

TUBERCULOSIS SITUATION IN INDIA: MEASURING IT THROUGH TIME*

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Introduction

For the planning and subsequent review of the strategy for control of any communicable disease, information on the epidemiological situation and its trend may be considered a vital input. Some may even view it to be a virtual pre-requisite for planned intervention. In a chronic disease like tuberculosis, the exact level of prevalence or incidence is of lesser importance than its time trend. Surveys, therefore, should be conducted repeatedly, if possible, in order to study the latter.¹ At the same time, it should be realised that a tuberculosis survey is an expensive exercise. It is difficult to set up the organisation, with the required training and discipline, and ensure the availability of funds to carry out the survey. The problems could be compounded many times over in the case of repeat surveys necessary for a long term disease like tuberculosis. Consequently, many countries, especially those smaller in size and with a developing infrastructure, may not find it practicable to conduct even the baseline survey. Epidemiological information from neighbouring countries was, in fact, used by many countries to formulate their anti-tuberculosis programmes.

For the planning of tuberculosis control programme for a country of India's size and complexity, it was considered necessary to have factual information on the problem at hand, since no worth while information from any of the neighbouring countries was available for use. Even if it were available, its epidemiological value could have been irrelevant, given the near-continental dimensions of this country. A nationwide tuberculosis prevalence survey was, therefore, conducted in India during 1955-58.²

That survey provided the basis for planned action. Data generated from the study were profitably used by programme planners to decide

about the form and scale of the national programme which was formulated a few years later.³ For example, the question of providing tuberculosis services in urban and rural areas was based on the observed near equal distribution of the disease in them. Further, the overwhelmingly larger distribution of infectious cases among the adults, who could complain of symptoms rather than the uncommunicating children in the community, had a considerable bearing on the development of a simplified symptoms based programme on a national scale. The behavioural studies in adult patients, carried out after the National Sample Survey (NSS), provided the clue to the daunting problem of finding cases in the vast rural population.⁴ It was realised that for tuberculosis case detection, the programme could rely only on self-reporting patients and yet discover a significant proportion of the prevalence. Incidentally, in the use of NSS data, the information on the disease/case distribution was more meaningfully used than the actual disease and case rates, for developing the tuberculosis control programme.

While dwelling on the size of the problem of tuberculosis and the relevant intervention measures, it is debatable if a working hypothesis was formulated, then, on the trend of disease, for the planning of initial and subsequent tuberculosis surveys. For example, what was the estimated rate of probable change, as part of the natural dynamics, that the investigators had in mind while designing the cross sectional and repeat studies? What did the programme planners, strategists and epidemiologists expect to achieve through the District Tuberculosis Programme (DTP), as a planned intervention system? Was the epidemiological impact, as envisaged by them, of DTP expressed in specific terms? The initial papers on the feasibility of the programme

* The topic was dealt with briefly under "Case for a Repeat Epidemiological Survey in India" as a Leading Article: *Ind J. Tub.*; 1992, 39, 209.

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did express some expectations. For example, as early as 1967, Nagpaul estimated that more than the annual incidence of cases was “bound to be diagnosed in a well running DTP”³ every year. This was expected to be achieved through the implementation of all the eligible Peripheral Health Institutions (PHIs) in the district. However, no mention was made of a hypothesis on the efficiency with which the health services were required to perform the case-finding activity to achieve the expectation and the likely level at which they were capable of performing. It was perhaps believed that once implemented, the functions will be carried out by the centres with the expected degree of efficiency on a continuous basis. Moreover, the likely epidemiological impact of the programme, even under a situation of high efficiency was not spelt out in objective terms.

The vagueness on the mentioned points is quite understandable since the planners at that stage had only the epidemiological data from the NSS and a few other surveys available to them.⁵ None of these, however, made it possible for them to formulate a viable hypothesis on the dynamics of tuberculosis, without or with intervention. In the report of the Tumkur district tuberculosis survey⁵ (1960-61), the preamble mentions that the survey was carried out to provide data for planning and assessment of that pilot control programme. The designers already had the information from the NSS to expect an average bacillary case prevalence rate of about 4.0 per 1000 (range for 95% confidence limit: between 1.54 and 6.36 per 1000 in areas with the most favourable situation and between 6.58 and 9.60 in unfavourable situations²)*. In spite of this, the sample size of about 35,000 persons was selected for the initial Tumkur District Survey (observed average prevalence rate of 4.1 per 1000-range for 95% confidence limit : 3.1 and 5.1). The second survey in Tumkur district was carried out in 1972, in a sample population of about 41,000 persons which probably gives a clue to the expectation of the epidemiologists regarding the change in tuberculosis case rates, following the DTP implemented in the district⁶ after the initial survey. It could only mean at this point of time that nearly 30% reduction in case rate was

expected, to be measured through a second survey after 12 years, i.e., around 3% annually. In the context of the above expectation of change, it must have been a revelation that there was no change at all in the case prevalence rates of bacteriological cases after 12 years of DTP in the district.⁶ A reasonable estimate of efficiency of case-finding under DTP Tumkur could only be between 3% to 4.5%, on the average, during the intervening period⁷ : These considerations suggest that the epidemiologists and planners had grossly over-estimated the efficiency of intervention and rate of decline. Similarly, from the sizes of populations selected during the initial survey, for each of the sets of repeat surveys conducted by the National Tuberculosis Institute (NTI), Bangalore and the New Delhi Tuberculosis Centre, respectively, it would appear that a high rate of decline was expected;^{8,9} otherwise a much higher sample size of population would have been selected. For example, had the planners an expectation of about 1% decline in case prevalence rate annually to be statistically recognised (being the most likely rate of decline, as evident from mathematical models in later years-shown later), not less than a sample size of 445,000 should have been decided for the Tumkur survey with the plan to repeat the survey after 12 years (see Appendix).

