuberculosis centres are established in another sub-divisional town of the district. To cater to the needs of a small population of a district, a mini district TB centre is being established. It is not necessary to provide the full complement of key personnel at these mini district TB centres and these centres are not provided with any X-ray facilities. Instead, the X-ray facilities at the general hospital in the district are used.

INFRASTRUCTURE OF THE PROGRAMME

Out of the 434 districts in the country, the district TB programme has been implemented in 371 districts.

On an average, in a district there are about 50 implementable PHCs and other institutions (PHIs) and till now about 75 per cent of the PHIs have been brought under the National Tuberculosis Programme.

In addition, there are about 300 ordinary Tuberculosis clinics which are functioning in the country and are mostly located in big towns and cities. These are equipped with either static X-ray unit or Fluoroscopy and laboratory facilities and look after the needs of the local population living nearby.

There are about 46,000 TB beds available in the country to cater mainly to the needs of the selected group of patients, *i.e.* those who are seriously sick or suffering from some emergency or need surgical treatment or are social destitutes, etc. We are making efforts to establish sufficient numbers of Tuberculosis beds, as per the needs in every district of the country.

The Tuberculosis Institute, Bangalore, was established in 1959 with the aim of evolving nationally applicable methods of Tuberculosis control and training of key personnel for the Tuberculosis programme. Till now, about 4,600 key personnel of different categories have been trained. The Institute holds reorientation/training seminars for senior health administrators and professors of medical colleges, etc. Trainees from abroad also attend various international courses at the Institute. This Institute is also carrying out epidemiological, sociological, bacteriological and operational research connected with the Tuberculosis programme. It has also been selected to monitor the National Tuberculosis Programme on the basis of reports received from the DTCs and to provide suitable technical guidance to the district Tuberculosis centres to improve their performance.

This Institute is also carrying out short course chemotherapy regimen trials under operational conditions in the field area.

The Tuberculosis Research Centre, Madras, was established in 1956 for studying the feasibility and efficacy of domiciliary treatment of patients suffering from pulmonary Tuberculosis, and evaluation of inexpensive, effective chemotherapy regimens on mass application. The centre is at present engaged in conducting control clinical trials on chemotherapy in 18 districts of the country, clinical trials on Tuberculosis meningitis, Tuberculosis of the spine, etc. It has established a cardio-pulmonary physiology laboratory and epidemiology unit.

Seventeen Tuberculosis training and demonstration centres are functioning in the country to undertake the training of the medical and para-medical personnel required for manning the Tuberculosis centres; to give technical guidance to the district TB centres; to undertake the cultural and sensitivity tests; to give technical guidance to the complicated TB cases, etc. The State TB demonstration centre acts as a model TB centre for the State.

CONVENTIONAL DRUG REGIMENS RECOMMENDED UNDER THE PROGRAMME FOR SPUTUM POSITIVE PATIENTS (ADULTS)

Code No.	Drugs and Doses	Mode and Rhythm of administration	Instructions
R1	Isoniazid 300 mg + Thiacetazone 150 mg	Both drugs in a single dose or two divided doses, orally, daily	Self-administered at home after meals

R2	Bi-weekly regimen Inj. Streptomycin 0.75 gm/1 gm + Isoniazid 600 to 700 mgm (15 mgm/ kg body weight) with Pyridoxine	Intra-muscularly orally	Both drugs given at the same time under supervision of the treating physician twice weekly at intervals of 3 to 4 days
R3	Isoniazid 300 mg+ PAS 10 gms.	In a single dose in two divided doses both drugs orally, daily	Self-administered after meals
R4	Isoniazid 300 mg + Ethambutol 20 mg /kg body weight *i.e.* 800 mg per patients weight ∠50 kg and 1000 mg to 1200 mg >50 kg	Both drugs in a single dose; orally, daily	Self-administered at home after meals
R5	Biphasic regimen		
	a. *Intensive phase*	*For first two months*	
	Inj. Streptomycin 0.75 mg/1 gm + Isoniazid 300 mg + Thiacetazone 150 mgm or Ethambutol 200 mg per kg body weight *i.e.* 800 mg for patients ∠50 kg and 1000 to 1200 mg for those more than 50 kg or PAS 10 gms.	In a single dose, orally, daily, (PAS and Thiaceta-zone should be given in two divided doses)	Inj. given under supervision and rest to be self-administered at home
	b. *Continuation phase*		
	With R1, R2, R3 or R4	As per each regimen	As per each regimen

Remarks: Drug regimens comprising Inj. Streptomycine 0.75 gm/1 gm twice or even thrice a week + INH 200 mg or 300 mg daily is not sufficiently effective and, hence, not recommended.

For the Negative Tuberculosis Patients (Suspected Cases)

Tuberculosis paitents in whose sputum A F B are not seen, are advised Regimen R1; *i.e.* Isoniazid 300 mg + Thiacetazone 150 mgm in single dose orally, daily for one to one and a half years. Patients allergic to Thiacetazone can be treated with R4.

Note: The Drug PAS is gradually being withdrawn from the programme due to cost, non-availability, etc.

INTERNATIONAL ASSISTANCE TO THE TB PROGRAMME

By Swedish International Development Agency (SIDA): The Swedish International Development Agency has been supporting the case finding and treatment activities of the programme by supplying X-ray units with Odelca cameras, miniature X-ray film rolls, drugs needed for conducting the short course chemotherapy trial under pilot study, etc. since 1979. These X-ray machines with Odelca cameras are supplied to the unequipped district TB centres of the States/Union Territories, and as replacements to those district TB centres where the X-ray machines with Odelca cameras have outlived their utility. They are also are supplied to the additional TB centres, wherever created. The miniature X-ray film rolls are supplied to the district TB centres. Till now, the SIDA authorities have supplied about 175 X-ray machines with Odelca cameras. The short course chemotherapy trial under pilot study is being conducted in 18 districts of the country since 1983-84. The SIDA have also agreed to give additional assistance within June 1989 for supply of another 25 X-ray machines with Odelca cameras, miniature X-ray film rolls and 100 vehicles. These vehicles would be supplied to the different district TB centres of the country where either the vehicles have outlived their utility or to the newly created district TB centres for proper implementation and supervision of the programme by the DTCs. The SIDA is also helping the National Tuberculosis Institute, Bangalore, in various ways.

Assistance by the WHO: The WHO has been assisting the NTI, Bangalore, since its inception in 1959 and the TB Research Centre, Madras (ICMR) since 1956 by providing short-term consultants, fellowships, and essential supplies and equipment. They are also providing assistance to these two institutions for conducting short-term reorientation courses/seminars for senior health administrators of the States/Union Territories, teachers of medical colleges and refresher courses for the medical and paramedical personnel of the district TB centres.

EXPANSION OF THE PROGRAMME DURING THE VI AND VII PLANS

Expansion Under the 20-point Programme: A new thrust has been given to case finding activities of the NTP under the 20-point programme. Under the 20-point programme, targets for new TB case detection have been laid down

Tuberculosis Association of India
Institutional Area, South of I.I.T. N.

since 1982-83 and these targets are being increased every year. The achievement of the targets of new TB case detection has been satisfactory from the beginning.

Prior to the laying down of targets, only about 7 lakh new TB cases under the programme had been detected, but at the present moment more than 1.4 million new Tuberculosis cases have been detected under the programme. To involve the primary health centres in more and more case finding activities in the rural areas, targets for new sputum examinations have been laid down since 1983-84. With this, the PHCs are being more actively involved than before in case finding activities, and a target for 600 new sputum examinations per year by each PHC has been laid down. Initially, the achievement of targets of new sputum examinations at PHCs was not very satisfactory but considerable improvements are being noticed gradually.

TARGETS AND ACHIEVEMENTS SINCE 1982-83 UNDER THE PROGRAMME

Year	Target for detection of new TB cases (in lakhs)	Achievements (in lakhs)	Target for conducting new sputum examinations at at PHCs (in lakhs)	Achievements (in lakhs)
82-83	10.00	10.80 (100%)	No target laid down	-
83-84	12.50	12.00 (96%)	34.00	12.00 (35%)
84-85	13.75	12.54 (91%)	34.00	17.31 (50.2%)
85-86	14.00	13.58 (97%)	34.00	20.3 (59.5%)
86-87	14.50	14.13 (97.5%)	34.00	21.69 (63.9%)
87-88	15.00	15.62 (104%)	34.00	24.11 (71%)
88-89	15.00	-	34.00	-

Expansion of the Programme in Rural Areas: To intensify the case finding and case holding activities under the programme in rural areas, it has been recommended that all the health workers of the peripheral health institutions are to be involved in case finding and domiciliary treatment of the Tuberculosis patients and also to be engaged in BCG vaccination of the newborns and infants. It has been recommended that the MPWs, during their

routine rounds in the villages, should identify the chest symptomatics suspected to be suffering from pulmonary Tuberculosis and motivate them to go to the nearest health institutions for necessary investigations, motivate the diagnosed Tuberculosis cases to continue the anti-TB drugs uninterruptedly for the prescribed period, and take defaulter action on the patients who have defaulted in continuing the drugs. The MPWs also involve themselves in health educational activities on TB amongst the villagers and TB patients. For conducting these activities, the MPWs in the PHCs and in the sub-centres are gradually trained in case finding, domiciliary treatment, BCG vaccination and also in health education activities.

The village health guides are also being involved in essential health educational activities under the programme including motivation of chest symptomatics to avail of all the diagnostic facilities of the health institutions, and in motivation of the Tuberculosis patients living in their areas to take the uninterrupted treatment for the prescribed period as per the advice of the treating physician.

To expand the treatment activities further for the rural people living in the far-flung villages, it has been recommended that all the sub-centres which have the necessary buildings for storage of drugs, and have the requisite staff, should be involved in the distribution of drugs to the Tuberculosis patients.

Expansion of the Programme in Urban Areas Under the City Tuberculosis Programme: The district Tuberculosis programme was planned mainly with rural India in mind. It has been observed that the problems in metropolitan and other big cities with a population over five lakhs are different and the district TB programme would not be able to serve the needs of these cities effectively. As such, it has been recommended that advantage should be taken of the newly created health posts in the big cities and towns with a population over five lakhs, for implementing the city TB programme, which is already functioning in some cities like Delhi, Bombay.

Extension of Short Course Chemotherapy Regimens (SCC): Under the clinical trial conditions, the conversion and relapse rates with the conventional drug regimens are 82 to 96 per cent and 7 to 15 per cent respectively, at the end of one year.

In a study conducted by the National Tuberculosis Institute, Bangalore, it was revealed that only 30 per cent of the cases completed treatment at the end of one year under programme conditions with the conventional regimens and the patients defaulted mostly after the first or second collection of drugs. It was further revealed that in spite of poor completion of treatment rate, the conversion rate of sputum was about 65 per cent at the end of one year.

But under the clinical trial conditions, there is about 100 per cent sputum conversion in six to eight weeks and the relapse rate is only around 2 per cent with the short course chemotherapy drug regimens. The duration of treatment

with these drugs is only six to eight months. The main handicap in using the short-term chemotherapy drugs was cost, but at the present moment, the cost of these drugs, specially of Refampicin has gone down considerably and it is expected that it will go down further.

The long duration of the treatment, for a period of one to two years, with the conventional anti-Tuberculosis drugs is believed to be one of the important causes for the irregularity and discontinuation of treatment. Hence, to cut short the duration of the treatment, achieve early conversion of the sputums, thereby, preventing the spread of the disease and also to lower the relapse rate etc., the short course chemotherapy drug regimens have been introduced on a pilot study basis since 1983-84 in 18 districts of the country to find out the feasibility of introducing these drugs under the programme conditions. With the encouraging results gained in the study, these regimens were introduced in another 101 districts by 1987-88 for the sputum positive newly detected Tuberculosis cases, excluding the 18 districts where these regimens were introduced under the pilot study. The short course chemotherapy regimens are going to be introduced in another 75 districts of the country during 1988-89. It is expected that the majority of the districts of our country would be covered with these regimens by the end of the VIIth Plan period.

It is hoped that by introducing these regimens, the defaulter rate of treatment will go down further.

SHORT COURSE CHEMOTHERAPY DRUG REGIMENS RECOMMENDED UNDER THE NATIONAL TUBERCULOSIS PROGRAMME

All sputum positive cases aged 15 years and above, irrespective of history and previous anti-TB treatment, are offered either of the following two drug regimens:

Drug Regimens

These regimens have two phases:

i. Intensive phase of the first two months with four drugs.
ii. Continuation phase of four to six months with two drugs.

Regimen A: Bi-weekly, intermittent supervised regimen

2S H R Z/ 4 H R
2 2 2 2 2 2

Regimen containing

Streptomycin	(S 0.75 g)
Isoniazid	(H 600 mg)
Rifampicin	(R 600 mg)
Pyrazinamide	(Z 2 g)

In this regimen, the total duration of treatment is only six months. In the first two months (intensive phase), the patient is given Streptomycin, Isoniazid, Rifampicin and Pyrazinamide in the dosage mentioned above, twice a week. In the remaining four months (continuation phase), INH 600 mg, Rifampicin 600 mg are given twice a week. The patient has to report to the DTC/PHI and all drugs should be swallowed by the patient under the supervision of the doctor/health staff. In case of non-availability of SM or intolerance to Streptomycin, Ethambutol in the dosage of 12.6 gm (bi-weekly) may be substituted for Streptomycin.

Regimen B: Daily self-administered regimen

2EHRZ/6TH OR 6 EH

Ethambutol	(E 1 g)
Isoniazid	(H 300 mg)
Rifampicin	(R 450 mg)
Pyrazinamide	(Z 1.5 g)
Thiacetazone	(T 150 mg)

In this regimen, the total duration of treatment is eight months. During the eight months of treatment, the drugs have to beconsumed daily by the patient. In the first two months (intensive phase), the patient is given Ethambutol, Isoniazid, Rifampicin and Pyrazinamide in the dosage mentioned above. During the remaining six months (continuation phase), INH 300 mg and Thiacetazone 150 mg daily have to be given. If the patient cannot tolerate Thiacetazone, Ethambutol 800 mg should be given daily.

Suitability of Patients for Appropriate Drug Regimen

The patients who reside near the centre, and who are willing to attend the centre twice a week for six months should be offered Regimen A.

The patients who express their inability to come to the centre twice a week or who repeatedly fail to come to the centre twice a week for one month for consumption of drugs are offered Regimen B, of eight months duration.

Patient 'Lost' from Treatment

A patient who does not come for drugs for one month from the due date even after two defaulter actions, is considered to be 'lost' from treatment. If the patient returns after becorning 'lost' he should be started on any one of the five standard drug regimens (R1 to R5). It is important to ensure that every patient put on short course regimens (either Regimen A or Regimen B) should have collected 75 per cent of the required doses of the intensive phase within three months from the start of treatment. Those patients who fail to complete this will not be eligible for the continuation phase and will be offered the standard drug regimen.

Compensatory Phase

Every effort has to be made to ensure that each patient put on SCC Regimen A or B, completes treatment within the stipulated period. However, due to unavoidable reasons, if any patient defaults, the compensatory phase may be allowed. For the intensive phase of chemotherapy, an extension of one month may be given to the patient to complete the required number of doses. That means that under drug Regimen A, 17 doses should be taken in two months. This may be allowed to be completed in three months. Under drug Regimen B, four fortnightly collections of drugs should be made in two months. This may be completed in three months.

Similarly, an extension of one month in the continuation phase may be allowed to compensate for the missing doses. However, the total duration of chemotherapy, including the compensatory phase, should not exceed eight months in drug Regimen A and ten months in drug Regimen B.

Termination of SCC

For any patient remaining sputum positive after six months from the time of initiating SCC on either of the regimens, the SCC is terminated and the treatment card is closed.

For such patients, a new treatment card is to be opened (prolonged treatment card) and the patient is put on INH and Thiacetazone (or Ethambutol) for one year. This is called prolonged treatment. Any patient remaining sputum positive after six months of prolonged treatment has to be referred to specialised institutions for management of treatment failure.

Follow-up Examination

Every patient should be followed up strictly with sputum smear examinations - once at the end of six months after starting treatment and another at the end of chemotherapy (inclusive of compensatory period, if any).

Completion of Treatment

A patient who has completed 75 per cent or more doses of the required number, during the intensive phase (including compensatory phase), is considered to have completed the intensive phase and is eligible to enter the continuation phase.

A patient who has completed 75 per cent or more of the required number of doses of the continuation phase is considered to have completed optimum treatment.

Expansion of Health Education Activities: Any health programme, specially the NTP, a programme of great magnitude, cannot succeed without the active involvement and cooperation of the community, village Panchayats,

Zilla Parishad, community leaders, youth leaders, etc. Ninety-five per cent of the infectious sputum positive cases are already conscious of their chest symptoms and a country-wide health education campaign must be carried out to educate this group of chest symptomatics so that they get themselves investigated and utilise the facilities available at the institutions nearest to their homes.

A vast majority of patients suffering from Tuberculosis either report first to the general practitioners or to the Government hospitals/dispensaries. As such, the active participation of these health institutions and general practitioners is a must for the success of the programme. The most important point is to create active interest in the minds of general practitioners/medical practitioners regarding the problem and the NTP and also to up-date their knowledge about the present philosophy, diagnosis and treatment of Tuberculosis through refresher courses. These courses are being conducted by the Tuberculosis Association of India.

Keeping this in mind, much stress has already been given to various health educational aspects of the Tuberculosis programme by bringing out TV spots, radio spots, advertisements in newspapers, material for medical practitioners and the general population, etc. under the programme during the VIIth Plan period.

The funds provided on health education activities till, now, during the VIIth Plan period, are as follows:

1985-86	Rs.10.00 lakhs
1986-87	Rs.40.00 lakhs
1987-88	Rs.60.00 lakhs
1988-89	Rs.50.00 lakhs

SCHEMES DURING THE VIITH PLAN PERIOD

As in the VIth Plan period, the schemes of establishment of more district Tuberculosis centres, TB beds, etc. have been included in the State plan sector.

Centrally Sponsored Sector: Under the Centrally sponsored sector, the following schemes are being implemented:

a. Supply of anti-TB drugs/equipment to the States on 50:50 sharing basis between the Centre and the States.

b. Supply of anti-TB drugs/equipment to the Union Territories as a 100 per cent Centrally sponsored scheme.

c. Supply of anti-TB drugs to the TB clinics run by voluntary bodies as a 100 per cent Centrally sponsored scheme.

d. Expenditure on health education activities as a 100 per cent Centrally sponsored scheme.

FINANCIAL OUTLAYS AND ACTUAL EXPENDITURE INCURRED DURING THE VITH AND VIITH PLAN PERIODS

VIth Plan Period

Against the actual allotment of Rs.700 lakhs, the actual expenditure was Rs.2040.00 lakhs.

VIIth Plan Period

Financial outlays Rs.5500.00 lakhs

Actual expenditure incurred during the first three years of the VIIth Plan:

1985-86	Rs.1112.00 lakhs
1986-87	Rs.1125.00 lakhs
1987-88	Rs.1415.00 lakhs

BCG Vaccine, Its Efficacy and Current Status NTP *vs* EPI

The BCG vaccination programme has been in operation since 1951. However, as the coverage of the susceptible population was not found to be very satisfactory, it was decided that instead of carrying out the campaign through BCG teams alone, the activity was to be integrated with the general health services so that the newborns and infants, specially in the vast rural areas, may be covered expeditiously under the EPI programme The present BCG teams (available in the States and Union Territories) in addition to their current duties under the vaccination programme, are also engaged in proper training of the health workers in the technique of vaccination.

A study of the integration of the BCG vaccination programme with the general health services indicated that the services of Auxiliary Nurse Midwives (ANMs) who are now designated as Female Health Workers, could be utilised for BCG vaccination of infants without detriment to the ANMs' other functions. (Baily, Kulbhushan, etc. *Ind. J. Tub.* XX, 4, 155 (1973).

The Chingleput study on BCG vaccination clearly indicated that the BCG vaccination did not give any protections against the development of adult type TB. Several animal studies and several controlled trials (BMRC, 72, Rosenthal-61) had clearly shown that BCG vaccine almost always conferred a measurable degree of protection more closely to the childhood form of TB and its associate complications like meningeal and milliary type of TB. Hence, the present policy of BCG vaccination is to vaccinate the child soon after birth. In urban areas, the newborns are vaccinated just after birth in Maternity Hospitals and Child Welfare Clinics. In the rural areas, under the EPI programme, multipurpose health workers, vaccinate all the newborns before they are one year old alongwith other immunization.

Bovine Type of Bacilli and the Infection

A majority of the TB cases in the world are due to infection with human type of

bacilli except in the developed countries where a few cases of TB were due to the bovine type of infection. In India, the TB due to bovine type of infection is rare as milk is boiled before use. In the developed countries, TB due to the bovine type of infection has been controlled by pasteurising milk and other measures.

EVALUATION OF THE PROGRAMME

The programme was evaluated by the expert committee formed by the ICMR in the year 1975. The committee concluded that while the concept of the programme was sound, there was considerable scope for improvement in the implementation of the programme, specially at the peripheral health service levels. The committee made certain recommendations for further improvements which were then examined by an empowered committee appointed by the Ministry of Health and Family Welfare and the detailed guidelines for further improvement of the programme were given to the States for implementation.

From time to time, the experts of the Swedish International Development Agency (SIDA) evaluate the functioning of the programme before signing the agreement for aid to the programme and also during the agreement period. Recently, the programme has been evaluated by the expert team of the SIDA which has recognised the soundness of the programme and has also observed that the programme is working more or less satisfactorily and in the right direction.

They have, however, made some recommendations to improve upon the case detection and case holding activities of the programme, specially for the rural regions.

The NTI, Bangalore, has been entrusted with monitoring and evaluating the programme on the basis of the performance reports of the DTPs.

The programme is reviewed from time to time at the meetings of the Health Secretaries of the States/Union Territories and also during the meeting of the Central Council of Health, at the Central level.

The programme is also reviewed every month by the Ministry of Health and Family Welfare at the Central level and often at the levels of Health Secretaries/Ministry.

At the State level, the programme is reviewed and evaluated regularly at the State and district headquarters.

Recently, an independent organisation has been appointed by the Ministry of Health and Family Welfare to evaluate the programme independently.

RECOMMENDATIONS OF THE EVALUATION

A seminar held at the NTI, Bangalore, on 5th and 6th January, 1988, which was

attended by the health authorities of States/Union Territories, made some suggestions/recommendations for improvement of the programme. The salient recommendations/suggestions made by the ICMR committee and at the seminar held at Bangalore are as follows:

1. For the speedy expansion and intensification of the activities under the programme, the essential schemes which have a direct bearing on the expansions of the case finding activity and treatment programme should be taken up as a 100 per cent Centrally sponsored scheme. Due to financial constraints, the State/Union Territory health authorities are not able to provide sufficient funds for establishment of DTCs and for the procurement of anti-TB drugs, etc. out of their share. As such, it has been recommended that the scheme of establishment of DTCs in those districts where they are not available at all and the scheme of establishment of additional DTCs for the thickly populated districts be taken up as 100 per cent Centrally sponsored schemes and cash assistance be provided to the States/Union Territories for:

   a. provision of essential medical/paramedical staff;
   b. recurring expenditure for running of DTCs; and
   c. provision of essential equipment.

2. The performance under the programme should be reviewed regularly on a monthly basis at every level, just like the review of activities under the family welfare or MCH programme, etc.

3. Over half of the cases of PTB requiring treatment are sputum negative and cannot be diagnosed either due to non-availability of X-ray facilities at the PHCs or due to the distance of the PHCs and DTCs from the patients home. Under the minimum needs programme, it has been proposed to upgrade some of PHCs to community centres and rural dispensaries to health centres which would be equipped with general purpose X-ray units. The case finding activities under the TB programme can be substantially increased by the establishment of such equipped community health centres, etc. under the Minimum Needs Programme.

4. In about 30 per cent PHCs either no multipurpose laboratory technicians have been posted, or if posted, they are overloaded with work like malaria work, etc. It has been recommended that the admission capacity of the Laboratory Technicians Training School may be enlarged so that the existing PHCs and newly established PHCs are provided with multipurpose trained laboratory technicians.

5. Full-time NTI trained medical and paramedical personnel should be posted at the DTCs throughout the year for proper implementation and supervision of the programme.

6. A vehicle alongwith suitable POL charges should be provided in each district TB centre for proper implementation and supervision of the programme.

7. The MPWs and ANMs while receiving their basic training in the training institutes should be imparted the requisite training in the essential aspects of the TB programme.

8. Ever since the MPWs were entrusted the duty of collecting the sputum of the chest symptomatics in the field, making slides and sending them for examination through the microscopic centres, the quality of the work has deteriorated considerably. It has been recommended that the MPWs, instead of collecting sputums in the field during their home visits and preparing smear slides of such patients, may motivate the chest symptomatics to report to the nearest PHC for investigation. The group was of the view that MPWs should not be entrusted with the duty of supplying anti-TB drugs at the homes of the patients.

9. In a large number of PHCs, functioning microscopes are not available. It has been recommended that the microscopes may be supplied by the Government of India for the use of PHCs. It has been further recommended that oil immersion lenses may also be supplied by the Government to bring back into use the non-functioning microscopes available at the PHCs.

10. Additional district TB centres may be established in thickly populated districts or in those districts which are very large in area. It has been further recommended that the additional district TB centre should not be located in the city or town where a district TB centre is already functioning and it may be established in another town or city of the district so that the referral and supervision activities can be properly developed.

11. For improvement of case holding activities under the programme, the medical and paramedical personnel of the district TB centre and peripheral medical and health institutions have to play a vital role. Repeated motivation of the patients and members of their families would considerably reduce the defaulter rates. The multipurpose health workers should keep a list of TB patients living in their area so that during their visits to the field, the patients and their families are repeatedly educated about the need to take regular and uninterrupted treatment for the prescribed period of time, as advised by the medical attendant.

12. Voluntary organisations are playing an important role under the NTP. It has been recommended that existing provisions made for the supply of anti-TB drugs to such organisations be enhanced so that their total requirement of anti-TB drugs for domiciliary treatment can be met. It has been further recommended that those voluntary run TB institutions, which have already been provided with an X-ray unit with Odelca camera, may be supplied with miniature X-ray films for the expansion of case finding activities.

Requests for cash assistance for purchase of essential X-ray/laboratory equipment as well as for construction of buildings for TB institutions by such voluntary organisations should be suitably considered by the Government.

Section 35 CCA of the Income Tax Act may be amended to include donors for the establishment of TB hospitals and clinics.

13. The attitude and behaviour of the medical officers of the health institutions towards TB patients has to be more effective. Therefore, it has been recommended that continued medical education programmes from the grassroots to the State level for all medical and health personnel are essential. Medical colleges should be more actively involved in the implementation of the programme and undergraduate students may be sent for training at the DTCs.

14. The possibility of involving volunteers, Youth Clubs, Mahila Mandals for health education of the community should be explored.

15. The poor and the deserving indigent TB patients may be granted some cash assistance by the voluntary organisations to meet the expenses and other essential needs.

16. It has been recommended that in every major State, the posting of trained State TB officers alongwith requisite infrastructure is a MUST for improvement of the programme.

17. The drugs should be made available not only in the primary health centres, but also in the sub-centres where facilities of storage and distribution are available.

18. The TB clinic and demonstration centre/State TB centres should play a more active role in the implementation of the TB programme in the region. Besides running a district TB programme in the district, in which it is located, this training centre should also undertake the culture examination work and be a key referral centre for the entire State. The centre should also undertake the reorientation training of the CMO/DMO/Civil Surgeons of the State, conduct reorientation training of the X-ray technicians, laboratory technicians, etc. so that such functions which are being undertaken by the NTI, Bangalore, at present, can be transferred to the TB training and demonstration centre. It has been recommended that from 1.1.1990, the NTI may conduct only two regular training courses for the district medical and paramedical personnel.

19. It has been recommended that short course chemotherapy regimens may be extended to more districts in the country so that by the end of the VIIth Plan period, a majority of the districts can be covered by these regimens.

PRESENT POSITION OF NTP AND SHORTFALLS/PROBLEMS IN THE IMPLEMENTATION OF THE PROGRAMME

Since Independence, there have been considerable improvements in the developments of anti-TB measures, in our country. Prior to 1947, we had only about 85 ordinary TB clinics and about 6000 TB beds in the country. Against these, we have, at present, more than 600 TB clinics, which include district TB centres, and about 46,000 TB beds. A total of 371 districts have been covered under the district TB programme till now, out of the existing 434 districts of the

country, as we could not keep pace with the carving out of new districts out of bigger districts. At least 75 per cent of the implementable PHIs have been brought under the DTPs in the implemented DTPs. About 4600 key personnel have been trained by the NTI, Bangalore, for the uniform implementation and development of the programme throughout the country. With the inclusion of NTP under the 20-point programme, about 14 lakh new TB cases are being detected at the present moment as against about 7 lakh cases detected few years back. In addition to that, it is estimated that about 5 lakh new TB cases are being detected and treated by the GPs, voluntary organisations, general hospitals as well as by other agencies like Railways, ESI, Defence Services, etc. which usually do not notify the cases under their care to the district TB centres.

As a result of the active involvement of PHCs, the number of new sputum examinations are increasing year by year. To cut short the duration of treatment, short course chemotherapy drug regimens have already been introduced for the newly detected sputum positive Tuberculosis cases in 119 districts of the country and the same is going to be introduced in another 75 districts during 1988-89. There has been substantial augmentation of the financial allocation and expenditure as a Central share for the expansion of the activities of the programme. In spite of financial constraints, shortage of technical manpower, illiteracy, population explosion and poor socio-economic conditions etc., of the country, the achievements are by no means negligible.

But even with the extension of facilities and allocation of more and more funds, the programme has not progressed as expected earlier. The reasons for this are many and varied. In spite of more and more new sputum examinations being done at the PHCs, the quality of the sputum examinations has deteriorated. The achievements of case detection and case holdings have been below expectation.

The operational research study conducted by the NTI, Bangalore, on the POTENTIAL YIELD OF BACILLARY CASES IN NTP showed that each DTP can detect about 2000 bacillary cases annually, whereas actually, on an average, each DTP diagnosed only about 700 bacillary cases annually, that is, about 35 per cent of the potential yield. Irregularity of drug intake and inadequate duration of chemotherapy are the two major operational problems in the case holding activity of the programme. Only about 30 to 35 per cent cases complete the treatment with conventional regimens under the programme conditions.

In another study conducted by the NTI, Bangalore, investigating the efficacy of two standard regimens under programme conditions, the initial as well as subsequent motivation of the patients was done exactly according to the recommendation made in the programme which revealed similar completion rates at the end of one year. In all probability, the DTPs are not achieving results very close to the potentials.

But even with such defaulter rates, the conversion rate of sputums at the end of one year is about 65 per cent. Indeed, in the programme, neither the case finding nor the treatment activity are considered to be satisfactory. But there appears to be a much larger gap i the case finding achievements than in the treatment achievements.

From the operational study on DTP by the NTI, Bangalore, it is observed that there is enough scope for improvement in the case finding activities of the programme but this cannot possibly influence the treatment which could probably be improved by technical considerations and, to a certain extent, by modifying the operational conditions.

The reasons for the shortfall of the achievements of the NTP are many and varied. But the two major reasons are the poor and slow development of the general health services and poor socio-economic conditions/population explosion of the country.

The NTP has been rightly integrated with the general health services. Without the proper development of the general health services, the programme cannot improve and function in the right direction. Unfortunately, the primary health care facilities have not developed to the extent envisaged. In 1946, the Bhore Committee recommended that each PHC should cater to the needs of 30,000 population but due to the financial constraints, etc. this was not found to be feasible. So in the early 50s, it was initially planned to establish one PHC to cater to the needs of about 1,00,000 population, covering an area of about 200 to 900 sq. kms. The studies conducted by the National Institute of Health and Family Welfare and A.P. Jain's Committee report have indicated that the ACTIVE AREA OF INFLUENCE of a PHC does not go beyond the radius of 8 to 10 kms. Obviously, only the TB patients who are living close to these institutions have been availing of the facilities of the PHCs. This is an important reason for the poor performance of the programme due to the inadequate development of general health services.

Even before the advent of chemotherapy, the problem of TB could be controlled due to improved socio-economic conditions in the developed countries. It is estimated that about 35 per cent of the people in our country are living below the poverty line, which is one of the main hurdles to be faced.

Health being a State subject, the scheme of implementation and supervision of the NTP has been classified as a State Plan Activity and the following difficulties are often encountered in the States in the proper implementation and supervision of the programme:

1. Due to lack of financial resources, the State/Union Territory health authorities cannot implement and supervise the programme effectively.

2. In some of the States, there exist different administrative controls of the personnel working at the district TB centres and at the peripheral levels of the same district causing difficulty in the implementation and smooth running of the programme.

3. Equal priority has not been given to the TB programme as to the other programmes like Malaria, Family Planning, by the States/Union Territories health authorities.

4. The proper status has not been given to the district TB officers by many States/Union Territories authorities which hinders the proper implementation and supervision of the programme at the PHC level.

5. Non-availability of trained whole time State TB Officers in many of the major States is a big problem. A trained whole time STO is absolutely essential for the proper implementation and supervision of the DTP in the State.

6. The apathetic attitude of the medical and paramedical, personnel specially at the peripheral levels is another hurdle for the programme.

7. DTPs have to be implemented in about 66 districts of the country. Additional district TB centres are to be established in all the thickly populated districts. Twenty-five per cent of PHIs are yet to be brought under the ambit of the DTP.

8. In many of the district TB centres, trained key personnel and vehicles are not available throughout the year. This is a serious drawback since they are absolutely essential for the proper implementation and supervision of the programme.

9. In a good number of districts in some of the States either there are no TB bed or if there are, the number is less than ten.

10. In about 30 per cent of the PHCs either no NTI trained lab technician has been posted or if posted, the lone technician is overburdened with work like malaria work, etc. and findslittle time for sputum slide examinations.

11. The potentialities of the MPWs in case finding and case holding activities of the programme have not been fully exploited.

12. Great difficulties are often encountered in the case finding programme due to non-availability of essential materials and equipment like microscopes, glass slides, chemicals, etc. at the peripheral levels.

13. The potential of the case holding activities of the sub-centres that have sufficient staff and storage facilities for drugs, are not being fully exploited.

14. Poor development of health education activities on Tuberculosis.

Present Trends of Tuberculosis in India

In the opinion of many experienced clinicians in the country, the Tuberculosis disease has undergone a considerable change in its clinical presentation, specially over the last quarter of the century.

Many retrospective studies (TAI, 1958, 1968), despite their scientific weakness, have clearly brought out the gradual change in profile from a

prevalence of more acute and extensive disease among the young to a more chronic, or a less severe disease among the elderly people. The near consensus of these reports has been on a marked decrease of concomitant complications of pulmonary Tuberculosis as, for example, Enteritis, Laryngitis, Amyloid diseases, matted lymph glands with discharging sinuses, etc. It is very significant that very similar changes were noticed in countries where Tuberculosis has definitely declined.

Available epidemiological information signifies no change in the prevalence of bacillary Tuberculosis in the country, at least during the last three decades and that equal prevalence in urban and rural areas means that we are truly in the endemic phase of the disease and that there is a gradual but slow natural decline of Tuberculosis in the country. The reason for the slow and natural decline of Tuberculosis in the country, is probably the continued poverty, malnutrition, overcrowding, etc.

As already stated, the epidemiology indicates that TB situation is almost constant in India, and, if at all, shows a very slow downward trend. The downward trend is evidenced by the apparent shift in the age of first infection during the later decades of life and a gradual reduction in the incidence of the childhood form of Tuberculosis resulting from the first infection. Indications are also available that where the programme is functioning well, the problem, of Tuberculosis in the community does show a downward trend.

Prospects of TB Control in India

The present epidemic in India might have started in the 17th century and there is evidence to indicate that the epidemic has been declining since the turn of the 20th century. All available knowledge about the epidemiology indicates that the Tuberculosis situation is almost constant in our country and, if at all, shows a very slow downward decline.

At present, when the case finding activity is functioning at about 35 per cent of the potential, and treatment efficacy is about 65 per cent, it can be shown that per unit of investment in resources, improvement in case finding would give higher dividends than the improvement in the treatment activities.

The District TB Programme, even at the present level of efficacy, has the potential of enhancing the natural decline. Improved programme efficiency, specially under case finding, is likely to produce a quicker decline. Rapid socio-economic development and improved standards of living would lead to a more spectacular decline in Tuberculosis, but that would not fall strictly within the ambit of the control programme.

TB Programme for Urban Areas

The DTP was planned mainly with rural India in mind. However, the problems of metropolitan and other large cities with a population of over 5 lakhs are different and the DTP would not be able to serve the cities effectively. It is, therefore, imperative to have different programme for these cities. Such city

TB programmes are already functioning in Delhi and Bombay. The same programmes should be implemented in large towns with a population over 5 lakhs.

Since continued motivation and education of the masses in various aspects of the case finding, treatment and preventive activities under the programme is necessary to enlist their cooperation, an intensive health education campaign must be carried out and the necessary publicity material brought out periodically.

Mortality Trend

Tuberculosis is not a notifiable disease and the exact cause of death in each case cannot be ascertained. As such, it is not possible to spell out the exact number of deaths due to TB.

In a longitudinal study conducted by the NTI, Bangalore, in the Bangalore district, where no anti-TB services were conducted, the mortality rate during the period 1961 to 1968 was found to be 80 to 100 per lakh population. It has been found recently that the mortality rate has come down where the programme is functioning satisfactorily. As per the recent studies, conducted by the NTI, Bangalore, and the New Delhi TB Centre in their field areas, the mortality rates were found to be 53 and 40 per lakh population respectively.

SUMMARY

About 50 per cent of the people in our country are already infected with TB germs, and about 1.5 per cent of the people above five years of age are suffering from radiologically active pulmonary Tuberculosis; of these, 0.4 per cent are infectious. The mortality rate has come down from 80 to 100 per 100,000 population to 53 and 40 per 100,000 population in Bangalore and Delhi respectively where the programme is working satisfactorily. As 80 per cent of the people in our country are living in the rual areas; the Tuberculosis problem in this country is really a rural one.

The National Tuberculosis Programme, as envisaged by the National Tuberculosis Institute, Bangalore, has been functioning since 1962, and is a permanent country-wide programme, integrated with the general health services. It is based on epidemiological, sociological and economical conditions prevailing in the country. The objectives of the programme are to diagnose, treat and give preventive services to the bulk of the TB patients and to the community, nearest to their homes with a view to meet their 'felt needs' and also to reduce their suffering and prevent disability and death, with the ultimate objective of reducing the problem to such an extent that it ceases to be a public health problem.

