125 medico friend circle bulletin

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Confusion—A Way to Knowledge

U.N. Jajoo

The Annual MFC meet at Bangalore on tuberculosis (1985) has provoked much critical thinking to the extent that a consensus on the crtique of NTP is yet to emerge. Anant and Binayak tried to prepare a note which Anil Patel found uncompromising. I add to the confusion here by placing some facts and figures with the hope that it will pave the way to knowledge.

Question I: What is the fate of radiologically positive and sputum AFB negative patients, if untreated?

Let me quote an editorial from the *Indian Journal of Tuberculosis* (1). "For many years there has been an increasing awareness of a need to study the fate of sputum negative patients who seek treatment at various centres for symptoms suggestive of chest diseases. Some workers have recommended that such patients should be kept under observation while many clinicians prefer to put them on prolonged intensive anti TB drug therapy. In July 1974, this problem was discussed in the pages of this journal. The National Conference at Hyderabad in 1975 devoted a full session to this important problem. A study based on a long term follow-up by the New Delhi TB Centre showed most of such patient to be definitely active and tuberculous.

A study carried out in Hong Kong recently with the collaboration of the British Medical Research Council has shown that 34% of the patients whose five sputum specimens were negative by direct smear became sputum positive during the course of one year when left untreated.

A controlled study of such patients was undertaken recently by the National TB Institute, Bangalore also. The patients included in this study were freshly detected, previously untreated residents of Bangalore City, judged as active by two miniature X-ray film readers. Half of these were randomly allocated to treatment regimen of INH and TCZ and the other half were on placebo. 31% of those who were initially sputum negative by one smear examination were found to be sputum positive on second examination. 10.7% by smear and 20.8% by culture alone. Even those patients who were not read as active by any of the two readers, 2.8% proved to be sputum positive on second examination. A few more became sputum positive or showed radiological progress of the disease during the course of follow-up with no treatment. Thus about 40% out of initially sputum negative continued to be sputum negative, while 60% of them proved definitely to be active tuberculous at some stage or the other, more often within first four months following detection. Among sputum negative treated group, regression of lesions was more frequent than in the untreated.

In rural areas where follow-up for observation is not easily possible and is hardly ever done, patients with highly suspicious X-ray shadows should be offered anti TB drug therapy if clinical picture is also suggestive since tuberculosis continues to be the most common pathology. Mistakes in diagnosis though few, will continue to occur even in the best of hands, the question is which is less risky and likely to be more profitable generally—to treat or not to treat."

The conclusions drawn are;

—The radiological reading of active tuberculosis in suspect cases must be considered fairly sensitive (more/than 2/3 at least) and if coupled with clinical judgement should be regarded as reliable tool.

—The epidemiological surveys done till date are based on the evidence of 'active pulmonary TB lesion' in X-ray, and therefore stand as fairly reliable evidence of quantum of pulmonary tuberculosis in the community.

—In a clinic situation (PHC or DTC), it is fairly logical to treat suspect cases i.e., radiologically positive but smear negative.

Under NTP, a person with tuberculosis who matters is one who brings out AFB in sputum smear. The efficacy of case detection by microscopy in the present situation is as follows: (2,3)

—Total number of sputum positive cases in average district (infectious cases only) = 5,000

—Potential of case detection by meticulous sputum examination (passive case detection in clinic setting) = 2,000 (40%)

—Number of cases detected in actual field situations =776*

Thus, those who do not bring out AFB in sputum smear (thanks to our inefficiency), are very graciously shown the way to DTC for MMR which in practice is out of the reach of the majority. It has been found that only 20% report to DTC (4) and much less turn up to collect the report, since patients are not prepared to travel more than 5 kms (5) unless symptoms are very pressing. The wage loss implicit in such action is never taken care of. In reality what it boils down to is, if you have faith enough to take pains to reach the peripheral microscopy centre, and bring out AFB in smear detectable by our microscopists, only then you matter us enough for inclusion under NTP. We (the NTP) full of sympathy for your sufferings, will send you back with tonics and cough mixtures and will consider it your fault if you fail to turn up again for unrelenting symptoms. *NTP merely looks at the impact of the strategy on the prevalence of TB and forgets the agony of the sufferers.*

