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 desperately 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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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 '<u>interaction</u>' 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 embarrassment.

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 isn't 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 are started 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 becomes 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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