Under the programme, a District TB Programme, is being implemented in every district of the country in association with all the existing general health institutions of the district. Emphasis has been laid mainly on microscopic

examination of sputum. Radiological examinations are restricted for patients whose sputum is repeatedly negative. Patients are treated primarily on domiciliary basis with the five regimens of conventional anti-TB drugs. To cut short the duration of the treatment, short course chemotherapy drug regimens have recently been introduced, or are going to be introduced, in 194 districts of the country by 1988-89. By the end of the VIIth Plan period, most districts will have been covered with these regimens. BCG vaccination is given only to infants below one year of age under the expanded programme of immunisation.

Multipurpose workers/village health guides are being involved in case finding and case holding activities. The drug delivery system is being expanded to the farthest corners of the districts by involving the sub-centres. Much stress has been laid on the health education activities. The programme is evaluated at various levels regularly.

Since independence, considerable improvements in anti-TB measures have been noticed. The major districts of the country have already been brought under the District Tuberculosis Programme. About 300 TB clinics and 46,000 TB beds are functioning, and about 76 per cent of the implementable PHIs have been brought under the DTP. About 4600 key personnel required to run the district TB centres have been trained.

The detection of new TB cases has more than doubled and the sputum examination of new cases in rural areas has increased considerably during the last few years. Considerable augmentation of funds to the programme as the Centre's share has been made during the VIth and VIIth Plan periods.

But in spite of extension of facilities and augmentation of funds, the progress has not been as expected.

The case finding efficiency of the District TB Programme is about 35 per cent of the potential. Studies conducted at the National Tuberculosis Institute, Bangalore, revealed that 82 per cent of the sputum positive cases can be diagnosed by examining the sputum twice. If the medical/paramedical personnel including the multipurpose workers are trained properly, effective supervision of their working is provided, additional laboratory technicians are posted wherever required and if a static miniature radiography equipment is provided to all big general hospitals, the case finding activities would improve considerably.

Similarly, the case holding efficiency of the programme is about 30 per cent of the expectation. The condition can improve considerably if the medical/paramedical personnel of the health institutions and also multi-purpose health workers are actively involved in repeated motivation of patients, their families and communities to take regular treatment for the prescribed period. The short course chemotherapy regimens already introduced in the programme, are likely to reduce the defaulter rate considerably.

The involvement of the general practitioners and voluntary organisations, and community participation in the programme is a MUST for the development of the programme. A health education campaign in the community should develop along with the proper functioning of our health and medical institutions. Rapid socio-economic developments and improved standards of living could lead to a more spectacular decline in Tuberculosis.

At present, our country is truly in the endemic phase of the disease and there is a gradual and slow natural decline of Tuberculosis.

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As an Apex Technical Institute of its own kind in the country, the NIHFW has been actively engaged in the promotion of health and family welfare programmes through education, training, research, evaluation and advisory-consultancy and other specialised services.

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DIS 5.5

SERIOUS IMPLICATIONS OF THE WORLD BANK'S REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME FOR INDIA

(A POSITION PAPER FOR DISCUSSIONS AMONG CONCERNED SCHOLARS OF THE COUNTRY. THE AUTHOR WELCOMES COMMENTS AND CRITICISM)

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CHAPTER 1

AN OVERVIEW

The proposal of the World Bank for what they call "Revised National Tuberculosis Control Programme" (RNTCP) for India is going to have very damaging consequences for development of the health services of the country, as it suffers from serious infirmities. The Voluntary Health Association of India and the Nucleus for Health Policies and Programmes have got together to produce this document, which contains a scientific analysis of the RNTPC to draw attention to its infirmities and to formulate an alternative proposal for strengthening the National Tuberculosis Programme (NTP) of India. While the RNTCP will be analysed in detail at a later stage, it will be worthwhile here to note that the infirmities belong to three categories. The most important among them is that the RNTCP has been developed without paying adequate attention to the process of formulation of the NTP and the factors which have come in the way of its implementation over the more than three decades since it was adopted by the Government of India. Secondly, in considering the conceptualisation of the RNTCP as an outcome of an interdisciplinary study, adopting a systems approach, there are very serious flaws in project formulation in terms of system optimisation, epidemiological and sociological analyses, managerial and technological perspectives, coverage, epidemiological impact, repayment of the World Bank loan, replicability of the RNTCP, and other such considerations. Thirdly, the World Bank promoted RNTCP is a part of the sequence of what are termed as "International Initiatives" thrust on the country from outside at the instance of international agencies, backed up by strong support from many powerful western countries, which make substantial contributions to the budgets of the former. Ironically, as will be demonstrated later on, it is these international initiatives which have been proved to be the major hurdles in the way of implementation of the NTP all these years. The RNTCP thus appears as a not well thought out operation performed by persons from the very same group who, in the first place, have been responsible for the damage done to the NTP.

Even from this very broad mention of the RNTCP it is possible to discern an underlying deep streak of dogmatism among the exponents of the RNTCP, which has impelled them to 'forget' the enormous and very substantial public health research in tuberculosis conducted within the country and put enormous

pressure on the national authorities to submit to 'models' developed by them outside the country. Apart from very serious conceptual flaws, these western models are technocentric, imposed on the people from above and make the country dependent on assistance from outside. 'Forgetting' ideas developed indigenously has thus become almost a prerequisite for taking international initiative in health fields; the fields gets closed to scientific discussions and only those 'natives' who do not do question them, or are incapable of doing so, are allowed entry into the privileged group by the international syndicate. Soon after the poor countries of the world had dared to make a declaration of self-reliance in health in the Alma-Ata Declaration of 1978 (WHO 1978), the affluent countries 'invented' what they called "Selective Primary Health Care" (Walshe and Warren 1979), which was almost immediately followed by the unleashing of a series of international initiatives in health. This provides a frightening example of the extent to which the more affluent countries of the world are prepared to go in imposing their will on the countries that are economically and politically dependent on them. Significantly, there has been little protest from the concerned community of public health scholars even in the affluent countries to such brazen forms of manipulation of science to impose programmes on 'defenceless' countries, from outside. The World Bank backed RNTCP is a particularly unfortunate example of imposition of such international initiatives.

The drive towards globalisation of the economy and polity has made the poor countries even more vulnerable to manipulation by the rich countries. In the so-called global village, the poor countries are condemned to serve as bonded hirelings of the rich kulaks and cowboys. A 'dialectical' outcome of this form of international relations is for the oppressed peoples to make conscious efforts to prevent the dominant powers to 'forget' their historical heritage. To adapt a quotation from Milan Kundera, it becomes a struggle between memory and forgetfulness. Just as ahistoricity becomes an important weapon in the hands of those who would fight to continue to monopolise the control over the bulk of the resources of the world, breaking into their consciousness to 'remind' them about the history they try to forget becomes a weapon in the hands of the oppressed to fight oppression.

At a time when a concerted effort is being made by World Bank officials to promote RNTCP in this country, this document may be considered as a modest effort to 'remind' them as well as the concerned authorities in the country about the very significant work that has been done in India to deal with tuberculosis as a

public health problem. No apologies will be offered here for consciously taking the side of the people by bringing out well researched data which had formed the basis of the NTP some three and a half decades ago. A very deliberate effort is made here to describe the work rather extensively. The 'battle lines' are clear: on one side are the indigenous research efforts made to formulate a nationally applicable, socially acceptable and epidemiologically effective tuberculosis programme, and on the other side is a 'foreign inspired', prepackaged programme that is sought to be thrust on the country by powerful countries and international organisations.

CHAPTER 7

CONCLUSIONS AND AN ALTERNATIVE FRAMEWORK FOR ACTION

The above account shows how a well researched and reasonably simple and straight forward programme can get hopelessly confounded due to interplay of a variety of social, political and economic forces. NTP essentially involved offering diagnosis and treatment to the very substantial portion of tuberculosis patients who were actively seeking treatment in various health institutions, both in rural and urban areas. These institutions were offered a referral support system which extended right up to the super-specialists in post-graduate teaching hospitals. State Tuberculosis Centres and NTI and other tuberculosis research and teaching institutes were meant to provide support to the programme in the form of training, monitoring, evaluation and operational research.

But as pointed out by Halfdan Mahler, 'even the simplest technology, if it is not properly deployed and utilised by the infrastructure, just will not move, will not control tuberculosis, will not meet people's felt-needs.' This is what has befallen on NTP. The infrastructure has been grievously damaged because of sharp decline in the quality of public health practice and research, filling up of key public health posts by the persons who do not have technical competence, by imposition of target oriented specialised programmes on an already weak infrastructure and a correspondingly sharp fall in the quality of administrators and research personnel in the field of tuberculosis.

From the basic premises presented above, some important suggestions are being made below:

1. While tuberculosis workers cannot take on themselves the onerous task of rejuvenating the moribund health and family planning services systems, the crisis has become so profound that there are good chances that the political leaders will have to wake up to it. A detailed programme for rejuvenation of the health services is given in the author's B.C.Dasgupta Oration of the Indian Public Health Association in 1988 (Banerji 1988b; 1984b). Some important components are:

a. Building up a critical mass of public health workers in the fields of education, training, research and practice.

b. Restructuring the cadre structure to place competent public health specialists in key public health positions.

c. Concurrent removal of the square pegs in the round holes of the system.

d. Making "conditional" integration of the special target oriented family planning and other programmes "unconditional". This will lead to according much higher priority to NTP as the problem is responsible for a substantial part of the total suffering caused by health problems as a whole.

2. Tuberculosis workers can help in the process of rejuvenation of the health and family planning service systems by insisting that this process is critical for providing good tuberculosis services to be suffering masses of the country.

3. On its own, even considering the constraints of the general health services as given, there is still considerable scope for improving the NTP system through use of operational research and systems analysis. The Surajkund Conclave recommendations can serve as a starting point.

4. The very improvement in the NTP system might stimulate improvement in the wider health and family planning services systems, by providing an example.

5. NTI can be rejuvenated by bringing together a competent interdisciplinary team of workers, so that it can play a role in strengthening the NTP. It can even extend its activities to serve as one of the many institutions which would be necessary to strengthen the general health services.

6. Concurrently, competent tuberculosis workers are placed as heads of tuberculosis wings of the central and state health services.

7. Other tuberculosis institutions, such as TRC, should be tuned to serve the NTP, i.e., the problems they deal with must emerge from the field situation, and not the other way round, as is often the case at present.

8. The idea of Task Force (Editorial 1990), or a similar set up (Fox 1990), which is vested with power and resources to act as a watchdog for the implementation of NTP, very well blends with the other suggestions for improving NTP given here.

9. Again, there is considerable scope for optimising the urban components of the NTP.

10. Tuberculosis Association of India and its branches can be revamped to perform a complementary role in strengthening of NTP - e.g., conducting independent evaluation, offering technical assistance, providing logistical support, providing training, and so forth.

In sum, the suggestion is that we take steps to unleash the social forces which ensure that simple and efficacious technology developed in India is made accessible to the hundreds of thousands of sputum positive cases, who are actively seeking relief for suffering but who are still being thrown out of the health institutions with a bottle of useless cough mixture. Sociologically, it is contended that the very meeting of the felt need generates more needs, and, if that does not happen, active educational steps are taken to generate more needs to reach a level when it starts having an epidemiological impact. This epidemiological impact will occur in consonance with the impact that might occur as a result of changes in the natural history of tuberculosis in India.

To Dr's SPT/CMF/VB,
This was presented at the VHAI TB consult in July '94 JN

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DIS 5.6

CM 16/8/94

TB CONTROL PROGRAMME IN INDIA

BY DR.K.K.DATTA

The National TB Control Programme has been in operation in India since 1962. India was among the pioneers in discovering and testing the efficacy of ambulatory treatment which obviated the requirement of prolonged hospitalisation in most TB cases. Treatment through prolonged stay in sanatoria of the 40s was replaced by domiciliary management of cases for a period of 18 months or so. This has been replaced by a technical break through in the nature of short course multi-drug therapy consisting of INH, Rifampicin, Pyrazinamide and Ethambutol. The Short Course Chemotherapy was incorporated into the programme in 1982, for a limited number of cases.

India is a very large country with a current estimated population of around 900 million. It has 32 provinces and 459 districts. A district has an average population of 1.7 million (Annex - 1). (1)

The organization structure of the programme consists of (i) 390 District TB Centres having the composite function of case detection through clinical examination of symptomatics, sputum and x-ray examinations, case management and follow-up, epidemiological services including monitoring, supervision and reporting; (ii) 330 TB clinics with diagnostic and case management services, in the urban areas. 47,300 TB beds are also available for treatment of seriously ill TB cases (Annex - 2). TB case detection and management services are also available in general health facilities like general hospitals, Medical College hospitals, etc. In India a large number of medical professionals are working in the private Sector (hospitals, clinics etc) and it is estimated that an almost similar number of TB cases as under the NTP seek treatment in the private sector. However they are not notified. It is also important to note that the infrastructure for TB was more organised and efficient in terms of domiciliary management in rural areas compared to urban areas. In many municipalities the infrastructure for TB is very inadequate and poor. (2)

In India the population has been growing at the rate of over 2% per annum and the urban population has grown from around 17.97% in 1961 to 25.73% in 1991. The number of new TB cases detected per 1000 population under the NTP has increased from 1.13/1000 in 1981 to 1.80/1000 in 1991. However, the rate of new smear positive TB cases recorded no increase or only a marginal increase was seen (Annexure - 3). It clearly indicates that the

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programme did not function as efficiently as expected. It may be stated here that the supervised Short Course Chemotherapy is available in 253 districts. It has a very low coverage because of non availability of adequate quantum of drugs. It is also clear that though the existing National TB Control Programme laid an emphasis to detect more number of TB cases but the rate of smear positive case detection is very low (less than 25% of the diagnosed of TB are one smear positive). This is due to continued over reliance on x-ray diagnosis. In fact often cases are diagnosed on clinical and x-ray investigations and put on treatment without sputum examinations being done.

Case holding is very poor, with only about one quarter of the cases notified completing the course of therapy. Therefore the existing National TB Control Programme strategy has been revised with the objective of achieving a high cure rate (85%) and treating at least 100 sputum positive patients per 100,000 population thereby reducing morbidity and mortality and cutting down the transmission. It is expected that about 100 smear positive cases per 100,000 will be detected of which about two thirds will be new and the rest will be relapses, failure etc.

The broad strategy of the revised NTP are: (Annex 4 - 5)

1. To change the current emphasis on radiological diagnosis to sputum microscopy diagnosis.

2. To treat with SCC, directly supervised in the intensive phase, all sputum positive and seriously ill sputum negative cases, and to involve the peripheral health functionary in supervised treatment administration .

3. To make available all categories of anti-TB drugs in appropriate multi-drug blister packs, uninterrupted to all peripheral points.

4. To strengthen the capability of DTC and State TB Centres for effective implementation, monitoring and evaluation of the programme including cohort analysis.

5. To augment and improve the training capabilities both at the national and state level

6. Professionally managed IEC campaign.

7. Operational Research.

The revised strategy is in line with the recommendations made by WHO. The Government of India is also committed to maintain the strengthened revised National TB Control Programme as a permanent health system activity integrated into the existing health structure with strong leadership from a central unit. The Governments commitment is evident from enhanced central plan budgetary allocation from 150 million Indian rupees per annum 3 years ago to 460 million Indian rupees during the current financial year.

Annual risk of infection (Annex - 6)

The intensity of disease transmission in the community is best reflected by the annual risk of infection which represents the probability of a previously uninfected individual becoming infected with TB during a one year period. (6)

The estimated risk of infection ranges from 0.6 to 2.3%. Epidemiological interpretation is difficult because of the variable methods used in various studies. However there is no evidence of a substantial decrease in the risk of infection over the last 30 years. The stagnant situation has been further corroborated with 2 recent studies in the rural areas of South India. One shows that the risk of infection has decreased from 1% in 1961 to 0.61% in 1985. The other did not show any change in the risk of infection between 1969 to 1984 (risk of infection 1.7% in both years). This result is considered consistent with a poorly functioning control programme leading to creation of chronic cases and drug resistance. In fact in clinical practice chronic cases are often seen and resistance in tuberculosis is also becoming a matter of concern. Only a few laboratories are conducting drug sensitivity testing for TB in India. Although data on drug resistance is scarce & resistance is not systematically monitored, available information (Annex - 7 & 8) is a cause for concern. The very high rate of secondary resistance to both Rifampicin and Isoniazid is particularly very serious, with long term implications as these patients will transmit incurable form of Tuberculosis in the community.

Because most adults were infected in their youth, a small decrease in RI would not have any rapid impact on the prevalence of infection in the adult population. It is safe to estimate that at least 50% of the population above the age of 20 years is infected and will remain at risk of disease and death from tuberculosis for their lifetime. A conservative estimate is that, currently, the RI for India is 1.7 to 2%.

Notifications

Registration under the National Tuberculosis Control Programme highlights the problem of increasing over diagnosis of smear negative and under diagnosis of smear positive cases. During the period from 1980 to 1991, the number of District TB Centres increased from 320 to 387. However the trend reflects (Annex - 9) an increased proportion of cases not confirmed by smear examination. The proportion of smear positive cases has decreased from 25% in 1980 to about 20% in the late 80s. lapses, failures, partially treated patients are often inappropriately included in these notifications.

Current TB rates

As per NTI estimates of 1974, about 8,70,000 new smear positive TB cases have occured in 1992. This number is very similar to the 850000 estimated on the basis of incidence rate from the Tuberculosis prevention trial undertaken by TRC Madras. If the current average annual risk of infection is 1.7%, 1.6 million new TB cases occur annually of which 7,10,000 are smear positive. About 1/3rd of the total Tuberculosis burden is borne by the urban conglomeration (Annex - 10).

Age and Sex Distribution

The majority of tuberculosis cases in India occur below the age of 45 years, with about 75% of the diagnosed cases between 15 and 44 years old. Age-specific estimates of incidence during 1974 applied to the 1992 population, suggest that about 58% of all cases today occur between 15 and 44 years old. Two thirds of the cases are estimated to occur among males but tuberculosis takes a proportionally larger toll on young females than among young males. More than 50% of female cases occur before age 34.

Mortality

Total mortality due to TB is uncertain but by any estimate it poses a huge economic burden for India. TB mortality is estimated to be 420000 deaths every year (50/100000 population).

Cumulative mortality during the decade to the year 2000 will probably exceed 3.5 million deaths, an enormous burden for the society. A large share of these premature deaths can be avoided with a well-functioning programme. Given the ages at which deaths from tuberculosis are now occurring and the low costs for tuberculosis programme inputs in India, it is probable that the discounted cost per healthy year of life gained as a result of a

well-functioning tuberculosis control programme will be well under $ US 10, making tuberculosis control one of the highest priority interventions for the State and Central Governments.

HIV & Tuberculosis

HIV was first reported in Indian in 1986. There is no significant evidence yet available indicating its likely impact on the TB situation in India. As a large proportion of Indian population (50% of the adult population) is already infected with tuberculosis, it is most likely that with the spread of HIV, the epidemiological situation of tuberculosis will detoriate. Limited data indicate that sero-positivity for HIV among TB patients is much higher than that of the rest of the general population. Upto the end of 1993 of the 559 AIDS patients 331 (60%) had evidence of active tuberculosis. As per the National AIDS Control Programme currently there are about 0.75 million persons infected with HIV. Assuming half of these people are infected with tuberculosis and that the break down rate from TB infection to disease among dually infected individual is 10% per year, more than 35000 HIV related TB cases are likely to occur annually.

With the spread of HIV renewed concern for tuberculosis made authorities to look into the implementation of the programme critically and the programme was nationally reviewed through a group of national and international experts. Some of the observations of the review committee are (Annex - 11):

1. Inadequate budgetary outlays and shortage of drugs
2. Undue emphasis on X-ray instead of sputum testing for diagnosis.
3. Poor quality of microscopy.
4. Emphasis on detection of new cases instead of achievement of cure.
5. Poor organisational set-up and support for T.B.
6. Lack of consensus among practitioners regarding treatment regimens.

As a follow up measure the National Technical Management Group was strengthened through induction of senior level experts and a revised strategy was drafted.

Several core-trainers were trained in the implementation of the revised NTP at the national and international level with the support of WHO and a large number of professionals were trained to implement the revised NTP on a pilot basis in 5 sites namely Delhi, Bombay, Calcutta, Bangalore and Gujarat. These pilot projects are being implemented with SIDA support. The results are found to be very encouraging; smear conversion rate after having 3 months of treatment was around 85%. During the coming one year more pilot sites are being included for the implementation of the revised NTP with World Bank Project Preparation Facility Advance. It has been proposed that during this year one district in each of the 5 states and 1 site in each of the 10 metropolitan cities will be covered with the revised National Tuberculosis Control Programme on a pilot basis with World Bank assistance, with a total population around 14 million.

Operational components of the revised NTP

Some of the important operational components of the revised NTP will be (Annex 12 - 13):

(1) To strengthen the sputum microscopy facilities so that quality sputum microscopy is available as close to the people as possible through training of Laboratory Technicians and expanding the network of laboratory facilities and diagnosing Tuberculosis cases at least on 3 sputum smear examination instead of only one as it is done now.

(2) To involve the most peripheral health functionary in supervised drug administration of anti-TB drugs during the intensive phase.

(3) To make available anti-TB drugs uninterrupted to all the peripheral health facilities in multi-drug blister packs.

(4) To create supervisory team at the sub-district level (0.5 million population) to improve the quality of supervision, monitoring and evaluation.

(5) To decentralise District TB cases registration at the sub-district level.

(6) To strengthen the epidemiological capability in cohort analysis etc through proper training and strengthening of the infrastructure.

(7) To augment operational research activities to improve the programme implementation.

(8) To augment training facilities both at the National and State level through expansion of the existing infrastructure.

(9) To establish professionally designed IEC activities to support the implementation of the programme.

The initial results available from the pilot sites indicate high sputum conversion rate around 85% and it appears that it will be possible to achieve high cure rate through revised strategy. Under the revised strategy it is envisaged that the new sputum positive cases and seriously ill sputum negative cases will be on 4 anti-TB drugs nemely INH, rifampicin, pyrazinamide and ethambutol for a period of 2 months and then during the continuation phase of 4 months they will be given INH and Rifampicin. All the drugs will be administered 3 days in a week. All cases of sputum positive relapses, failures etc. will be given the above mentioned 4 anti-TB drugs for a period of 3 months. In addition injection streptomycin will also be given. During the continuation phase these patients will receive 3 anti-TB drugs nemely INH, Rifampicin and Ethambutol for a period of 5 months. All the drugs will be administered 3 days in a week. Sputum negative less seriously ill cases will be either given standard conventional chemotherapy for a period of 12 months with INH and Ethambutol or INH and Thaicetazone or they may also be given if resources are available 3 anti-TB drugs for a period of 2 months like INH, Rifampicin and Pyrazinamide. Subsequently they will receive 2 drugs INH and Rifampicin for a period of 4 months.

Operational Research

Operational research activities are going to be augmented so that the National Tuberculosis Control Programme gets appropriate support for improving the efficiency of the implementation of the programme.

Let me put on record the appreciation of our country for the technical cooperation and guidance of WHO in implementing the revised NTP on a pilot basis as well as the financial support of the Government of Sweden. Several operational studies to assist in the formulation of the revised NTP and implementing the same are under consideration. Some of the operational studies which are under progress and which are going to be initiated are (Annex - 14):-

(1) Studies on risk of infection in different parts of India.

(2) Cohort analysis

(3) Perception and attitude towards tuberculosis for professionals and general population.

(4) Revaluation of the reasons and level of delay in the diagnosis of sputum positive pulmonary tuberculosis under programme conditions in South India.

(5) Effectiveness of village-based health functionaries in improving treatment adherence of tuberculosis patients.

(6) Minimising mis-diagnosis in smear negative Tuberculosis.

ANNEXURE - 1

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

IN INDIA

INDIA AT A GLANCE

POPULATION (1991 CENSUS)	-	840 MILLION
PROVINCES (INCLUDING UTS)	-	32
DISTRICTS	-	459
STANDARD DISTRICT POPULATION	-	1.7 MILLION

ANNEXURE - 2

NATIONAL TUBERCULOSIS CONTROL PROGRAMME IN INDIA

TUBERCULOSIS SERVICES

NO. OF DISTRICT TB CENTRES	-	390
NO. OF TB CLINICS	-	330
NO. OF TB BEDS	-	47,300
NO. OF DISTRICTS WITH S.C.C.	-	253

INDIA - TUBERCULOSIS CONTROL PROGRAMME

YEAR	RATE OF NEW TB CASES DETECTED UNDER NTP PER 1000 POPULATION	RATE OF SMEARS POSITIVE TB CASES DETECTED UNDER NTP PER 1000 POPULATION
1981	1.13	0.28
1982	1.32	0.31
1983	1.51	0.36
1984	1.52	0.36
1985	1.57	0.36
1986	1.68	0.37
1987	1.81	0.37
1988	1.85	0.37
1989	1.87	0.38
1990	1.84	0.38
1991	1.79	0.38

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

IN INDIA

REVISED NTP

STRATEGY

1. TO CHANGE THE CURRENT EMPHASIS ON RADIOLOGICAL DIAGNOSIS TO SPUTUM MICROSCOPIC DIAGNOSIS

2. TO MAKE AVAILABLE DIRECTLY SUPERVISED S.C.C. TO ALL SPUTUM POSITIVE AND SERIOUSLY ILL SPUTUM NEGATIVE CASES INVOLVING PERIPHERAL HEALTH FUNCTIONARY

3. TO MAKE AVAILABLE ALL CATEGORIES OF ANTI-TB DRUGS IN APPROPRIATE MULTI-DRUG BLISTER PACKS, UNINTERRUPTED TO ALL PERIPHERAL POINTS

ANNEXURE - 5

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

IN INDIA

REVISED NTP

STRATEGY

4. TO STRENGTHEN EPIDEMIOLOGICAL CAPABILITY OF DTC AND STATE TB CENTRES IN EFFECTIVE IMPLEMENTATION, MONITORING AND EVALUATION INCLUDING COHORT ANALYSIS.

5. PROFESSIONALLY MANAGED IEC CAMPAIGN

6. OPERATIONAL RESEARCH

ANNEXURE -

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

IN INDIA

EPIDEMIOLOGICAL PICTURE

RISK OF INFECTION

PREVALENCE OF INFECTION	RI	YEAR	LOCATION	SOURCE
4.9%	1.0%	1961	TUMKUR	NTI
9.6%	2.0%	1969	TIRUVALLORE	TRC
10.1%	2.1%	1983	BANGALORE	NTI
10.4%	2.2%	1984	DHARMAPURI	NTI
3.1%	0.6%	1985	BANGALORE	TRC
9.0%	1.9%	1989	KADAMBATMUR	TRC
11.2%	2.3%	1989	THIRUVELANGADU	TRC
6.7%	1.4%	1989	NORTH ARCOT	TRC

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

IN INDIA

DRUG RESISTANCE

DATA ON DRUG RESISTANCE SCARCE

RESISTANCE IS NOT SYSTEMATICALLY MONITORED

SOME STUDIES REVEAL THE FOLLOWING:

PRIMARY/INITIAL DRUG RESISTANCE

TYPE OF PATIENT AND SAMPLE SIZE		% RESISTANCE TO S	H	R	RH	SRH
NEW CASES BY HISTORY						
241	MADRAS	7.3	12.6	1.6	0.8	0.8
244	RAICHUR	11.0	19.1	3.2	2.0	1.2
324	DELHI	-	18.5	-	0.6	-

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

IN INDIA

DRUG RESISTANCE

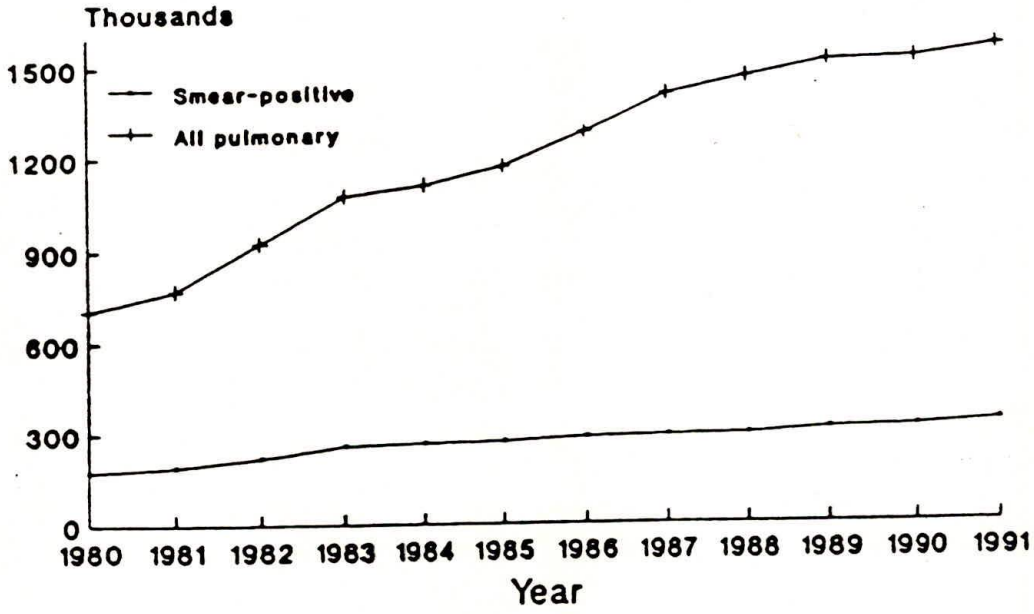
ACQUIRED DRUG RESISTANCE

TYPE OF PATIENT AND SAMPLE SIZE		% RESISTANCE TO S	H	R	RH	SRH
PREVIOUSLY TREATED						
37	MADRAS	35.0	62.0	13.5	5.4	8.1
111	RAICHUR	11.7	52.7	17.1	5.4	11.7
FAILURE						
81	DELHI CENTRE	-	50.7	-	33.3	-
354	DELHI SUBURBS	-	78.8	-	61.5	-
560	NORTH ARCOT	30.0	65.0	16.0	6.0	9.0

*

* Ind. J.Tub. Vol.39 No.2 pp 121-124.
* WHO TB Programme Review - 1992

Figure 1. India: Notifications of cases of tuberculosis, 1980-1991



Extra-pulmonary cases are not reported
Source: NTI, 1992

NATIONAL TUBERCULOSIS CONTROL PROGRAMME IN INDIA

EPIDEMIOLOGICAL PICTURE

CURRENT A.R.I	- 1.7%
NEW CASES (ALL FORMS)	- 1.6 MILLION PER YEAR
NEW SMEAR POSITIVE CASES	- 0.71 MILLION PER YEAR
MORTALITY	- 0.42 MILLION PER YEAR

SOURCE: WHO REVIEW, 1992

ANNEXURE - 11

OBSERVATIONS OF THE REVIEW COMMITTEE

1. INADEQUATE BUDGETARY OUTLAYS AND SHORTAGE OF DRUGS

2. UNDUE EMPHASIS ON X-RAY INSTEAD OF SPUTUM TESTING FOR DIAGNOSIS

3. POOR QUALITY OF MICROSCOPY

4. EMPHASIS ON DETECTION OF NEW CASES INSTEAD OF ACHIEVEMENT OF CURE

5. POOR ORGANISATIONAL SET-UP AND SUPPORT FOR T.B.

6. LACK OF CONSENSUS AMONG PRACTITIONERS REGARDING TREATMENT REGIMENS

ANNEXURE - 12

OPERATIONAL COMPONENTS OF THE REVISED NTP

1. TO STRENGTHEN THE SPUTUM MICROSCOPY FACILITIES SO THAT QUALITY SPUTUM MICROSCOPY IS AVAILABLE AS CLOSE TO THE PEOPLE AS POSSIBLE THROUGH TRAINING OF LABORATORY TECHNICIANS AND EXPANDING THE NETWORK OF LABORATORY FACILITIES AND DIAGNOSING TUBERCULOSIS CASES AT LEAST ON 3 SPUTUM SMEAR EXAMINATION INSTEAD OF ONLY ONE AS IT IS DONE NOW.

2. TO INVOLVE THE MOST PERIPHERAL HEALTH FUNCTIONARY IN SUPERVISED DRUG ADMINISTRATION OF ANTI-TB DRUGS DURING THE INTENSIVE PHASE.

3. TO MAKE AVAILABLE ANTI-TB DRUGS UNINTERRUPTED TO ALL THE PERIPHERAL HEALTH FACILITIES IN MULTI-DRUG BLISTER PACKS.

4. TO CREATE SUPERVISORY TEAM AT THE SUB-DISTRICT LEVEL (0.5 MILLION POPULATION) TO IMPROVE THE QUALITY OF SUPERVISION, MONITORING AND EVALUATION.

OPERATIONAL COMPONENTS OF THE REVISED NTP

5. TO DECENTRALISE DISTRICT TB CASES REGISTRATION AT THE SUB-DISTRICT LEVEL.

6. TO STRENGTHEN THE EPIDEMIOLOGICAL CAPABILITY IN COHORT ANALYSIS ETC THROUGH PROPER TRAINING AND STRENGTHENING OF THE INFRASTRUCTURE.

7. TO AUGMENT OPERATIONAL RESEARCH ACTIVITIES TO IMPROVE THE PROGRAMME IMPLEMENTATION

8. TO AUGMENT TRAINING FACILITIES BOTH AT THE NATIONAL AND STATE LEVEL THROUGH EXPANSION OF THE EXISTING INFRASTRUCTURE.

9. TO ESTABLISH PROFESSIONALLY DESIGNED IEC ACTIVITIES TO SUPPORT THE IMPLEMENTATION OF THE PROGRAMME.

ANNEXURE - 1

OPERATIONAL RESEARCH

1. STUDIES ON RISK OF INFECTION IN DIFFERENT PARTS OF INDIA

2. COHORT ANALYSIS

3. PERCEPTION AND ATTITUDE TOWARDS TUBERCULOSIS FOR PROFESSIONALS AND GENERAL POPULATION.

4. REVALUATION OF THE REASONS AND LEVEL OF DELAY IN THE DIAGNOSIS OF SPUTUM POSITIVE PULMONARY TUBERCULOSIS UNDER PROGRAMME CONDITIONS IN SOUTH INDIA.

5. EFFECTIVENESS OF VILLAGE-BASED HEALTH FUNCTIONARIES IN IMPROVING TREATMENT ADHERENCE OF TUBERCULOSIS PATIENTS.

6. MINIMISING MIS-DIAGNOSIS IN SMEAR NEGATIVE TUBERCULOSIS

NATIONAL CONSULTATION ON TUBERCULOSIS

Venue : VHAI Conference Room.

PROGRAMME

13 July 1994

09.30 - 10.30 a.m.	Inauguration. Mr.Alok Mukhopadhyay Introduction of Objectives. Dr.H.Sudarshan Introduction of Participants.
10.30 - 10.45 a.m.	TEA
10.45 - 12.45 p.m.	Chairperson: Dr.Mira Shiva National TB Control Programme. Concept and bottlenecks. Dr.B.T.Uke Present status of TB in India Revised National TB Control Programme Dr.K.K.Datta NTP- Past, Present and Future Dr.D.Banerjee
12.45 - 01.30 p.m.	LUNCH
01.30 - 02.30 p.m.	Chairperson: Dr.Thelma Narayanan TB as part of Comprehensive Health Care Dr.M.A.Seetha Dr.Mukund Uplekar Dr.Shavinder Singh Dr.Narendra Gupta TB in certain Occupations Dr.J.R.Parikh Mr.L.C.Tyagi

02.30 - 03.00 p.m.	Chairperson: Dr.P.K.Choudhari General Practitioners in TB care. Dr.S.N.Misra Dr.Jagdish Sobti Dr.Kalindi Thomas Dr.Alfred Edwards
03.00 - 03.30 p.m.	Chairperson: Dr.M.A.Seetha TB in Women and Children Dr.Sarah Walters Dr.Virender Singh
03.30 - 03.45 p.m.	TEA
03.45 - 05.00 p.m.	Chairperson: Dr.Anil P Group Discussion: Problems in TB care

14 July 1994

09.30 - 10.30 a.m.	Chairperson: Dr.Mukund Uplekar
	TB and AIDS. Dr.P.N.Sehgal Dr.D.Banerjee
	TB and Leprosy Dr.Cornelius Walters Dr.H.Sudarshan
10.30 - 10.45 a.m.	TEA
10.45 - 11.45 a.m.	Chairperson: Dr.H.Sudarshan
	Drug therapy, Drug resistance and Drug availability. Dr.L.Suryanarayana Dr.Mira Shiva
11.45 - 01.00 p.m.	Chairperson: Dr.S.P.Pamra
	NGO experiences in TB care Dr.H.Sudarshan Dr.Prabir Chatterjee Mr.Joseph Vazhakala Mr.Sanjoy Ghosh Dr.S.K.Singh
01.00 - 01.45 p.m.	LUNCH
01.45 - 03.00 p.m.	Chairperson: Dr.Mira Shiva
	Group Discussion: Solutions to Problems identified
03.00 - 04.00 p.m.	Chairperson:Dr.H.Sudarshan
	Plan of action.
04.00 - 04.15 p.m.	TEA
04.15 - 05.30 p.m.	Valedictory session. Dr.D.Banerjee Dr.K.K.Datta Dr.B.T.Uke Dr.H.Sudarshan Dr.Mira Shiva
	Vote of Thanks Dr.Anil P

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Name of the Paper : MID-DAY
Published at : NEW DELHI
Dated : 17 MAY 1994

Drug shortage adds to TB patients' woes

DELHI MID DAY CORRESPONDENT
NEW DELHI, May 17

The shortage of essential drugs in the city hospitals has compounded the Capital's deteriorating tuberculosis problem. However the patients seem to have found a new way of adjusting to this menace — by developing drug resistance!

According to health experts, frequent shortage of TB drugs in the TB clinics and chest clinics, have caused patients to develop a resistance to the drugs. The discontinuity in the intake of drugs due to irregular drug supply in the hospitals has resulted in such a situation.

"Drug resistance is showing a rising trend", says Dr Rupak Singhla of Lalla Ram Swaroop Institute for TB and Allied Diseases. However, Dr KK Datta, project manager of the National Tuberculosis Control Programme maintains that this problem is not of much concern for TB is still curable.

In a recent study made by the New Delhi TB Clinic Centre, the prevalence of acquired resistance was found to be 50 per cent for Iso Nicotonic Acidhydrazide and 33 per cent for Rifampcin, the first line of drugs given to tuberculosis patients. However, more cases of drug resistance were noticed in Gujarat.

Acquired resistance develops due to irregular intake of the drugs. Besides natural resistance, primary resistance is also responsible for drug failure.

Drug failure can be defined as the temporary or permanent capacity of organisms and their progeny to remain viable and multiply in the presence of a concentration of the drug, that would normally destroy or inhibit the growth of these cells.