The reliance of microscopic examination alone for the diagnosis of TB must be weighed against the following considerations, (i) microscopic detection of AFB is a tool which requires sincerity of human element involved—something which cannot be legislated in our setting. (ii) There is a phenomena of 'intermittent positivity' (6) which further reduces the reliability of one sputum examination, a general practice in PHCs.

NTP banks on those patients who themselves report to medical opinion for relief of sufferings and presupposes that all who take action will come to these centres for their expertise. The credibility 'enjoyed' by these centres is obvious from the fact that, "out of those registered at the DTC, only 27% have not received treatment earlier" (7). It is not only the distance of the diagnostic centre but the behaviour, the care, the concern shown towards human sufferings that attracts the poor ill person, the absence of which is obvious from the figure that only 23% seek relief from the nearest health centre. The inefficiency of case detection, the non-availability of drugs/detectors erode the credibility of these peripheral units. It is this faith in the healer that matters for the patient and not merely a free technical expertise. At the time NTP was conceptualised this important sociological dimension of patient care was forgotten.

Question 2: Isn't it true that Indian and WHO documents say that MMR does not help in detecting more cases than is possible by microscopy alone?

Let us not confuse between active case finding and passive case detection in a clinic situation. The above statement is true only for active case finding. To quote verbatim, "For sputum positive cases, large majority of patients could not be found even if services were provided close to their villages. The number of patients found under such conditions was considerably short of estimated total prevalence. It was not possible to diagnose even about 50% of the existing cases in the community i.e. number that was already reporting to the PHC for examination because of their chest symptoms by any of the currently available methods (community development approach—active detection of symptomatics and referral to microscopy centres or mass campaign with X-ray available at few miles distance) (9).

However a situation in an accessible clinic where static MMR facility is available will be entirely different. The purpose of installing an MMR machine in these peripheral clinics is not to mop up the 'non-action' taking cases of the community but to detect precisely the action taking group (52% smear positive). The moot question is whether we expect bonus of this radiological support or not. It is a known fact that 70% of the registered cases every year are AFB negative (radiologically diagnosed) in DTC. This is a clear indication that the concept of case detection by microscopy has not even been conceived by the district centre and that radiological support

* 20 to 30% of expected potential or 15% of the total infectious pool.

has considerable potential of dividends to be paid in our existing inefficency.

Question 3: The radiological facility at PHC (accessible clinic) is a costly proposition and should its appropriateness not be judged before it is pleaded for?

The logic that recurring cost of MMR static unit will be too much is negated by the following observations: (10)

The cost in US$ of diagnosing one case by different methods

Examination	Approximate cost per examination	Approximate cost of diagnosing a case
Direct microscopy	0.21	3.4
Culture exam	0.49	12.1
70 mm x-ray film (static unit) passive detection	0.26	3.5
70mm x-ray film (mobile unit) active detection)	0.50	73.0

The radiological facility at the PHC has an added spin-off benefit in the early diagnosis of bronchopneumonia in children—the number one killer in under fives. While limitations of financial stringency towards non-recurring cost is put, at least principally a need of radiological back-up support must be accepted and its feasability must be tested in field situations.

I suggest the strategy given below.

