1. EPIDEMIOLOGY AND MEASUREMENTS OF ITS PARAMETERS

One of the key inputs required for evolving a programme for combating tuberculosis (TB) in the community, is the information on its extent as well as the distribution, through a systematic study of events/occurrences among the people and its determinants and denominations, i.e. the study of epidemiology. The latter could include not only information pertaining to health, as also those to socio-economic preferences, nutrition and existing inequities e.g., by gender, age, etc. Other issues could be as varied as characteristic of infective organism, mode of transmission, individual & community response to the infecting agents, nature of progressiveness of primary (initial) and subsequent infections in different kinds of host, responses of implanted organisms lodged at various sites of the host, the process of cellular immunity at play, natural course of diseases without intervention measures and contagious parameter of the disease, etc. Two important indices are relevant: namely, 'Prevalence' and 'Incidence'. 'Prevalence' is a measure of persons affected by the disease/infection, from among those in the community at any given point (point prevalence or "Prevalence" for this paper) or over a period of time (period prevalence), and is expressed per unit of population (say per hundred or thousand). It could be obtained from notification data or in the absence of which, as in India, by prevalence survey. 'Incidence' on the other hand, is the number of persons developing disease/infection, over a period of time, from among the known number of persons at risk, i.e. persons not affected by the disease/infection initially. This rate is also expressed per unit of population as say, per thousand, in time (say, annually). Incidence in India for tuberculosis could only be obtained from repeat surveys in the absence of appropriate notification system. These could even be computed from prevalence rates by a mathematical exercise (e.g.: The Annual Rate of Tuberculosis Infection or ‘ARI’ (1)). The knowledge on the relevant issues, besides that on disease parameters, enable the health managers to develop the strategies for control of the disease by favourably influencing its course. Besides, information available on the reliability of the diagnostic tools, effectiveness of the preventive vaccine for a disease, the therapeutic values of curative and preventive drugs etc., also act as inputs for the formulation of the control strategies.

II. BASIC CHARACTERISTICS OF EPIDEMIC DISEASES

Infectious organisms, infecting the community either cause epidemics of short duration as in the case of the flu, cholera etc, or epidemics of longer duration as in tuberculosis (TB) (2) or leprosy. The latter, sometimes could stretch for several centuries and one could miss the epidemic nature of the disease, when the disease occurrences are not studied in a long term perspective. The epidemic course could be aggravated, when either the community resistance is compromised (say HIV-infection), ethnic/agewise population structure undergoes changes, or the guard exercised by the community is lowered (3). These instances of worsening of the epidemic are observed in recent times in case of TB, in Alaska, New York, and Japan (4,5,6). Intervention measures, if available are, however, known to be effective and would enhance the decline, if applied judiciously, especially in the descending phase of the epidemic, as in Europe (2).

In the light of the above information, let us examine the evolution of the TB programme and its management in India. In other words, how has the programme been planned and operated, especially with regard both to the availability as well as to the utilisation of available epidemiological data.

III. EPIDEMIOLOGICAL AND OTHER INPUTS AVAILABLE PRIOR TO THE NATIONAL TB PROGRAMME (NTP)

The epidemiological characteristics and other inputs, which could be seen as having influenced the formulation of NTP in 1962, could be summarised as follows:

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Prevalence of bacteriologically positive cases in a district of an average population of about 1.5 million, is 5000 bacillary cases (2-8.0 per thousand culture positive cases, irrespective of smear status)(7), of which 3000 (about 60%) could be smear positive cases.

Of the TB cases, 95% could be aware of one or more cardinal symptoms of TB and 52% reporting to General Health Institutions (GHIs), for alleviation of their suffering(8).

It is feasible to diagnose about 2000 cases in a district in a year, by providing microscopic investigation facility for those aged 10 years and more having one or more cardinal symptoms of TB, present singly or in combination, for 2 weeks and more, reporting to various peripheral GHls, through self motivation. (On the average there could be 35-50 such centres in a district)(9).

District population, which had distributed in the proportion of 20:80 (now 30:70) in urban and rural areas respectively, could be provided the TB services, only by integrating the services with the existing General Health Institutions (GHI-s)(10). The integration was a key element, since providing vertical services, as was done hitherto, was expensive and not sustainable. One had to take into consideration that the TB programme had to run for a long period, with the epidemic curve of TB, stretching for centuries.