Following this drug failure the second line of drugs like Kananmycin, Capreomycin , Viomycin Amikacin, Cycloserine, Ethionamide, Prothionamlide are prescribed which are more costly and less effective, and have side effects, says Dr RC Jain, director of the hospital. The first line of drugs are streptomycin, Isoniazid, Rifampcin, Ethionamide, Pyrazinamide and Thiacetazone.

However, for matters to have reached this level, the patients too are to be blamed, as they do not take the prescribed drugs regularly, adds the director. The patients discontinue the drug intake as soon as they get well despite instructions from the doctors. Due to the premature discontinuance of the medicines, the disease manifests itself again within two years, explained the director. The chemotherapy varies from six months to a year and varies from individual to individual depending on the severity of the disease caused by the bacteria, Mycobacterium Tuberculosis.

Most of the hospitals at one time or the other face a shortage of drugs. Guru Teg Bahadur hospital, which also has a chest clinic, was short of Rifampcin in March this year. The other TB clinics in the city are often short of drugs.

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Name of the Paper : THE HINDU BUSINESS LINE
Published at : NEW DELHI
Dated : 17 APR 1994 (Delhi Edition)

Glaxo plans to make TB drugs

Our Staff Correspondent
BOMBAY,

GLAXO India Ltd has drawn up plans to enter the anti-TB drug market in a big way.

The company has entered into a licensing arrangement with an Italian company for a long-acting compound which may be required to be taken in lesser doses and at longer intervals compared to the conventional rifampicin therapy. The company has already started pre-registration clinical trials, expected to be completed in a couple of years, according to a company official.

As a precursor to the introduction of this new molecule, the company plans to make its presence felt in the conventional anti-TB drug market by marketing rifampicin.

Glaxo Plc, UK, had initiated a collaborative programme of research to combat TB, early last year. Titled 'Action TB', the programme brought together research centres in the UK and South Africa.

The four UK-based research centres are Glaxo group research, Middlesex, the London School of Hygiene and Tropical Medicine, St. Mary's Hospital Medical School, London and the University of Birmingham. The South African centres collaborating in this venture have been formed into three groups centred at the Universities of Capetown and Stellenbosch as well as the South African Medical Research Council.

A statement issued by Glaxo pointed out that although it was believed that TB had been eliminated, it had been proved wrong and that the World Health Organisation had once again declared TB a global public health emergency. One of the major reasons attributed to the resurgence of TB is its close association with the HIV virus. Another factor is the emerging resistance to commonly used antibiotics.

Action TB is a five-year programme initially and is to be funded and managed by Glaxo Plc with a total investment of 10 million pounds.

However, Glaxo India's foray into this area has not been prompted by its parent company's collaborative programme and the two decisions together are coincidental, says a top company official.

Name of the Papar : PATRIOT
Published at : NEW DELHI
Dated :

5 lakh die of TB each year: Report

United News of India

The Health Ministry has prepared a project proposal for obtaining World Bank financial assistance based on short-term course chemotherapy for sputum positive tuberculosis cases.

This has been revealed in the departments of health and family welfare annual report for 1993-94 in the Capital which admits that there are about 500,000 death in the country annually on account of tuberculosis.

The report expresses concern that while 500,000 tuberculosis patients are cured every year, this is being overshadowed by an addition of one million sputum positive cases annually.

The cost of drugs alone for ensuring coverage of these sputum positive cases would come to about Rs 150 crore per year. The central plan outlay for 1994-95 for the programme was Rs 50 crore.

The Ministry is of the view that World Bank assistance for tackling the sputum positive cases was necessary, while the non- infectious cases could be treated with cheaper conventional therapy.

According to the report, the Ministry has also approached the World Bank for Rs 554 crore assistance for an intensive blindness control programme in the seven States, Tamilnadu, Andhra Pradesh, Maharashtra, Madhya Pradesh, Uttar Pradesh, Rajasthan and Orissa.

The sanction of Rs 302 crore World Bank aid for leprosy eradication, the ban by 23 States on salt other than iodised salt to check Iodine Deficiency Disorders (IDD), a 90 per cent drop in leprosy cases in the 40 districts covered by Multi-Drug Therapy (MDT) in five years or more and 16.6 per cent increase in acceptors of family planning methods over the last year, marginal fall in infant mortality rate are some of the achievements highlighted in the annual report.

On the health sector, the report says that in the proposed World Bank project for leprosy eradication Rs 302 crore would be provided to cover 66 endemic districts under MDT of the 201 endemic districts in the country, 135 have been covered by MDT services.

In addition, 77 moderately endemic districts would be taken up under the modified MDT programme which involves treatment with the combination of three drugs — rifampicin, clofazimine and dapsone.

The report says more than 10.52 lakh cases had been discharged as cured as against the target of 5.73 lakh in 1993-94.

The Ministry had a plan outlay of Rs 483 crore for health for 1993-94, of which more than 60 per cent had been used for national programmes for the control and eradication of communicable diseases including malaria, AIDS, leprosy, TB and blindness.

On the family welfare sector the report notes that under the programme about 155 million births had been averted so far. It has also succeeded in reducing birth rate from 41.7 per thousand in 1951-61 to 29 in 1991, the total fertility rate from 5.97 to 3.8 during the same period, the infant mortality rate from 146 to 79 and increasing the couple protection rate from 10.4 per cent in 1070-71 to 43.4 per cent by March 1993.

Dated 11 MAR 1994

Lack of drugs plagues MCD TB clinics

Vidya Deshpande
New Delhi

IRREGULAR SUPPLY of drugs at the seven Municipal Corporation of Delhi-run chest clinics in the Capital has resulted in a longer and avoidable period of treatment for sundry TB patients.

A random check at the chest clinics revealed that many patients have been visiting the clinics for over a year, though TB is usually cured within a year, if the drugs are taken regularly. The clinics are located in Gulabi Bagh, Jhandewalan, Kilokri, Kingsway Camp, Moti Nagar, Narela and Shahdara.

The erratic supply of medicines is a fallout of a faulty drug purchasing policy and lack of adequate funds. Because of this irregular supply, the medication routine of patients is getting upset, leading to drug resistance in many cases. As a result, the disease takes a longer time to get cured and patients suffer for longer period.

Mr Trilok Singh, a resident of Kalyanpuri, has been visiting the Shahdara chest clinic for the past 18 months, but is still continuing with medication. "Sometimes the medicines are not available and we are asked to buy them from the market. But how can I afford to buy the tablet, which costs Rs 6," he said.

The Medical Superintendent of the 1,200-bed Rajan Babu TB Hospital, Dr J N Banvaliker, said the national policy on TB had to be radically changed, if TB were to be contained.

The two drugs being supplied to the MCD clinics, which were also part of the National TB Control Programme, were not readily available in the market, Dr Banvaliker said. The manufacturers concentrate on producing the more sophisticated drugs, which are naturally more expensive. "And the TB medicine budgets are so low that they are insufficient to even supply the cheaper drugs to all the patients," he said.

The RBTB Hospital has a budget of Rs 60 lakh for medicines, while the hospital needs Rs 2 crore to supply all the medicines to its indoor patients.

Dr S U Bhakta, in-charge of the MCD programme, said though the requirement was Rs 1 crore, the entire MCD health budget was just Rs 35 lakh. The MCD was getting an aid of Rs 45 lakh from the Central Government for medicines, but this too was insufficient, he said.

The National TB Control Programme is being run on the sample survey, conducted by the Indian Council of Medical Research (ICMR) way back in 1957. "No national survey has been conducted after this, though a couple of local surveys have been done up to 1983," Dr Bhakta admitted.

The 1957 survey showed that 15 persons per 1,000 were "radiologically TB active". And only a fourth of these patients were high-risk cases, showing positive sputum results. "The number of TB cases has not increased since then," Dr Bhakta maintained.

He blamed the patients for the prolonged duration of the disease, saying many of them defaulted on the prescribed course. "After a month, when they begin to feel all right, they usually stop taking the medicines," Dr Bhakta said. It is hoping to bag a World Bank aid of Rs 900 crore for the national programme. Till such time, the patients will continue to suffer.

Name of the Paper : FREE PRESS JOURNAL
Published at : BOMBAY
Dated : 27 MAR 1994

Is tuberculosis becoming drug-resistant?

By Pravin Kumar

TUBERCULOSIS (TB) has been on the run during this century, thanks to powerful drugs like isoniazid, rifampicin and pyrazinamide. But since 1985, the microbe causing the disease, 'Mycobacterium Tuberculosis', seems to be fighting back. For instance, 20.57 per cent of 588 patients attending the Lady Willingdon State TB Centre, Bangalore, were found resistant to one drug or another. The team of scientists of the National Tuberculosis Institute, Bangalore, conducted the study and regard the findings as disquieting. These come at a time when Short Course Chemotherapy, including rifampicin, is proposed to be introduced on a nationwide basis, for similar results have been reported elsewhere.

TB is one of the many bacterial infections like pneumonia, dysentery and malaria which are showing resistance to drugs. Doctors in hospitals and clinics around the world are losing the battle. "We don't have any more new effective drugs in sight for managing these resistant cases," says Dr. B. T. Uke, Director of the National Tuberculosis Institute, Bangalore.

Among infectious diseases, TB remains the leading cause of death. Each year, there are an estimated 8 million new cases of TB and 2.9 million deaths from the disease. In global terms, TB accounts for 6.7 per cent of all deaths in the developing world and for 18.5 per cent of all deaths in adults aged 15 to 59. Last April, the World Health Organisation (WHO) declared tuberculosis a 'global emergency' and warned that the disease would claim 30 million lives in the next decade. What is worse, the disease is working in tandem with AIDS, the disease that breaks down the body's immune system. In fact, TB has become a 'sentinel' disease for AIDS, often being the first hint that a person has the latter disease.

BCG vaccine

For long, it was believed that the only treatment for TB was improved sanitation and outdoor life. In 1908, Albert Calmette and Camille Guerin showed that a non-virulent strain of the bacterium could provide immunity against the disease. The vaccine, BCG (Bacille Calmette Guerin) is now the most widely used vaccine in the world. Effective treatment for the disease came with streptomycin (1947) and isoniazid (1952), which dramatically reduced the number of TB deaths.

The bacteria usually spread through an infected person's cough. About 10 per cent of infected persons develop the active disease. The main symptoms are fever, night sweats, weight loss, racking cough and spitting of blood. From the lungs, the initial site of infection, the bacilli spread through the lymphatic system and the blood to the bones, genito-urinary system and the skin; this occurs in about 15 per cent of patients.

The infected persons themselves don't notice the symptoms. 40 to 60 per cent of untreated TB patients die. Treatment with a combination of isoniazid, rifampicin and pyrazinamide for six months cures 90 per cent of them. But the new drug-resistant strains of the bacillus are resistant even to the combination of two or more drugs. "This is the result of irregular treatment due to non-compliance by patients," explains Dr. R. Prabhakar, Director of the Tuberculosis Centre of the ICMR, Madras. In the USA, more than 20 per cent of TB patients fail to complete their course of drugs, according to the Centre for Disease Control and Prevention (CDC), Atlanta.

Conventional wisdom holds that a single infection confers immunity against second attack of TB, but this is no longer true with the appearance of multi-drug resistant TB. "Multi-drug resistant TB is in fact pushing us back to the pre-antibiotic days," warned Louis W. Sullivan, former US Secretary of Health and Human Services. Since 1986, there has been an overall increase of about 18 per cent in TB cases in the US. The active transmission of the disease is greater in high-risk groups like those living in homeless shelters and prisons, in intravenous drug users and health care workers, but it is feared that the disease is also spreading into the general population.

Sporadic treatment

The effect of sporadic treatment is merely to kill off microbe strains that lack resistance to the drugs, enriching the population of resistant ones, so that they eventually break down the body's natural defences. Since each site of TB infection in the patient's lungs contains 10 to 100 million microbes, this can happen in a matter of months.

The AIDS connection

What is worse, the AIDS epidemic has given a boost to TB. In India, the link between TB and AIDS has been noticed at various research centres. With a million identified HIV carriers in the country, the threat of a TB epidemic cannot be taken lightly. According to Dr. Uke, the risk of HIV-positive patients developing TB is about 10 per cent every year. A few sporadic reports indicate that 3 to 8 per cent of new TB patients are HIV-positive and 50 to 60 per cent of HIV-positive may develop TB. Dr. Prabhakar says that the attack rate of TB could be 20 to 30 times higher among HIV cases than in normal individuals.

Hence, all efforts should be made to control HIV infection in order to contain TB.

Ironically, most HIV-infected patients often test negative to the tuberculin skin test because their weakened immune systems cannot produce the tell-tale red welt that signals TB infection. However, comments Dr. Prabhakar, "it may be presumed that tuberculin sensitivity in a HIV-infected individual could be used as an indicator of the progression of HIV infection to full-blown cases."

Losing battle

Medicine has so far kept one step ahead of bacterial mutations with new drugs, but bacteria with new resistance genes have been appearing much more rapidly — just two years after the newest batch of antibiotics appeared in the late 1980s. Drug companies have lost interest in developing expensive TB drugs for patients in developing countries (which can't afford them). However, discoveries like that of Douglas Young regarding the nature of drug resistance could spur better drug design. Until new drugs come up, it would be worthwhile for health care workers to pay more attention to basic sanitation. Even more importantly, to educate doctors to prescribe the right antibiotic for a disease, particularly in hospitals, where one-third of the patients are on antibiotics and where selective pressure leading to drug-resistant microbes is highest. Patients, too, should make sure that they complete a course of antibiotics in order to wipe out all infecting bacteria.

It will also be critical to identify reservoirs of drug-resistant strains of bacteria. For this, WHO has set up WHONET, which aims to link hundreds of microbiology laboratories round the world to pool information about drug-resistant strains of bacteria and viruses.

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Spreading risk of tuberculosis

Jaidev Sharma

A recent report of the World Health Organisation (WHO) states that tuberculosis kills around three million people a year worldwide. The death rate is highest around the age of 30, so those deaths represent a lot of lost years. Now the chances of sick people dying, and of infected people sickening, are quickly getting worse. Yet those responsible for making funding decisions in the international community have failed to supply the money needed to curtail the epidemic. Because little is being done by international agencies to halt the rapid spread of tuberculosis and that incurable forms of the disease will become more common and if it continues to be given low priority, the report says.

According to experts, TB is caused by a bacterium that can be passed through the air when someone with the disease sneezes of coughs. While the majority of the people with TB show no symptoms and are not infections, they are at risks of developing active TV throughout their lives. And that TB, which is trated by giving patients medication over a six month period can become resistant to drugs when the treatment is inadequate or interupted.

Surprisingly, the New York city in order to combat prevalent epidemic of TB is given itself the right to lock away its TB patients who persistently fail to complete their TB treatment course, But the situation is worse in the developing countries like India who have poor tuberculosis programmes.

Earlier, TB was caused by cramped living conditions, poor hygeine, lack of nutritious diet and poverty but now AIDS have further triggered off this epidemic in most part of the world.

A survey conducted recently in Africa and other countries where the prevalence of HIV and TB infection is very high, reveals the close link between these two infections diseases. In Africa TB is present in 50 per cent of the AIDS patients. While studies carried out in Bombay show that about 6 per cent of the TB patients also have HIV infection. Deadly association between HIV infection and TB has also been reported from Europe, America, Thailand and Australia.

An expert of the Tuberculosis Association of India estimates that in the next ten years or so the number of TB cases in India will considerably go up. The Deputy Director of the New Delhi TB centre also presents the grim scenario in our country about this infectious disease in more revealing terms. He states that at present, India alone has 50 per cent of the TB population in the world. He argues that the problem of TB is increasing because of day by day increase in population.

Evidentally, government agencise telling us that TB is under control is not true. An expert reacts strongly to some reports which appeared lately claiming that TB has re-emerged in our country. He says that TB was never controlled in India, so there is no question of its coming back. It has always been a serious health problem in our country for the last four decades.

A study on the epidemicological aspects of the TB, conducted for a period of 20 years in New Delhi Tuberculosis Centre (1962-82), found no appreciable change in the TB graph of our country.

So, if no adequate and immediate effective control measures are taken to combat the TB problem, our experts estimate that our country by the year 2001 might have 20 million TB patients of which over 4.21 million would be spreading in infection to their fellow Indians and more than 73,000 Indians may die due to TB, every month.

In my view, there should be a concrete plan for running mobile clinics in tuberculosis control measures. These clinics should he provided with X-Ray apparatus for taking miniature films, the collection of specimens and for conducting simple examination. It will operate in such a way that the villages and the slum areas covered by the mobile clinic will be taken up a new once every two months, The working of this clinic should be attached with the National Tuberculosis Association of India (TAI) New Delhi.

The TAI is an organisation which is wholly devoted to the eradication of TB in India. The Association was founded in February 1939 as a voluntary body for carrying out an informed and sustained compaign against this dreaded disease and to take such steps as are feasible by arranging conferences, establishing model institutions and training tuberculosis workers and carrying out health education activities.

It is reported that is Denmark TB hospitals had to be turned to other uses because there were no cases of TB. No doubt, such progress in India seems a rosy dream, but where there is a will, there is a way.

The science of modern warfare gives the destruction of enemy bases and of their lines of communication a very high place in its operational reportory. In our war against this disease we must give it an equal importance.
— INFA

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Tuberculosis
AIDS

VH PK

Rx HEALTHFILE

PRASHANT TRIKANNAD

Made for each other

FOR a country which has the misfortune of accounting for more than 6 lakh TB deaths out of an estimated worldwide mortality rate of 3 million annually, India – where a TB victim dies every single minute – is totally unprepared to counter the global resurgence of a disease that was long thought of as vanquished. It is not just tuberculosis that is looming up out of the darkness, but its menacing connection with HIV, the virus that causes AIDS. While the World Health Organisation wasted no time in labelling the disease as a "global public health enemy", the Indian government, which ought to have taken the lead in neutralising the new and far deadlier threat, did nothing. The Union Health Ministry, it would seem, is not even aware of the TB-HIV nexus.

A poor country like India can afford to ignore the deadly AIDS-TB combination at its own peril. The harsh reality is that treating a drug-resistant patient becomes a hundred times more expensive than treating one who adheres to the six to eight months anti-TB therapy. The resurgence of TB, especially through HIV carriers, is dangerous because an AIDS patient — whose defence mechanisms are already down — contracts TB that much faster. While such a victim may not pass on AIDS to one who has neither, he just might transmit the TB virus to the unsuspecting victim. And the net result: a killer epidemic that no one knows of.

TB has always been a time bomb.

While India is in an unenviable position to rattle off grim statistics on TB, it has no such data on the number of HIV patients who might have contracted the disease too. "In Bombay alone, at least 40,000-50,000 HIV patients are believed to have TB," prominent member of The American College of Chest Physicians (Western India Chapter) Dr. V. S. J. Rao said. The chest specialist cited a few case histories that could be a foretaste of the horrifying epidemic to come. Of the 920 patients examined for the HIV virus at the Watumull Chest Hospital at Mahim in Bombay, 29 were diagnosed as having both AIDS and TB.

"AIDS with TB is almost always fatal," world-renowned chest physician Dr. Edward A. Nardell told Blitz. The Assistant Professor of Medicine, Harvard Medical School, who was on a Lupin-sponsored lecture tour to India last month, feared

While TB is actually going down in the West, its resurgence, if any, in America, is multifactorial with AIDS playing a large part. "In my country, 5% of all TB cases are also HIV positive or 5% of the AIDS patients have TB," Dr. Nardell disclosed. The percentage of AIDS-TB victims in the US is, no doubt, negligible, but it has nevertheless shaken America's medical fraternity into doing something about it. Said Dr. Rao, "TB is transmitted in slow motion. Add HIV and the time for TB infection becomes shorter than you would think."

In many countries in the West, treatment of TB is either free or highly subsidised. In the US, for example, TB victims, particularly those who refuse to abide by the therapy, are isolated until they are fully cured. In fact, the patient automatically becomes a state responsibility. In India, there is no such thing as health subsidy. What little free health care and subsidies the government has to offer is nothing short of a farce. In Bombay's acclaimed KEM Municipal Hospital, TB patients have frequently complained of being told to buy drugs from private chemists. But, where is the money?

AIDS has just shortened

that the revival of TB and its link with the AIDS virus could hit India hardest. "In New York City, for instance, intravenous drug users and commercial sex workers who have AIDS are at gravest risk of getting TB, too. When they shirk anti-TB therapy, they develop drug resistance making curage for patients difficult," he said adding: "There is no good treatment that can wipe out TB in an AIDS patient. The case, thus, becomes complicated, Could India fare any better?"

Dr. Nardell might have something there. WHO has forecast as much as 5 crore AIDS patients in India by the year 2000 AD. Probably, even earlier than that. Just imagine the impact of AIDS with TB in a country which is the second most populated nation in the world... where the momentum of sex education has just begun to pick up... where the significance of proper health care is totally lost on the ignorant public... where the government really doesn't care a damn about health care. Said Dr. Nardell: "Today, in New York City, 20% of all HIV-positive cases having TB are resistant to anti-TB drugs." How long will it be before Bombay, Delhi, Madras and Calcutta follow suit?

"HIV positive patients risk a 5% to 10% chance of getting TB every year," Lupin's Medical Director Dr. (Mrs) U. K. Sharma said. In the course of her research, Dr. Sharma found that five Indians out of every 1,000 developed TB, many at an earlier stage. "Just one victim can infect at least 12 others in his or her lifetime."

It was keeping in mind these important drawbacks in our health-care system and the resurgence of TB and AIDS that prompted Lupin Laboratories to sponsor The American College of Chest Physicians (Western India Chapter)-

the fuse.

organised lecture series of Dr. Edward A. Nardell on "Multi-drug Resistant Tuberculosis: Implications for the Present, Strategies for the Future" in Bombay last month. But are lectures, no matter how enlightening they are, merely enough to shake a government out of its slumber? What do you think?

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Dated :

Tuberculosis

(Delhi Edition)

"Not a history book disease"

THE number of cases of tuberculosis reported in the United Kingdom is on the increase especially among women aged between 25 and 44, according to the latest figures released.

Dr. Peter Davies, of the TB Research Unit and the Cardiothoracic Centre, Liverpool, is urging the doctors in England to be on the alert and look out for the predominant symptoms among the patients.

"TB is not a disease of the history books....the factors, such as poverty and immigration, seemed to be responsible for the increase," he warned.

It hardly seems believable, but tuberculosis — a scourge of the Victorians, then called by the dreaded name, "consumption" and the disease of the great depression — is making a frightening re-emergence in the capital city of London.

The BCG Vaccine given to all the children in English schools is only a precautionary measure and this does not necessarily either guarantee a non occurrence or provide a cure definitely that the disease will not affect them.

It all begins as a small inflamed area in the lung, which turns into a cavity. This is caused by the mycobacterium tuberculosis. However, in Britain, pulmonary TB is the most common form of the disease. Droplets from the infected patients are dispersed through coughing. The enhancing factor of this, however, is attributed to overcrowding, malnutrition and immigration. Admittedly, poverty, social depravation and bad housing also add to the misery.

The WHO (World Health Organisation) recently announced that three million prople will die in the world from TB this year alone, more than any other infectious disease. There are "two engines" driving the epidemic world-wide — AIDS and poor TB control programmes. Nearly one in five tuberculosis deaths occurs in people from Africa. TB will develop only in those whose bodies are unable to fight off the infection, particularly AIDS victims.

Symptoms include coughing, often of blood, chest pain, shortness of breath, weight loss, high temperature, especially in the evenings and poor appetite.

There are a number of antibiotics that can be used to combat this disease successfully. But, according to the medical reports, now that dangerous strains of TB have emerged, mainly in the US complete drug resistance is becoming a common feature in New York. Failure of treatment in Britain, where medical treatment and care are totally free under the National Health Service system, is usually because a doctor has either inadvertently prescribed the wrong drugs or because the patient has not taken the right ones. In some instances, it is stated that the patients are themselves to blame for not taking the prescribed antibiotics regularly for a period of nearly one year. Admittedly, the administration of antibiotics in the drug management of the TB patients, who are eventually to be fully cured, is a sustained and a prolonged affair. ■

P. SUBRAMANYAM

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Tuberculosis

Plea to tackle TB on priority

HT Correspondent

NEW DELHI, Jan. 13

While the incidence of tuberculosis in a country like Israel is barely ten per cent per lakh population, in India there are three million active cases and three lakh deaths per year.

Dr Abraham Eliraz, chairman of the Israel League of Lung Diseases and Tuberculosis, who is recently on a visit to India, is disappointed by the general health condition prevailing in the country.

Citing an example, he says during his recent visit to Bombay for the first International Congress on Human Immunodeficiency Virus (HIV) and Tuberculosis, he was taken aback by the ignorant attitude of a patient who spat blood continuously while coughing but "never bothered to ask for help".

Dr Eliraz, as an international expert on lung diseases feels that unless TB is taken up as a national issue and given priority to prevent it from spreading further, it may become impossible to live here.

Besides this, he emphasised that it is necessary to make the people aware of their health and the facilities available for treatment. However, the need to motivate the medicos is also a must.

He says before the problem reaches a saturation point, it is necessary to collaborate with the developed countries in the health sector and collect funds from international health community.

He has no doubt about the capability of the Indian doctors to handle the situation, but "Israel can also help them to overcome the situation", Dr Eliraz said.

"By remaining blind to the disease, one is forcing a situation when it would become difficult to live here because the disease will get spread. It is already quite late, but not too late to control," he said.

Dr Eliraz, who specialises in Internal Medicine and Pulmonary Medicine and presently holds the rank of a Major in the Israeli Army, is conscious of the fact that the incidence of tuberculosis which had come down to four per lakh in Israel, is gradually rising. Presently the number is as much as ten per lakh. Though this number is far less than the existing incidence of tuberculosis in India, but it is a matter of concern for the Israelis, he says.

While in 1948 in Israel, the rate of tuberculosis cases was 150 per lakh, in 1958 it came down to 50 per lakh and in 1968 it was 22, in 1978 it was seven only and in 1988 it further dropped to four per lakh.

Dr Abraham Eliraz — HT photo

Since Israel experienced such a low rate of incidence of tuberculosis in the past, the present number is obviously a matter of concern. "I had predicted that by the year 2,000, TB will be eliminated from my country but I was wrong," he said.

According to him, the rise in the number of TB cases is due to the immigrants who after getting the initial treatment for a short while, vanish from the scene. And since the disease is infectious, it spreads and infects others. In Israel, there is an influx of immigrants from Ethiopia, Russia and other countries. Despite all out efforts by doctors and social workers, the immigrants are negligent about the preventive and curative measures.

The treatment given to TB patient in Israel is initially confined to prescribing three to four drugs. However, depending on the condition of the patient, the treatment continues for six months. If less than three drugs are used and that too, for a short while, there is a risk of recurrence and aggravation of the disease also, he said. Micro-bacterial TB could be resistant to one drug or more, he added.

"In Israel, efforts are on for research work to fight the disease with only one drug in a short period of time. Cooperation by immunologists, epidemiologists and others is required for the research work", he said.

In his country, there are 200 HIV active and 2,000 sero-positive cases. More than half of the HIV-positive patients have also developed tuberculosis. In the whole world, there are 12 million HIV sero-positive cases and the World Health Organisation has predicted that it could go up to 40 million by the year 2,000. "In India, the suggested number till now is one million HIV sero-positive cases," he said.

Dr Eliraz feels that the international health community should have handled the situation more seriously in 1986 itself.

Regarding lung diseases, the 55-year-old doctor from Jerusalem stated that chronic obstructive pulmonary diseases are caused due to smoke inhalation and pollution which destroy lungs and cause bronchitis and emphysema. In Israel, 2,000 new cases of lung cancer are reported every year and incidence of lung cancer among women is also high. Dr Eliraz feels that, cigarette smoking is the main cause of this disease, as 30 per cent of the total population of five million is addicted to cigarettes.

In fact, 20 per cent of children, below the age group of 12 and 10 per cent of adults, are suffering from asthma. Fortunately, he says, in India the incidence of asthma is low compared to other countries. In Israel lung diseases like bronchial asthma are more because of food habits than industrial pollution, he said.

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Tuberculosis

VH

TB threat looms large in HP

ASHWINI SHARMA

SHIMLA

PREVENTION, it is said, is better than cure. But what if preventive methods are implemented in a casual, slow and ineffective manner. That is one reason why the shadow of tuberculosis, a dreaded disease second only to AIDS, looms large over the entire population of Himachal Pradesh, especially those living in the tribal and backward areas.

Health experts and medical scientists are alarmed over the rise in TB cases in the state during the past few years. Over two per cent of the state's population suffers from the disease and 20,000 new cases are reported every year.

Many go unreported as people in urban areas prefer to remain secretive about it. "In fact, this section poses more danger than the illiterates of backward areas," claims K. L. Kapoor, the state TB Control Officer.

A Health Department survey shows that 189 persons died due to TB during 1992. At least 77,500 persons are infected by radiologically active TB of which 19,300 are bacillary cases. Of the 20,000 new cases coming every year, one-fourth turn out to be sputum positive, which can be easily transmitted to others. The other form of X-ray positive TB is equally dangerous for the infected persons as it mainly damages lungs and other vital human organs.

Certain backward areas of Himachal Pradesh, where people live in congested dwellings, are more prone to the disease. For example, in the land-locked valleys of Dodra-Kawar, six to eight or even more members of a family live in single-room houses.

They cook, sleep and stay for days together during the winters. "If one member is infected by TB, he can easily pass it on to one or two others," says Hardayal Chauhan, in charge of a mobile health camp.

There has been an alarming rise in the cases of TB in all 61 villages of Pangi tribal areas, Dodra-Kawar and parts of Lahaul and Spiti. Cases of TB have also been detected in interiors of Sirmaur, Mandi, Kangra, especially Bara-Bhangal areas, Chamba, Kullu, Shimla and Kinnaur. "We are asking the health authorities to send a special team for door-to-door survey of TB patients in Pangi" says Rakesh Kanwar, SDM, Pangi.

The Tuberculosis Control Programme being implemented by the Health Department under the National TB Programme has failed to achieve tangible results during the past over two decades. There has been no noticeable decline in the number of cases.

The health authorities complain of shortage of funds, untimely and insufficient medicine supplies and the non-cooperative attitude of the urban patients. "There is no anti-TB medicine available for the past few months in Sirmaur. Will it not allow the disease to relapse in case of those already under treatment," questions a health volunteer.

According to Director, Health Services, J. K. Kakkar, the main thrust of the programme is on preventing transmission of the disease from an infected to a normal healthy person. "There is a need for revising the strategy to tackle all types of cases and to achieve at least 90 per cent cure rate", he feels.

The state has specialised TB hospitals at Dharampur, Tanda, (both 200 bedded) and a 20-bed hospital at Balieuganj in Shimla. Besides, a facility of 20 to 60 beds has also been created in the district hospitals of Mandi, Chamba, Bilaspur and Nahan. The Health Department has also set up district TB centres in 11 districts, excluding Lahaul-Spiti, where a tuberculosis clinic is working. The health officials are not very optimistic of the eradication of this disease from the state by the turn of the century unless the programme is given a shape of a movement involving social workers and voluntary organisations.

Though the TB control officer recently issued guidelines to the field staff and chief medical officers for effective implementation of the programme, unless the state government makes a determined efforts, the disease may assume a serious dimension.

Dated 10 JAN 1994

Tuberc. AIDS

VH/PR

Alarming rise of TB through HIV

Staff Reporter
Bombay

IT IS a well-established fact today that the Aids pandemic is bringing about a resurgence of tuberculosis. Most TB-infected people go through their lives without suffering active tuberculosis because the bacteria is kept in check by their immune system.

"But like the cobras kept in baskets, the bacteria quickly escapes when HIV comes along and lifts the lid," said the executive director of the Global Programme on Aids, Dr Michael Merson, in his keynote dress at the 'First International Conference on HIV/Aids Infection, Tuberculosis and Respiratory Diseases.' The three-day conference started in the city on January 8.

According to recent Who calculations, the number of new TB cases each year worldwide is set to rise from 7.5 million in 1990—with 2.1 million, or nearly 30 per cent of them, in India—to 12 million in 2005. Between 1990 and 1999, eight million people are expected to have developed TB as a consequence of HIV infection.

In African countries particularly affected by Aids, the annual number of reported TB cases has doubled, or even tripled, within the last five years. In Asia the same picture is starting to appear. This is not very surprising, given the fact that there are an estimated one billion people in Asia latently infected with the tubercle bacilli.

Clinical and surveillance data suggest that in Thailand TB is the most important life-threatening infection associated with HIV. In one large Bangkok hospital, three in five of all Aids patients admitted between 1985 and 1991 had pulmonary TB.

Rising trends of HIV infection among TB patients can also be seen in India. In Manipur, more than 11 per cent of reported TB patients are HIV-positive. And at the JJ Hospital HIV prevalence among TB patients rose from 2 per cent in 1989 to a 11 per cent this year.

It has become essential today to combat this dual epidemic. One obvious way, pointed out Dr Merson, is to do all we can to prevent HIV infection. Another, is for TB programmes to accelerate their efforts to interrupt TB transmission by the curative treatment of infectious tuberculosis cases.

Dr Merson said that while the two routes of infection, namely the sharing of needles and contaminated blood, are more easy to talk about, it is sexual intercourse which accounts for nine out of ten HIV infections among adults and adolescents. "Therefore, the main focus must be on preventing the sexual transmission of HIV," he stressed.

Apart from abstinence, safe sexual practice includes mutual fidelity, non-penetrative sex and protected sexual intercourse, he pointed out. "We need to provide information about these safe sex options through many different channels to reach everyone," he said.

"Condoms are a very highly effective means of preventing HIV transmission and we must dispel all myths to the contrary," said Dr Merson. "Their use needs to be promoted through social marketing campaigns that make the condom as much a part of life as toothpaste and soap."

Dr Merson said that the second method for preventing sexual transmission is the early diagnosis and treatment of sexually transmitted diseases.

According to Who estimates, by the end of 1993, 14 million adolescents and adults and one million children worldwide would have been infected with HIV since the start of the epidemic. Approximately two million people were infected in 1993.

In India, the estimated number of HIV infections has risen by 60 per cent over the past year to around 1.6 million. Many of Asia's other HIV infections are in Thailand, where in the north one in five military recruits and one in 25 pregnant women are now HIV-positive.

By the year 2000 as many as half a million Asians each year are expected to develop Aids. This will have enormous consequences for health care systems in some countries, including ones which are currently well developed and financed.

Dr Merson said that in the absence of any cure for HIV infection and none foreseen in the near future, compassionate care in a climate of understanding and non-discrimination can prolong both the duration and quality of life of those infected.

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Tuberculosis

VH

Nation-wide TB control plan flops

by BM Kaura

CALCUTTA – The nation-wide tuberculosis control programme, launched with great fanfare 32 years back, has come a cropper. In West Bengal alone, there are 14 lakh victims of TB.

So disappointing has been the TB control programme that the West Bengal government has had to change its strategy altogether. In a changed strategy, the programme will now be funded by the World Bank under WHO auspices. In the first phase six states and five metro cities including Calcutta have been selected.

The main objective of the new programme is to reduce mortality rate, attack rate and to break the transmission chain of infection at the source on account of tuberculosis.

According to Abul Hasant, the state tuberculosis control programme officer, the revised programme will be launched in the state from Murshidabad district from April 15, which is the most affected district in the state. He said the WHO has promised to spend Rs 38 crore in West Bengal for treatment and training the staff in five years, the target period.

In the first phase six districts - Jalpaiguri, Darjeeling, CoochBihar, Nadia, Murshidabad and Malda have been selected for the programme. The main emphasis of the revised programme will be to provide a short course chemotherapy to all "smear positive and cavity cases" and to detect and treat at least 1500 petients annually.

Hasant told ENS that short course chemotherapy programme has already been launched in Calcutta from January. The state Government has already given training to ten state medical officers and 12 Calcutta Municipal Corporation officers so for treating the patients. He said the need for revamping the existing programme arose because of inadequate coverage of TB services in primary health centres and inadequate drug supply. This has resulted in the treatment of only one-third of detected cases. Patient dropout after initial treatment has also hampered treatment.

SN Sengupta, specialist at the local SSKM hospital, said that 0.4 per cent of the total affected people were the main carriers of the disease, which is spreading fast.

Published at : BOMBAY
Dated : 12 FEB 1994

Tuberculosis

India's TB capital may lose Rs.1,100 cr WB aid

CHANDRA SHEKHAR YADAV
Patna

BIHAR is, perhaps, a first-class example of high-handed bureaucracy coupled with shameless laxity. The TB capital of India is on the point of losing out a World Bank aid of Rs. 1,100 crore that was to assist the Centrally-managed nationwide anti-Tuberculosis project. The reason? Bihar Health Commissioner K. Arumugam, it seems, has failed to finalise the proposals, thus, forcing World Bank authorities to reconsider the whopping grant.

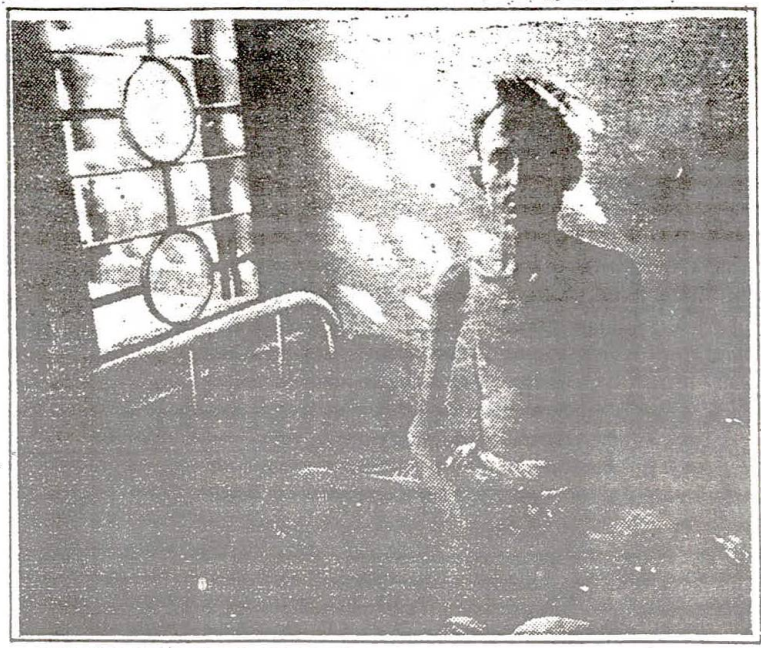
As per the Central plan, five states having comparatively higher number of TB cases were selected by the World Bank for implementation of the anti-TB Action Programme. Of the five states, Bihar topped the Bank's preference list and an unprecedented Rs. 1,100-crore aid was sanctioned, and was there for the state's asking.

But, as things stand today, Bihar Health Minister Sudha Shrivastava admitted that the state was about to lose out on the project, especially since there were other states ready with their proposals and are demanding additional allotment for their own action programmes to be initiated next year.