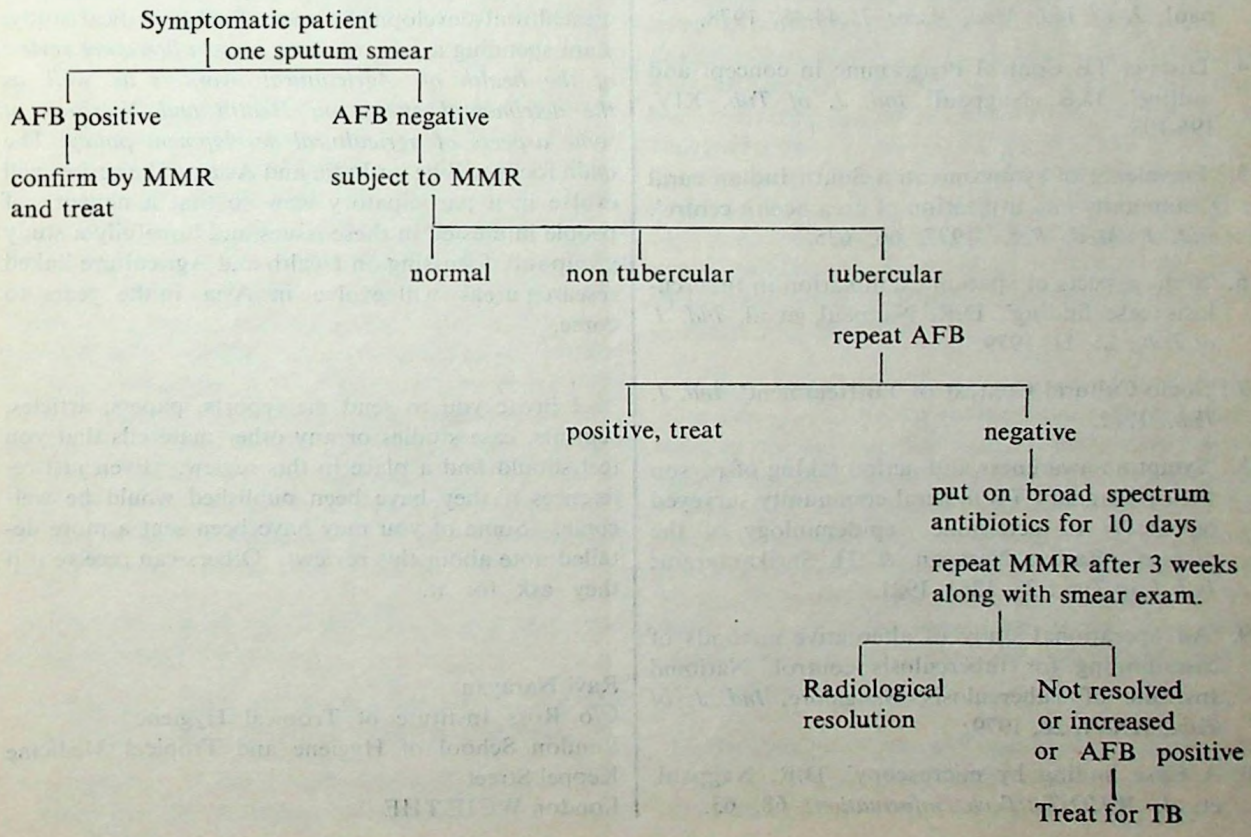
Question 4: Can culture facility at PHC add significantly to case detection at PHC?

Not much really, due to the following reasons—

(i) Out of 20 cases/1000 population, 2.5/1000 are smear positive and 1.6/1000 are only culture positive. In passive case detection at PHC where around 52% of infectious pool is expected to turn up, the bonus of 'only culture positive' will be reduced further.

(ii) Culture report takes at least 6 weeks—a time lag which will shift the ailing patient elsewhere in pursuit of relief.

(iii) The cost involved in detecting a case is 4 times higher than that by smear examination or static MMR (10).



Question 5: Can tuberculosis prevalence be brought down by medical intervention? Should the aim of NTP be only alleviation of human suffering?