From a public health point of view, it is more essential to diagnose and treat infectious cases of TB than radiologically active cases, more so smear positive cases.

Integrating the services would enable the health system to provide the services, as nearest as possible to the door steps of the patients, raising the access and acceptability levels of the services(10).

The presence of a good network of health services throughout the country facilitates the integrated delivery of TB services, so necessary for the sake of sustainability.

The programme can be managed efficiently by deploying a team, consisting of trained key personnel, like District TB Officer (DTO), and his team.

Thus a unique health programme in the nature of NTP, came into existence, taking into cognizance the various epidemiological, sociological and economic aspects of the problem. The innate strength of a health programme, evolved through operational research in the nature of NTP, lies in its epidemiological and operational rationale, as outlined above. The approach to the programme was hailed by the WHO Expert committee on Tuberculosis(11). It had further found its way to almost all other developing countries in the world, without much modification.

IV. PROGRAMME MANAGEMENT

As the programme was implemented throughout the country, over the next four decades or so, the maintenance and monitoring needs of the NTP, had to be attended to.

In order to evaluate the programme efficiency of NTP in an ongoing manner, Potential as well as Expectations for case finding and treatment, were evolved again from the epidemiological and operational studies in the following manner:

Of the 5000 culture positive cases (C+), in an average Indian district, among those aged 5+ years, estimated on the basis of initial surveys carried out in the country (7,12,13,14) about 2500 cases (8), would be expected to report at various peripheral health facilities located in the district. Of them 80% could be smear positive cases (S+). Thus the potential of case finding under DTP was put at 2000 cases (S+), per annum. Besides, from an operational study(9) it was observed that at a peripheral centre with 50 daily new attendance, about 1-2 would report with cardinal symptoms of tuberculosis (2-3%). They would need sputum microscopic examination. Ten such examinations, on the average, could yield one microscopic positive case (S+). Thus, one case could be detected at a centre, every day, on an average. It was considered possible to diagnose the above 2000 cases in a district, in a year, provided 35-50 centres, operated under the DTP with the given expectation(15). The efficiency with regard to case finding (CFE) was judged against this potential, under NTP.(16)

Treatment efficiency (TE) could, in its turn, be computed based on diagnosed cases, completing the prescribed period of treatment, be it Standard Regimen” (SR) or “Short Course Chemotherapy” (SCC)16.

It was hypothesised that the programme could influence the trend of tuberculosis, provided the combined programme efficiency (CFEXTE), exceeded in converting more cases than the equivalent number of incidence cases, occurring in the population over a year. In other words, an efficiency represented by (CFEXTE), could be epidemiologically meaningful,
provided it was more than the equivalent of the total expected annual incidence of S+ cases. The latter could be a third of the prevalence, seeking relief, (say 660 ‘S+’ cases for a district population of 1.5 million), and could be called as “Expectation”, as different from “Potential” (2000 ‘S+’ cases).(16) These estimates could be revised to the current average population of a district, which could be in the region of about 2.0 million.

It could be observed that the above calculations to build the “Potential/Expectation” were developed on using an average prevalence rates for the country in general. This was seen as inadequate, as the country was a vast one, with varying prevalence rates from area to area.(17) For example, reported prevalence of cases in Chengulpet, in Tamil Nadu, was 10.8/1000.(18) Consistently higher prevalence than the rational average was reported from the repeat surveys in the same area carried out in later years.(19) Therefore, one would wonder, if the use of uniform average potential/expectation for all the districts in the country could be rational.