Health Commissioner K. Arumugam is not in the eye of controversy. He is the "very point of the controversy". The proposal of the World Bank and the Central government was received by Arumugam over three months ago. However, he failed to get the proposal finalised and accepted by the Centre.

Surprisingly, the proposal was not even put before Health Minister Sudha Shrivastava — a fact that came to light only when the minister convened a departmental review meeting to assess the progress made towards controlling TB in the state.

Worse still, Arumugam did not deem it fit to attend the three-day review session, that too, at a time when the state department is already strapped for cash, particularly, for strengthening the infrastructure of its existing TB hospitals or increasing the number of beds therein.



VICTIM OF BUREAUCRATIC LAXITY: *A TB patient languishes in a Bihar hospital*

The Health Department estimated as many as 12 lakh TB patients out of a population of 8 crore, and put sputum positive cases requiring close institutional care at 3 lakh in Bihar.

Department officials are now sure that because of the laxity of just one man — the Health Commissioner — to initiate a move, the grant could be diverted by the Centre to some other needy state.

All that World Bank and government required was a detailed assessment of the ground situation on TB in Bihar for a sanctioned amount of Rs. 100 crore per year for the next 10 years, and a further grant of Rs. 100 crore for establishment charges, vehicles purchase, etc.

The total annual grant on Tuberculosis which the Bihar government has been able to muster until now is around Rs. 8 crore in the non-plan head and Rs. 1.5 crore in the plan head as against the Rs. 100 crore per year grant from the World Bank — a project which would have come as a nutritive health dose for an ailing state if the proposal had been finalised.

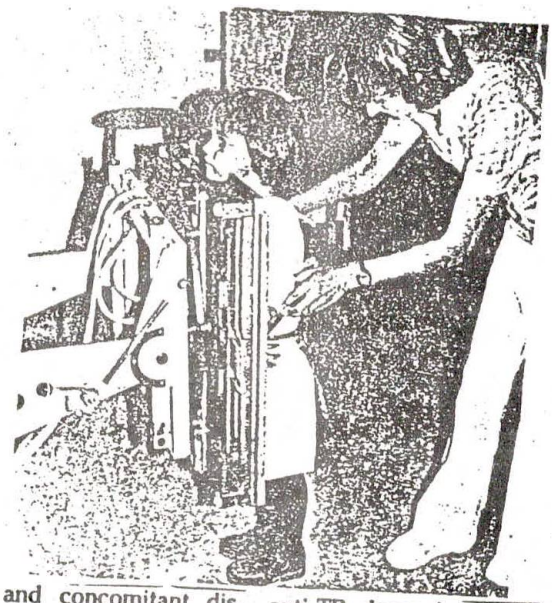
Name of the Paper : LOKMAT TIMES
Published at : NAGPUR
Dated : 23 FEB 1996

Tuberculosis

Tuberculosis: A social problem

When we are unable to control tuberculosis despite the availability of effective drugs to treat it,indicates that tuberculosis is now a social problem. The cause of a social problem may be many and involves different people including doctors, patients, paramedicals, relatives of patients and the social worker. The most painful attitude seen in the approach of social workers towards tuberculosis is, the admission of the patient in hosipital. Despite repeated and conti

Dr R F Jain



nuous health education at all levels there is no satisfactory response of patients to the proper treatment of tuberculosis. Let us look at the problem and remedies available at various levels.

The role of the doctor

The patient coming with symptoms suggestive of tuberculosis is to be investigated, keeping in mind the problem of tuberculosis in India. Once the investigations for detecting pulmonary TB are not conclusive and when the patient is not responding to the usual line of symptomatic treatment, we can think of investigations for the other organs of the body which could be affected.

Once the diagnosis of tuberculosis is confirmed, the symptoms pertaining to other diseases like diabetes, enteric fever, hepatitis etc are not to be overlooked. Treatment of tuberculosis and concomitant diseases should go hand in hand.

If the anti-TB drugs are administered in the right combination and doses the treatment will be effective. It is necessary to explain to the patient the regimen and side effects or reactions if any of the drugs being administered. Treatment by a TB specialist rather than following prescription of unauthorised publications stems the deterioration of the disease. The major problem in treating tuberculosis is that most patients are irregular in their treatment thereby developing a drug resistance. Drug resistance is caused due to the administration of improper doses and duration and improper combination of various drugs. It is not uncommon to find some qualified medical practitioners prescribing many anti-TB drugs in small doses. This too has its dangers and can lead to the development of drug resistance. These problems can be avoided by consulting a TB specialist.

Prolonged use of corticosteroids could create complication for the patient in the long run and could lead to the development of cavities in the lungs.

It is a usual practice to treat patients suffering from haemoptysis with anti-TB drugs. This needs to be discontinued for the beneifit of the patient, who may think he once again tuberculosis thereby having a psychological effect on the patient.

In some cases it has been observed that injection Streptomycin is prescribed for years together as and when patient desires. This practice needs to be discontinued and if necessary other injectable vitamin preparations could be prescribed.

Before prescribing drugs to patients whose sputum test proves TB positive their case history should be reviewed, to avoid a waste of time, money and health.

The patient:

Most often patients approach the doctor for treatment in the advanced stages of TB. One way of detecting TB early is to take cognisance of symptoms like cough, fever, pain in chest, breathlessness which do not respond to usual treatment. Should this problem occur the patient should get himselfor herself treated immediately at a TB hospital or any other medical centre to avoid damage to the lungs which is the most vital organ for respiration.

Patients should not stop or change their treatment without the knowledge of the doctors. It could result in the deterioration of the patients condition. Studies have shown that some of the reasons for the abrupt interruption in the treatment by patients is due the attitude of the staff at the TB clinic, the general practitioners and the social workers.

The role of social worker:

Social workers have a major role to play in curbing the spread of TB through their involvement in health education programmes at the local and community level.

Whilst it is easy to treat TB it is difficult to cure tuberculosis for want of proper treatment,followup and co-operation of patients. Let us make it our responsibility to erradicate TB.

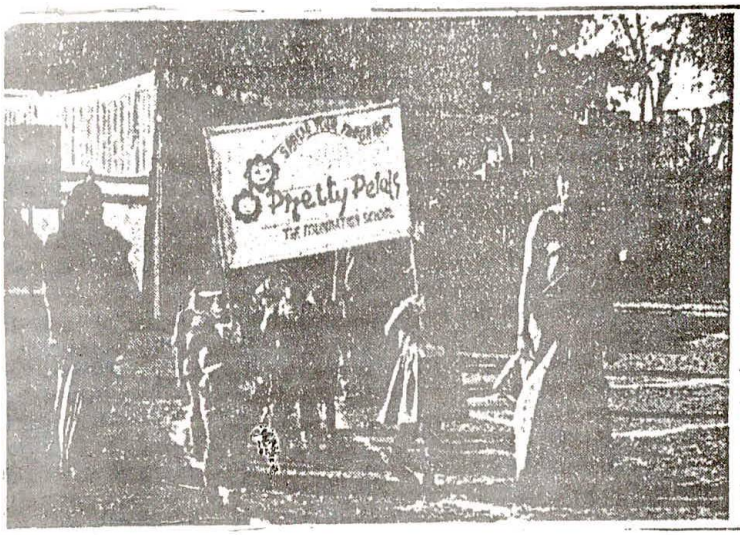
Name of the Paper : MADHYA PRADESH CHRONICLE
Published at : BHOPAL
Dated : 12 DEC 1993
(City Edition)

Tuberculosis

Experts discuss TB in women

By Our Staff Reporter

BHOPAL: One of the important and emotionally most disturbing manifestation of tuberculosis among women in the child bearing age is the disturbance in the reproduction function. Speaking at the 48th National Conference on Tuberculosis and Chest Diseases in Bhopal, Dr (Mrs) SN Tripathy disclosed that in 84 percent women disturbance of the ovarian function occurs but only in 2 percent there is tuberculous involvement of the ovaries. Research has disclosed that the reproductive malfunction is due to the hypothalmus in the brain in 31 percent hyperlactemia in 41 percent ovarien hypofunction in 28 percent, and is reversible in most cases with proper treatment.



Dr DDS Kulpati delivered the prestigious Ranbaxy Robert Koch Oration on Interstilial Lung Diseases, based on his extensive experience in the Lok Nayak Jaiprakash Hospital in New Delhi.

He pointed out the problem involved in clinical assessment of these cases, which mimic pulmonary tuberculosis closely. Their management with steroids and immunsuppressants and poor prognosis were stressed.

A ray of hope for the chronic failure patients who have multiple drug resistance but cannot be treated with the very costly and mostly unavoidable reserve drugs was given by Dr Baldev Raj from Rohtak who showed very encouraging results with artificial pneumoperitoneum, a therapy widely practical in the nineteen fiftees and now largely given up.

THURSDAY AUGUST 5 1993

Indian Express

Rich man's disease afflicts poor Paniyas

by Rajeev P.I.

KALPETTA

APPU AND his sister Koyma wonder which will kill them first: The tuberculosis that has already gnawed them down to wheezing bundles of skin and bones, or the spectre of starvation looming closer each miserable day.

The lethal disease has ensured that these two young Paniya tribals of Nenmeni Kunnu never again toil in a settler's farm nearby, as they had been doing since childhood. Their sole lifeline to survival now is the Rs 20 or so which Appu's wife ekes out, on her especially lucky days.

But in this poverty-stricken tribal hamlet in Wayanad, the plight of these two – condemned to lie in their squalid, fly-infested hut – is nothing unique, not even special. Men die a living death, flies live on. And most do not even know what better to expect.

No one knows just how many among the district's roughly 1,30,000 tribals have TB, or how many it might have actually decimated thus far. Guestimates vary sharply, while local authorities scoff at apprehensions even as no comprehensive screening has been done yet.

But available indications are, in any case, ominous: Sources at a charitable hospital, which concessionally screened 81 tribals of Nenmeni Kunnu as a humanitarian gesture last week, said that almost one out of every four was found afflicted with the disease.

Appu and his sister Koyma, both afflicted with tuberculosis, are haunted by the spectre of starvation since the lethal disease has rendered them unfit to eke out a living. Express photo.

The district TB officer told this correspondent that he was still to see all the test reports of this group, but added there was precious little his office could do anyway. He had never received his mandatory training at the National Institute of Tuberculosis, has no lab, no diagnostic equipment and not even the compulsory minimum staff.

Worse still, the young doctor has no clue as to what he will do for medicines in case the TB threat is eventually detected to be as severe as being apprehended: The last time medicines from the CGHS reached him was in March last, that too only a quarter of the year's needs.

But at least he is determined to stay put and try, unlike many others. As a rule, impoverished and unremunerative areas here with a predominantly tribal concentration are being increasingly shunned by doctors: There are about 16 Primary Health Centres in such locales still abegging for doctors. Even the only Central Government-sponsored Tribal Health Centre in Manantavady with 100 tribal patients a day, has ceased functioning for the same reason.

Then there is sickle cell anaemia, the crippling, killing genetic scourge which an unestimated number of tribal families reel under – in some instances those hit by TB as well. Like that of Kannady, of Noolpuzha: More than the pain typical of the disease's peak that has now permenantly confined him to the damp mud floor of his crumbling home, what breaks him is watching his three-year-old daughter, already a TB patient, withering by the day.

The only known medicine for sickle cell anaemia – albiet of unconfirmed utility – is hydroxy urea, which costs a whopping Rs 251 per week's course and is imported. Many tribals now beg, borrow or pawn their lands to enterprising settlers to buy this for their stricken kin. Like Mathevan, a Kuruma tribal of Kottoor who lost his daughter to the disease last month and is now trying to save his only son.

The proud owner of over an acre of paddy fields once, his children's disease has already reduced him to a famished labourer.

From Dr. A. Kochi, Director, Global TB Programme WHO.

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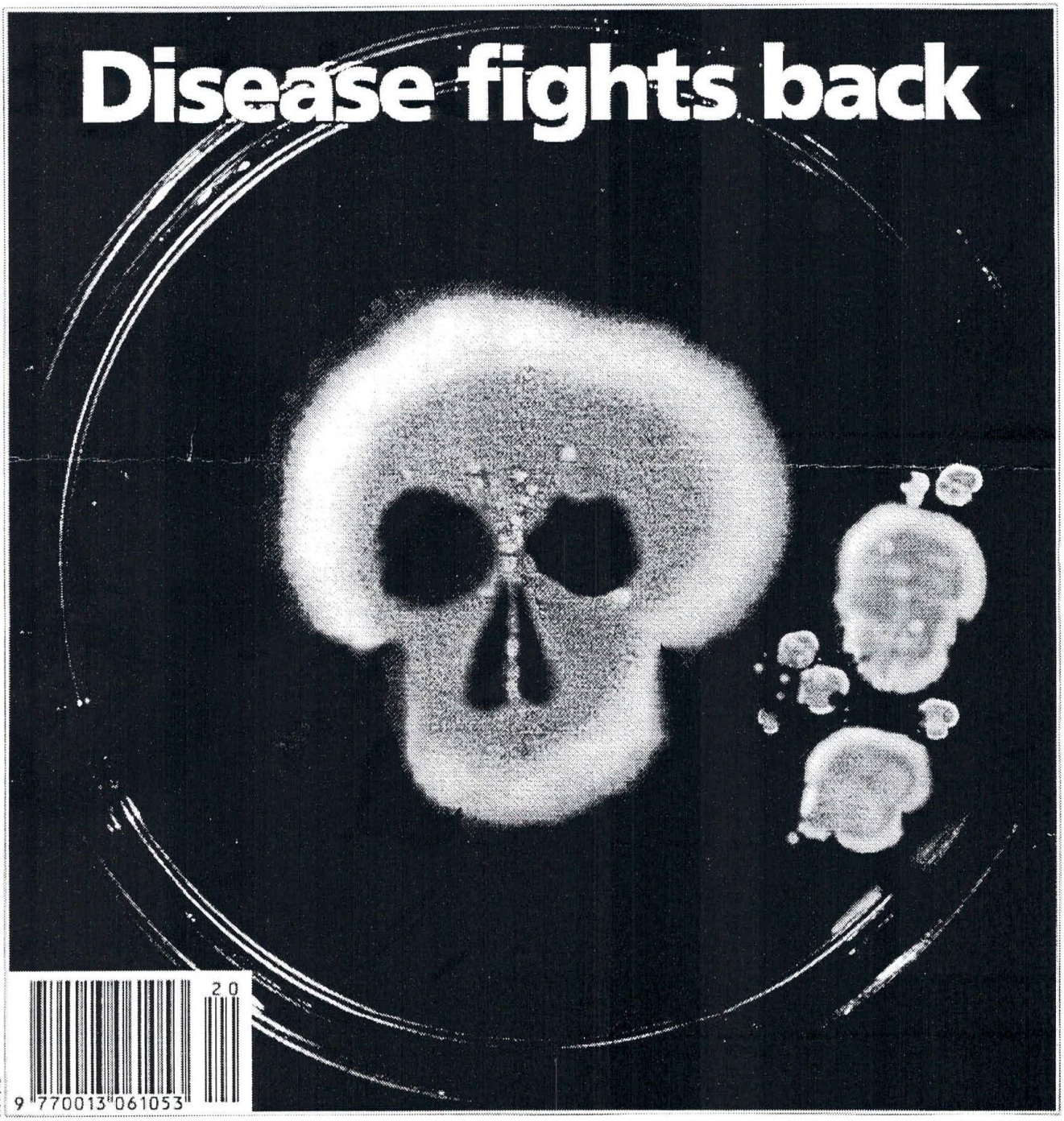
SOUTH AFRICA
A survey after page 60

The Economist

MAY 20TH-26TH 1995



Disease fights back

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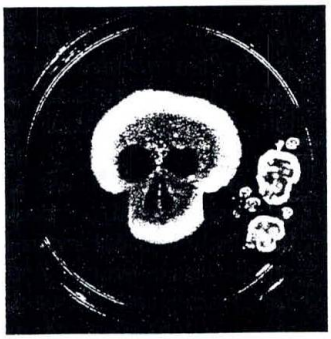
Austria	A$60	Denmark	DKr32	Germany	DM7.90	Iceland	IKr250	Kenya	KSh300	Nigeria	Naira 180	Portugal	Esc620	Spain	PTA$550	UAE	Dirhams 25
Bahrain	Dinar 3.5	Egypt	E£18	Greece	GRD900	Ireland	IR£2.20	Luxembourg	Lfr155	Norway	NKr30	Qatar	Riyal 35.00	Sweden	SEK32	UK	£2.00
Belgium	BF155	Finland	FIM24	Holland	Hfl 8.75	Israel	NIS17	Malta	Lm1.45	Panama	US$5.50	Saudi Arabia	Riyals25	Switzerland	Sfr7.70	USA	$3.50
Cyprus	C£2.20	France	FF26	Hungary	Ft450	Italy	Lire 7,500	Namibia	N$16.60	Peru	SV.16.40	South Africa	R15.50	Turkey	TL95,000	Zimbabwe	Z$23.00

The Economist

Disease fights back



EBOLA is a terrifying illness. It kills quickly. Nine in every ten of those who become infected die, and it is an especially hideous death. Thanks to its speed and gruesomeness, this virus has commanded front-page headlines all over the world in recent days. Sleeping sickness—which can be just as deadly and whose spread across large parts of Zaire is virtually unchecked—has commanded no such attention. This is not so surprising: Ebola is new and untreatable, sleeping sickness is old and treatable—merely untreated. The outbreak of Ebola in Kikwit has so far claimed about 100 victims; sleeping sickness kills 200,000 Zairois a year.

Established and curable diseases are doing far more harm to people than new diseases. What is worse, their strength is growing, not fading. These diseases do not, by and large, kill the affluent westerners who now shudder at Ebola. But they should, at least, prick their consciences. In due course, these diseases may do far worse than that.

Never look away

The problem humans have with germs is that they work by rules that humans find hard to deal with, rules so different that before Pasteur no one knew what they were. Germs are quick; humans are slow. Germs have no thought for the future; humans plan. Germs have no technologies; humans are consummate users of tools. Most important, germs never give up. Humans do so all too readily.

For centuries staphylococcus bacteria made trivial wounds fatal injuries. Then science came up with a tool to use against them: penicillin. In 1952 staphylococcus bacteria were almost 100% susceptible to penicillin, and the scourge became an irritant. By 1982 90% of the strains had become resistant to the drug. Clever humans, not unduly worried, changed tools. The germs developed resistance to the new ones. Now, only one safe drug can be relied upon to fight staphylococcus: vancomycin. Other bugs are already resistant to it; their relevant know-how, bits of information encoded in DNA, may be all too easily transferred. Then the game will be back to square one—except that far more people undergo surgery now than before antibiotics made it safe. In 1992 4% of Americans who underwent surgery became infected. Most of those 920,000 people were infected with staphylococcus.

In late 18th century Europe, tuberculosis killed perhaps one in five. Careful use of antibiotics gradually put paid to it. After a while, the world decided that the fight was over; but no one told the tuberculosis bacillus. In New York city, spending on tuberculosis fell from $40m in 1968 to $2m in 1989. The cuts hit outpatient work, so no one was there to ensure that the sick—often homeless drug addicts—took their medicine properly. That let resistance bloom. By the beginning of 1991 almost half of New York's new cases of tuberculosis were resistant to the two main drugs previously used, and the costs of hospitalising people with tuberculosis in the city had reached $50m a year.

Many problems fail to yield to public spending. Tuberculosis in America is not one of them. National surveillance worked well until the 1970s. When, against expert advice, responsibility for this work was given to the states, the programme fell apart. In 1986, just as the comeback was getting under way, the multi-drug-resistance unit at the Centres for Disease Control in Atlanta was closed. All told, cuts in tuberculosis programmes during the 1980s saved America perhaps $200m. According to one estimate, America spent more than $1 billion on multi-drug-resistant tuberculosis in the five years up to 1994.

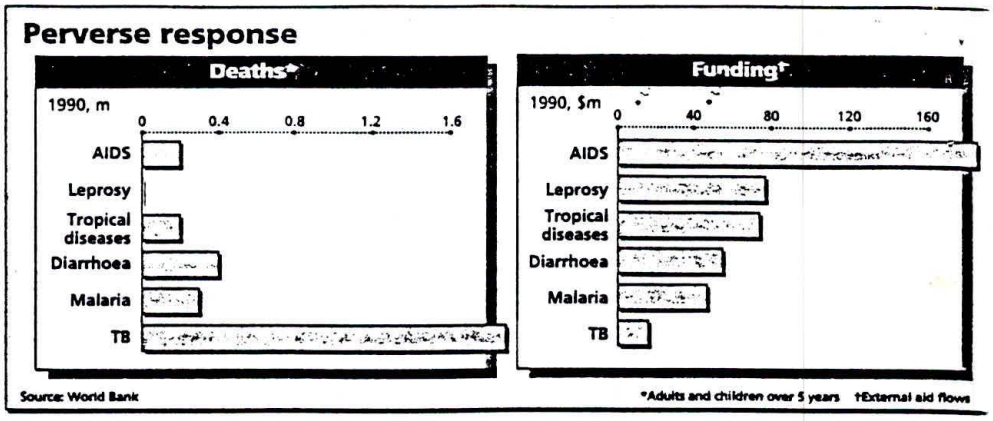
America stands out only because it is rich enough and knowledgable enough to lack excuse. But similar stories, and worse, have unfolded around the world. In developing countries, most cases of tuberculosis could be cured with drugs that cost as little as $13 a patient. Yet, worldwide, less than 50% of detected cases are being cured. There seems no fundamental reason why the world should not achieve a success rate of at least 85%. Clinics in Somalia already do. The World Health Organisation, itself in dire need of reform (see page 83), estimates that cheap, systematic interventions might save 12m of the 30m likely to die from tuberculosis in the next ten years.

More surveillance and better use of resources is only part of the answer. Some new diseases will need new treatments. Unfortunately, work on these tends not to start unless the diseases attack the rich. Antibiotic research has been neglected while drug companies turned to chronic diseases of the old and wealthy, which are far more profitable. Some perfectly good antibiotics have even slipped out of production because only the poor needed them. All the same, there are areas where humans can fight back; and they may even learn to play by the germs' rules. Antibiotics may well in future be developed using the same random but effective evolutionary techniques that give germs the power to develop resistance; the harnessing of such methods in the test tube is one of the most potent new approaches to pharmacology. And new data networks could make the infrastructure of surveillance possible to build even where little physical infrastructure exists. That will let people pool their knowledge, much as the germs transfer their villainous coils of DNA.

However, the wonderdrug mentality that allowed humanity to see antibiotics as a once-and-for-all solution, rather than a tactical victory that needed following through, should not be allowed to return. Final victories, if any, will be few and far between. This is a race with no foreseeable end.

Evolution is a response to changing environments, and the human environment is changing with unprecedented rapidity. Ecosystems are being altered across the planet. Climate may be changing too. People are cramming themselves into vast cities, and travelling between continents with hitherto unheard-of ease. These changes may not have much effect on human evolution—at least not yet—but the evolution of germs is vastly quicker.

New diseases like Ebola may be less threatening in themselves than as harbingers of activity in the microbial world within. The chance that a plague from Kinshasa will bring the world to its knees may be small this time. But if the world fails to pay attention, next time could be worse.



Tuberculosis

Join the DOTS

TWO years ago the World Health Organisation (WHO) declared tuberculosis a global emergency—an unprecedented step. Tuberculosis was, by that time, killing more adults than any other infectious disease. Unfortunately efforts to halt its resurgent spread have had only limited effects. In 1990 tuberculosis was responsible for 2.5m deaths at all ages. By 2005 the figure is expected to be nearer 4m. However, stemming the problem is not seen as a high priority. As the chart shows, tuberculosis is as easy for foreign-aid donors to ignore as it is for poor people to die of.

In rich countries, the discovery of antibiotics and the spread of health-care systems robbed tuberculosis of its terror from the 1940s onwards. Levels of the disease fell steadily. Its return in the 1980s was due to a number of different factors undermining that progress: AIDS, fractured health-care systems and drug resistance.

The tuberculosis bacillus thrives in people infected with the human immunodeficiency virus (HIV) because they lack the immune cells to keep the tuberculosis bacteria at bay. People who are "immunocompromised" are perhaps 25 times more likely to contract tuberculosis. If they are already infected but not sick (as many people are) the erosion of their immune system will allow the disease to take hold. Once people are ill, the disease begins to spread—and it is much easier to catch than HIV. A rise in local cases of tuberculosis is often the first clue that HIV has arrived.

Poor health-care systems make it more likely that people with tuberculosis will die. They also increase the spread and potency of the disease. If sick people are on the street, not in the sanitorium, they are more likely to infect others. And a lack of consistent health care makes the disease grow hardier. If the antibiotics that kill the bacterium are not taken according to a strict regime, which will often be the case if there is no supervision, the bugs may develop resistance. Many of them already have. This worsens the prognosis for the patient and drives up the costs of treatment. More analysis has to be done to see which drugs will work in which cases.

The WHO believes that if health workers simply made sure that drug regimens were strictly adhered to—in a programme the WHO now describes as "directly observed treatment, short-course" (DOTS)—the tuberculosis crisis would be slowed down significantly, and drug resistance brought to some extent under control. The logic seems correct. But there have been few successes.

Tanzania offers one. In the late 1970s Karel Styblo, a Dutch physician, convinced the authorities to treat the disease with a cocktail of antibiotics. This increased the proportion of victims cured from 40% to nearly 80% in 1990. When, in the early 1990s, tuberculosis looked like becoming a serious problem again, the authorities were quick to act, increasing their vigilance to make sure infections were dealt with. It cost Tanzania up to $10 per life saved and $3 per new infection avoided.

China, home to a quarter of the world's tuberculosis cases, has recently stepped up its supervision of patients and changed the way treatment is paid for. Doctors now make money by curing people, not by selling drugs. Around half of China has entered into the DOTS programme; 90% of patient treated since 1993 have been cured, at a cos of $100 per patient. Each sufferer so cured might have infected 10-15 other people had the disease run its course.

In New York city the number of tuberculosis cases soared in the 1980s as public health services deteriorated and HIV began to emerge. In 1991 the city started sending outreach workers to patients' ho anc workplaces to make sure they complied with their prescriptions. Around 40% of th city's tuberculosis cases are now under th DOTS regime. The caseload stands at 3,000 a decline of 15% since 1992.

In the rest of the world, though, tuberculosis continues to rage. Twenty of the 2 countries in central and eastern Europe anc the former Soviet Union are seeing a resurgence. In most of Africa and Asia rates of infection are increasing. In America DOTS ha been extended to only 17% of the caseloac outside New York. And responses to the disease that are less than helpful are still being practised in many places: the treatment o infected people with anti-tuberculosi drugs before they become sick, which is good way to breed drug resistance; ventila tion systems which, while providing pa tients with fresh air, also spread the diseas further; and X-rays to reduce the tion which do no good.

The DOTS strategy is an improvement but it will certainly not eradicate tuberculosis. The only global eradication mankind has yet engineered has been of smallpox which was a much easier challenge. There was an effective vaccine, and the paths of infection were relatively controllable. Th BCG vaccine for tuberculosis is effective primarily, if not only, in preventing non-infectious forms of the disease in children. It can not stop the spread of adult pulmonar pneumonia. Yet eradication is not the onl way to make the world better. According t the WHO, as many as 12m more people wi die over the next decade from tuberculosi without worldwide DOTS than would wit it—and at the end of that grim decade, ther will be yet more resistant strains of the virus It sounds like something to avoid.

The New York Times

MONDAY, APRIL 3, 1995

Editorial

Tuberculosis Resurgent

Health professionals are losing the struggle to control tuberculosis, an infectious disease that will kill some three million people this year, mostly in poor nations but increasingly in wealthy societies as well. The woefully underfinanced campaign has had only scattered successes around the world. Worse yet, skimpy or misdirected programs in many countries may inadvertently be spreading the disease, thus doing more harm than good.

That tragic development does not mean health professionals should give up the fight and let nature take its devastating course. The only sensible response is to refashion tuberculosis control programs and boost their funding by the modest amounts needed to make them truly effective.

Tuberculosis, once a leading cause of death in North America and Europe, had seemed on the run since mid-century, thanks to improved living conditions and antibiotics. But recently it has resurged as nations let down their guard, leaving tuberculosis "the world's most neglected health crisis," in the opinion of the World Health Organization.

The resurgence has been accelerated by AIDS, which weakens the immune system and allows tuberculosis to fulminate. It has also been fueled by inadequate TB-control programs that fail to administer the right mix of drugs over the prolonged, six-month course of treatment. In many nations, programs are just good enough to save many victims from prompt death but not good enough to cure most of them. They survive to spread the infection, often in a new form resistant to antibiotics.

The most effective tactic for controlling the spread is "directly observed treatment," in which health workers provide the required medicine to infected people and watch them take it. That approach has already succeeded in curing sick patients and thus cutting the rate of transmission in New York City, Tanzania and China.

W.H.O. estimates that $360 million a year is needed to apply the same tactics widely. The developing nations, with most of the cases, would be expected to supply $250 million, either from new money or money they currently spend on less-effective control strategies.

The industrialized nations would be asked to put up about $100 million a year, mostly to buy drugs. That wise investment would not only help the poor countries, it would cut transmission to the rich countries as well. Already a third of this nation's new TB cases are among foreign-born residents, and the percentage is expected to rise. The best place to defeat this epidemic is at the source, before migration and international travel spread the disease far and wide. This is one foreign aid program that would clearly pay health dividends at home.

INFECTIOUS DISEASE

WHO Calls for Action Against TB

In the movie *Outbreak*, an exotic virus breaks out of Africa, killing everyone it infects. In real life, however, pathogens don't have to be exotic to cause a deadly epidemic. In a report released on 20 March, the World Health Organization (WHO) reveals that an old scourge—tuberculosis—is still rampaging out of control despite the organization's 2-year-old campaign to prevent its spread. Even more chilling, drug-resistant strains of *Mycobacterium tuberculosis*, the bacterium that causes TB, are on the rise.

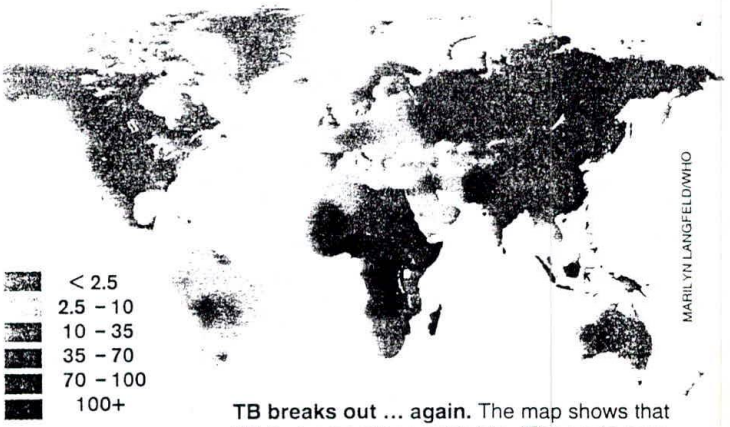
To combat these outbreaks, the WHO report, entitled "Stop TB at the Source," recommends international adoption of a control strategy called Directly Observed Treatment—Short-course (DOTS), which aims to ensure that all patients complete their full course of treatment. Without an effective treatment program, WHO predicts that by the year 2005, TB will kill 4 million people a year—up from about 2.5 million. The toll could be even worse if the multidrug-resistant strains continue to spread.

The upswing in incidence of TB is being fueled by what WHO spokesperson Kraig Klaudt calls "worldwide medical chaos." In the West, efforts to combat TB have largely slackened off due to the mistaken belief that the disease was brought under control with the introduction of effective drugs in the 1940s. In fact, the epidemic had simply been pushed into the poorer reaches of society—the inner-city dwellers and the homeless—and is now re-emerging with a vengeance, partially fueled by the spread of the AIDS virus, which increases susceptibility to TB. Governments in developing countries, says WHO, have been slow to channel resources into TB control, even though studies show that in terms of productive lives saved it's cost-effective.

Because only patients with active TB can transmit the disease, WHO argues that control programs should focus on people with symptoms—usually a chronic cough—rather than waste resources on screening programs that also pick up patients with inactive forms of TB. "It's the cough that spreads the disease," says Paul Nunn, WHO's chief of TB research and development. "The cough to TB is the same as sex to HIV."

But TB treatment requires taking antibiotics for a full 6 months. Symptoms abate within a few weeks, however, and patients, thinking they are cured, may stop their treatment, allowing the disease to spread and encouraging the emergence of drug-resistant strains of TB. To stop that from happening, WHO is campaigning for governments to adopt the DOTS treatment strategy: Use trained health workers to check that patients take every pill, and supply free drugs and other incentives to ensure that patients finish their treatment. "TB control is basically a management problem," says Thomas Frieden, head of the New York City Health Department's Bureau of TB Control. Frieden should know, because New York is one of the few places in the world that has turned its current TB epidemic around. In the past 2 years the number of new TB cases has been reduced more than 20% to about 3000 by using the DOTS regimen, as well as treatment incentives such as free subway tokens.

Despite New York's best efforts, however, "a handful of patients are resistant to all [anti-TB] drugs," says Frieden. To curb the resurgence of those lethal strains of TB, since 1993, the city health department has resorted to placing patients who persistently refuse to complete treatment under "detention until cured" in the hospital.



TB breaks out ... again. The map shows that TB is re-emerging worldwide. (The scale numbers indicate deaths per 100,000 people.)

In developing countries, says Nunn, "the chances are that multidrug resistance is less of a problem," because patients are more likely to go untreated than to receive partial treatment. Hot spots of resistant strains have been identified in India, Brazil, and some other developing countries, however. TB strains have no respect for international borders, notes Nunn, which is another reason that "governments need to be made aware that TB is a huge problem [for which] there is a cost-effective treatment."

–Rachel Nowak

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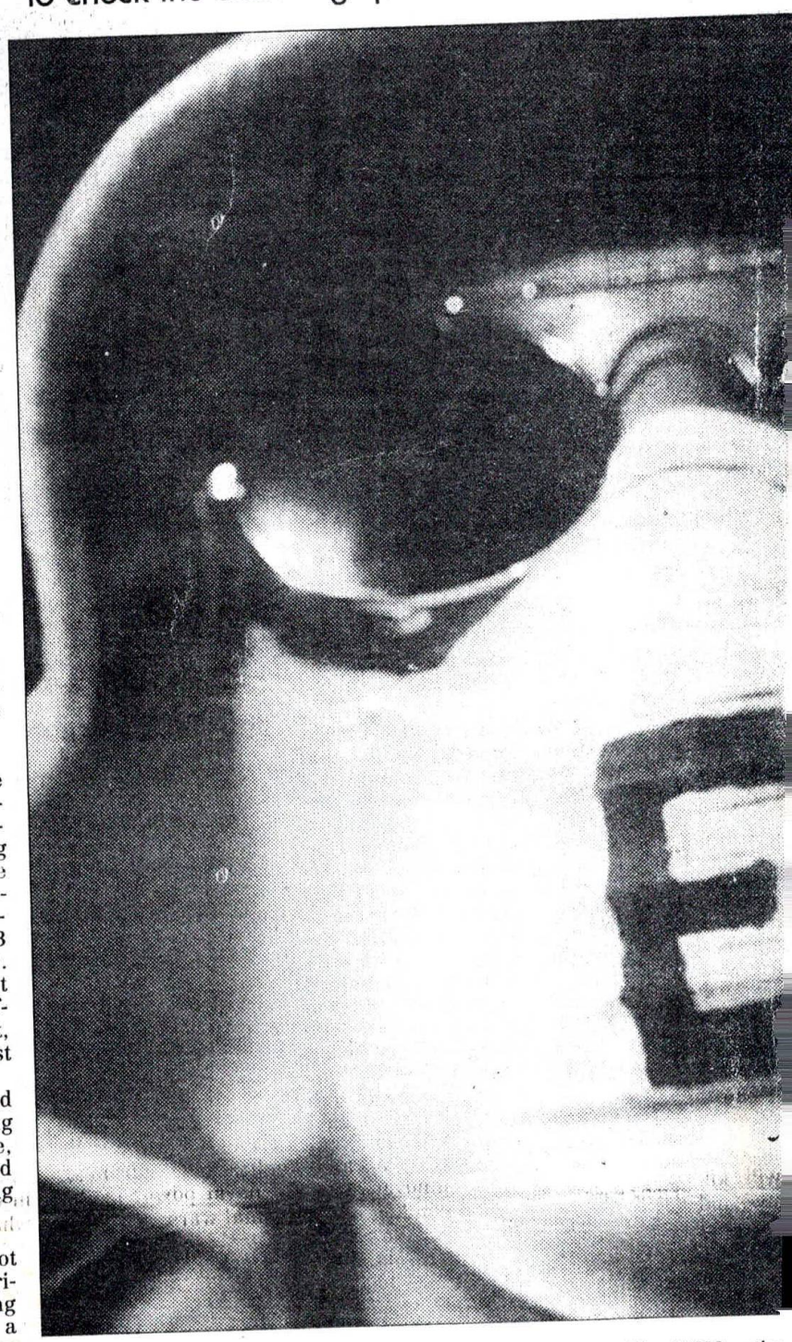
TB TROU

Tuberculosis kills a thousand Indians every day, yet p to check the alarming spread of the silent scourge,



Tuberculosis is the world's leading infectious killer. In a report on the global threat from tuberculosis, the WHO estimated that three million people died from the disease in 1995 — more than at the peak of the TB epidemics in the late 19th century when modern antibiotics were not available. The deadly lung disease is expected to kill 30 million people, most of them in developing world over the next 10 years unless the WHO's guidelines are followed. At present the TB epidemic is worse than at any other time in human history. TB is the only disease the WHO has ever classified as a 'global emergency' — a classification which confirms that we are at war with a terrible enemy.

Stopping the source

The most effective way to fight tuberculosis is to stop it at its source. Which, in this case, is the sick and infectious TB patient who has not been treated much less cured. Infectious cases are considered to be those patients with TB of the lung, who cough up many tubercle bacilli which can be seen if the sputum is examined under a microscope. These patient are termed smear positive pulmonary TB cases.

The use of a combination of anti-TB drugs called short course chemotherapy are at least 95 percent effective in treating these sick patients. However, TB medicines must be taken for a long time — at least 6 months. Frequently, once the coughing ends and other symptoms go away, TB patients lose the incentive to continue taking their medicines. When the treatment is interrupted or incomplete, the bacilli in a person's lungs can survive, multiply, or form a more dangerous form of TB known as Drug Resistant TB. Such a person is very likely to have a relapse again and infect others. Only, this time the same medicines may not work.

Desperately seeking drugs

It has been more than thirty years since a new TB drug has been brought to the market. There is no cure for some multi-drug resistant strains. If the epidemic continues to be neglected, the future generations will remember this decade as the time when humanity allowed deadly bacilli swarming the air to become drug resistant and incurable, throughout the world.