Socio-economic factors being important in causation of tuberculosis, we are tempted to argue that any amount of medical intervention alone cannot reduce the prevalence of tuberculosis. However, the figures drawn up after careful analysis do not favour this hypothesis. If the full potential of microscopic detection is tapped and all geographical area is covered by NTP, estimated probable reduction in prevalence of TB is 6.4% per year. With the present case detection rate (30% of the expected), 4.8% reduction can still be achieved (3). NTP is epidemiologically a sound proposition but has failed to make a dent due to operational failure in case detection/case holding.

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Letter from a friend
Health and Agriculture—a literature review

In the 1981 census it was established that 70.6 percent of the working population in India are employed in Agriculture and related occupations. Various reviews of Occupational Health Research in India show, however, that the agricultural worker has generally been neglected and that the main focus of research has been on the industrial workers and factory jobs. The situation is similar in most of Asia.

In recent years another aspect of this complex relationship between Health and Agricultrual development is coming into focus—the detrimental health effects of some aspects of modern agricultural development policies—be it agrochemicals, mechanisation, dams, irrigation projects and so on. Evidence on marginalisation of the rural poor and the ecological changes consequent to agro-technological development have been well established in the last decade. What is less well established is the effect on the health and the nutrition of rural communities and particularly the underprivileged among them.

Both these problems indicate that the multifaceted, intersectoral relationship between health and agricultural development needs further critical study. I am spending a year working on a *a literature review of the health of Agricultural workers as well as the detrimental effects on Health and Nutrition of some aspects of agricultural development policy*. The main focus will be on India and Asia. The review will evolve in a participatory view so that a network of people interested in these issues and hopefully a study group too, focussing on Health and Agriculture linked research areas will evolve in Asia in the years to come.

I invite you to send me reports, papers, articles, reprints, case studies or any other materials that you feel should find a place in this review. Even just references if they have been published would be welcome. Some of you may have been sent a more detailed note about this review. Others can receive it if they ask for it.

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Worthless Therapy : A Case Study

— Elina Hemminki

(Medicine provides many examples of therapies that have been condemned after earlier acceptance and wide application. This study from Finland considers whether anything can be learnt from one such therapy, the use of diuretics for the prevention and treatment of toxaemia of pregnancy.)

Toxaemia of pregnancy is an important problem in antenatal care: it is common, its etiology is largely unknown, and it is connected with increased morbidity and mortality in infants and mothers. Today, many experts reject the whole concept of toxaemia and divide it into several diseases and symptoms. I use the concept as it was commonly used in the 1960s and 1970s: when a pregnant woman had hypertension, proteinuria and/or oedema, she was said to have toxaemia. Toxaemia was divided in two main categories: (1) pre-eclampsia and eclampsia, and (2) chronic hypertensive and renal diseases. In this article the interest is in pre-eclampsia.

It was believed by many that excess salt intake and retention caused pre-eclampsia. Because diuretics were known to promote the excretion of sodium and to decrease oedema and blood pressure in non-pregnant people, it was assumed that diuretics would be beneficial in toxaemia.

In Finland, diuretics were already being recommended for toxaemia of pregnancy in the 1950s. Not to give them for marked oedema was considered a deviation from accepted practice. Diurectics were widely used during pregnancy in the 1960s and 1970s in Finland, as in many other countries. In 1969 and 1975, *Therapia Fennica* stated that hydrochlorothiazides should be given if oedema existed despite the avoidence of salt. Similar, but more reserved recommendations were given in the Finnish textbook for midwives. Starting from the first drug catalogue in 1962, pregnancy oedema and/or pregnancy toxaemia were given as indications for most diuretics. Diuretics were still prescribed in 1983, but not prophylactically; in cases of established oedema and pre-eclampsia they were given less readily than in earlier years.

The widespread use of diuretics in pregnancy was apparently favoured by:

* enthusiasm generated by the introduction of new diuretics considered better than the old ones;
* acceptance of the theory that salt retention was crucial in the pathology of toxaemia;
* improvement reported by mothers;
* neglect of the results of controlled clinical trials.