It is true, that in case the CFE in the country was as high as in the west, and the notification of these cases was maintained at a high level, as being done in the developed countries, the trend of the cases could have been recorded over the years from notified cases. However, the maintenance of records and reporting of the cases diagnosed and treated, under the NTP, is still unsatisfactory. Therefore, CFE, estimated from such records may not reflect the actual programme efficiency. One would also need to take into account the situational changes with the passage of time, as regards the cases presenting to the GHIs. This was since the potential and expectations were arrived at, on the basis of cases, found in surveys, carried out 4-5 decades back. Over the last 50 years or so, the number of health institutions available under private sector have increased by leaps and bounds in most parts of the country. The current proportion of cases, initially availing the services at GHIs and private sector respectively in different areas of the country, has not been derived from any study in the recent years. Thus the hypothesis that some half of the prevalent cases reported at GHIs, may not be tenable any more. Using this hypothesis for calculating CFE may not be justifiable any longer(20). The procedure of Monitoring the efficiency of the programme, to evaluate the number of cases diagnosed and treated against given indices, thus requires a rethink. One needs to modify the potential/expectation on case finding, if possible, area wise. This should bear relation to the present level of prevalent cases likely to be found in a given area, based on area specific average prevalence rates. The existing deficiencies of arriving at potentials expectations are already a matter of concern to the planners. In the process of finding out an alternative method, they have initiated Annual Risk of Infection (ARI) studies, all over the country. It is expected that the ARI would bring out the variability in the TB situation from area to area and the changes in ARI is amenable for measurement, at short durations (say 5 years).

V. PERFORMANCE OF ‘NTP’ OVER 30 YEARS

Nagpaul, while reviewing the DTP activities between 1978-88, had reported that the total number of S+ cases diagnosed had increased by one and half times over the 10 years period(20). However, actual new cases diagnosed per DTP, stood at 286 cases in 1988(20). This was about 15% of the expected prevalence of the S+ cases in a district of 1.5 million population or about 50% of the incidence cases. Further Channabasaviah et al, while correlating the cases diagnosed in a prevalence survey, with the cases diagnosed by DTP located in the same area, for the corresponding period of the survey and to previous years, had shown that a reasonable estimate of case finding efficiency under DTP, could only be between 3-4.5%, on the average, over 12 years period(21). Even the treatment efficiency as reported by Nagpaul in 1985 had stood at 30% for the (SR) and 55% for (SCC)(20). In 1996, Chakraborty(22), based on the report on monitoring published by NTI, had estimated the overall efficiency of NTP at 18% for “SR” and 28% for “SCC”(16). Such a performance, under a well conceived TB Programme is unfortunate, to say the least. Several Review Committees, which had made indepth review of NTP at various times had attributed the poor performance of the NTP, more to administrative and managerial lapses than to its technical ones (23,24,25,26).

VI. MONITORING INDICES USED UNDER ‘RNTCP,’ AND THEIR EPIDEMIOLOGICAL RELEVANCE

With some escalation of TB situation in the developed countries from mid-eighties, there was an enhanced global awareness on the magnitude of the TB problem and its trend. The international community and the WHO were concerned and came forward to support the cases of control of TB, the world over. Consequently, the NTP was revised following on its review in 1992, by the Government of India, SIDA and WHO(26). The Revised National Tuberculosis Control Programme (RNTCP), was formulated as a result. The diagnostic paradigm was changed to three
sputum examinations in patients self reporting to GHs, with cough of 3 weeks or more and for other cardinal symptoms of TB, with twin objectives. The first was to increase the “specificity” of case finding and the second, to detect cases, which would have been missed with single sputum examination. The RNTCP, had set for itself, a changed and pre-stated set of goals (and “Targets”) and this was different from the NTP. Whereas the NTP had the objective of reducing suffering of TB patients among self-reporting chest symptomatics, by organising scientific diagnosis of TB and arranging for the appropriate treatment to them, RNTCP had the objective of “control”, inserted into its framework. A” Global Target” came into operation -85% cure to be achieved among smear positive cases diagnosed and 70% smear positive cases to be detected out of total incidence (27). It was also laid down that the achievement of case finding “Target” was not being attempted in an area, unless the operational system was in place and able to treat the available cases to achieve the cure rate of 85% (27). For the first time ever, the epidemiological targets were placed, inside the evaluatory framework of operations. This was to replace the subtle system of monitoring, under the erstwhile NTP, wherein no targets were placed for the system to achieve. Only the monitoring agencies under the NTP, were hitherto collecting and reporting the performance of DTPs and evaluating these against CFE/TE and other indices under development (16,28). The peripheral and district supervisory units by themselves, were hitherto left unfettered, without any assigned and stated responsibility to achieve a target under NTP.It may be worthwhile, examining the concept  of   targets,   as   used   under   the     RNTCP:

1. The RNTCP performance is constantly monitored against the Annualised Case Detection Rate, and a few other indices developed on the basis of the epidemiological data, as well as on performance of RNTCP in the pilot sites, starting from Oct 1993 onwards(27,29). The WHO review 2000 in its report has noted, with disapproval, the practice of reviewing RNTCP performances against such ‘targets’, even as such monitoring continues(SO).