Shadow of suspicion

The majority of the world's health care systems are doing a poor job of curing TB patients. In many countries, patients are diagnosed only on the basis of X-Ray shadows. As a result, many people with other lung diseases or those who have had TB in the past but are now cured, have shadows on their X-rays and are incorrectly diagnosed with tuberculosis. WHO recommends that health workers should look for actual TB bacilli rather than just shadows when diagnosing TB.

Many countries are still not properly using short course chemotherapy to treat their patients. They often adhere to a 12 month 'long course' treatment, which is initially less expensive until one adds the cost of increased treatment failures.

The situation is even worse in some parts of the world where treatment practices are accomplishing nothing other than creating drug resistant TB. For example, in a survey of 100 doctors in Mumbai, it was found that up to 80 different drug combinations were being used — most of which were inappropriate.

Spinning out of control

The vast majority of the world's TB patients are not supervised during treatment. Some programmes or private doctors provide patients with a bag containing several weeks' worth of medicines — or worse — a prescription for 6 months treatment — and send them on their way. After taking just enough medicine to feel better, patients frequently sell their remaining medicine at a profit, or share it with other sick members of their family.

A significant share of the health budgets in many developing countries is spent on expensive medical services that benefit only a few members of society. The World Development Report, 1993, concluded that too much public health money is spent on health expenditures in developing countries — such as heart surgery and surgery for most cancers.

The result? Very little money is left over to spend on highly cost-effective health interventions that could save millions of lives. One of the findings of the report is that tuberculosis is among the most cost effective diseases to control in adults over the age of 15 years.

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TROUBLE

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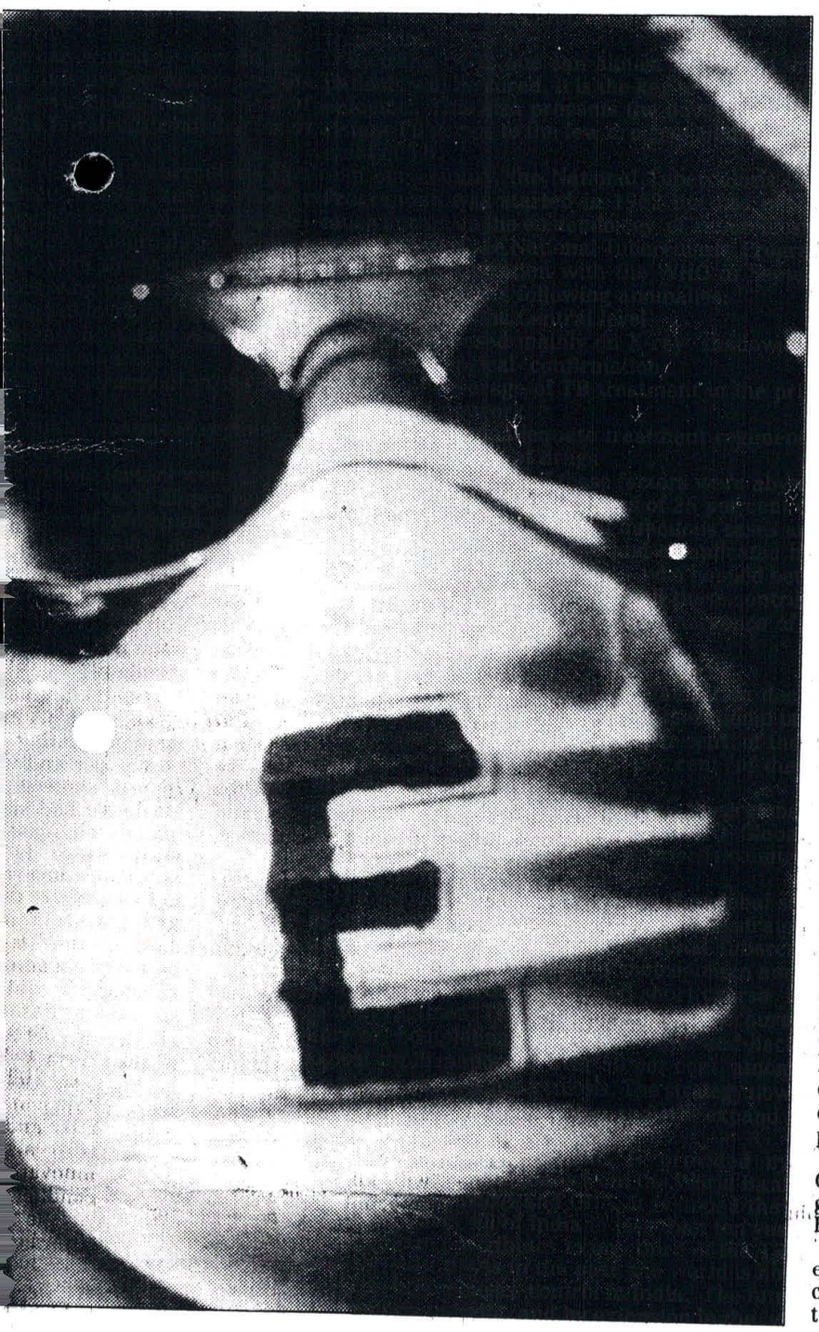

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The WHO estimates that $100 million (0.2 percent of donor government's foreign aid budgets) is needed each year from the world's wealthiest countries to fight TB in poorer nations. But in 1990, the world's foreign aid programme spent just $ 14 million to fight 8 million new TB cases in developing countries.

The American Medical Association estimates that in the United States alone that same year, just 26,000 cases cost the country approximately $700 million. Nearly one third of these US cases were foreign born. These figures have led the US Center for Disease Control to stress the importance of investing in global TB control as a means of eventually reducing the number of domestic TB cases.

Bitter pill to swallow

The WHO's strategy for curing TB patients is to use directly observed treatment, short course (DOTs). DOTs is a system where health workers watch as each patient takes the correct medication. Health workers must watch their patients actually swallow each dose of medicines. This supervision must continue every day for the first two months and, ideally, for all six months of treatment.

By using DOTs one can almost be certain that TB patients will be cured. It is the key to stopping the TB epidemic. This also prevents the development of resistant TB germs to the few drugs available for treatment of TB.

In our country, the National Tuberculosis Control Programme was started in 1962 but has not made much impact on the epidemiology of Tuberculosis. An evaluate ion of the National Tuberculosis Programme (NTP) in collaboration with the WHO in September 1992, detected the following anomalies:

- Weakness of the Central level
- Diagnosis based mainly on X-ray shadows without bacteriological confirmation
- Lack of coverage of TB treatment in the primary health care network
- Multiple and inadequate treatment regimens and irregular supplies of drugs

The consequences of these factors were abysmally low treatment completion rates of 25 per cent on an average, a low proportion of infectious cases among patients diagnosed with TB, and complicated health seeking behaviour of patients — who hopped between the public and private sectors. All these contributed to high default rates, and to the emergence of drug resistance.

Global red alert

In 1993, the World Health Organisation declared Tuberculosis a global emergency. Operational targets were pegged to cure at least 85 per cent of the cases diagnosed and to detect 70 per cent of the estimated incidence.

To achieve rapid progress towards these global targets, technical support from the WHO Global TB Programme was concentrated in priority countries — those with large number of cases.

The Indian government adopted the global strategy for effective TB control and tested this strategy as a development of the Revised National Tuberculosis Programme (RNTP), both in metropolitan and rural areas, with directly observed short course intermittent regimen. The results were very encouraging: Cure or completion rates of over 808 and bacteriological confirmation of over 50 per cent among the diagnosed cases of tuberculosis. The strategy now covers a population of 12 million and will expand to 20 per cent by 1999.

Financial support for this is provided by the Government of India, loans from the World Bank and grants from DANIDA and ODA. It is hoped that the RNTP will cover all of India in less than ten years.

India alone contributes to one third of the TB cases in the world. As in the past, the world is now focused on tuberculosis control in India. The future of tuberculosis in India, and by extension in the world, will depend more on the capacity of general hospitals and primary health care facilities to adopt the WHO's strategy. This entails applying today's knowledge and the medicines discovered long ago for the benefit of the patients and the community in general.

(The author is a Senior Specialist at the Lala Ram Sarup Institute of Tuberculosis and Allied Diseases, New Delhi)

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chemotherapy period and as against sputum conversion rates of 82% and 94% respectively, obtained in controlled trials of these two regimens (TB Chemotherapy Centre, Madras, 1966 and 1964) a difference in bacteriological conversion of about 20-30% being observed between clinical trials and programme conditions.

Though the two studies may not be considered strictly comparable, it is observed that the acceptability and final result are far superior with short course chemotherapy.

The outcome of SCC in patients with initial Isoniazid resistance (without histor of previous anti-TB treatment) deserves a brief mention. Over 60% of such patients were converted, most of them having also achieved a satisfactory level of treatment compliance.

Ignoring the initial drug sensitivity status, out of the 225 patients put on SCC and assessed at the end of chemotherapy, 84% became bacteriologically negative, and of them, 16% relapsed over the next 16 months.

It is possible that other sturdier short course regimens will achieve even higher acceptability and sputum conversion and, especially, lower relapse rates.

Acknowledgement

The authors are grateful to Dr .A Banerji Dr. K.S. Aneja and G.E. Rupert Samuel who initiated the study, to Dr. Iqbal Begum and later Dr. B. Krishnacharya, Joint Directors (TB), Karnataka at LWSTC, to Dr. S. Hanumanthappa, Medical Officer and all the other staff of LWSTC who assisted in conducting the study, to Mr. B.K. Keshavamurthy, Mrs. A. Korah, Mrs. Victoria Lalitha, Mr. B.A. Eswara and Mr. N. Narahari Rao, Health Visitors of NTI, Mr. M.V. Jaigopal of the Statistical Section of NTI and all the other staff of NTI who participated in the study, to Mr. P. Perumal for the secretarial assistance, and to Dr. Sudha Xirasagar, Medical Officer, NTI who assisted in drafting the report.

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Of the 94 patients on Regimen A and 107 patients on Regimen B, 76 and 90 respectively who achieved bacteriological negativity at the end of 8th month, were eligible for follow up till the completion of 24th month after start of chemotherapy. Patients who did not report to the centre on their own for any complaint, during the follow up period, were actively followed up at the end of 12th, 15th and 24th months after the start of chemotherapy.

Of the 76 patients on Regimen A, 9 patients (11.8%) and of the 90 patients on Regimen B, 15 (16.7%) had bacteriological relapse during the sixteen months of follow up. The difference did not attain statistical significance.

15. Patients in the subsidiary analysis

Patients who were admitted to the core group of the study but were found to excrete Isoniazid resistant organisms, pre-treatment, were analysed separately.

There were 44 cases, 24 on Regimen A and 20 on Regimen B, who did not give any history of treatment prior to intake, but excreted Isonazid resistant organisms at intake. Comparison of these two groups for age, sex and distance from home to Centre did not show any differences.

Of the 24 patients on Regimen A, 22 and all the 20 patients on Regimen B completed either the 3rd or the 4th level of drug collection/intake. Of the 24 patients on Regimen A, 23 were examined at the end of treatment and of them, 15 (65.2%) were bacteriologically negative. Similarly, of the 20 patients on Regimen B, one died at the end of 7th month (he was culture negative at 4th month), 17 were examined and 9 became bacteriologically negative.

Thus, of the total 40 drug resistant patients examined at end of treatment, 24 (60%) showed bacteriological conversion.

Of the 15 patients on Regimen A and the 9 patients on Regimen B who were bacteriologically negative at the completion of eight months of treatment, two and five patients respectively relapsed by the end of 24th month. One patient (Regimen A) was reported dead at the 12th month follow up.

Discussion

The applicability of a treatment regimen in programme conditions depends upon a high level of efficacy in controlled clinical trials, a high degree of acceptability to the patients, and the resilience of the regimen to withstand its use under widely varying conditions prevailing in the different district TB programmes of the country. Hence a three step evaluation of a regimen becomes necessary firstly, to estimate its efficacy under ideal conditions; secondly, to estimate its operational efficacy and thirdly, to assess the regimen through monitoring of several DTPs under which it has been introduced on a pilot basis.

This study presents the acceptability of two 8-month short course drug regimens and the consequent bacteriological conversions observed under the operational constraints of an urban tuberculosis programme, after strictly following the recommendations in the programme manuals. Thus, these findings represent what can at best be achieved under programme conditions—the *potentials* of acceptability and resulting cure rates. The operational aspects such as drug costs work load, etc., in order to achieve this order of treatment efficiency, will be reported in a subsequent paper.

It is seen that around 80% of patients starting on either drug regimen completed optimum treatment (i.e. more than 80% of drug intake or collection). Only a small proportion of patients did not complete satisfactory level of treatment. The bacteriological conversion in either regimen was of the order of 91% as against almost 100% obtained in controlled clinical trials. In this study relapse rates within 16 months after stopping chemotherapy were of the order of 12% and 17% respectively for Regimens A and B, the difference failing to achieve statistical significance. These regimens had shown a relapse rate of about 7% under controlled trial conditions. Thus it could be seen that both bacteriological conversion and relapse rates are quite close to rates observed in controlled trials.

A similar study was conducted at the same Centre, in 1973, in order to study the acceptability and bacteriological conversion of two conventional drug regimens of one year duration—the daily self-administered Isoniazid and Thiacetazone (TH-R_1 of DTP) and supervised twice weekly Streptomycin and Isoniazid (G.V.J. Baily et al 1974) (SHTW) In this study only 56% of patients put on TH, and 31% of patients put on SH two completed satisfactory treatment (i.e. more than 80% of treatment). Among the patients who initiated treatment, 60% of those initiated on TH and 68% of those initiated on SHTW were bacteriologically negative at the end of

put on Regimen A and 92 patients (i.e. 87%) on Regimen B were examined. The bacteriological status at the end of each period is given in the Table.

14.6 *Bacteriological response to treatment as related to level of drug collection*

Table 7 presents the bacteriological response to treatment as related to level of drug collection.

It is observed that about 87% of patients on Regimen A and 92% on Regimen B showed a favourable response, judged bacteriologically. Of those that continued to remain bacteriologically positive, only three patients excreted Isoniazid resistant organisms (all of them with an MIC of 5 μgm or more). There were no deaths.

Radiological response to chemotherapy :

There was radiological improvement in 93% of patients on either regimen. However, lesions healed by complete clearing in 6% of patients on Regimen A and 21% of patients on Regimen B, the difference being statistically significant.

14.7 *Bacteriological relapses by the end of 24 months after the start of chemotherapy*

Table 8 presents the bacteriological relapses (among patients bacteriologically negative at the end of chemotherapy).

Table 7

Bacteriological Response to Treatment as Related to Level of Drug Collection

Culture and Sensitivity	Level of Drug collection				
	1	2	3	4	Total
			Regimen A		
Negative No. %	2	1	7	66	76 (87.4%)
Positive	—	—	5	6	11
Sensitive	—	—	4	4	8
Resistant	—	—	1	2	3
Dead	—	—	—	—	—
Not Examined	—	—	6	1	7
Total					94
			Regimen B		
Negative No. %	3	—	10	77	90 (91.8%)
Positive	4	—	2	2	8
Sensitive	4	—	2	2	8
Resistant	—	—	—	—	—
Dead	—	—	—	—	—
Not Examined	2	—	5	2	9
Total					107

Table 8

(Bacteriological Relapses among Patients with Culture Negative at the end of Chemotherapy)

Initial Culture Status	Regimen	No. Eligible	Relapse	
			No.	%
Sensitive	A	76	9	11.8
	B	90	15	16.7
	Both	166	24	14.5
Resistant	A	15	2	
	B	9	5	
	Both	24	7	29.2
Sensitive & Resistant	A	91	11	12.1
	B	99	20	20.2
	Both	190	31	61.3

It is observed that 73 (77.7%) patients on Regimen A and 81 (75.7%) patients on Regimen B completed the 4th level of drug collection i.e. they completed more than 80% drug intake in both the phases. Only 12 of the total 201 patients on either regimen completed only the 1st or 2nd levels of treatment.

14.5 *Bacteriological response during and at the end of treatment*

Table 6 presents the bacteriological status of patients during chemotherapy at the 4th, 7th and 8th months of treatment. At the end of the eighth month, 84 patients (i.e. 89.4%)

Table 4

Levels of Drug Collection

Level	Proportion of expected No. of doses/collections made during 8 months		Regimen A		Regimen B	
	Intensive phase	Continuation phase	Intensive phase Doses	Cont. Phase collections	Intensive phase Doses	Cont. Phase collections
1	(50-79) %	< 80%	15-23	0-5	30-47	0-4
2	(50-79) %	⩾ 80%	15-23	6-7	30-47	5-9
3	⩾ 80%	< 80%	24-30	0-5	48-60	0-4
4	⩾ 80%	⩾ 80%	24-30	6-7	48-60	5-6

Table 5

Distribution of cases in the main analysis by the the level of Drug Collection

Level	Regimen A		Regimen B	
	No.	%	No.	%
1	2	2.1	9	8.4
2	1	1.1	—	—
3	18	19.1	17	15.9
4	73	77.7	81	75.7
Total	94	100.0	107	100.0

Table 6

Bacteriological Status at the end of 4th, 7th and 8th months

Bact. Status (culture)	Regimen A	Regimen B	Total
		4th Month	
Negative	66	83	149
Positive	11	3	14
Not done	17	21	38
		7th Month	
Negative	73	85	158
Positive	4	6	10
Not done	17	16	33
		8th Month	
Negative	73	85	158
Positive	11	7	18
Not done	10	15	25
Total	94	107	201

Table 2

Comparison of Cases in the main analysis with respect to age, sex and distance from Residence to Centre

		Regimen A		Regimen B		Total	
		No.	%	No.	%	No.	%
Age	12 — 24	32	34.0	43	40.2	75	37.3
	25 — 44	46	48.9	54	50.5	100	49.8
	45 +	16	17.0	10	9.3	26	12.9
Sex	Male	55	58.5	68	63.6	123	61.2
	Female	39	41.5	39	36.4	78	38.8
	M + F	94		107		201	
Distance	< 4 KMs	35	37.2	39	36.4	74	36.8
	5-8 „	43	45.7	54	50.5	97	48.3
	9 + „	16	17.0	14	13.1	30	14.9
	Total	94	100.0	107	100.0	201	100.0

Table 3

Coverages for Sputum Examination at Check-up

Month of Check-up	Regimen A		Regimen B	
	No.	%	No.	%
4	77	81.9	87*	81.3
7	79*	84.0	93*	86.9
8	84	89.4	93*	86.9
Total cases	94	100.0	107	100.0

*Includes sputum collected but found contaminated.

visits if necessary to collect sputum specimens in order to obtain accurate information on the bacteriological response to chemotherapy. Such attempts were not made at the end of the 4th month, as they would have influenced the treatment compliance pattern.

14.3 *Levels of drug collection*

Patients in the main analysis were distributed according to the criteria defined in Table 4. These criteria were adopted to assess the relative role of intensive phase and continuation phase under different patterns of treatment compliance.

Compliance Level 1 comprises patients who in their intensive phase have taken <80% of the due doses and in the continuation phase, less than 80% of their due drug collections. Thus, for Regimen A, a patient making 15-23 visits for supervised drug administration (as against the full 30) and 0-5 monthly collections (as against the full 7) is classified as "Level 1" compliance. Similarly Levels 2, 3 and 4 are also shown in the table.

14 4 *Treatment Compliance*

Table 5 presents the levels of drug collection achieved by the 94 patients on Regimen A and 107 patients on Regimen B according to the levels of drug collection.

negative at the end of chemotherapy were eligible for follow up investigations at the end of the 12th, 15th and 24th months after admission to the study. At each follow up, one spot and one overnight/spot specimen of sputum were collected for bacteriological investigations; history of symptoms and subsequent antitubercular treatment taken after the eight month period were elicited.

At the end of the 12th and 24th months, patients were also eligible for a 70 mm photofluorogram of the chest.

All follow-up and check-up investigations were done within a period of one week prior to and two weeks after the exact due date of follow-up.

13. Classification of Patients Admitted to the Study

The intake of patients lasted from January '83 to May '84. During this period 1,822 bacillary cases were diagnosed. Of these, 1,418 patients were excluded, of whom 696 were residing outside the city limits, 695 (38.1%) were not willing to attend the centre for treatment and 27 did not satisfy the other criteria for admission to the study. Of the 404 patients admitted to the study, 322 were classified as core group and the remaining 82 patients with history of previous anti-TB treatment, as non-core group. One patient of the core group was excluded by mistake, on grounds of allergy to Streptomycin.

Table 1 presents the distribution of the 321 patients in the core group according to regimen, exclusions and drug sensitivity pattern. Of the 150 patients allocated to Regimen A, and 171 to Regimen B, 23 and 33 respectively were excluded from the study as they did not complete even half the number of the doses in intensive phase of chemotherapy. Of the 127 patients on Regimen A, 94 excreted organisms sensitive to Isoniazid, 24 excreted Isoniazid resistant strains, and 9 were negative on culture. Similarly of the 138 patients put on Regimen B, 107 had drug sensitive organisms pre-treatment, and the rest were either resistant or negative. The 94 and 107 drug sensitive patients on Regimen A and B respectively are classified as patients in the main analysis, and the rest for subsidiary analysis.

14. Results—Patients in the main analysis

14.1 *Comparison of patients allocated to the two regimens in the main analysis*

Table 2 presents the comparison of the 94 patients allocated to Regimen A and 107 patients allocated to Regimen B with regard to initial culture status, age, sex and distance from residence to the Centre.

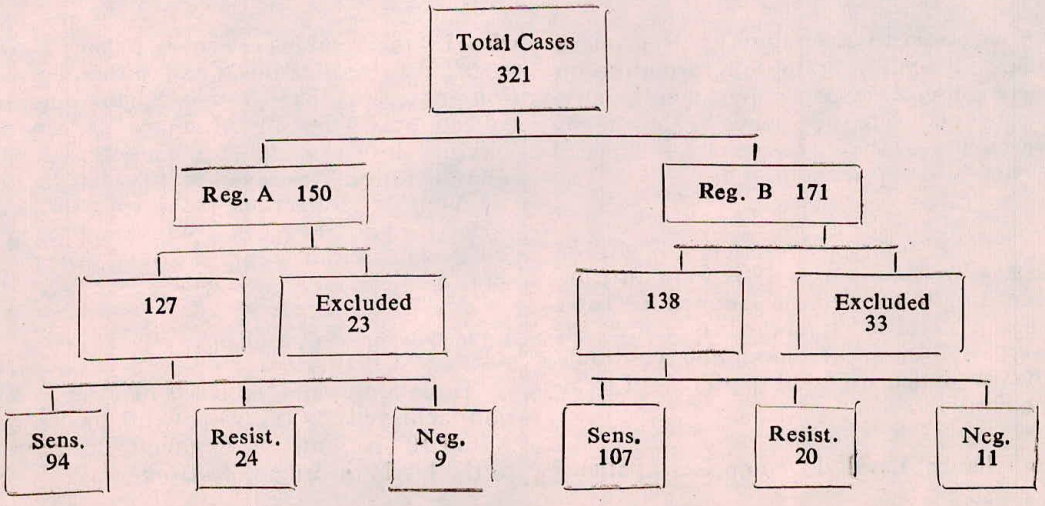
14.2 *Coverages for bacteriological check-up*

Table 3 presents the coverages for bacteriological check-up at the end of 4th, 7th and 8th month.

The 4th month check-up coverages are lower than those of 7th and 8th months. This is because, at the end of chemotherapy period, extra efforts were made by additional home

Table 1

Distribution of Previously Untreated Patients by Allocation to Drug Regimen, and Initial Drug Sensitivity Status



6. Chemotherapy Regimens

Two 8 month regimens were studied :

(1) *Regimen A* i 1SHRZ+7TH i.e,

Streptomycin (S)	0.75 g.
Isoniazid (H)	300 mg.
Rifampicin (R)	450 mg. for patients weighing <50 kgs. and 600 mg. for ≥ 50 kgs.
Pyrazinamide (Z)	1.5 g. for patients weighing <50 kgs. 2 g. for ≥ 50 kgs.
Thioacetazone (T)	150 mg.

S+H+R+Z in daily doses as described above was administered under supervision for one month followed by H+T in doses as mentioned above for the next seven months. H+T was dispensed as monthly supplies, and self administered by the patient on a domiciliary basis.

(2) *Regimen B* : 2SHR+6TH

Regimen B differed from Regimen A in that the initial intensive phase did not contain Pyrazinamide and that the period was extended to two months. The continuation phase was limited to six months.

7. Compensatory Period

Keeping in mind the crucial contribution of the intensive phase to the success of an SCC regimen, it was decided to provide a reasonable period of time as "Compensatory Period" to compensate for the missed doses.

To qualify for compensatory period, the patient had to have completed at least 50% of the prescribed number of doses within the originally stipulated period. A compensatory period of upto 15 days in case of Regimen A, and 1 month in case of Regimen B was offered to patients to compensate for the missed doses.

8. Defaulter Actions

A patient was considered a "defaulter" if he did not attend the clinic on the due date for administration or for collection of drugs.

For each default, a patient was given a maximum of two defaulter actions. The first action was in the form of a letter written and posted on the evening of the date of default. If he failed to turn up within the next three days, a second action i.e. a home visit, was made. During compensatory phase, no defaulter actions were takcn.

9. Exclusions from the Study

Patients who did not complete at least 50% of the due daily doses in the originally stipulated period of intensive phase, were excluded from the study. On exclusion from study, the treatment cards were transferred to the treatment section of LWSTDC for routine management under DTP; no further check up or follow up actions were undertaken for them.

10. Check-up Examinations

(i) One specimen of sputum each, at the end of the 4th month and 7th month, and two specimens (one spot and another overnight/spot) at the end of the 8th month for direct smear, culture and sensitivity tests.

(ii) One 70 mm photofluorogram at the end of the 8th month of initiation of chemotherapy.

(iii) Brief interview to elicit symptom status and additional anti-tuberculosis treatment from other sources, if any.

11. Criteria for Favourable and Unfavourable Response at the end of Treatment

Death during the treatment period was considered an unfavourable response. A patient was also defined to have had an unfavourable response if any one of three specimens of sputum collected at the end of the 7th and 8th months was bacteriologically positive by culture. If, from any one of these specimens, Isoniazid resistant organisms were isolated, the patient was considered to have developed drug resistance.

However, even if all three specimens (at the end of 7th and 8th months) were not available, the result of the available (one or two) specimens has been used to report the response to treatment.

12. Follow-up Procedures After 8th Month of Chemotherapy

Initial culture negatives were not eligible for follow up after chemotherapy. Patients with unfavourable response to treatment were also not eligible for follow up at 12th and 15th months. They were put on a DTP regimen and followed up only at 24th month to ascertain their status.

Patients who became bacteriologically

Further, no extra efforts were put in to retrieve patients particularly for a check-up examination, before the end of the chemotherapy period.

2. Objectives

The main objectives of the investigation were to study :

(i) the acceptability of two eight-month regimens of short course chemotherapy in terms of initial willingness to attend clinic daily for two months, and the actual pattern of drug collection,

(ii) the response to treatment assessed in terms of bacteriological status at the end of 8 months after the start of chemotherapy, and relapses by the end of the 24th month after starting treatment,

(iii)* the operational aspects of implementing short course domiciliary chemotherapy, in an urban tuberculosis programme.

3. Criteria for Admission of Patients to the Study

Core group : All new patients diagnosed at LWSTDC, Bangalore satisfying the following criteria were admitted to the study :

(a) Sputum positive on direct microscopy

(b) No previous treatment or not more than two weeks of chemotherapy

(c) Aged 12 years or more

(d) Judged as bona fide residents of Bangalore City

(e) Physically fit to attend the clinic daily, in intensive phase

(f) Without clinically evident liver, kidney or joint disease, advanced pregnancy, or diabetes mellitus.

It may be noted that the above group of patients, by and large, represents the type of patients admitted to controlled clinical trials, and as such, the efficacy of the regimen observed under programme conditions among such patients could be compared to the true efficacy observed under conditions of a controlled clinical trial

Non-core group : Under programme conditions, however, patients who have had previous chemotherapy have also to be put on treatment despite the fact that the patient may even have become drug resistant—a fact that will not be known in a vast majority of TB centres in the country, as drug sensitivity tests are not undertaken at most centres. Thus, patients who had been previously treated for more than 15 days, were also included in the study in a separate random allocation and were termed the "Non-Core Group".

Analysis of non-core group of patients will be reported as part of the operational aspects of the study, separately.

4. Pre-Treatment Investigations

(a) One 70 mm PA photofluorogram of the chest

(b) Two specimens of sputum—one supervised spot specimen and another overnight specimen, (collected within four days of admission to the study), both examined by direct smear Ziehl-Neilsen technique, and culture and sensitivity tests to Isoniazid, Streptomycin and Rifampicin,

(c) *Pre-treatment interview & examinations*

Pre-treatment interview consisted of :

(i) History of symptoms, with duration

(ii) Clinical examination

(iii) Willingness to attend the clinic daily for two months and monthly for the rest of the duration

(iv) History of previous chemotherapy.

(v) Careful re-elicitation of the conditions listed under item 3.

5. Allocation to Regimen

As soon as the medical officer ensured that all the conditions listed under item 3 were satisfied, and the patient was willing to attend the clinic as required, allocation to regimen was done on the basis of random sampling numbers placed in serially numbered sealed envelopes provided by the Statistical Section of the National Tuberculosis Institute (NTI), Bangalore. For each patient, the next in the serially numbered envelopes was opened and allocation made. Each envelope contained a slip indicating the regimen.

Allocation of patients to the regimen in the non-core group was done through a separate random allocation. But all other activities were the same for both groups.

*Will be reported separately.

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THE ACCEPTABILITY AND EFFICACY OF TWO REGIMENS OF SHORT COURSE CHEMOTHERAPY UNDER CONDITIONS OF AN URBAN TUBERCULOSIS PROGRAMME

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Introduction

The availability of potent bactericidal drugs such as Rifampicin, Pyrazinamide and Isoniazid has made it possible to reduce the duration of treatment of tuberculosis from 12 months in case of coventional regimens to 6 months in Short Course Chemotherapy (SCC) regimens. This development holds out the promise of better treatment compliance by patients, resulting in better cure rates under programme conditions.

At this juncture, it would be pertinent to recapitulate that, before a treatment regimen is recommended for mass use under a programme, it undergoes evaluation in at least 3 stages. At the first tier, controlled clinical trials of the drug regimen testify to its efficacy under ideal conditions after ensuring that every patient put on treatment consumes most, if not all, of the doses of prescribed chemotherapy within the stipulated period.

In the second and third tiers of evaluation, regimens are studied for widespread applicability on a routine basis. The second tier consists of an *operational* study of the *potential* efficacy, when *all the programme recomendations* are satisfied ; the effort possible under a routine tuberculosis service programme is invested in an operational trial, no less and no more. The "operational efficacy" within the frame work of a programme comes to be defined thus. Sputum conversion and relapse rates under various treatment compliance patterns are observed.

In the third stage, the regimen is actually introduced in a National Tuberculosis Programme (NTP) in several units of the NTP, on a pilot basis, and, carefully monitored with selected indices, over a period of time, to assess its success and shortcomings, on a large scale. At this stage, the regimen would be applied under a broad range of conditions, prevailing in the different district tuberculosis programmes (DTP), where it is introduced. The NTP in India consists of several hundred DTPs. Though, in principle, they are expected to function according to recommendations in the manuals, the actual functioning may be ideal in one DTP, and rather less than ideal in another. For example, at one centre, a patient may be carefully motivated about his disease, intake of drugs etc, but at another, motivation of the patient may be rather casual. Many such factors could influence the actual efficiency of the treatment programme in a DTP.

This study attempts to evaluate the operational efficacy of two short course chemotherapy regimens when a certain, well-defined amount of effort is invested, under conditions of an urban tuberculosis programme.

These two regimens of eight months' duration had been studied under controlled trial conditions (East African BMRC, 1980), in sputum smear positive patients, without history of previous chemotherapy. Almost 100% of patients, with drug sensitive strains pretreatment, had a favourable response at the end of chemotherapy and the relapse rates over 30 months in the 2 regimens were : 6% for the regimen with a two month intensive phase with three drugs (2SHR/6TH), and 7% for the regimen with a one month intensive phase with four drugs (1SHRZ/7TH)

The acceptability and efficacies of the above two regimens of SCC offered to tuberculosis patients on a domiciliary basis, were studied at the Lady Willingdon State TB Demonstration and Training Centre (LWSTDC) in Bangalore City. In addition, it was also planned to obtain data on various organisational aspects of an urban domiciliary chemotherapy programme.

The study design aimed at maximum simulation of programme conditions, avoiding any undue influence of the research effort on patient compliance. For example, in the attempt to study bacteriological response to treatment, the number of interim check up examinations were kept to the bare minimum,

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Original Article

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OPERATIONAL FEASIBILITY OF AN UNSUPERVISED INTERMITTENT SHORT COURSE CHEMOTHERAPY REGIMEN AT THE DISTRICT TUBERCULOSIS CENTRE*

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Summary : **The acceptability, treatment compliance and efficacy of a self-administered short course intermittent regimen were studied under programme conditions. Of 244 smear positive patients eligible for intake, 150 accepted the regimen. Results of 123 among them, who had initial drug sensitive organisms, are presented. At the end of chemotherapy, 86 were culture negative, irrespective of the amount of treatment taken. Sputum conversion was directly related to the level of drug collection, 92.8% patients with ≥ 80% drug collection attaining bacteriological conversion. Among the rest, who made < 80% drug collection, 60% became sputum negative. Relapses, over a period of three years from the date of diagnosis, were 10%.**

Proportion of patients who returned for treatment following defaulter action was 90% throughout the period of treatment. The workload due to drug collection and defaulter retrieval actions were within manageable limits and there was no workload due to adverse reactions.

The availability of many highly efficacious intermittent Short Course Chemotherapy (SCC) regimens can be viewed as a promising development, considering reduced cost, lower incidence of adverse reactions, reduction in the total amount of drugs to be consumed and less frequent administration of drugs. However, the virtues of intermittent regimens notwithstanding, feasibility of their use as a twelve month conventional or a six month SCC regimen in the District Tuberculosis Programme (DTP) has always been debatable, owing to low initial acceptance and treatment completion rates, resulting from the requirement of supervised administration. It may be recalled that whereas in daily regimens under the DTP, drugs can not only be collected on monthly/fortnightly basis but by proxy as well, in intermittent regimens it is obligatory to have each dose consumed by the patient under supervision at the centre.

This study attempts to investigate the operational problems in the delivery of an intermittent SCC regimen and its efficacy when drugs are issued on fortnightly basis for self-administration at home.

2. Objectives

The objectives of the study were to study

(*i*) acceptability of an all oral self-administered six month intermittent regimen of SCC in terms of initial willingness to collect drugs,

(*ii*) response to treatment assessed in terms of bacteriological status at the end of six months and relapses over a period of 36 months after starting the treatment,

(*iii*) operational aspects of implementation of unsupervised intermittent SCC regimen in terms of workload.

3. Material and Methods

3.1 *Method*

The study was conducted at Lady Willingdon State Tuberculosis Centre (LWSTC), Bangalore. The intake period was one year (Jan. 1985 to

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* Paper presented at the 45th National Conference on TB and Chest Diseases held at Rohtak in January 1991.

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Dec. 1985). The drugs were issued once weekly in the intensive phase for 2 months initially and on fortnightly basis for 4 months of continuation phase.

3.2 *Eligibility*

All the patients diagnosed as sputum positive on direct smear at LWSTC were eligible for intake if the following criteria were satisfied :

(*a*) Living within city limits of Bangalore

(*b*) Aged 12 years or more

(*c*) Willing to take treatment

(*d*) No history of previous anti-tubercular treatment

(*e*) No serious concomitant disease.

3.3 *Regimen*

The regimen selected for the study was :

$2EHR/4H_2R_2$

(*a*) *Intensive phase* 2EHR

Ethambutol (E) 800 mg Isoniazid (H) 300 mg Rifampicin (R) 450 mg	All drugs consumed together daily for 2 months. Self administered at home.

(*b*) *Continuation phase* $4H_2R_2$

Isoniazid (H) 600 mg Rifampicin (R) 600 mg	Both drugs taken together twice weekly for 4 months. Self-administered at home.

3.4 *Pre-treatment investigations*

(*a*) One 70 mm PA photofluorogram of the chest.

(*b*) Two specimens of sputum–one supervised spot and another overnight (collected within eight days of initiation of treatment). Both were examined by direct smear and culture. Sensitivity tests to Isoniazid, Streptomycin and Rifampicin were performed.

3.5 *Management of drug default*

A patient was considered a 'defaulter' if he did not attend the centre on the due date for drug collection. The first defaulter action was taken in the form of a letter on the due date (instead of third day, as recommended under DTP). Second defaulter action was taken on the fourth day of default in the form of home visit. A patient not collecting the drugs within one month from the due date was considered 'lost'.

3.6 *Adverse reactions and their management*

An adverse reaction was classified minor if it subsided with or without symptomatic treatment. It was classified as major if it warranted modification of chemotherapy e.g., jaundice disturbance in vision, etc.

3.7 *Check up and follow up examination*

Check up examinations were carried out during chemotherapy at the end of second and sixth months from start of treatment and follow up examinations at the end of twelve and thirty-six months.

3.8 *Classification of patients during the intake*

Out of the total 680 sputum positive tuberculosis patients diagnosed at the centre during the intake period (1.1.85 to 6.12.85), 244 were eligible for intake into the study and the remaining 436 could not be offered this regimen for reasons shown in chart 1.

Of the patients offered the regimen, 15 (61.5%) accepted it and the remaining 94 did not. Of those who accepted, 123 had initial drug sensitive organisms and 25 were drug resistant. Remaining two cases were smear positive and culture negative. The results of 123 patients with initial drug sensitive organisms are reported in this paper.

4. Results

4.1 *Level of drug collection*

The patients were distributed according to the extent of treatment received in the intensive and continuation phase, as given in Table 1.