Changing attitudes

Reservations about the use of diuretics in pregnancy were already being voiced in the late 1950s. Epidemiological surveys found that oedema was common during pregnancy and that normotensive oedematous women had heavier babies and fewer premature births. In a trial it was found that pregnant women advised to use more salt had less toxaemia than women advised to use little salt. Because of methodological problems and contradictory results, controlled clinical trials conducted during the 1960s did not clearly answer the questions raised about the prophylactic value of diuretics for mothers. There was no reliable evidence about benefits for infants. Studies were also undertaken on the possible harmful effects of diuretics used in pregnancy. Pharmacological and physiological information suggested that diuretics were harmful both to mothers and fetuses, but quantification of the harm was not possible from the data sources used.

Today it is widely accepted that in pre-eclampsia there is hypovolaemia and that administration of diuretics aggravates pre-eclampsia rather than prevents or treats it. However, in the early 1970s there were warnings against sodium restriction and diuretic therapy in only a few countries (e.g., the USA). In Finland even though the proper indications diuretics had been discussed at local and national meetings of obstetricians since the mid 1960s, and despite growing opposition to the use of diuretics during the 1970s, major changes in practice seem to have occurred only at the end of the 1970s.

Information was slow to emerge in the non-commercial and commercial literature. In the Finnish medical journals the first articles cautiously warning against diuretics appeared in 1978, and articles clearly condemning their use appeared some what later. The literature has emphasised the importance of the drug industry in determining doctor's prescribing habits. In the 1960s and 1970s, however, promotion by drug firms did not seem important in this connection. Drug firms possibly did influence prescribing through the leading physicians.

The opinion of the chief obstetricians in the central hospitals seem to have been crucial in the rejection of diuretics. When they formed new opinions, these

were rapidly and effectively communicated to practitioners. Prior to the 1970s, the chief Finnish obstetricians exerted influence through the education fo medical students and specializing doctors, through articles in medical journals, and through their advisory positions in drug firms. The chief physicians' influence in determining therapeutic practice has apparently increased as a result of the increased regionalization of health care, frequent referral for consultation in hospitals, acceptance of the concept of local responsibility by central hospitals, and the increase in postgraduate education.

Since the 1970s an effective educational system and frequent referrals to antematal outpatient clinics have meant that the opinion of the chief obstetrictian in each central hospital has largely determined the prescribing of diuretics in his or her area. The opinion of these key obstetricians seem to have been passed quickly to the antenatal care providers. This is well illustrated in the following comment given by a general practitioner: "Prescribing habits are determined by the practice in the central hospital of the area and by local postgraduate education, even if the latest information in the literature goes against them. When a mother is sent for a consultation to a hospital outpatient clinic and comes back with a diuretic prescription, it is a clear message....."

With hindsight the whole episode of the widespread use of diuretics in pregnancy could have been avoided* The results of the controlled clinical trials carried out in the 1960s, not to mention their methodological deficiencies, should have alerted critical minds. Furthermore, epidemiological evidence suggested that oedema was a good prognostic sign, and all the time cogent critical arguments based on physiological and clinical findings were being expressed against diuretics.

The use of diuretics is just one outcome of a common form of reasoning in medicine: if a laboratory result or clinical sign correlating with poor health can be modified by a drug, it is often assumed that the drug is beneficial. The example of diuretics in pregnancy shows that this is not necessarily so. It also shows the importance of not only determining the facts of a situation, but also of informing practitioners about them.

Source : World Health Forum, Vol. 7, 1986.

*It is to be noted that in India, doctors still swear by diuretics for toxaemia - ed

MFC-B 125

Tuberculosis and Paramedical Workers
(Review of Training Manuals of Health Workers)

—Marie D'souza.