The epidemiological/operational basis of developing some of the indicies for monitoring the RNTCP are as follows:

(a) it has been estimated that the average ARI for India could be 1.7% (31). There could be 50 smear positive incidence cases per 1,00,000 (one Lakh) population arising against an ARI of 1.0%.

(b) Based on the above estimate, there could be 85 new smear positive cases per 100,000 population, arising annually (32).

(c) About 60% of the above would report to GHs, on their own, seeking medical care i.e: 51 cases (85x0.6).....nl

(d) it is observed that a high proportion of the radiologically active TB cases, placed on anti-TB treatment, do not have active TB at all(33,34). It is considered that with three microscopic examinations for diagnosis, under RNTCP, no more than ‘1.2’ sputum smear case per ‘l’ sputum smear positive cases could be expected (29) i.e (nl x 1.2 or 51 x 1.2) = 61 cases ...

(e) With 3 microscopic examinations made available under RNTCP, about, 15% of the new sputum examined were microscopy positive (29) as against about 10% expected under NTP(9).

(f) Nearly half the new cases diagnosed would be retreatment cases (29):i.e=26........n3

This proportion could reduce with progressive operationalisation and success of RNTCP.

(g) Therefore, the Annualised Case Detection Rate for 1,00,000 persons could be nl+n2+n3 ie:51+61+26 =138

The target Annualised Case Detection Rate used for monitoring the Programme Efficiency could be scaled up for achievement, depending on the age of RNTCP implementation. This is with the hypothesis that, with time, RNTCP would increase access to its services, with consequent higher and higher figures for ‘n1’.

2. There are some major problems with these epidemiological indices, as follows:

(a) The concept of using an average case prevalence/incidence rate for the entire country, as also the use of 1.7% of ARI, is patently fallacious, and could give high performance tag to the under performing units (DTPs) in areas with a high ARI and vice versa(20).

(b) The calculation is based on the hypothesis by Styblo(l) that there could be 50 smear positive incidence cases per 1.07%. ARI, for every 100,000 population. However, the same is not borne out from India data base, as revealed from later surveys at NTI (i.e., subsequent to the first survey)(35).

(c) As to why the incidence figures are used for evaluation of diagnostic performance under RNTCP is not understood for a country like India. Firstly, all cases diagnosed under the programme, are prevalent
cases, as existing on the day of diagnosis in the community. There is no way to label a diagnosed case as an incidence case occurring during the past year, either. Thirdly, where prevalence is three times the incidence, the cases diagnosed and cured, should have, instead been more meaningfully tallied against the existing load of prevalent cases in the community, rather than against a fictitiously calculated incidence case occurrence. Probably, this is an illustration of an unreasoned extrapolation to India of the western situation, where prevalence and incidence cases happen to be the same, there being no backlog. To disregard prevalence cases out of output calculations, for the effect evaluation of RNTCP, is non-informative for the purpose it is used.

VII. CONCLUSION

This paper outlines the epidemiological situation of TB in India. It attempts to rationalise on the programme operations and their evaluation exercises, against the available epidemiological parameters. It is heartening to observe that the evaluation of function under RNTCP has improved over time. We have a better data bank today, than anytime in the past, admittedly only for the population from a small geographical proportion of India (135 million i.e. about 15% of the total population upto 2000)(29). This has made the job of an objective evaluation of the programme-effect, possible. Virtually all (99.4%) of new sputum positive cases, registered under RNTCP were amenable to be evaluated, 1997 onwards (29). With wide areas of the country, subsequently to be covered by 2004, it is possible that the high quality data generated from the programme, could be used for validation of a suitable mathematical model for the country. This could really make a meaningful and ongoing evaluation, to be a reality.

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