4.2 *Treatment completion and default*

Table 2 gives the distribution of cases by levels of drug collection. It is observed that 70 (56.9%),

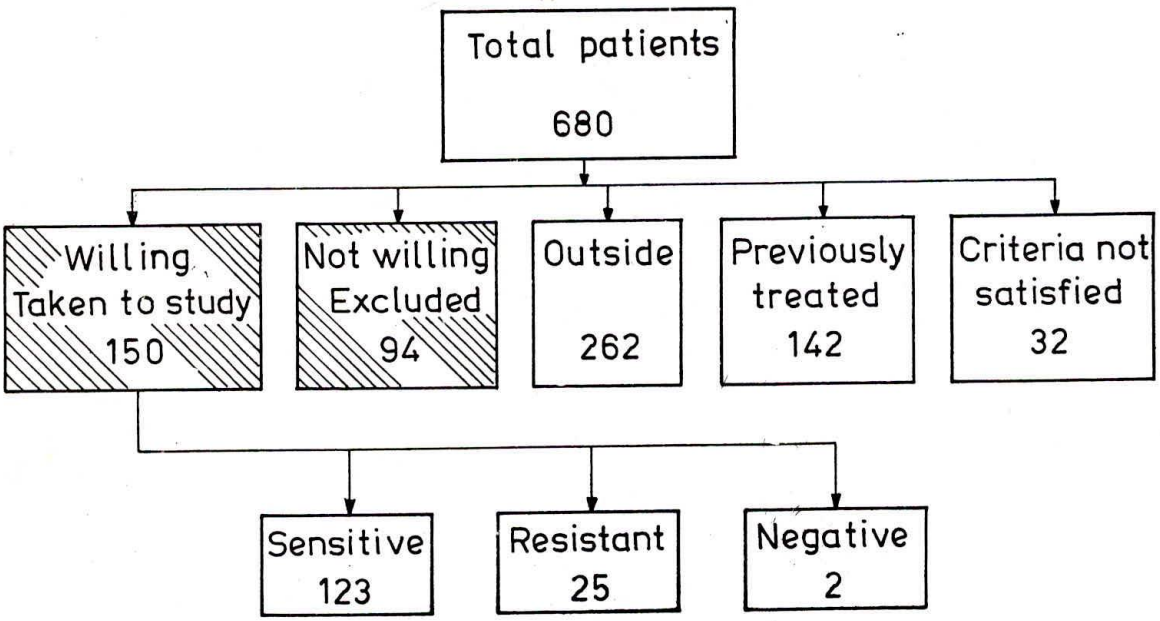

Chart 1. Classification of sputum smear positive patients diagnosed during 1-1-1985 to 6-12-1985

Table 1. *Definition of levels of drug collection*

Level	Proportion of expected no. of doses/ collections made during six months	
	Intensive phase	Continuation phase
1	< 80%	< 80%
2	< 80%	≥ 80%
3	≥ 80%	< 80%
4	≥ 80%	≥ 80%

Table 2. *Distribution of patients by the level of drug collection*

Level of drug collection	No.	%
1	23	18.7
2	5	4.1
3	25	20.3
4	70	56.9
Total	123	100.0

25 (20.3%) and 28 (2.8%) patients completed, 4, 3 and below 3 (2 and 1) levels of drug collection respectively.

4.3 *Regularity in drug collection*

Figure 1 shows the pattern of regularity in drug collection through the treatment period. Of the 123 patients, 75 (61%) made all the collections expected of them during the first month. Between 46% and 41% of patients made the collections due during each of the second through the sixth month. Overall, only 84 patients (68.3%) completed the intensive phase, 39 (35.5%) the continuation, and 39 (31.7%) the entire period of treatment with one or no default.

4.4 *Defaults*

Table 3 (*a*) shows distribution of expected drug collections by month, defaults and retrievals following defaulter action. Of 492 drug collections due to be made during the first month (excluding the 123 initial collections where chance of default did not exist), 52 (10.6%) defaults occurred. During the second month, of the 448 collections expected to be made, 87 (19.4%) did not take place on the due date. Similarly 19.1%, 33.2%, 32.5% and 29.8% of the expected collections were missed during the third, fourth, fifth and sixth months respectively, showing a rising trend in defaults with time ($P < 0.001$). However, return for drug collection after defaulter action was of the order of 78.8% and 81.4% at the first and sixth month respectively, compared to over 90% during the intervening period of second through fifth month, the differences being statistically significant ($P < 0.01$, 0.02 and 0.05) between the first month and the second, third and fourth or fifth month

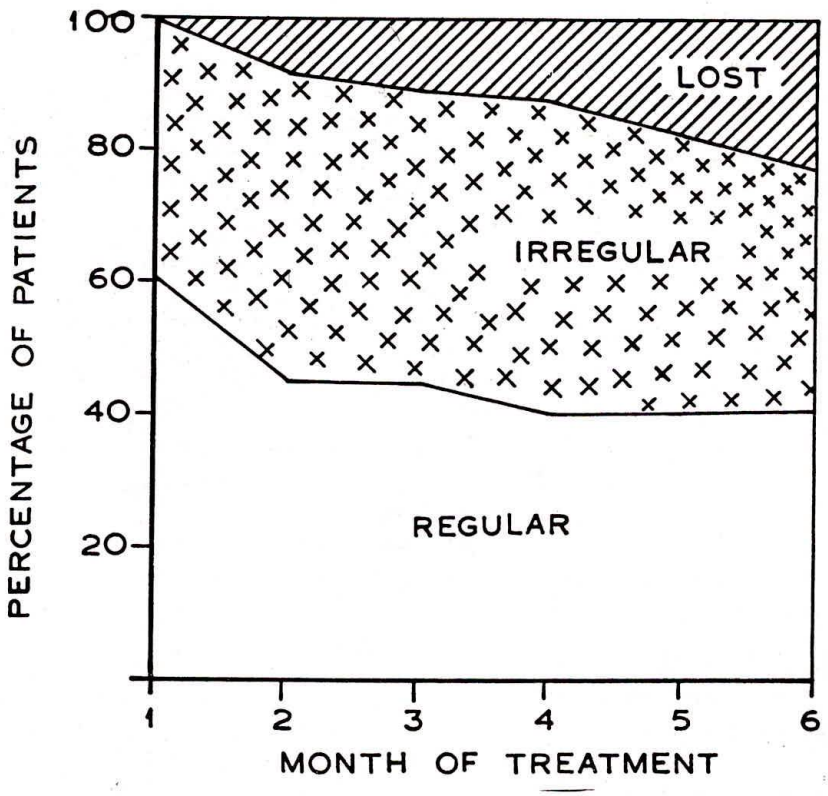

Fig. 1. Pattern of monthly drug collections among 123 patients on an SCC Regimen

Table 3 (a). *Distribution of drug collections by month*

	Month of treatment					
	1	2	3	4	5	6
No. of expected collections	492[+]	448	330	214	206	198
No. of defaults	52	87	63	71	67	59
Percent[•]	10.6	19.4	19.1	33.2	32.5	29.8
Returned for collection	41	85	60	67	63	48
Percent[••]	78.8	97.7	95.2	94.4	94.0	81.4

[+] Excluding 123 initial collections. Percentages as follows :

[•]Out of expected collections; [••]Out of defaults

respectively.

Table 3 (*b*) shows response to defaulter actions. A total of 399 defaults i.e., 139 in intensive and 260 in continuation phase, occurred during the period of chemotherapy. In each of the phases, the patient, in 90% instances of default, returned. The defaulting patients reported that the letters were not received by them in 169 instances and they visited the centre on their own before receipt of letter.

Home visit was done for the remaining 186 instances (60 in intensive and 126 in continuation phase), for patients who did not respond to the letter. Patients in 36 such instances reported for

Table 3 (b). *Retrieval of defaults*

Retrieval	Initial phase	Continuance phase
Drug collected (1-3) days–	79	134
–due to letter	19	25
–not due to letter	60	109
Drug collected (4-9) days–	38	82
–due to home visit	27	57
–not due to visit	11	25
Drug collected 10+ days	9	22
Drug not collected	13	22
Total defaults	139	260
Patients lost	13	11
Percent	10.6	10.0

drugs, when the team had just left for home visiting. Thus in 62% instances of default drugs were collected consequent to home visit.

4.5 *Coverages for bacteriological check up*

Table 4 presents the coverages for sputum examination at the end of second and sixth months, both of which were high.

Table 4. *Coverages of sputum examinations at check up*

Month of check up	Treatment initiated (drug sensitive) (No.)	Examined	
		No.	%
2	123	115	93.5
6	123	107	87.0

4.6 *Bacteriological response during chemotherapy*

Table 5 presents the bacteriological status of patients at the end of second and sixth month of chemotherapy, distributed according to the levels of drug collection.

It is observed that of the 123 patients a total of 92 (86%) showed a favourable response judged bacteriologically at the end of sixth month. Fifteen patients were found to be positive, seven

Table 5. *Bacteriological status at the end of second and sixth month*

Bacteriological status (culture)	Level of drug collection				Total
	1	2	3	4	
	Second month				
Negative	11	5	23	51	90
Percent		76.0		79.6	78.9
Positive	5	-	1	18	24
Total	16	5	24	69	114
Not done	7	-	1	1	9
	Sixth month				
Negative	7	4	17	64	92
Percent	-	-	85.0	92.8	86.0
Positive	6	1	3	5	15
Total	13	5	20	69	107
Not done	10	-	5	1	16
Grand total	23	5	25	70	123

of them excreting resistant organisms (not on Table). No deaths were reported during the period of chemotherapy.

Considering only those patients who completed level 4 of drug collection (≥ 80% in both phase i.e., completed optimum treatment), 64 of the 70 patients (92.8%) became culture negative by the end of chemotherapy.

Bacteriological conversion at the end of intensive phase, being the early index, was similar in both < 80% and ≥ 80% of drug collection (76.6% respectively).

4.7 *Relapses*

Bacteriological relapses over a period of 12 and 36 months of the start of chemotherapy among the 92 patients, who had achieved sputum negativity at the end of sixth month, are presented in Table 6. The relapse rates were observed to be 5.4% and 4.6% at the end of twelfth and thirty-sixth months respectively, adding up to a total of 9.9% within a period of 36 months.

Table 6. *Bacteriological relapse among converted patients*

Relapse at	No. eligible•	Relapse No.	Relapse %	Death
12th month	92	5	5.4	1
36th month	86	4	4.6	1
Total	92	9	9.8	-

•Converted at 6 month

4.6 *Fate of the total cohort over a period of 36 months*

Of the initial 123 patients, 95 (77.3%) could be followed up at the end of thirty-sixth month (Table 7). Of these, 7 (7.4%) were dead. Among the remaining patients, sputum could be collected from 74, of whom 69 (93.2%) were sputum nevative and five were positive.

Out of 28 patients not available for the thirty-sixth month follow up, 19 and 16 were examined at the sixth and twelfth months respectively. All of them except 3 were negative (not on Table).

4.9 *Adverse reactions*

Minor adverse symptoms were reported by seven patients in the intensive phase. No adverse reaction of major type requiring modification or stoppage of any anti-tuberculosis drugs was reported in the study. The incidence of adverse reactions of both minor and major type was virtually nil in this regimen.

4.10 *Workload in the centre*

4.10.1 *Due to drug distribution*

A change of policy from monthly drug distribution to weekly and fortnightly distribution in intensive and continuation phase respectively increased the frequency of visits by each patient but did not increase the workload as these 123 patients were treated for a period of six months only.

4.10.2 *Due to defaulter retrieval actions*

For 123 patients 399 defaulter actions in the form of letter posting or, on an average, 3.2 letters were posted per patient on treatment. Home visits became necessary on 186 occasions i.e. 1.5 home visits per patient on treatment.

4.10.3 *Due to adverse reactions*

There was no workload due to adverse reactions as patients were free from any kind of toxicity due to drugs.

5. Discussion

Intermittent anti-tuberculosis regimens are particularly recommended to be administered only on supervised basis. This is intended to guard against treatment failure due to irregular or selective consumption of drugs, or toxicity from inadvertent overdosage of a drug, which is already prescribed at a higher dose compared to that in daily regimens. Moreover, supervised drug administration is supposed to take care of a possible concealed default, which has been shown to occur in self-administered regimens. On the other hand, intermittent regimens require the patient to pay frequent visits to the centre imposing an extra burden on him. It is an additional workload for the organization as well. These factors seem to restrict the applicability of intermittent regimens in the programme in spite of its being less toxic and relatively cheaper. To

Table 7. *Fate of 123 patients at 36 months*

Total patients	Patients followed up	Dead	Sputum examination: Not examined	Positive: Sensitive	Positive: Resistant	Negative	Examined
123	95	7	14•	2	3	69 (93.2)	74

•Out of station-2; No sputum-12

overcome the above hurdle and at the same time retain the advantages of SCC regimens given intermittently, the feasibility of an unsupervised semi-intermittent all oral SCC regimen was studied under operation conditions of a District Tuberculosis Centre (DTC).

5.1 *Initial willingness*

The regimen was acceptable to the patients to the extent of 61.5%, when they were required to visit the centre weekly in the intensive phase and fortnightly in the continuation phase for drug collection. This is higher than the initial willingness of 38% observed in an earlier report', vherein the patients were asked to attend DTC daily for initial two months for supervised administration of drugs in the intensive phase. The present study, carried out in the same centre, immediately following the earlier study, therefore, represents an improvement in the acceptability of self-administered intermittent regimen, possible due to the reduced frequency of attendance required of the patients.

5.2 *Default*

Default in drug collection is generally known to affect the outcome of treatment results. Besides, default increases the workload of the treatment centre, since defaulters have to be identified on a day to day basis and letters have to be written or home visits made. In this study, more than 31.7% of patients completed ·eatment with or without a defaulter action. The remaining defaulters required two or more actions, sometime or the other. The occurrence of defaults out of collections due during a month was significantly less during the first month and appeared to rise thereafter. However, proportion of those returned for collection, out of those due but initially missed during a month was significantly less during the first and sixth months. Probably, defaulter actions were comparatively less successful during the first month due to lack of conviction among the newly diagnosed patients regarding treatment offered at the centre. In the sixth month, the higher drop out rate could be a result of complacency developing among patients, who were on the verge of achieving treatment completion, leading to a comparatively response to retrieval action.

It is seen that 56.8% of the patients completed optimum treatment (80% of drug collection). It could be achieved only due to defaulter actions, as patients in 90% of the instances of default were retrieved by letters or home visit. However, letters on the same day appeared to be a little premature, as a large number of defaulters attended the centre for the drug collection before the receipt of letter.

5.3 *Therapeutic efficacy*

Bacteriological conversion at the end of treatment period in this study was 86% and there was no death. Among the 95 patients who could be followed up for 36 months, only 7 (7.4%) were dead. Of the remaining 88, 69 were sputum negative and a sample of sputum could not be produced in 12 at thirty-sixth month. In all 81 patients could be considered to have a stable

Appendix-I. *Bacteriological status at the end of 6th month by level of drug collection*

Bacteriological status (culture)	Level of drug collection				Total
	1	2	3	4	
Negative	9	4	20	72	105 (80.8%)
Positive	7	2	5	11	25
Sensitive	3	-	5	3	11
Resistant	4	2	-	8	14
Death	-	-	-	-	-
Exam not done	14	-	5	1	20
Total	30	6	30	84	150

Appendix-II. *Completion of treatment, conversion and relapse according to initial culture status*

Initial culture status	No.	Completion of treatment %	Conversion (end of chemo-therapy) %	Relapse (at 36th month) %
Sensitive	123	56.9	86.0	9.8
Resistant	25	52.0	57.1	16.7
Negative	2	(1)	(1)	(1)
Total	150	56.0	80.8	11.5

Figures in brackets are actual numbers

bacteriologically converted status after 36 months (92%). Thus, initial as well as the ultimate sputum conversion and low death rates observed in the study, do not give scope for undue apprehension regarding irregular or selective consumption of any drug even though unsupervised. On the other hand, sputum conversions were directly related to level of drug collections, thereby strengthening the hypothesis that those who collected the drugs generally consumed them as per advice.[2]

As shown in the Appendix Tables, if all the 150 smear positive patients are assessed (culture facilities not being available in DTP), 84(56%) took at least 80% of the prescribed treatment and 105 (80.8%) became culture negative at end of chemotherapy. Of the latter, 12(11.5%) relapsed during a 30 month follow-up. Thus, the regimen has an overall efficacy of 71.5%.

5.4 *Workload*

Workload on account of treatment activity at any treatment centre can be envisaged due to the number of visits required by a set of patients to collect drugs, defaults necessitating retrieval action, and occurrence of adverse reactions calling for additional attention.

From data available in this study (not presented), 10 patients were estimated to attend DTC daily for drug collection on the average. Nearly 400 defaulter actions were required in six months, with the average of one action per patient every two months. It amounted to not more than three defaulter actions per working day. Moreover, there was virtually no adverse reaction requiring additional attention of the staff during the period of study.

In conclusion, the unsupervised intermittent regimen was found feasible for implementation in a DTP, as it was initially acceptable and had high treatment completion rate. These favourable operational aspects, taken along with the favourable outcome of chemotherapy, expressed as stable bacteriological conversion in a high proportion of cases and absence of adverse reactions, make it a suitable regimen for application in the programme.

Acknowledgement

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DISS:15

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GUIDELINES FOR THE TREATMENT OF TUBERCULOSIS

Compiled by
THE NATIONAL TUBERCULOSIS INSTITUTE
No. 8, Bellary Road,
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Phone 361192

COMMONLY USED ANTI TUBERCULOSIS DRUG REGIMENS IN THE TREATMENT OF TUBERCULOSIS

ABBREVIATIONS: H = Isoniazid; R = Rifampicin; S = Streptomycin; Z = Pyrazinamide; E = Ethambutol; T = Thioacetazone

UNDER NATIONAL TUBERCULOSIS PROGRAMME

A. Standard drug regimens (12-18 months)

Sl. No.	Regimen & dosage	Duration (months)	Mode & Rhythm	Approx. Cost
1.	2STH / 10TH or 10EH Intensive Phase (2 months) S = 0.75 g. H = 300 mg T = 150 mg or E = 1g Continuation Phase (10 months) H = 300 mg T = 150 mg or E = 800 mg	12	Inj. S (IM) to be given five days in a week either at Clinic/Home/Disp. DTC: Other two drugs as per the regimens to be taken daily, orally. Both drugs to be taken together daily, orally.	Rs. 350/- to Rs. 1,050/- (Cost as per the drugs used)
2.	EH E = 800-1200 mg (<50 - ≥ 50 kg) H = 300 mg	12	Both drugs to be taken together daily in single dose or in two divided doses orally. Collection: Monthly from Disp./Clinic/DTC/Shop.	Rs. 800/-
3.	TH T = 150 mg H = 300 mg	18	- do -	Rs. 125/-
4.	S_2H_2 S = 0.75 g. H = 600 mg.	12	Twice weekly with three-four days interval. Both drugs to be taken together under supervision at the Clinic/DTC.	Rs. 550/-

B. Short Course Chemotherapy (SCC) regimens (6-8 months)

1.	2EHRZ / 6TH or 6EH Intensive phase (2 months) E = 1 g H = 300 mg R = 450-600 mg (<50 - ≥ 50 kg) Z = 1.5 to 2 g Continuation phase (6 months) H = 300 mg T = 150 mg or E = 800 mg	8	All drugs to be taken daily, orally at the same time. - do -	Rs. 745/-
2.	$2S_2H_2R_2Z_2$ / $4H_2R_2$ Intensive phase (2 months) S = 0.75 g or E = 1.6 g H = 600 mg R = 600 mg Z = 2g Continuation phase (4 months) H = 600 mg R = 600 mg.	6	Twice weekly with three-four days interval. All drugs to be taken under supervision at the Clinic/DTC. - do -	Rs. 500/-

OTHER SHORT COURSE CHEMOTHERAPY (SCC) REGIMENS

1.	2SHRZ / 4HR Intensive phase (2 months) S = 0.75 g H = 300 gm R = 450-600 mg (<50 - ≥ 50 kg) 6 Z = 1.5 to 2 g Continuation phase (4 months) H = 300 mg R = 450-600 mg	Inj. S(IM) to be taken five days in a week either at the Clinic/Home/Disp./DTC. Other drugs to be taken daily, orally at the same time. Both the drugs to be taken together daily, orally.	Rs. 1,135/-
2.	2EHR / 7HR Intensive phase (2 months) E = 800 mg H = 300 mg R = 450-600 mg 9 Continuation phase (7 months) H = 300 mg R = 450 - 600 mg	All the drugs to be taken daily, orally at the same time. - do -	Rs. 800/-

Corrigendum

Under Instructions

Please Read *1 as : All drugs may preferably be taken before breakfast. If not tolerated, one hour after the breakfast.

*2 as : H = 5 mg;R = 10 - 12 mg;S = 20 mg;Z = 30 - 35 mg; E = 25 mg; 15 mg after 2 months; T = 4 mg.

- Wherever necessary, Injection Streptomycin may be replaced with tablet Ethambutol or vice-versa.
- Whenever patients have not been able to take all the prescribed doses in the stipulated time, a grace period of 15 days to one month may be allowed to complete the treatment in each phase.
- Always do sputum examination for AFB to confirm the diagnosis of tuberculosis.
- Avoid use of injection Streptomycin during PREGNANCY of any duration.
- The recommended SCC regimens are of 100% efficacy as proved under controlled clinical trials against different forms of tuberculosis viz., pulmonary, miliary and extra pulmonary disease.

COMMONLY OBSERVED ADVERSE REACTIONS TO ANTI TUBERCULOSIS DRUG REGIMENS

Sl. No.	Adverse reaction	Offending drug(s)	Symptoms and management
1.	Red Brown colour of urine and other body fluids	R	Harmless: No treatment required: Assurance to be given to the patient.
2.	Vestibular damage of VIII nerve	S	Giddiness & Vertigo: Can be prevented by giving Inj. S five days in a week, in daily phase regimen, specially in elderly patients: If symptoms persists, replace S with E.
3.	Gastro-Intestinal	T or RH or RHZ combination	Anorexia, vomiting, pain abdomen, mostly transient: Symptomatic relief to be given: Drugs to be taken after meals.
4.	Clinical jaundice	T or RH or RHZ combination	Nausea, vomiting, pain abdomen, fever, malaise, yellow colouration of urine, skin and eyes: STOP ALL DRUGS till recovery: Advise rest and symptomatic treatment: Later on, treat with EH or SH (twice weekly) regimen.
5.	Cutaneous and hypersensitive reactions	T, S: R, E (Rarely)	Mild - itching all over the body with or without rashes. Symptomatic treatment. Moderate - Swelling of periorbital area, conjuctivitis, rigors, malaise, headache, vomiting, lymphadenopathy, albuminuria - change the drug. Severe - (This stage should not be allowed to occur) Rarely - Exfoliative dermatitis with involvement of mucus membrane (Stevens-johnson syndrome) may occur particularly as a reaction to T - terminate the drug and hospitalise. Hypersensitive reaction - occur in early stage of treatment. Not dose related - change the drug. Anaphylactic shock - can occur rarely after a single large dose, if patient is already hypersensitive to the drug.
6.	Retrobulbar neuritis	E	Diminuition in acuity of vision and or colour vision. Terminate the drug. Avoid if possible, the drug in myopic and child patient.

DIS 5:16

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WHO Raises Awareness

Global TB Epidemic Called Out of Control

By Edith Lederer
The Associated Press

LONDON, March 18 — A tuberculosis epidemic is out of control in many countries and unless action is taken nearly 1 billion more people will become infected and 70 million will die in the next two decades, the World Health Organization says.

At a conference this week in London, public health and tuberculosis experts have been assessing whether 22 countries which account for 80 percent of the world's TB cases are making progress towards controlling the infectious disease.

"This year, more people will die of TB than in any other year in history."
— World Health Organization

"The TB epidemic is now increasing in many countries, with devastating consequences," WHO said in a statement summarizing a report to be released Thursday. "This year, more people will die of TB than in any other year in history."

Tuberculosis, which attacks mainly the lungs, intestines, skin and brain, is a bigger killer than malaria and AIDS combined, and kills more women than all the combined causes of maternal mortality. Every year, between 2 and 3 million people die from TB, including 100,000 children, the Geneva-based U.N. agency said.

RELATED LINKS

Global Infection Threat

HEALTH & LIVING HEADLINES

An Unprecedented Step

In 1993, WHO took an unprecedented step and declared tuberculosis a global emergency. Between 1993 and 1996, TB cases increased 13 percent worldwide.

Experts on the Ad Hoc Commission on the Global Tuberculosis Epidemic have been examining new data to see how well the 22 worst-affected countries are meeting WHO's global targets of detecting 70 percent of infectious TB

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cases and curing 85 percent of those by the year 2000.

The countries are **Afghanistan**, **Bangladesh**, **Brazil**, **China**, **Democratic Republic of Congo**, **Ethiopia**, **India**, **Indonesia**, **Iran**, **Mexico**, **Myanmar**, **Nigeria**, **Pakistan**, **Peru**, **Philippines**, **Russia**, **South Africa**, **Sudan**, **Tanzania**, **Thailand**, **Uganda** and **Vietnam**.

One-third of the world's population is infected with the TB bacillus, and between 5 and 10 percent will become sick with pulmonary TB during their lifetime, the WHO said. Only those who are sick are infectious, and they can transmit the disease by coughing, talking or spitting.

"It is estimated that between now and 2020, nearly 1 billion more people will be newly infected, 200 million people will get sick, and 70 million will die from TB—if control is not strengthened," the group said.

Poor Program Management

According to the WHO, there are nearly 3 million new TB cases in southeast Asia every year and nearly 2 million new cases in sub-Saharan Africa.

More than a quarter of a million new cases occur annually in Eastern Europe, which is experiencing an increase in TB deaths after almost 40 years of steady decline, WHO said.

Since the 1940s, there have been drugs to treat tuberculosis.

But WHO said poorly managed TB treatment programs are causing drug-resistant strains of tuberculosis to emerge, "which could render TB incurable."

Up to 50 million people may be infected with drug-resistant TB, either because they did not take all their medicines regularly for the required period—often because they start to feel better—or because they receive the wrong drugs or don't have a reliable drug supply, WHO said.

TB treatment costs around $2,000 per

patient, but rises 100-fold to about $250,000 for patients with drug-resistant strains, WHO said. ■

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UP

TB-control project: Doorstep treatment yields results

ISHA DAGA
JUNE 20

D52 IE 21/6/99

TWO non-governmental organisations (NGOs) have succeeded in achieving cure of eight tuberculosis (TB) patients early this month under a focused TB control programme launched in three civic wards in Mumbai.

The Rotary Club (RC) of Bombay Harbour and the Family Service Centre (FSC) traced and motivated 94 TB patients, who had stopped treatment halfway, to resume treatment which is based on Directly Observed Treatment Short-course (DOTS) model approved under the Revised National TB Control Programme (RNTCP) launched by the Central government in July last year.

The control programme launched in A, B and C wards in January 1998 targets defaulters since studies have shown that two thirds of TB patients do not complete their course. As each TB patient can infect 10 or more persons, 100 patients back on treatment will mean a check on at least 1000 new cases. 'Case-holding', or prevention of default, is also the goal of the new programme.

"Leaving a course midway often leads to multi-drug-resitant (MDR) TB," according to Dr A J Desai, Director of RC Bombay Harbour's TB project. "The patient then spreads MDR bacteria, making it even tougher to control the disease," he added. Out of 329 listed defaulters, the NGOs could follow up on only 303 cases but had to narrow down to 94 cases to be taken up for DOTS treatment.

On several reasons for default, Desai revealed, "Most patients cannot afford to leave their work and come for treatment. Many, on feeling better after a month, stop coming, assuming they are cured. In alcoholics, the combination of poor nourishment, strong medication and alcohol causes side-effects such as dizziness, so the patient defaults." By constantly interacting with the patient, reassuring him, and watching him take the drugs, the programme has countered most of these problems.

Nigama Mascarenhás, Director, FSC said, "We focus on the social aspect of TB, reminding patients of the consequences for their family if he does not recover." She says, "Our field worker goes to their homes to ensure that he takes the dose. Though municipal workers do the same thing, they have fixed hours of work, during which the patient may not be home."

A Central TB division document claims that DOTS model 'ensures cure by providing the most effective medicine and confirming that it is taken.' It is based on good diagnosis through top quality microscopy, an uninterrupted supply of high quality drugs, treatment that is directly observed and systematically monitored by a health worker. Perhaps the most important aspect of RNTCP is that seeks to treat the patient at a time and place convenient to him/her, and each patient has his/her own marked treatment kit with the full course supplies. Member-Secretary of the Mumbai District TB Control Society and Deputy Executive Health Officer of the BMC Dr K N Khergamkar said, "We have set up 256 DOTS centres in Mumbai. The patient can visit the centre closest to him. And the kit ensures that the patient is not told midway that there are no medicines."

However, Dr Sheela Rangan, Consultant to the Foundation for Research in Community Health points out that the programme fails to look at some crucial social and economic factors. "Many women are not allowed to travel alone to the centres for treatment and cannot leave household work."

Success in any TB project depends ultimately, on the motivation levels of the health and community workers who actually talk to patients, said BMC's Deputy Executive Health officer Dr Ramesh Kathuria, at a recent discussion hosted by RC of Bombay Harbour. He mused, "I don't know how many of us would be willing to spend half an hour with an MDR TB case." Kathuria stressed that "different theories of motivation need to be applied, again and again, to ensure success."

Another critical neglected area is the private sector. According to Rangan, " About 60 per cent of the population still visits Private Medical Practitioners (PMP). RNTCP must build faith in the public health system. Mahashur says, "PMPs have to be taken into confidence and explained the efficacy of DOTS."

Khergamkar assures that the BMC is planning workshops for PMPs in August. "We are trying to establish a standardised treatment. Since we have enough supplies of drugs, we can give the GPs treatment kits free of cost."

INDIAN EXPRESS (BOMBAY)
21 JUN 1999

DOTS

DNS 5:17

DIS 5:18

A Controlled Clinical Trial of 3- and 5-Month Regimens in the Treatment of Sputum-Positive Pulmonary Tuberculosis in South India[1,2]

TUBERCULOSIS RESEARCH CENTRE, MADRAS,[3] and NATIONAL TUBERCULOSIS INSTITUTE, BANGALORE[4]

SUMMARY A controlled comparison of 3 short-course regimens was undertaken in patients with newly diagnosed, sputum-positive, pulmonary tuberculosis in South India. The regimens were: (1) R3: rifampin plus streptomycin plus isoniazid plus pyrazinamide daily for 3 months; (2) R5: the same as regimen R3 followed by streptomycin plus isoniazid plus pyrazinamide twice weekly for 2 months; (3) Z5: the same as regimen R5 but without rifampin. The distributions of various pretreatment characteristics were similar in the 3 series. At the end of treatment, 6 patients (3 R3, 3 Z5) of 694 (228 R3, 230 R5, 236 Z5) with drug-sensitive organisms initially were classified as having an unfavorable response. By 24 months (21 months of follow-up for the R3 regimen and 19 months for the R5 and Z5 regimens), a bacteriologic relapse requiring treatment occurred in 20% of 200 R3, 4% of 187 R5, and 13% of 199 Z5 patients, the difference between the R3 and R5 series being highly significant ($p = 0.00001$). Considering patients with cultures initially resistant to isoniazid, 4 of 57 in the R3 and R5 series combined had an unfavorable response to treatment compared with 13 of 26 in the Z5 series ($p < 0.0001$). Of the 4 patients with an unfavorable response in the R3 and R5 series combined, resistance to rifampin emerged in 2. Complaints of arthralgia were made by 45% of the R3 and R5 patients combined and 70% of the Z5 patients ($p < 0.00001$). However, chemotherapy was modified in only 5 and 12%, respectively. Jaundice occurred in 7% of the R3 and R5 patients and 1% of the Z5 patients ($p < 0.00001$).

AM REV RESPIR DIS 1986; 134:27–33

Introduction

Several highly effective short-course regimens (6 to 9 months) have been evolved for the treatment of smear-positive pulmonary tuberculosis (1). But the crucial issue is to determine the shortest possible duration of chemotherapy that would be highly effective. The pioneer investigation of Kreis and associates (2) showed that 3-month regimens of streptomycin given daily with 900 mg of isoniazid and 1,200 mg of rifampin given daily or every other day to sputum-positive patients had a relapse rate of 13% in 91 patients in a 12-month period of follow-up. The preliminary findings of a 5-month regimen at this Centre, with a 2-month intensive phase of streptomycin, isoniazid, rifampin, and pyrazinamide daily followed by streptomycin, isoniazid, and pyrazinamide twice a week, indicated that the relapse rate was likely to be low.

Against this background, this Centre planned a large-scale investigation of a regimen in which all 4 drugs were given daily for 3 months in standard dosages, thus adding the important drug, pyrazinamide, to the combination studied by Kreis and associates (2). However, in case this regimen proved to have a substantial relapse rate, a second regimen, with the addition of a 2-month continuation phase of twice-weekly streptomycin, isoniazid, and pyrazinamide was also studied. Because rifampin was then very costly, it was decided to evaluate its contribution to the second regimen. A 7-month regimen of streptomycin, isoniazid, and pyrazinamide given daily for 2 months and twice-weekly thereafter had a low relapse rate (4%) in an earlier study from this Centre (3). So a similar nonrifampin regimen, but for 5 months instead of 7 months, with the 3 drugs given daily for 3 months and twice-weekly thereafter, was also studied.

A controlled clinical trial of the 3 regimens was carried out at the Tuberculosis Research Centre, Madras, and at the Lady Willingdon Tuberculosis Clinic, Bangalore, in collaboration with the National Tuberculosis Institute, Bangalore. The amalgamated results during chemotherapy and the bacteriologic relapses up to 24 months from the start of treatment, that is, a 21-month period of follow-up for the 3-month regimen and a 19-month follow-up for the 5-month regimens, are presented in this report.

Methods

Plan and Conduct of the Study

Patients. The patients were residents of either Madras or Bangalore City, came from poor sections of these communities, and had come to the outpatient chest clinics because of symptoms. The criteria for admission were similar to those in previous studies (4), that is, the patients were 12 yr of age or older, had newly diagnosed pulmonary tuberculosis, had not had previous chemotherapy for more than 2 wk, and had 2 sputum cultures positive for *M. tuberculosis.*

Chemotherapeutic regimens. The patients were allocated at random to one of the following 3 regimens.

R3: daily chemotherapy with rifampin, 12 mg/kg body weight in 3 graded doses, plus streptomycin sulphate, 0.75 g, plus isoniazid, 400 mg (incorporating pyridoxine, 10 mg), plus pyrazinamide, 35 mg/kg in 5 graded doses according to body weight. All the drugs were given in a single dose; the duration of chemotherapy was 3 months.

R5: the same as regimen R3, followed by twice-weekly chemotherapy for 2 months with streptomycin, 0.75 g, plus isoniazid, 15 mg/kg body weight in 3 graded doses (incorporating pyridoxine, 10 mg), plus pyrazinamide, 70 mg/kg in 5 graded doses according to body

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[1] This report was prepared on behalf of the supporting institutions by Dr. R. Parthasarathy, Dr. R. Prabhakar, and Mr. P. R. Somasundaram, in collaboration with the other members of the scientific staff.

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[3] Under the Indian Council of Medical Research, New Delhi.

[4] Under the Directorate General of Health Services, Government of India, New Delhi.

weight. The total duration of chemotherapy was 5 months.

Z5: The same as regimen R5 but without rifampin.

The dosages of drugs other than isoniazid in the daily phase and streptomycin in both phases were increased appropriately if the patient gained weight but were not reduced for weight loss.

Pretreatment investigations. The pretreatment investigations included a chest radiograph, the examination of 2 overnight and 2 spot specimens of sputum by smear and culture, sensitivity tests to streptomycin, isoniazid, and rifampin on 2 positive cultures, and identification tests on all positive cultures. In the Madras patients, serum concentrations of bilirubin, aspartate and alanine aminotransferase activities, and a blood platelet count were determined.

Investigations during treatment and follow-up. Every month during treatment, the physician recorded any departure from the prescribed regimen and drug intolerance. Sputum specimens were examined every month by microscopy and culture, 3 (2 overnight, 1 spot) from 1 to 6 months and 2 (1 overnight, 1 spot) from 7 to 24 months. One positive culture was tested each month for sensitivity to streptomycin and isoniazid and, in addition, to rifampin during the first 3 months for R3 and R5 patients. A chest radiograph was taken at 1, 3, 12, and 24 months and, in addition, at 5 months for R5 and Z5 patients. To check whether the patient took isoniazid from other sources, a clinic urine specimen was tested for acetylisoniazid (5) at least once a month.

General management. All the patients were treated as outpatients. They attended the clinic daily for 3 months (excepting holidays) and received their chemotherapy under the close supervision of a clinic nurse. The patients allocated to the 5-month regimens attended twice a week for the next 2 months. If a patient failed to attend, the home was visited by the next day.

Bacteriologic procedures. Sputum smears were examined by fluorescence microscopy (6), and the specimens were cultured by a modification of Petroff's method (4). Positive cultures were screened for *M. tuberculosis* (7) and were tested for sensitivity to isoniazid and rifampin by the minimal inhibitory concentration method and to streptomycin by the resistance ratio method (8). The definitions of drug resistance were the same as in previous studies for isoniazid (3, 4) and streptomycin (3). Resistance to rifampin was defined as a yield of 64 mg/L on both the cultures pretreatment and a yield of 64 mg/L during treatment.

Change of chemotherapy. The progress of each patient was reviewed regularly during chemotherapy. The allocated regimen was changed if the patient had clear-cut clinical and/or radiographic deterioration in the presence of a positive sputum, major drug toxicity, or an unfavorable bacteriologic response.

Extension of the duration of chemotherapy. Patients who had missed 1 or more doses or had had 2 or more drugs withheld had the duration of daily and/or twice-weekly chemotherapy, with all the drugs extended appropriately at the end of each phase of treatment.

Patients in analyses. In all, 919 patients (303 R3, 310 R5, 306 Z5) were admitted. Of these, 114 were excluded; 43 from all analyses because of ineligibility (7 had been infected by mycobacteria other than *M. tuberculosis*, 1 had spinal tuberculosis, 3 had less than 2 positive cultures, 32 had had previous chemotherapy for more than 2 wk); 71 from efficacy analyses (2 died of nontuberculous causes, 2 died of tuberculosis early in treatment, 3 had treatment changed on account of adverse reactions, and 64 had missed or had interruption of 25% or more of chemotherapy). There remained for analyses 694 patients (228 R3, 230 R5, 236 Z5) with bacilli initially sensitive to isoniazid, streptomycin, and rifampin and 111 (34 R3, 40 R5, 37 Z5) with bacilli initially resistant to 1 or more drugs. The results are presented separately for the 2 groups.