From the review of the training manuals prepared by the Ministry of Health and Family Welfare listed at the end of the article certain facts emerge clearly. (I was not able to get hold of the 'Manual for Health Workers, Female, Vol. II' and the 'Manual for Health Workers, Male Vol. I).

Family Planning is *the* programme to work for. Tuberculosis is not given any extra attention as compared to other diseases, though malaria holds precedence over tuberculosis in importance.

In a suggested schedule for a training programme for Community Health Volunteers (CHV) lasting ten weeks (4-day weeks), the time table is detailed. Family Planning is allotted 9 hours, malaria 7 hours, smallpox 5 hours, while tuberculosis is not even mentioned. I suppose it is included in the one hour allotted for immunization (6) (Why 5 hours for smallpox?) However, the 'Manual for Community Health Workers does have a chapter on tuberculosis from which it can be concluded that the CHVs are expected to know at least the minimum possible about TB. They are taught—that it is caused by germs, affects the lungs, is diagnosed by sputum examination and x-ray, is curable, treatment should last for at least 12 months and that the diagnostic and treatment facilities can be obtained free from the government health institutions. CHVs are advised to refer persons with cough and fever of more than 15 days, and are informed that infants are to be vaccinated with BCG.

The CHVs who are closest to the people..... infact one of the community, are not taught, much less motivated towards the preventive aspects of TB. Nor are they expected to give any health education to the people. Common beliefs and superstitions regarding TB are not discussed with the CHVs. Their tasks seem to be to report suspect cases to the Health Worker (HW) and advise patients to continue treatment.

All the training manuals emphasise only the germ theory of tuberculosis. HWs are informed that crowded and dirty living conditions help spread the disease (3). That the germ finds fertile soil in undernourished individuals is not even mentioned. To expect that the manuals will discuss causes of undernutrition (poverty, unemployment, unjust society)

is of course asking for too much. Nowhere is an *understanding* of the medico-technological aspects of TB attempted with any grade of health workers. 'Theirs is not to reason why.....' seems to be the general attitude. In their training, viewing the bacillus under a microscope is not even suggested.

The 'Manual for Health Workers' is available only in English, at least in Maharashtra. An enterprising Health Instructor in Dhule District translated it into Marathi and got it cyclostyled. HWs in training eagerly bought copies.....and it is now out of stock. The manual does have several lessons on tuberculosis (3). However in the training programme for Health Assistants and Health Workers lasting 6 weeks, (6-day weeks), 26 hours are for Family Planning, while only 4 hours are for TB (7). This is of course somewhat better than that allotted for CHVs.

The HWs are expected to carry out the preventive measures for TB control i.e., case-holding, BCG vaccination, and health education. The storage preparation, administration and the results of BCG vaccination is explained in great detail (2). As regards to health education, except for a film on TB no aids are available. But the Health Assistants are asked to check on the educational programmes on TB organized by the HWs..... whether talks, group meetings, exhibitions etc. And in their training, while the HWs have guidelines in plenty for educating the community on Family Planning, there are none on TB (7).

The focus of all the teaching and instructions on TB in the Health Manuals is the services offered to the community in the line of diagnosis, treatment, and prevention through BCG. As mentioned earlier, no stress is laid on health education of the community, for which purpose the CHVs should be trained and aids provided. In the preparation of aids it will be useful to keep in mind what is mentioned in their own manuals (5). Aids should be simple with emphasis on one idea. Therefore, EITHER treatment is free OR treatment must be taken for 18 to 24 months OR the result of indiscriminate spitting etc., must form the single messages. The health education material available so far have either too many messages incorporated into one presentation (eg. film by the TB Association, the slide show by Janseva Mandal), or only one message prepared by different organizations—"TB is curable" (eg, CMC, VHAI, CHETNA). VHAI does have two other sets on 'childhood TB' and 'BCG vaccination' which I have not been able to review.

In the Health Manuals, the following are some of the lacunae which needs to be filled in while preparing health education aids.