TABLE 1

CHARACTERISTICS ON ADMISSION TO TREATMENT

		R3		R5		Z5		All Regimens	
		(*n*)	(%)	(*n*)	(%)	(*n*)	(%)	(*n*)	(%)
Total radiographic extent of disease	Slight	9	4	17	7	14	6	40	6
	Limited	55	24	58	25	55	23	168	24
	Moderate	83	36	81	35	90	38	254	37
	Extensive	78	34	74	32	76	32	228	33
	Gross	3	1	0	0	1	1	4	1
Extent of cavitation	Nil	5	2	6	3	10	4	21	3
	Slight	85	37	74	32	82	35	241	35
	Moderate	69	30	81	35	74	31	224	32
	Extensive	69	30	69	30	70	30	208	30
Direct smear result of 1st collection specimen of sputum	Negative	18	8	20	9	17	7	55	8
	Positive								
	1+(scanty)	62	27	63	27	70	30	195	28
	2+(moderate)	114	50	119	52	114	48	347	50
	3+(heavy)	34	15	28	12	35	15	97	14
Total patients		228	100	230	100	236	100	694	100

Definition of abbreviations: R3 = Rifampin (R) plus streptomycin (S) plus isoniazid (H) plus pyrazinamide (Z) daily for 3 months; R5 = RSHZ daily for 3 months, then SHZ twice a week for 2 months; Z5 = SHZ daily for 3 months, then SHZ twice a week for 2 months.

Results

Patients with Bacilli Initially Sensitive to Isoniazid, Streptomycin, and Rifampin

Characteristics on admission. Of the 694 patients, 70% were males, 32% were younger than 25 yr of age, and 19% were 45 yr of age or older. The mean weight was 40 kg. The 3 series were similar with respect to these factors. The distributions of patients in the 3 series were similar with respect to radiographic extent of disease, extent of cavitation, and smear positivity on admission (table 1). Most of the patients had extensive, cavitary, smear-positive disease.

Tuberculosis deaths. Three patients (R3, 1 Z5) died of tuberculosis or its complications; 1 (R3) died on the second day of chemotherapy, and another (R3) died of hemoptysis on the twelfth day. Neither of them can be considered failures in antibacterial terms, and they have been

TABLE 2

CULTURE RESULTS BASED ON 3 SPECIMENS OF SPUTUM EACH MONTH

Month after Start of Treatment	R3+R5 Total Patients	R3+R5 All Cultures Negative (*n*)	R3+R5 All Cultures Negative (%)	Z5 Total Patients	Z5 All Cultures Negative (*n*)	Z5 All Cultures Negative (%)	p Value
1	458	169	37	236	45	19	0.001
2	457	415	91	236	175	74	0.001
3	455	439	96	235	218	93	NS*
4	229†	223	97	234	226	97	NS
5	228†	226	99	236	230	97	NS

* Contrast not significant ($p > 0.05$).

† Patients receiving the R5 regimen only.

TABLE 3

BACTERIOLOGIC RELAPSE DURING THE 24 MONTHS AFTER ADMISSION* REQUIRING TREATMENT IN PATIENTS WHO COMPLETED THEIR CHEMOTHERAPY WITHIN 15 DAYS AFTER THE PRESCRIBED PERIOD

	Patients with a Favorable or Doubtful Response†	Total Bacteriologic Relapses		Bacteriologic Relapses Requiring Treatment‡							
				Total		95% Confidence Limits	Month of Relapse after Stopping Chemotherapy				
Series	(*n*)	(*n*)	(%)	(*n*)	(%)	(%)	1–3	4–6	7–12	13–19	20 or 21
R3	200	44	22	39	20	14–26	11	17	7	3	1
R5	187	10	5	8	4	2–8	2	2	3	1	–
Z5	199	31	16	25	13	8–18	9	10	1	5	–

* That is, 21 months after stopping chemotherapy for the R3 regimen and 19 months for the R5 and Z5 regimens.

† Of the 11 patients (6 R3, 2 R5, 3 Z5) with a doubtful response, 2 (1 R3, 1 R5) had a bacteriologic relapse requiring treatment at 3 months and with drug-sensitive cultures in both.

‡ Three other patients had treatment restarted for other reasons—1 (R3) for hydropneumothorax in the 2nd month, 1 (R5) for a radiographic deterioration with positive smears in the 3rd month, and 1 (Z5) for tuberculous lymphadenitis in the 16th month.

excluded from the analyses of efficacy. The third patient (Z5), who was positive by smear and culture at 1 month, died of spontaneous pneumothorax in the seventh week.

Culture results. The proportions of patients with all cultures negative month by month are presented in table 2. At 1 and 2 months, the proportions were significantly higher in the R3 and R5 series than in the Z5 series ($p < 0.001$, in both instances). From the third month onward, the rates were very high, and similar in the rifampin and nonrifampin series.

Response at the end of chemotherapy. A patient was classified as having had an unfavorable bacteriologic response if 1 or more of 3 cultures were positive at each of the last 2 months of treatment, irrespective of the number of colonies.

In all, 6 patients (3 R3, 3 Z5) were classified as having had an unfavorable response. Two were clear-cut bacteriologic failures; 1 (Z5) had persistently positive smear and culture results, with the emergence of resistance to streptomycin and isoniazid, and had chemotherapy changed, and the other (Z5) had persistently positive culture results throughout the 5 months, the organisms being drug-sensitive, and was retreated. Three others (all R3), who had positive cultures at 1 and 2 months, each had a single positive culture (1 or 2 colonies) at 3 months, the bacilli being fully sensitive; 2 of them had chemotherapy continued, but the third was consistently culture negative from the fifth month without further chemotherapy. The sixth patient (Z5) died of spontaneous pneumothorax (listed in *Tuberculosis deaths* above).

A patient was classified as having had a doubtful response if 1 or 2 cultures were positive in the last month of treatment and all the cultures in the preceding month were negative; 11 patients (6 R3, 2 R5, 3 Z5) had a doubtful response, 10 with 1 positive culture and 1 with 2 positive cultures. Of the 12 cultures, the yield was 1 colony in 8, 2 or 3 colonies in 2, 16 colonies in 1, and 20 to 100 colonies in 1. The bacilli were resistant to isoniazid but sensitive to streptomycin in 2, and sensitive to both drugs in the rest. Chemotherapy was not continued for any of them.

Bacteriologic Relapse

Exclusions from relapse analyses. Of the above 225 R3, 230 R5, and 233 Z5 patients who had a favorable or doubtful response at the end of chemotherapy, 13 (6 R3, 1 R5, 6 Z5) have been excluded. Of these, 2 (both R3) had chemotherapy continued beyond 3 months because of 3 positive smears at 3 months, 7 died of nontuberculous causes, 2 migrated, and 2 discharged themselves. Thus, there remained 675 patients (219 R3, 229 R5, 227 Z5) in the relapse analysis.

A bacteriologic relapse was defined as a total of 2 or more cultures positive for *M. tuberculosis* in any 3 consecutive monthly examinations. Treatment was restarted if 1 of the cultures yielded 20 colonies or more and there was 1 positive smear, or if a patient intermittently produced positive cultures for several months.

The relapse rates in 586 patients (200 R3, 187 R5, 199 Z5) who completed their chemotherapy within 15 days of the prescribed 3- or 5-month period are presented in table 3.

A bacteriologic relapse occurred in 44 (22%) of the R3, 10 (5%) of the R5, and

TABLE 4

EXTENSION OF CHEMOTHERAPY BEYOND THE PRESCRIBED PERIOD AND RELATIONSHIP WITH INCIDENCE OF RELAPSE REQUIRING TREATMENT

Duration of Treatment beyond Prescribed Period	R3				R5				Z5			
	Patients in Analysis		Relapses Requiring Treatment		Patients in Analysis		Relapses Requiring Treatment		Patients in Analysis		Relapses Requiring Treatment	
(*days*)	(*n*) (A)	(%)	(*n*)	(% of A)	(*n*) (B)	(%)	(*n*)	(% of B)	(*n*) (C)	(%)	(*n*)	(% of C)
Nil	102	47	18	18	53	23	1	2	72	32	13	18
⩽ 15	98	45	21	21	134	59	7	5	127	56	12	9
> 15 but ⩽ 30	11		0		25		0		17		1	
> 30 but ⩽ 60	5	9	2	11	15	18	0	0	11	12	2	11
> 60 but ⩽ 75	3		0		2		0		0		–	
Total	219	100	41	19	229	100	8	3	227	100	28	12

31 (16%) of the Z5 patients. However, 5, 2, and 6, respectively, became persistently culture negative without retreatment. The proportions of patients with a bacteriologic relapse requiring treatment were 20% in the R3, 4% in the R5, and 13% in the Z5 series. The relapse rates in the R3 and Z5 series were significantly higher than that in the R5 series ($p = 0.00001$ and < 0.01, respectively); the difference between the relapse rates in the R3 and Z5 series was not significant ($p = 0.08$).

In all, 72 patients had a bacteriologic relapse requiring treatment; this occurred within 6 months of stopping chemotherapy in 51 (71%). The sensitivity test results of the different cultures tested at the time of relapse were consistent in 55 patients; 53 (32 R3, 5 R5, 16 Z5) had cultures sensitive to streptomycin and isoniazid, 1 (R3) had cultures resistant to streptomycin and sensitive to isoniazid, and the other (Z5) had cultures resistant to both drugs.

The distribution of the 675 patients in the analyses according to the period of extension of the duration of chemotherapy and the relationship with bacteriologic relapse requiring treatment is presented in table 4. There was a suggestion in the R3 and R5 series that prolongation by more than 15 days reduced the relapse rate.

Patients with Pretreatment Drug-Resistant Organisms

There were 111 patients in the analyses of efficacy with drug resistance initially (table 5). The distributions in the 3 series according to pretreatment characteristics were broadly similar. Of the 27 patients with bacilli resistant to streptomycin alone, only 1 (Z5) had an unfavorable response. Of the patients with strains resistant to isoniazid alone, 2 of 34 in the R3 and R5 series combined had an unfavorable response compared with 5 of 12 in the Z5 series ($p < 0.01$). Of the patients with bacilli resistant to both streptomycin and isoniazid, 2 of 23 in the R3 and R5 series combined and 8 of 14 in the Z5 series had an unfavorable response ($p < 0.01$).

Concerning rifampin sensitivity tests during treatment, of the 4 patients in the R3 and R5 series who had unfavorable responses, resistance to rifampin emerged in 1 of the 2 with resistance to isoniazid alone initially, and in 1 of the 2 with resistance to streptomycin and isoniazid; the resistance emerged at 1 month in both.

In all, 89 patients (30 R3, 37 R5, 22 Z5) with resistance to streptomycin and/or isoniazid initially could be assessed

TABLE 5

RESPONSE TO CHEMOTHERAPY AND BACTERIOLOGIC RELAPSE DURING THE 19 TO 21 MONTHS AFTER STOPPING CHEMOTHERAPY IN PATIENTS WITH DRUG-RESISTANT BACILLI INITIALLY

Pretreatment Resistance to:*	Series	Total Patients	Unfavorable Response at the End of Chemotherapy	Relapses Requiring Treatment
Streptomycin only	R3	7	0	1
	R5	9	0	1
	Z5	11	1	1*
Isoniazid only	R3	17	1	5
	R5	17	1	1
	Z5	12	5	1
Streptomycin and isoniazid	R3	9	1	1
	R5	14	1	1
	Z5	14	8	1
Streptomycin and/or isoniazid	R3	33	2	7
	R5	40	2	3
	Z5	37	14	3

* One patient (R3) had resistance to rifampin (only); he had a favorable response at the end of chemotherapy but had a bacteriologic relapse requiring treatment.

TABLE 6

INCIDENCE OF POSSIBLE ADVERSE REACTIONS TO ANTITUBERCULOSIS DRUGS IN 908 PATIENTS (297 R3, 307 R5, 304 Z5) AND THEIR MANAGEMENT

Adverse Reaction	Series	Patients with Reactions: Total (*n*) (A)	Total (%)	Onset in Daily Phase (% of A)	Chemotherapy Modification: Total (*n*)	Total (%)	Interruption	Dosage Reduction	Termination
Any	R3	186	63	100	53	18	17	25	11
	R5	203	66	92	51	17	24	21	6
	Z5	238	78	98	48	16	16	26	6*
Arthralgia	R3	137	46	100	15	5	2	10	3
	R5	133	43	94	13	4	3	8	2
	Z5	212	70	99	36	12	12	22	2
Jaundice	R3	18	6		18	6	10	6	2
	R5	26	8	93	25	8	15	8	2
	Z5	2	1		2	1	2	0	0
Giddiness	R3	42	14	100	15	5	3	8	4
	R5	54	18	81	10	3	1	8	1
	Z5	50	16	84	10	3	1	4	5
Others	R3	66	22	100	9	3	6	1	2
	R5	83	27	90	6	2	5	0	1
	Z5	67	22	84	3	1	1	1	1

* Two patients had streptomycin as well as pyrazinamide terminated because of giddiness and arthralgia in one and an anaphylactic reaction and arthralgia in the other.

for relapse. Of these, 13 (7 R3, 3 R5, 3 Z5) had a bacteriologic relapse requiring treatment (table 5). Although the relapse rate in the R3 series was higher than those in the other 2 series, it is similar to that in patients with initially drug-sensitive organisms in that series.

Adverse Reactions

Patients were not questioned about symptoms of adverse reactions, but every spontaneous complaint was recorded after careful questioning by a physician.

The 876 patients eligible for the study and the 32 who had received previous chemotherapy are considered in this section. Possible adverse reactions occurred in 63% of 297 R3, 66% of 307 R5, and 78% of 304 Z5 patients (table 6). The contrast between the incidence in the R3 and R5 series and that in the Z5 series is highly significant ($p < 0.001$); it is attributable to the high incidence of arthralgia in the Z5 series. However, modifications of chemotherapy were necessary in similar proportions of patients, namely, 18% of the R3, 17% of the R5, and 16% of the Z5 patients. One or more of the drugs had to be terminated in 11 (4%) R3, 6 (2%) R5, and 6 (2%) Z5 patients.

Arthralgia. A complaint of arthralgia was made by 270 (45%) of 604 rifampin patients and by 212 (70%) of 304 nonrifampin patients, a highly significant difference ($p < 0.00001$). In all but 12 patients (1 R3, 8 R5, 3 Z5), the onset was during the daily phase, particularly in the second month when 52% occurred. Chemotherapy was modified in 28 (5%) rifampin patients and in 36 (12%) nonrifampin patients ($p < 0.0001$). Pyrazinamide was terminated in 7 patients. Full details of the arthralgia have been reported elsewhere (9).

Jaundice. Jaundice occurred much more often in the rifampin series (7%) than in the nonrifampin series (1%) ($p < 0.00001$). The onset was during the daily phase in 43 patients, 34 occurring in the first month. In all but 1 (R5) the chemotherapy was modified. The usual policy was to interrupt all the drugs. The drug for which dosage was reduced or which was terminated was rifampin in all the cases.

Hepatitis without clinical jaundice (abnormal hepatic function test values, with symptoms) was observed in 5 (4 R3, 1 R5) of the total of 532 (173 R3, 180 R5, 179 Z5) Madras patients. The onset was in the first month in 3 (all R3) and the third month in 2 (1 R3, 1 R5). Two patients (both R3) had drugs interrupted.

Giddiness. Complaints of giddiness were made by 146 (42 R3, 54 R5, 50 Z5) patients. Streptomycin was interrupted in 5, the dosage was reduced in 20 (including 16 who had an interruption also), and it was terminated in 10.

Other adverse reactions. Complaints of other possible adverse reactions (mainly gastrointestinal or cutaneous) were made by 25% in the rifampin series and 22% in the nonrifampin series, but only 2% and 1%, respectively, required modification of chemotherapy. Serious adverse reactions warranting termination of drugs occurred in 4 (2 R3, 1 R5, 1 Z5) patients. One patient (R5) developed exfoliative dermatitis in the third month. A second patient (Z5) developed a severe anaphylactic reaction after the first dose of streptomycin. The other 2 patients (both R3) had severe episodes of vomiting.

Discussion

The most important finding of this study was the high relapse rate with the 3-month daily regimen of rifampin, streptomycin, isoniazid, and pyrazinamide, namely, 20% during a 21-month period of follow-up (i.e., after stopping chemotherapy) in 200 patients with drug-sensitive cultures initially, the 95% confidence limits being 14 to 26%. This finding is in agreement with those of 4 other studies of 3- or 4-month regimens. Thus, Eule and associates (10, and personal communication), using the same drugs daily for 3 months, reported a relapse rate of 20% in 61 patients during a 3- to 5-yr period of follow-up. In a study in New Delhi of rifampin, isoniazid, and pyrazinamide daily for 8 wk, followed by rifampin plus isoniazid daily for 4 wk, the relapse rate in a follow-up period of 21 months was 23% in 52 patients (11). The only study reporting a low relapse rate (6% of 53 patients in a 24-month period of follow-up) was that of Mehrotra and associates (12, 13) from Agra, India. The drugs and duration were the same as in the present study, but the patients were classified as having relapsed only if radiographic deterioration was observed, in addition to reversal to culture positivity for at least 2 consecutive months. Considering 4-month daily regimens containing rifampin and isoniazid throughout and pyrazinamide for at least 2 months, the relapse rates were 13% of 208 patients in East Africa (14) and 10% of 156 in Singapore (15), during 24 and 26 months of follow-up, respectively. These findings suggest that short-course regimens (3 or 4 months) are inadequate as the treatment for sputum-positive pulmonary tuberculosis.

Fox (1, 16) has presented information on the influence of the duration of chemotherapy in smear-positive disease, comparing bacteriologic relapse rates in a number of studies with regimens all of which contained daily streptomycin, isoniazid, rifampin, and pyrazinamide, at least in the initial phase (1); the updated figures (16) were 1% for the 6-month regimens, 4% for the 4.5- to 5-month regimens, 12% for the 4-month regimens, and 16% for the 3-month regimens.

Even in patients who had consistently smear-negative pulmonary tuberculosis with small lesions, a study in Hong Kong (17) showed that neither 2 nor 3 months of daily chemotherapy with streptomycin, isoniazid, rifampin, and pyrazinamide was adequate, the bacteriologic relapse rates in a 5-yr period being 23% and 10%, respectively, and the relapse rates including patients with radiographic deterioration but no bacteriologic confirmation being 32 and 13%, respectively.

Although the relapse rate with the 3-month rifampin-containing regimen of the present study is unacceptably high, it is noteworthy that practically all the patients with initially drug-sensitive bacilli attained sputum conversion by 3 months, and nearly 80% remained bacteriologically negative for as long as 2 yr; most of the latter are likely to have been cured. This finding is of interest in the context of patient compliance, because the patients stand a good chance of attaining a cure even if they discontinue treatment well before the completion of a 6-month regimen.

Considering next the 5-month rifampin-containing regimen (R5) in the present study, the findings were substantially better than with the 3-month regimen; none of 230 patients in the R5 series had an unfavorable response, and only 4% of 187 (95% confidence limits, 2 to 8%) had a bacteriologic relapse requiring treatment in 19 months of follow-up. An earlier study (6) from this Centre had shown that a similar regimen but with a 2-month intensive phase and a 3-month continuation phase also had no failures and a low relapse rate (5%) in 19 months. This suggests that in 5-month regimens consisting of rifampin, streptomycin, isoniazid, and pyrazinamide daily followed by streptomycin, isoniazid, and pyrazinamide twice a week, a third month of daily chemotherapy confers little additional benefit in patients with drug-

sensitive cultures initially. In contrast, the 5-month nonrifampin regimen in the present study (Z5) was clearly inferior to the R5 regimen (3 of 236 patients had an unfavorable response, and 13% of 199 had a bacteriologic relapse requiring treatment) and was only marginally better than the 3-month regimen—a clear demonstration of the importance of rifampin in short-course chemotherapy.

The high relapse rate of 20% was observed in the R3 regimen of the present study, with 90 doses of rifampin, isoniazid, streptomycin, and pyrazinamide given daily for a period of 3 months. A similar number of doses (95) had been prescribed by Snider and associates (18) but had a relapse rate of 0% of 84 patients during an 18-month period of follow-up; the same 4 drugs had been given daily for 2 months, followed by rifampin and isoniazid twice-weekly in the next 4 months. This suggests that it would be more profitable to spread out the 90 doses by giving them intermittently after an initial daily phase. Indeed, intermittent chemotherapy from the beginning could be highly effective and also result in a considerable reduction in the number of doses, which would reduce the cost and probably lower the incidence of side effects. Thus, 78 doses of the 4 drugs given thrice a week over 6 months in Hong Kong (19) resulted in a relapse rate of 1% in 151 patients. Eule and coworkers (10) gave 52 doses of the 4 drugs twice a week for 6 months and reported a relapse rate of 0% in 61 patients in a 12-month period (10), and 3.3% in 121 patients during a 36- to 48-month period (personal communication).

In patients with initial resistance to isoniazid, the contribution made by rifampin is noteworthy. Thus, 13 (50%) of 26 such patients who received the nonrifampin (Z5) regimen had an unfavorable response, as compared with 4 (7%) of 57 who received the rifampin regimens (R3 and R5). This is in conformity with our earlier findings (3) and those of Mitchison and Nunn (20).

The incidence of jaundice was significantly higher ($p < 0.00001$) in the 2 rifampin series (7%) than in the nonrifampin series (1%). Furthermore, its onset was early, 34 (77%) of 44 in the rifampin series developing it in the first month. A higher incidence of clinical jaundice in patients who received rifampin in addition to isoniazid, streptomycin, and thioacetazone (17% of 63 patients) than in those who did not receive rifampin (6% of 67 patients) has been reported by Rao and associates (21), also from India, the mean time of onset being 15.5 and 71 days, respectively. These findings strongly suggest that adding rifampin to isoniazid or isoniazid and pyrazinamide substantially increases heptatotoxicity. In contrast, there is evidence that when pyrazinamide is added to isoniazid and rifampin in daily chemotherapy, there is no increase in hepatotoxicity (22–25). However, a low incidence of hepatotoxicity (1% or less) in patients receiving rifampin, isoniazid, and pyrazinamide daily for 2 months or more has been reported from East Africa (14, 26) and Hong Kong (25). Various factors that probably influence the occurrence of hepatitis in South Indian patients (27) and the possible mechanism by which combinations of rifampin and isoniazid cause hepatitis (28) are discussed in detail elsewhere.

Arthralgia, attributable to pyrazinamide, was a common complaint, but chemotherapy had to be modified in only 4% in the rifampin and 12% in the nonrifampin series. As in the previous study (3), the incidence in the rifampin series (45%) was appreciably lower than in the nonrifampin series (70%). This is probably due to an increase in the renal excretion of uric acid caused by rifampin, which could lead to a decrease in the deposition of uric acid in the joints (29).

In conclusion, this study has shown that the 5-month rifampin-containing regimen is highly effective both in patients with drug-sensitive cultures initially and in those with drug-resistant cultures. Its limitations include the daily attendance for 3 months and a high incidence of side effects. Hence this Centre is currently investigating fully intermittent regimens that involve less frequent attendances by the patients, are likely to have fewer adverse reactions, and are less expensive.

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TUBERCULOSIS CONTROL IN INDIA-CURRENT PROBLEMS AND POSSIBLE SOLUTIONS

G.V.J. BAILY

Attempts to reduce the problem of tuberculosis through organised efforts had their beginnings in India in the late thirties. With the introduction of chemotherapy, organised home treatment of tuberculosis from the TB clinics, situated mainly in cities and district headquarter towns, was started. The mass BCG campaign, started in 2052, gave the first indications that the problems of tuberculosis in rural areas could be as big as that in the urban areas. The need for extending case-finding and treatment of tuberculosis to the rural areas, in addition to urban areas, was confirmed by the sample survey (1) of tuberculosis conducted by the I.C.M.R. The concept of offering tuberculosis services as a component of the comprehensive health care delivered by the general health services was evolved in the country over two decades ago. The concept has been endorsed by the WHO (2) (3) and recommended for application in its member countries in accordance with the developmental situation in each country. In evolving this concept, cognisance was taken not only of the size and extent of the problem of tuberculosis but also of the fact that the rural areas continue to remain ill served. In the words of Morley (4) "Although three quarters of the population in most developing countries live in rural areas, three quarters of the spending on the medical care is in urban areas, where three quarters of doctors live. Three quarters of the deaths are caused by conditions that can be prevented at low cost, but three quarters of the medical budget is spent on curative services, manyof them provided for the elite at high cost".

But, the picture is changing. Primary Health Care, as enunciated by the WHO (5), and to which India is strongly committed, holds the promise that a drastic reallocation of national resources will be made, in an all out effort to provide essential health care to the rural population. The report of Working Group appointed by the Govt. of India on Health for All by 2000 A.D. (6) recognises tuberculosis services as an important component of Primary Health care. The inclusion of tuberculosis in the nation's 20-point programme is indeed the beginning of the realisation of the commitment.

In dealing with the tuberculosis problem and the National Tuberculosis Programme, it is appropriate to realise that the past, and even to-day, several organisations, notably the Tuberculosis Associations, institutions and private practitioners have contributed considerably and continue to do so, for the alleviation of the suffering caused by tuberculosis. However, in this presentation on the problems of and prospects for tuberculosis control in India, the rural areas as also the National Tuberculosis Programme have been selected for the main emphasis. It is probably appropriate to do so as that is where most of the problems exist.

I. THE PROBLEM OF TUBERCULOSIS AND THE PROGRAMME OF COMBAT:

1. The epidemiological dimensions of the tuberculosis problem in India:

India is one of the few developing countries of the world where epidemiology of pulmonary tuberculosis has been studied for a relatively long time. In recent years, a large amount of documentation has come to be available mainly through epidemiological studies conducted in different parts of the country. In most of these studies, either one or more of the three main epidemiological tools, viz., tuberculin test, chest X-ray examinations and

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NATIONAL TUBERCULOSIS PROGRAMME

:some problems and issues:

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1. conceptual problems

IN THEIR seminal 1962 paper on symptom awareness in tuberculosis, Banerjee and Anderson, re-emphasized the probelm of tuberculosis as a problem of human suffering, and outlined a strategy for tuberculosis control based on this concept. This strategy, abjured a policy of active case finding. Instead, it concentrated its attention on greater diagnostic sensitivity towards and adequate treatment for those people suffering from symptoms suggestive of tuberculosis who presented themselves at the existing hospitals and clinics. Together with the Madras Chemotherapy Centre study on domiciliary treatment, it forms the theoretical basis of our present day tuberculosis programme.

THE CREDIBILITY of this system rests on the adequacy with which the entire range of presenting symptoms is handled. The logical corrolary of the adoption of this approach would, therefore, be the development of an integrated and well-defined system for tackling the entire range of tuberculosis symptomatology.

INSTEAD, THE National Tuberculosis programme has set its sights on a Mirage - the interruption of bacterial transmission. To this end, it defines a'case' of tuberculosis as a person excreting tubercle bacilli, in his sputum. This approach is unscientific because it is only at a much later stage along the exponential curve of falling prevalence that the interruption of transmission becomes even a remote possibility. It also ignores the fact that never in the history of human tuberculosis has a reduction in transmission been brought about by a specifically medical intervention.

AS A result of my four years experience of working in voluntary institutions participating in district tuberculosis control programmes - in Hoshangabad and in Durg - I am familiar with the way in which this approach works in practice. A person who presents himself at a Public Health Institution with symptoms suggestive of tuberculosis is not regarded as a person suffering from a disability and consequently in need of help but simply as an entity to be categorised, ie., TB or not TB. After a cursory physical examination he is sent for a sputum test. If he obliges by producing a positive sputum, that is the end of the matter. He can then be placed on a standard treatment regime (generally INH and Thiacetazone daily) and forgotten about. Once in a way his sputum may be checked but the treatment regime is not affected thereby. I have documented evidence of patients, sputum positive after a year's treatment with INH and thacetazone, being continued on the same drug. When challenged, the government doctor has explained, "that is the only regime available". In point of fact, in practice this is often true.

BUT WE will come to problems of chemotherapy later. The point I am trying to make is that from the point of view of of a desparately sick man, frightened by a dreaded diagnosis, it is cold comfort to be given 30 tablets and told to come back again after a month's treatment and assured that he will get well in 18 months time. This is particularly so since

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A note prepared for the mfc core group meeting (July 84) at Wardha.

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there are doctors at every street corner assuring patients (with considerable honesty) that they will get well with some private treatment in six months or less.

LET US now come to the case of those who were sputum negative. The cost of a 'free' MMR X-ray from Durg to a person in Rajhara, is well over Rs.50-00. The cost of a local private X-ray is Rs.35-00. Which should the patient choose?

IT SHOULD be noted that I have been talking all along of the ideal case. We have not taken any account of the government doctor nudging the patient towards his private clinic; the laboratory technician asking for his 'fee'; the X-ray technician's rudeness, or the irregularity in drug supply.

THE PATIENT of tuberculosis is basically a suffering person. It is the least of his concern that he is excreting M tuberculosis in his sputum. What he is much more worried about is the fact that he has cough, chest pain, fever, body ache and nausea. He cannot work. He feels weak. He loses his sexual potency. His children starve and often fall ill in their turn. A physically distant and emotionally remote health centre can offer him nothing. It is well to remember that the Madras Chemotherapy Centre study on domiciliary treatment had weekly home visits as part of their protocol. It is a great pity that this investigation has formed the basis for a programme that thinks it sufficient to throw some tablets once a month at a desperately sick man.

2. primary tb and extra-pulmonary tb

TREATING THE problem of tuberculosis as a problem of suffering people, rather than as a problem of successfully eliminated parasitic myco-bacteria brings us to two sets of illnesses often neglected in the current programmes.

a. primary tuberculosis

Between 10 & 20 percent of Indian children are tuberculin-sensitive by the time they are five years old, though some surveys (Raj Narayan) yield a lower estimate. The popular (medical) conception of primary tuberculosis is of a mild intercurrent illness that is only incidentally detected in a chest X-ray and attains clinical significance only in the 'progressive' form. This is not true. In malnourished children not only is infection itself accompanied by significant morbidity but it is the 'interaction' between infection and nutrition--that is the factor that needs to be considered. When we consider that, according to ICMR, 65% of Indian children are severely malnourished, the dimension of the problem become a little more plain.

It is a common misconception (even, as I have discovered, among TB 'Specialists'), that clinically apparent primary tuberculosis can safely be treated by a short course of INH alone. This is a notion that goes against all bacteriological logic. One only creates a population of INH resistant bacteria strategically situated to subsequently produce reactivation disease.

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b. Extra Pulmonary Tuberculosis

The chapter on Epidemiology in the Text Book of Tuberculosis (by the Tuberculosis Association of India) has nothing to say about extra pulmonary disease. In my experience this forms a significant proportion of cases of tuberculosis. In particular, scrofula burnt out tuberculous cervical lymphadenitis is still a common finding in backward areas of the country.

3. staff problems

SUCH CASES of ignorance among people working in the field of tuberculosis are not rare. This is because almost the entire field level medical staff of the tuberculosis programme are 'dead-beats' people who have been promoted to an administrative position because their seniority has become an administrative embarassment.

IN A Government District Hospital, despite all the other problems one can atleast meet doctors who are interested in their work in the medical, surgical, gynaecological and other specialist departments. Not so in tuberculosis. The department which should, by all epidemiological logic, claim the most brilliant and dedicated of our technical manpower, is invariably academically dead. In Hoshangabad, the District Tuberculosis Officer was simply absent for a long period of time.

THE PARA-MEDICAL staff on the other hand are often exceptionally dedicated and able. They often run the programme practically independentally. However, they have to pay the price for their competence. In Durg, the statistical assistant--a key person and in this case extremely competent and dedicated--has been on full time deputation to the Civil Surgeon's office, helping to administer the hospital.

4. chemotherapy

a. Existing patterns

In theory, the National Tuberculosis programme provides a wide choice among several alternative regimes. These include daily INH and thiacetazone with or without an initial period of intensive treatment with daily streptomycin and/or PAS. The bi-weekly supervised regimes consisting of INH/SM and INH/PAS, have been designed specially to ensure patient compliance.

Even according to the treatment manual supplied to the district Tuberculosis Officers, only sputum positive patients are eligible for all these regimes. X-ray positive, sputum negative patients often just as sick as their 'positive' brethren and about 5 times as numerous, are eligible only for the daily self-administered INH/-TH regime. Presumably compliance isnot a consideration where they are concerned.

In actual practice, the only regime available with any regularity is daily INH/TH. (Incidentally, pyridoxine tablets necessary to counteract INH induced pyridoxin deficiency are practically unheard of. Patients are told to eat lots of peanuts!) PAS I have not seen in the past one year. Streptomycin is constantly in short supply so that patients are often randomly shuffled back and forth between regimes containing SM and those without. The effect of such regime changes in 'midstream', on treatment effectivity, bacteria

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sensitivity, and patient compliance remains, as they say, a subject for research.

Coming to the INH/TH regime, TH is by no means an uncontroversial drug. Its use is banned in some countries but let that pass. The incidence of 'major' toxicity in a study in Madras showed the following incidence of side effects:

Cutaneous hypersensitivity reactions - 7%;
Jaundice - 3%;
Intractable vomiting - 3%

Apart from these, there are minor side effects such as anorexia, nausea, vomiting and head ache. Weight gain and rise in haemoglobin level are less in patients on TH as compared with those on PAS. The effect of such minor side effects on patient compliance, especially in the absence of adequate medical supervision and reassurance, can only be imagined.

We will consider possible alternative regimes in the next section. For the moment let us stick to the first line/second line chemotherapy model. We have already noted, some of the problems with the bi-weekly INH/SM regime not available for sputum negative patients, and limited and irregular supply of SM. In addition, there is a rule that SM injections can only be given at the PHC level. In other words, this regime is effectively available only to those who live within about 5 kms of a PHC.

b. Drug resistance

Coming now to the problem of resistant tuberculosis there are a number of problems in the existing framework.

(1) Drug resistance in tuberculosis is not a rare phenomenon. Existing studies show that the prevalence of primary drug resistance to both INH and SM in India are (individually) of the order of 5 to 10 percent. The prevalence of acquired drug resistance is not known to me. But the success rate of the standard first line treatment regime is of the order of 80 to 85 percent under ideal conditions.

(2) There is evidence to show that pre-treatment drug sensitivity tests do not affect the outcome of treatment provided standard two phase regimes are used, with an initial intensive phase using three drugs. However in my experience such regimes are available only to a very small proportion of patients even in the district centres, and to practically none in the peripheral centres. Most patients go on a standard two drug regime (general INH-TH).

(3) When a patient fails to respond clinically to a particular regime, there are no facilities for drug sensitivity testing even in these selected cases. Theoretically, in the existing model, they can be referred to Tuberculosis Sanatoria for treatment with 2nd line drugs. In practice, however, (a) practically none of these patients do get referred to Sanatoria; and (b) even among those who arestarted on second line drugs at such centres, there are no facilities to continue such drugs after the patient is discharged.

The lone patient I managed to get referred to a Sanatorium in Bhopal emerged after two months looking much better and clutching a prescription for rifampicin and ethambutol.

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c. Possible Alternatives

It is well known that there now exists a wide variety of alternative drug regimes, for the treatment of tuberculosis many of which result in cure of a higher proportion of patients in a much shorter period of time than existing standard regimes. The conventional wisdom is that these alternative regimes comprise a 'second line' of treatment for patients resistant to the standard regimes.

The fact that the government itself does not take this argument seriously is shown by the free availability of the so called 'second line' drugs in the open market. Of course, the price is far beyond the reach of the ordinary tuberculosis patient. As a result, we have in India the ironic situation, where the District Tuberculosis Officer and the PHC Medical Officers are the only medical practitioners who (in their official capacity) have no access to the newer drugs for the treatment of tuberculosis.

In effect there are today, in tuberculosis, as in every other field of medical and indeed of public life, two sets of policies in operation--one for the poor and one set for those who can (even if only with difficulty) pay.

The argument against the newer regimes can now be seen plainly for what it is a question of cost. It is worth going into this question in some details.

5. the question of cost

a. How much?

The cost of a complete course of treatment with the newer drugs at current market prices is of the order of Rs.500-00 to Rs.1000-00. Regimes containing Streptomycin are liable to cost more because of the administrative cost of giving the injection.

We are not talking of enormous sums of money. The cost of bi-weekly INH/SM with an initial intensive phase, is not much less. Neither is the cost of INH/PAS regimes. The logic of the exclusive dependence on INH/TH now become clear.

Put another way, the cost of treating a case of tuberculosis with the newer drugs and the cost of treating a case of intestinal obstruction or pyogenic meningitis is about the same. The cost of treating a case of ischaemic heart disease or lung cancer or brain tumor or diabetes mellitus or chronic renal failure is several times higher. The comparison becomes ridiculous when one carries the contrast to fields outside medicine--say, to defence or CHOGM.

b. Cost to whom?

The second aspect of the cost equation. Whatis the 'cost' of a twenty percent relapse rate which is the best result obtainable with standard 'first line' regime? What is the 'cost' of a case of thiacetazone induced agranulocytosis or Stevens-Johnson Syndrome? What is the 'cost' of travelling up and down from village to PHC, village to District centre, village to wherever, for 18 months as against the six months with newer regimes? What is the 'cost' in bus fare? What is the 'cost' in lost income? What is the 'cost' in the suffering of a poor man? This is a question which the policy makers of tuberculosis must answer.

..... 6 (objectives of the meet)

A note on the objectives of an mfc annual meeting on tuberculosis

(1) The objectives of the conference should not include the framing of alternative policies to government programmes. The existing policies are faulty both in concept and in implementation. Any alternative systems we may be able to formulate will involve a restructuring too radical for their acceptance to be feasible, quite apart from any other factors militating against their acceptance.

(2) An important part of the programme for the conference should be the understanding of the problem of tuberculosis in its national perspective. Not many mfc people have much an understanding. Unless we can share a common understanding of the problem, it is useless to try to devise programmes of action.

Possible programme outcomes of the conference:

a. A concerted effort to work out a solid critique of existing government policy and its implementation. The responsibility would largely be on academics with access to literature and data.

b. Working out and executing pilot projects based on alternative approaches to the problem of tuberculosis, utilising newer technological as well as sociological insights. These would include intensive small scale field level studies.

i. Surveying the problems of tuberculosis, including the much neglected epidemiological implications of primary tuberculosis in pre-school children, extent and implications of drug resistance etc.

ii. Monitoring government activities intensively including the actual execution of treatment guidelines, patient compliance in government programmes etc.

iii. Working out alternative approaches including newer ways to improve patient compliance, newer treatment regimes, newer diagnostic approaches including newer approaches to diagnosing drug resistance.

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PRIMARY HEALTH CARE AND TUBERCULOSIS PROGRAMME*

P. Chandrasekhar**

I am grateful to the Tuberculosis Association of Andhra Pradesh for selecting me to deliver "Dr P.V.Benjamin Memorial Oration for 1988".

To be asked to deliver an oration in memory of the Late Dr P.V.Benjamin, is in itself a great honour and privilege, most challenging and I accept it with utmost humility, dedication and devotion.

Dr Benjamin, has been a powerful personality in the field of Tuberculosis and has been regarded as "Father of Anti-Tuberculosis movement in India and an elder statesman among International Experts". To talk about Dr Benjamin is like describing a multi-dimensional and multifaceted individual. It is our good fortune that we have encountered this remarkable man who had the unique power of presenting novel ideas in the control of tuberculosis and at the same time a genial and practical man. He was a symbol of hard and dedicated work and his forceful and persuasive personality is a thing worth remembering and emulating.

I had the unique experience and privilege to avail of his guidance and I owe my speciality - 'Tuberculosis', to his advice and initiative. He had shown that one should have a cause to pursue, have sufficient motivation to pursue the cause, and should be willing to make sacrifices to achieve the cause to which one is deeply committed.

In the early part of the century, it became very clear to Dr Benjamin that the 'western model' of dealing with the problem of tuberculosis viz., training of thousands of specialists, creating number of beds and running several vehicles would not be in consonance with the realities existing in our country like meagre resources and huge size of problem of tuberculosis. He strongly felt that we should forcefully repudiate the western model totally, if we have to move forward and generate a National Tuberculosis Programme, in the spirit of social equity and this was the basis and the background why the National Tuberculosis Institute, Bangalore was established in early 1960s. And, being an impatient man, a two

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*Dr P.V.Benjamin Memorial Oration delivered at the 15th Andhra Pradesh Tuberculosis & Chest Disease Workers' Conference, Hyderabad - 9th & 10th April, 1988.

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years time was given to NTI to formulate and evolve a programme, although many of us would have liked to continue research for 5 to 10 years. The challenge was to develop a suitable and appropriate technology which would be subservient to the people, applicable and acceptable to the community.

HEALTH SCENARIO OF INDIA

I wish to briefly review the health scenario of our country. The Constitution of India envisages the establishment of a new social order based on equality, freedom, justice and dignity of the individuals. It aims at elimination of poverty, ignorance and ill health and makes the States responsible in raising the level of nutrition and the standard of living of its people. The improvement of public health is among its primary duties and forms the main thrust of our health policy. It was felt during the early stages that an integrated comprehensive approach in health services, medical education and research should be established in order to serve the health needs and the priorities of the country.

OUR HERITAGE

India has rich, centuries old heritage of medical and health sciences. The philosophy of ayurveda and surgical skills enunciated by Charaka and Shushruta bear testimony to our ancient tradition in the scientific health care of our people. The approach of this ancient medical system was of a holistic nature and took account of all aspects of human health and disease. Over centuries, this system of medicine continued to be practised widely. However, the allopathic system of medicine has in a relatively short period of time made a major impact on the natural approach to health care and the pattern of development of health services in our country.

PAST ACHIEVEMENT

During the last few decades since the attainment of independence, considerable progress has been achieved in improving the health status of our people. Smallpox has been eliminated, Plague is no longer a problem, mortality from Cholera and related diseases have declined and Malaria has been brought under control to a great extent.

In spite of such impressive gains, the health scene of our country constitutes a serious threat and urgent concern. The high rate of population growth continues to have an adverse impact on the health of our people and the quality of their lives. The mortality rate for women and children are still distressingly high. Communicable and non-communicable diseases are yet to be brought under the effective control. Blindness, Leprosy and Tuberculosis continues to have a high incidence. Hardly 30% of our rural population have access to potable water supply and 5% enjoy basic sanitation.

The existing situation is largely endangered by the development policies and the establishment of curative centres based on 'western models' which are

inappropriate and totally irrelevant to the real needs of our people and entirely out of context to the socio-economic conditions prevailing in the country. The hospital based and the cure oriented approach have benefited only the upper crust of our society specially those residing in the urban areas. The uncontrolled proliferation of this approach has been at the cost of providing comprehensive primary health care services to the entire population both in the urban and rural areas. The high technology boom which our country is passing through is responsible for distorting the picture of the actual health needs of the community.

> "It is easy for a developing country to go from ox cart to the jet age; but in the process it leaves 90% of its people behind".
>
> - John Balcomb, World Health Forum, Vol.5, 1984

Further, continued high emphasis on curative services have lead to the neglect of the essentials of health care viz., preventive, promotive, curative and rehabilitative aspects of health care. The prevailing policies with regard to medical education and training of medical and para-medical personnel at various levels have resulted in a wide gap between the consumers and the providers of health care. Present day doctors whom we train are not fully qualified to deliver or participate in the primary health care activities, because they are not adequately trained to meet the concepts of primary health care. The vast majority are still narrowly focussed on 'curative care', i.e., removing symptoms rather than eliminating the causes that lead to symptoms. It is said that:

> "Trying to promote primary health care through medical profession is like trying to promote land reforms through big landlords/owners"
>
> - Dr David Werner, Director of Californian Foundation

NATIONAL HEALTH POLICY

Over years, the planning process has become oblivious of the fact that the ultimate goal of achieving a satisfactory health status for our people cannot be secured without involving the community. In other words, community participation is essential and depends upon proper identification of their health needs, their priorities as well as in the proper implementation and management of various health and related programmes.

A national health policy has to be necessarily within the integrated planning frame work which seeks to provide universal, comprehensive health services relevant to the actual needs and priorities of the community at a cost people can afford ensuring at every stage total involvement and participation of the community. Health policy has to go in search of equity - oriented components

of other sectors to form part of a movement towards the integrated improvement of well being. Equity in health is above all equity in development. It implies that foremost attention to those who are in the lowest segment of national health profile. The health of these vulnerable groups will reveal how and why the national health strategy fails to reach persons of this group, often due to multisectoral complexity.

> "It must be borne in mind that the tragedy of life doesn't lie in not reaching your goal. The tragedy lies in having no goal to reach. It isn't a calamity to die with dreams unfulfilled, but it is a calamity not to dream. It is not a disaster to be unable to capture your ideal, but it is a disaster to have no ideal to capture. It is not a disgrace not to reach the stars, but it is a disgrace to have no stars to reach for. Not failure, but low aim is sin"
>
> Dr Benjamin Mays, Former
> President of Morehouse College
> in Atlanta, Georgia, U.S.A.

'Comprehensive health care' is the key stone to community health and consists of health care delivery system at the primary, secondary and tertiary levels.

Primary Health Care

Primary health care does not mean the first contact only, but it is the very essence of all health activity. It is the prime and central core of health and underlines primacy. Figs. 1 and 2 show the basic components of primary health care and includes disease prevention, health promotion, curative and rehabilitative aspects of health. The main emphasis shifts from curative aspect to health care activities. The idea of reaching out to people is a laudable one but extremely difficult to organise. It suggests that all health efforts should emerge from within the community and directed to the community. Briefly, the emphasis in primary health care is a shift:

Fig. 3
(See next page)

It strongly advocates the use of enlightened and highly motivated individuals within the community as the first contact health personnel, in the total national health system.

The concept of primary health care depends upon the relative roles of primary, secondary and tertiary levels of health care and has been depicted in Fig.4, and is based fundamentally on the triad of:

(1) Community involvement (2) Intersectoral co-ordination, and (3) Appropriate technology.

Fig. 3

From		To
Illness	:	Health
Cure	:	Care
Treatment	:	Health promotion
Episodic treatment	:	Continuous treatment
Specialists & Physicians	:	General physicians, para-professionals - Social Workers, Health Visitors, etc.
Specific problem	:	Comprehensive health care
Single handed Physician/Doctor	:	Health Teams
Health sector alone	:	Collaboration among all sectors - housing, economy etc. Intersectoral collaboration
Clinical decision making	:	Community participation

In other words, primary health care means essential, necessary and relevant to the individual, the family and the community. It does not mean a diluted or second rate service for the poor. The usual definition and which is a comprehensive one, is as follows: Fig.5

> "Essential health care made universally available to individuals and families in the community by methods acceptable to them through full participation and at a cost that the community and country can afford"

The essence of this concept is the involvement of the community and the use of appropriate technology which would be subservient to the community.

Components of primary health care are:

1. Comprehensiveness; includes prevention, promotion, curative and rehabilitative services.
2. Regionalisation - peripheralisation of services - reaching out to people.
3. Stress on rural areas.
4. Appropriate technology - peoples' oriented technology.
5. Universally accessible/acceptable.
6. Community participation.

7. Two-way referral system.
8. Evolution through evaluation.
9. Intersectoral co-ordination - in planning, programming, other areas of education, housing, sanitation, socio-economic conditions leading to overall development.

Secondary Health Care

Secondary health care is essentially delivered at the subdistrict and district levels. Essential prerequisite is an interlinkage between Primary Health Centre, subdistrict and district levels. Unless there is functional and well organised two-way referral system, it is not likely to be successful. There should be a continuous interaction between doctors of Primary Health Centre and the Specialists at the district hospital. Such interaction will necessarily improve the knowledge and skills of those involved in the delivery of primary health care.

Tertiary Health Care

The main objective at this level is to provide Specialists' services in all the disciplines with supportive laboratory as well as appropriate facilities. Concept of tertiary health care is through medical colleges, regional institutions or specialised care. They should be responsible for organising refresher courses for medical professionals in peripheral areas. The concept of different levels of health care and their interlinkages have been shown in Figs. 1 and 2. For a final level of comprehensive health care, better understanding of co-ordination and 'linkage' have to be firmly established.

The Bhore Committee of 1946 recognised this intersectoral efforts and linkages. The Primary Health Centre was conceived as a nucleus from which primary health care services would radiate through subcentres over to the country side - a process of complete decentralisation of all activities. The Primary Health Centre was conceived as an institutional structure to provide integrated comprehensive services to the rural population of our country i.e. preventive, promotive, curative and rehabilitative aspects of health care. This was a response of the political leadership of the freedom movement to meet the rising aspirations of the masses of people. The first batch of Primary Health Centres was set up in 1952. Quantitatively there has been a significant increase in the number of medical and para-medical personnel in Primary Health Centres. Qualitatively there has been major changes viz., many mass campaigns have been integrated with Primary Health Centres, both in terms of their staff as well as function. There has been national programmes which were developed as an integrated component of Primary Health Centre for e.g. tuberculosis, integrated child development programme and blindness.

Kartar Singh Committee of 1973, however, extended the outreaches of Primary Health Centres by the introduction of Multi-purpose Health Workers Scheme and establishment of a subcentre for over 5,000 rural population. The

Community Health Workers Scheme launched in 1977 is structured around the central philosophy of "placing peoples' health in their hands" by providing one Community Health Volunteer/Guide for every 1,000 population. The Community Health Volunteer/Guide Scheme was of profound social and political significance. In effect it meant going directly to the people to strengthen their capacities to cope up with their health problems themselves and seek and demand services from the Primary Health Centres and other referral health institutions. The infrastructure described above was considered adequate to provide primary health care to the rural population and it would require proper back up by providing two-way referral services.

Fig. 6

The success of comprehensive health care is very well illustrated by the Chinese example, where China's great achievement in public health has been due to total political commitment at all levels of Government and society, and regards health as an integral part of social equity. Health is everyone's right and responsibility and the 'bare foot doctor' became only a feasible symbol of this approach.

A Chinese dictum says:

Go in search of your people
Love them
Learn from them
Plan with them
Serve them
Begin with what they have
Build on what they know

Mao

Many a developing countries have tried to follow this approach by training a large cadre of para-professionals viz., Multi-purpose Workers, Village Health Guides, but without making adequate provision for referrals, technical back up and administrative support.

"The greatest tragedy of all is when a developing country builds a health plan for the needs of tomorrow on the imported solutions of yesterday"

Dr David Morley

The desirability of training large number of auxiliary health workers is very much a political decision than a technical one. India's conscious decision to train a large number of para-professionals is an expression of this political decision.

"Therapeusis of social medicine is not social action but political action based on medical recommendation"

Francis Crew
Professor of Social Medicine

ALMA ATA PLEDGE

The historic Alma Ata pledge of 1978 on primary health care called for total coverage of the population with comprehensive integrated health services, based on active participation of the people. There was to be a social control over health services, intersectoral action covering other fields like water supply, environmental sanitation, education, employment, to improve the health status of the people. Health for all (HFA) through primary health care became a catchy slogan of the WHO and member States.

India is one of the signatories of this pledge and is committed to attaining the goal of "Health for All by 2000 AD" through the universal provision of comprehensive primary health care services which includes disease prevention, health promotion, curative and rehabilitative services. Achievement of this objective is a big challenge to any country with a huge population and demands that each country has to prepare its own strategy and plan of action depending on the prevailing health problems, priorities and available resources. In this herculean task, it is not possible for health services alone to undertake this heavy responsibility as it needs the sustained efforts and co-operation of all the departments concerned with the total development of the country leading to overall socio-economic improvement. The whole concept of intersectoral collaboration is based on the effectiveness of a multi sectoral approach and which has been tried in countries like Sri Lanka, Cuba, China, Costa Rica and Kerala in India. Cuba vaccinated the entire eligible population within 72 hours and eliminated Polio which indicated the strong political motivation.

In these countries, the political and/or social will resulted in the development of health education, agriculture, nutrition, water and sanitation, and other programmes with a subsequent decline in mortality and which is considered remarkable when compared to socio-economic situation. Simultaneous development of programmes in several sectors has a synergistic effect on health. Health is an excellent point of entry into multi sectoral approach to overall development. The importance of multi sectoral action is explained by the inter dependence of 'basic needs'; satisfying one need may strengthen peoples' capacity to satisfy others.

The Alma Ata Declaration of 1978 paved the road towards the provision of providing primary health care and it has given a time dimension of 2000 AD. This declaration emphasised that some of the worst health problems could be tackled not by training more doctors and establishing more hospitals, but by simple preventive measures and the use of basic essential drugs. The principle was simple enough, viz., if 80% of all illnesses stem from the lack of clean drinking water and adequate sanitation, then improving water supply and sanitation would

become a priority. With severe malnutrition, both adults and children become more vulnerable to disease and hence, nutrition forms an important component. On the medical front, simple vaccination could prevent 6 communicable diseases which has defied all attempts so far, hence Expanded Programme of Immunisation forms yet another avenue.

It is exactly a decade since the Alma Ata Declaration was made and accepted by the member States. During this period, several important events have taken place, for e.g:

1. World economy underwent severe economic shock waves in the form of prolonged recession.
2. World population swept past 4,800 million mark.
3. Urbanisation grew at a disturbing rate, creating new challenges for health and developmental plans.
4. Rise in absolute number of children and old people adding to the burden of work force, unemployment aggravating the situation together with a variety of political conflicts, threat of nuclear accident/war, violation of human rights, growing environmental pollution, selfgenerating and self-expanding poverty leading to malnutrition, and the spectre of starvation in the form of severe floods and drought in the areas of cultivable lands, all seem to proclaim approaching world catastrophe.

In such an alarming scenario of adversity, it needs lot of courage,foresight and efforts for member States to pursue programmes for human development. Despite many set backs, the gains during the past decade has been quite substantial. There is now a dense net work of health services in rural areas. One Community Health Volunteer/Guide for 1,000 population, a sub centre with male and female health workers for every 5,000 population, a Primary Health Centre for 30,000 people, a community health centre for 1,00,000 people and a 25 bed hospital for 40,000 population. No other country in the third world with similar resource constraints can claim to have such an infrastructure of health services for its rural population.

India's political commitment was made in the form of 20 Point Programme. It is the agenda given to the nation in 1982 which pinpoints special areas of thrust to produce tangible results. It is the nation's commitment and calls for hard work,helped by a clear sense of purpose and discipline. The intension is to move the whole economy of the nation and it is left to us to maintain the momentum. The whole nation is on the move on several fronts (20 Point). It has generated a wave of commitment and there is no stopping till the targets are achieved. It has created an awareness, urgency and accountability among all the health workers at all levels to complete the targets. Tuberculosis has been one of the programmes included in this agenda.

TUBERCULOSIS & PRIMARY HEALTH CARE

Tuberculosis continues to be a public health hazard in our country despite several outstanding research in the field of tuberculosis. It still continues to bother the health planners despite the fact that it is preventable, and definitely curable. The reasons for our failure could be medical, organisational, economical and most often political.

It is almost scandalous having to witness millions of cases of tuberculosis dying without the benefit of modern drugs and simpler methods of diagnosis. In spite of several scientific break throughs, we still find the problem of tuberculosis haunting us.

Tuberculosis through centuries have been considered as an affliction of the individual rather than a public health problem, not being endemic to territorial distinctions and not being absorbable in epidemic proportions, it has been regarded as a silent disease, though its main symptom 'cough' is by no means silent. Tuberculosis does not provoke communities to get together to fight it nor does it provide a cause which readily attracts attention of those who guide the destinies of the nation.

Around 1912, about 30 years after the discovery of Mycobacterium tuberculosis, the Sanitary Commissioner to the Government of India urged that tuberculosis be dealt with as a public health problem. The immediate response from the Government was to open Sanatoria and institutions for treatment in different parts of the country. This approach emphasised more on individualising the patient and his treatment and isolate him from his physical and social environment. During the crucial years immediately after the independence, it seemed possible to embark on an effective programme which would have a marked influence on the problem of tuberculosis.

In 1951, India launched a massive National BCG Programme, the biggest in the world in terms of population covered. The '50s was also the time when the enormous potential of drugs on domiciliary basis was demonstrated by the Tuberculosis Chemotherapy Centre, Madras. This created a sense of euphoria resulting in the firm conviction that the control of tuberculosis was still within the foreseeable future and the end of tuberculosis was in sight.

About two decades ago National Tuberculosis Institute made a giant stride in the field of public health in formulating the tuberculosis programme within the frame work of General Health Services. Right from the start, the programme was evolved and planned on the concept of full integration at all levels with the General Health Services.

This high sense of optimism lead to the formulation of National Tuberculosis Programme by National Tuberculosis Institute in 1960s based on the clear dictum 'start from where the people are' and a peoples' oriented programme was implemented in the country. The emphasis was on changing and developing

General Health Services and the concept of integration was an added dimension along with other national health programmes, dove tailing with other socio-economic priorities of the country. Reaching out to the people through the Multi-purpose Workers/Community Health Guides is an added feature of National Tuberculosis Programme. In other words, tuberculosis programme fitted very well with the concepts of primary health care.

Soon this optimism became hazy and distorted not because of any upward trend in the disease, but because of the country's sagging commitments to the cause. This malaise took various forms such as dislocation of trained personnel, improper utilisation of resources, haphazard and disproportion of supplies.

The tuberculosis programme is so structured that it provides greater resilience so that it can change and modify according to the General Health Services. It would swim or sink with General Health Services. The clarion call to provide primary health care found a response in the National Tuberculosis Programme as well. In 1980s, it had the expectation to see the tuberculosis programme unfurled to the full extent through the Primary Health Care, a strategy that would make health services available to those who need them specially in rural areas and in 1990s it should be possible to make it a component in a package for Health for All by 2000 AD.

TECHNOLOGY

A peoples' oriented technology was the main stay in the formulation and implementation of the tuberculosis programme of India, during the early '60s at the National Tuberculosis Institute, Bangalore and was based on the following premise:

- About two thirds of all cases of tuberculosis in a district was found to be worried about the disease and half of the cases had actually gone to the nearby Government institutions to seek relief of their symptoms. And what was more revealing was the fact that no serious attempt was made to diagnose them at these health institutions. This finding was crucial in formulating a "peoples' oriented" National Tuberculosis Programme of India which ensured that:

- Top priority is given to tuberculosis patients who are actually seeking relief of their symptoms, i.e.'felt need' (social priority)

- As patients seek treatment at the health institutions which is part of the General Health Services, tuberculosis services is made available to them within the frame work of General Health Services themselves with proper back up of referral services (choice of a peoples' oriented health service delivery system)

- Since all sputum positive cases have cough, they could easily be diagnosed at any or all the rural institutions by simply examining the

sputum of cough cases for tubercle bacilli. Once the case is diagnosed, these cases are offered domiciliary treatment by these very same health institutions (peoples' oriented technology)

.. Meeting the existing felt need will generate further felt needs and this will persuade others who have not sought treatment to seek relief, because of this spread effect of 'satisfied customer', it is possible to cover most of the 'cases' in the community.

Fig. 7

From the above, it would be seen that the tuberculosis programme as conceived, planned and implemented in the country has taken care of all the principles and concepts of primary health care. The emphasis right from the beginning has been on peoples' participation which is a process in which the felt need of the community is duly taken care of. Communities have always shown enough potential to be self-reliant. Village knowledge, village skills and rural wisdom have to be appreciated while planning a health programme. The concept of community participation is not at all a new one, since the dawn of collective human living - living participatory life, facing odds together, sharing common problems and objectives, i.e., collective hunting and shared games. The need for this concept is totally reflected in the 1st Five Year Plan where the emphasis was on community developmental programmes in the form of green revolution.

FUTURE PERSPECTIVES

Tuberculosis Programme has the potential and the flexibility to adapt and change with the General Health Services. This is a unique feature and has sustained the programme all along in its full potential. The time for empty slogans is over and it is now time for prompt and effective action, so that these slogans could be converted into more meaningful and purposeful action.

Alma Ata has provided the prescription and pledge - "Health for All by 2090 AD". Since then, scores of planning committees have met and pious resolutions and policies have been made. Now is the time for action. Action must be in right earnest.

Those born after 1978 cannot and possibly will not wait any longer. Future generations will never forgive us for the lapses specially when we are having all the necessary technology and skill to control tuberculosis. The human suffering which goes with tuberculosis cannot precisely be quantified. It is shocking to realise that while half of the infectious cases are seeking medical help on their own initiative for relief of their suffering, most of them are turned away without proper diagnosis. It is indeed a great crime to treat an individual for tuberculosis without proper diagnosis and to withhold treatment when the diagnosis is firmly established. Ignorance of drugs, dosage and duration of treatment by qualified personnel cannot any more be tolerated. Expensive

second line drugs are being pushed into market and are being prescribed often in sub-therapeutic doses with irrational combination, leading to emergence of drug resistance. Resistance to Rifampicin is already assuming alarming proportions due to indiscriminate use, and it is a clear warning and indication of the extent to which there is a complete anarchy in the treatment of tuberculosis in the country.

In the words of Dr J.R.Bignall, "the story of tuberculosis during the past 30 years has been one of great triumph and tragedy - the triumph of the scientist who has provided the means to control and ultimately eradicate tuberculosis and the tragedy of the widespread failures to exploit these discoveries. Each and every discovery in the field of tuberculosis has been fully exploited by the technically advanced countries, so much so that some of these countries will reach the limit of eradication by 2000 AD, while in developing and underdeveloped countries, the problem of tuberculosis has increased in terms of absolute numbers because of sheer increase in population. This dismal tuberculosis scene has some redeeming features.

Diagnosis and treatment of tuberculosis is now no longer the domain of the Tuberculosis Specialist - This is mainly due to the availability of standardised technique of sputum microscopy for diagnosis and standard drug regimens of long and short duration - The position today is that any qualified doctor can confidently diagnose and treat tuberculosis, is an accepted fact. Still sadly it is not practised widely due to lack of dissemination of knowledge in this regard".

Let us pledge ourselves today and make the slogan "Defeat tuberculosis now and for ever" a reality. Time has come when our actions and performances would be audited by the people. There is no excuse whatsoever in allowing a patient to go undiagnosed and untreated when we have the appropriate technology with us. This is perhaps the last chance we have and let us not throw it away in the midst of committees and seminars.

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Fig. 1

Structural organisation & organisational frame work in comprehensive health care

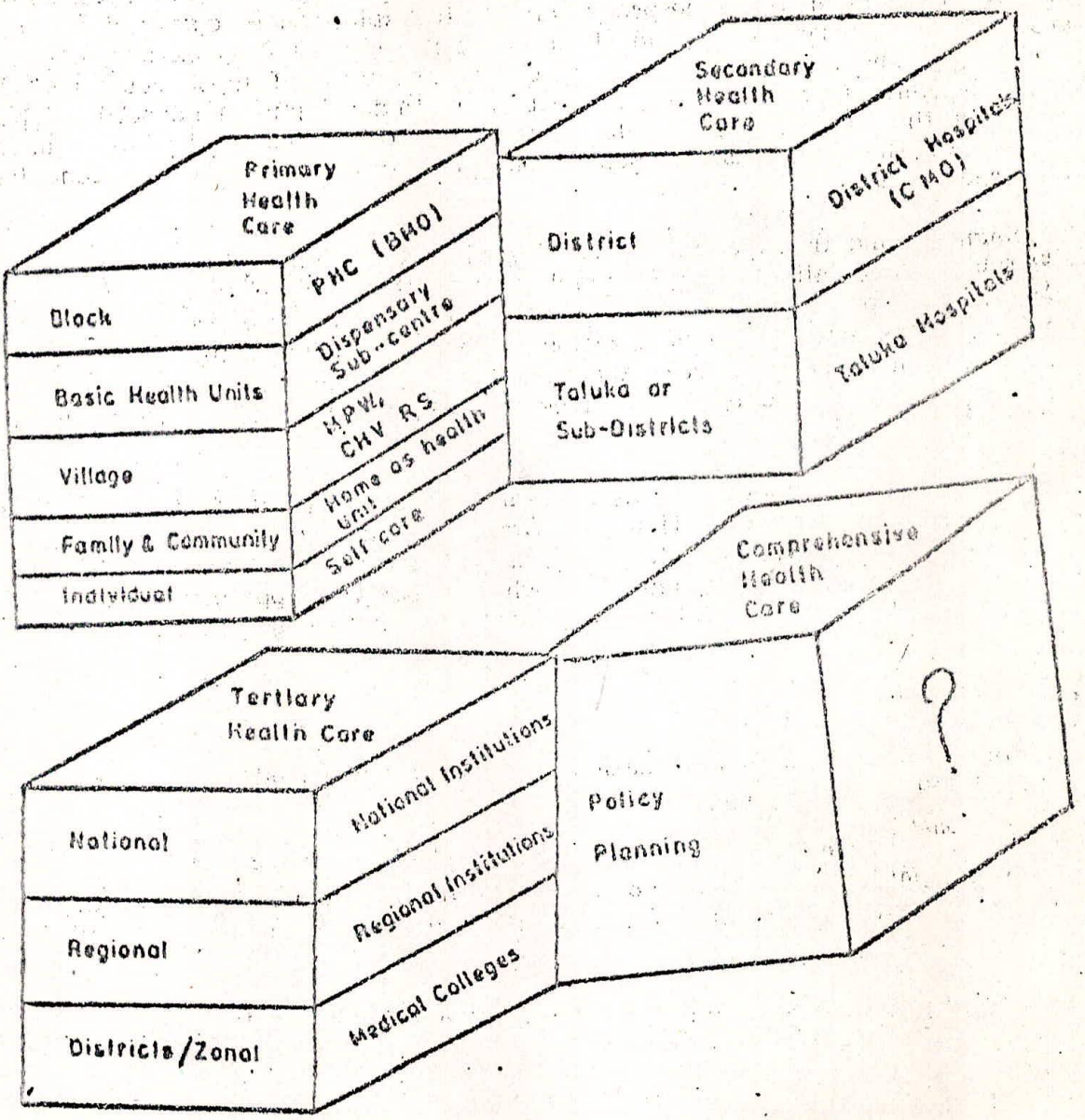

Fig. 2

Pyramid of health services

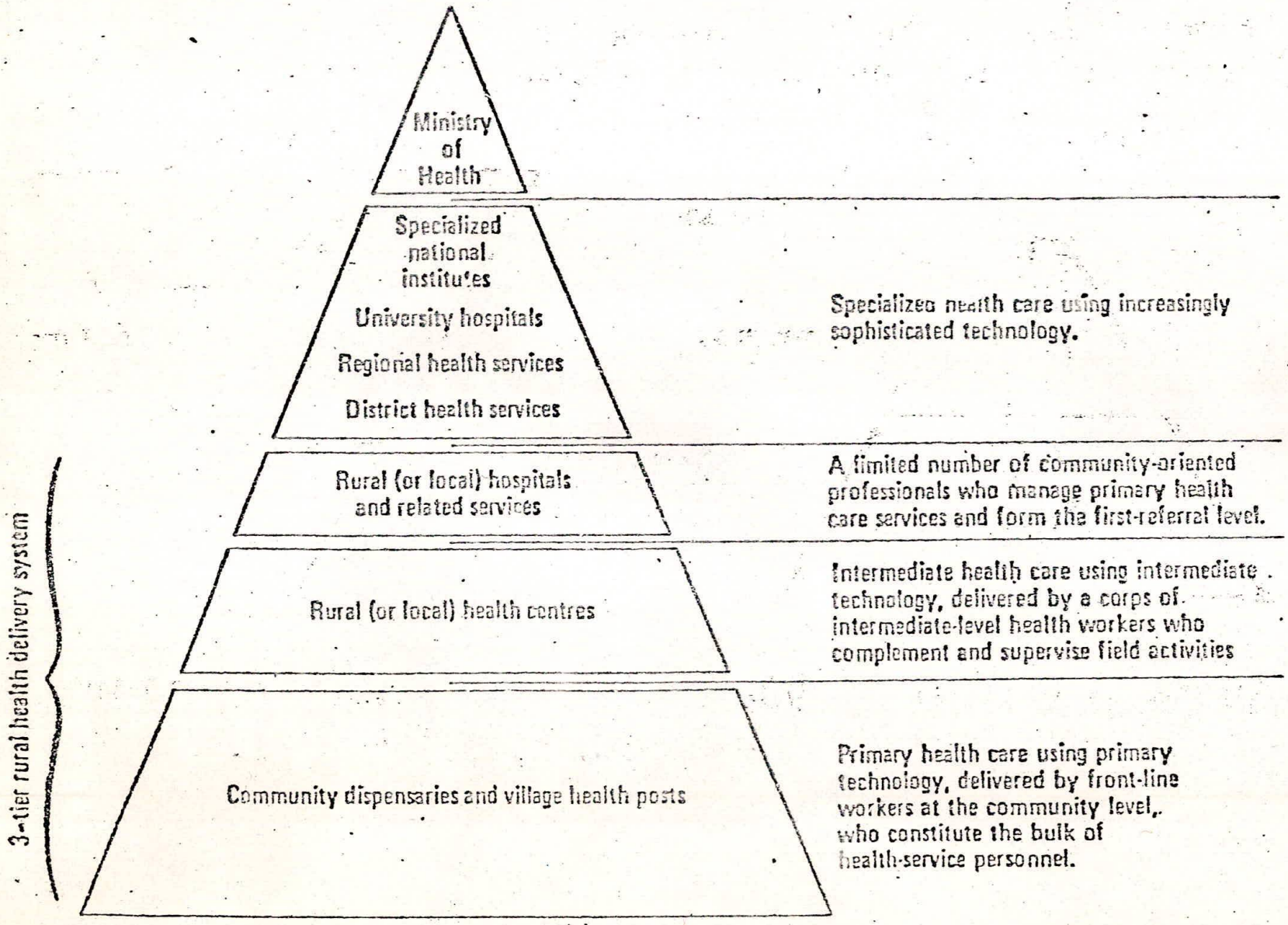

Fig. 4

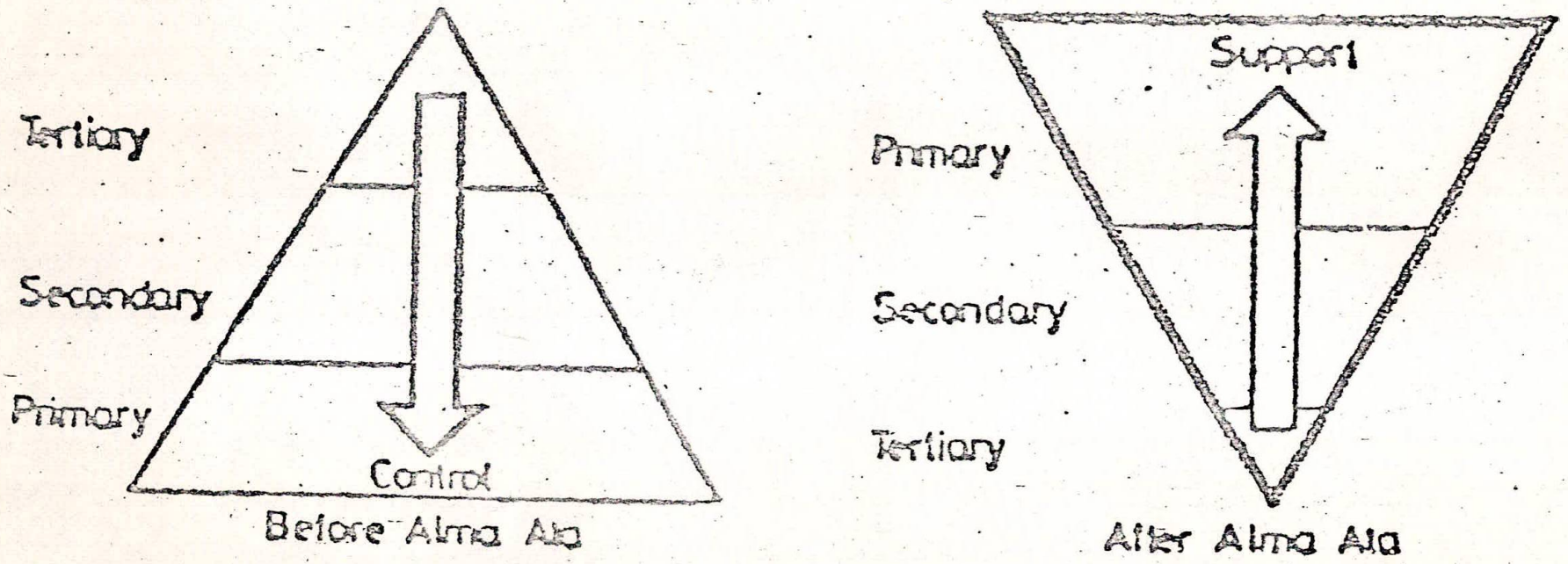

FIG 2—The relative roles of primary, secondary, and tertiary care before and after the Alma Ata Declaration. Reproduced with the permission of Professor H Vuori.

Fig. 5

PRIMARY HEALTH CARE

DEFINITION:

ESSENTIAL HEALTH CARE MADE UNIVERSALLY AVAILABLE TO INDIVIDUALS AND FAMILIES IN THE COMMUNITY BY METHODS ACCEPTABLE TO THEM THROUGH FULL PARTICIPATION AND AT A COST THAT THE COMMUNITY AND COUNTRY CAN AFFORD.

PRINCIPLES OF:

1. COMPREHENSIVENESS, PREVENTION, PROMOTION, CURATIVE AND REHABILITATIVE SERVICES
2. REGIONALISATION - PERIPHERALISATION OF SERVICES - REACHING OUT TO PEOPLE
3. STRESS ON RURAL AREAS
4. APPROPRIATE TECHNOLOGY - PEOPLE'S ORIENTED TECHNOLOGY
5. UNIVERSALLY ACCESSIBLE/ACCEPTABLE
6. COMMUNITY PARTICIPATION
7. TWO WAY REFERRALS
8. INTERSECTORAL CO-ORDINATION - IN PLANNING, PROGRAMMING - IN OTHER DEVELOPMENTAL AREAS OF EDUCATION, HOUSING, SANITATION, SOCIO-ECONOMIC CONDITIONS ETC. LEADING TO TOTAL DEVELOPMENT
9. EVOLUTION THROUGH EVALUATION

Fig. 6

Referral System

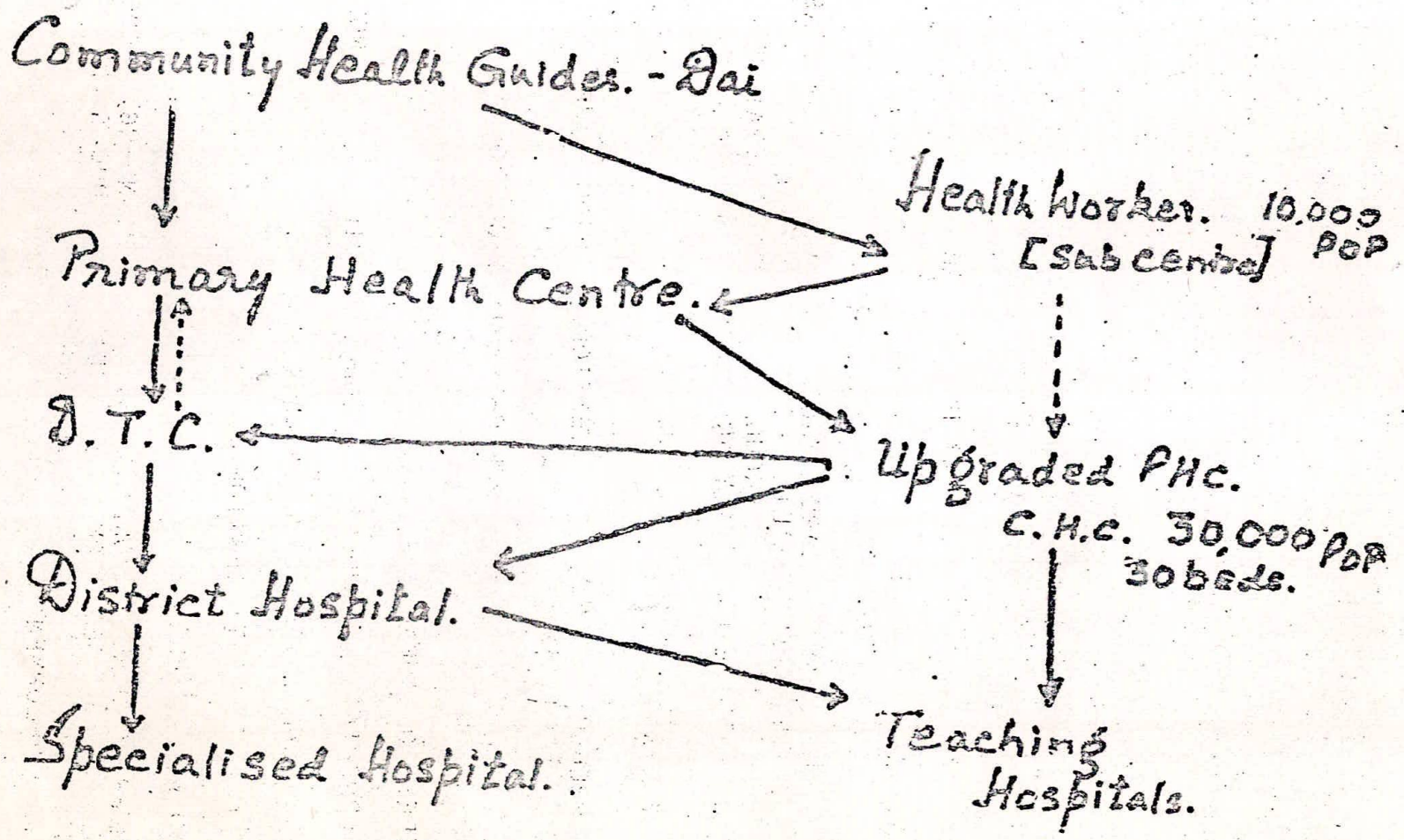

Fig.7

DISTRICT TUBERCULOSIS PROGRAMME

(DIAGRAMMATIC REPRESENTATION)