1. Relatives of TB patients to be checked for TB.

2. Patient to cover the mouth while coughing and to spit into a receptacle; sputum to be later disposed off.

3. Study made of local diet habits in order to suggest improvements on what foods the patient should take more of. (The Manuals only say there is no need for expensive or extra nutritious food.)

4. The bacilli find fertile soil in a malnourished individual.

5. Taking irregular and haphazard treatment builds resistant strains of bacilli with the resultant resistance to drugs.

6. As a result, responsibility of the community to see to that the patients avail of the treatment available at the Govt. health institutions.

7. This requires awareness on the part of the community about the TB Control programme, the funds available for TB Control in the District and the drugs available at the PHC so that if drugs run short.....as often happens with streptomycin injections.....demands be made for allocation of the required amount of drugs.

Lately, in Nandurbar Taluka of Dhule District, people diagnosed as having TB, receive their tablets at home, every month, delivered to them by the HW. Presumably this is one activity now included in the NTP all over India. Surely case-holding will have improved since previously patients had to cover long distances to reach their PHCs losing their wages etc.

Hopefully the NTI, who had decided at their Silver Jublee Proceedings that one of their future efforts will be health education, will take note of the above recommendations.

Materials reviewed:

1. Manual for Community Health Workers.

2. Manual for Health Worker (Female), Vol. I.

3. Manual for Health Worker (Male), Vol. II.

(*Continued on p. 8*)

R.N. 27565/76

From the Editor's Desk

Like the proverbial wolf, the drug policy when finally announced, has taken the pro-people drug networks by surprise. Since discussions were going on for the last three years, since announcement had been postponed often, and since active campaigning seemed to make a headway, it was thought that the new policy would settle issues pending for long. Surprisingly (perhaps not so surprisingly, if one considers the other economic policies of the present government), it is silent on most issues directly affecting the common people.

The policy does not specify production quotas for essential drugs so that there is no shortage; on the need to abolish brand names there is no mention; about quality control, there is no mention of improving and strengthening the extremely weak and corrupt drug-regulatory machinery nor is there any policy on research on medicine especially dangerous new contraceptives.

The only important change spelt out is about price controls. Earlier there were three categories of drugs under price control with different rates of profit—40% for life saving drugs, 55% for 'essential drugs' and 100% for new and 'other useful' drugs. The rest had no limits to profits. The new policy has proposed only two categories—drugs required for the National Health Programme (a list of 40 drugs) at 75% profit-rate and "essential drugs" (not specified) at 100% profit rate. The rest, which form the majority, are being decontrolled. According to the government's own admission, this would lead to an increase in prices of life-saving and essential drugs by a range of 12 to 25%. According to IMA., the price rise would be from 60 to 320%. The price rise among decontrolled drugs is anybody's guess!

It has been argued that the earlier profit-rates were unremunerative and hence the present hike is justified. But this argument is misleading for two reasons. Firstly, as much as 33% of the toatal costs is spent on sales promotion, overhead and administrative expenses of the drug companies. Secondly, most medicines are in the form of drug combinations leading to unnecessary increase in prices.

The simple scientific demand made by the All India Drug Action Net-work that all irrational combination drugs should be banned so that drug prices could come down substantially (even if profit rates are increased to a certain extent) has been completely ignored.

It is certainly not because of a lack of data that the present policy is skewed in favour of the drug industry. One is tired of criticising the policy again and again. It is clear that only if a concerted effort is made by all consumers to pressurise the government, can a change in policy, as if people mattered, take place.

—Anant R. S.
(Rational drug policy cell).

(*Continued from p. 7*)

4. Manual for Health Assistants (Male and Female).
5. Primary Health Centre Training Guide, Part I, Training Methodology.
6. Primary Health Centre Training Guide, Part II, Training of Community Health Volunteers.
7. Primary Health Centre Training Guide Part IV, Training of Health Assistants (Male and Female) and Health Workers (Male and Female).

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