The inadequate size of the sample selected for the surveys could perhaps be attributed to an inadequate appreciation of the likely time trend of tuberculosis at that time, being the initial years of the control programme. Alternatively, it is possible that the statistical concept of epidemiological assessment, through repeated measurement of the problem, had not yet concretised in the minds of the epidemiologists and the programme planners. It is more likely that no scientific measurement of change was meant to be attempted through the repeat surveys except to get information on the incidence of the disease in relation to the other measurements and a general idea of the disease dynamics to be obtained for the first time in India. It is likely that through such information, the planners had sought the basis for designing epidemiological assessments through the epidemetric model approach.¹⁰ It was probably

* It is important to stress the value of presenting the rates as ranges: Unless the discriminatory power of rates is provided from sample size, as done here for 95% confidence limits, it could be possible to lay wrong claim on change of rates for an area

not realised at that time that the small population size would give little statistical support to the coefficient of variations of the observed rates, thus imparting little discriminatory power to the observed rates. Consequently, the epidemetric models built with their use would also suffer from the inherent infirmity.

The following brief critical review of some aspects of the epidemiology of tuberculosis in general, and India in particular, could provide ground for further discussion on the subject :

- (i) Tuberculosis is an epidemic. Like any other infectious disease, it has a secular epidemic curve with the difference, however, that in tuberculosis, the curve is hypothesised to span several centuries^{11,12,13} (Fig. 1). Hence, any two points on this secular curve, if separated by 5-20 years, will be so close, as to appear super-imposed. Hence, no change could really be appreciated over such a small period.
- (ii) So far, only one tuberculosis survey has been carried out on an all India basis, which was itself not based on a national sample.²
- (iii) The later surveys were conducted in a few selected areas at different times, one of which was carried out to study the effect of a specific intervention i.e., BCG.^{6,8,9,14}
- (iv) The comparatively low initial prevalence rates of cases have been observed to have remained unchanged in all subsequent surveys, carried out so far in selected areas : representing a very small rate of change, if at all. The explanation for the unchanging rate became clear from the natural dynamics of tuberculosis in India as observed in the NTI Longitudinal Surveys.⁸ Of the cases constituting the initial case prevalence, one third were eliminated in a year due to death or natural cure, but the new cases added to the pool during the year were found to be in the same proportion. Thus, the pool of cases continued unchanged over short periods of observation, provided the rate of population escalation is not considered (Fig. 2).
- (v) On account of the relatively low initial case prevalence rate and the very small

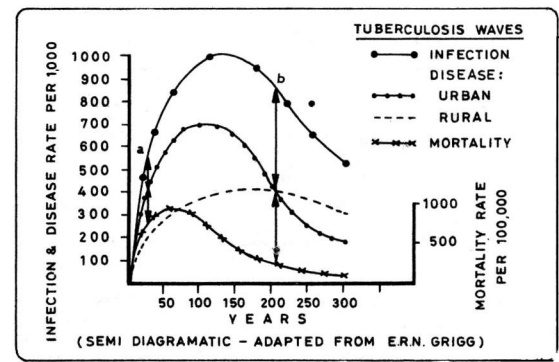


Fig. 1 Development of the wave of tuberculosis epidemic through time : The tuberculosis epidemic curve appears similar in form to those of other infectious diseases. However, the former develops through centuries. It has an ascending limb (phase of spread), a peak (phase of transition) and a descending limb (phase of decline), followed by endemicity. The essential proximity of infection, disease and mortality curves characterises the phase of spread (shown with arrow 'a'). Wide gaps between one and the other rate develop at the peak and descending limb (shown with arrow 'b'). In India, gaps similar to the latter, exist now. An inference that could be derived is obviously of an advanced epidemic curve, probably in declining phase. The urban-rural epidemic curves are different entities - but could cross at some point in the descending phase. The urban - rural distribution presently observed in India, may be viewed in this light.

change anticipated over a comparatively short time span, the population sample size for the repeat surveys would have to be statistically valid change.¹⁵

- (vi) **Prevalence rates of cases in urban and rural areas were similar in the NSS (1955-58).² From a single point prevalence it was concluded that tuberculosis situation as a whole was similar in the urban and rural areas. It is realised today that unless such a similarity is observed over a period of time, there is insufficient justification to form such a hypothesis.** In fact, the epidemic curves in urban and rural areas, as per the known behaviour of tuberculosis epidemic, may well be different,¹¹ intersecting at some point to give similar rates, only to pursue their different time trends prior to the intersection. (Fig.1). Recent studies on the tuberculosis situation in both the urban and rural areas of the

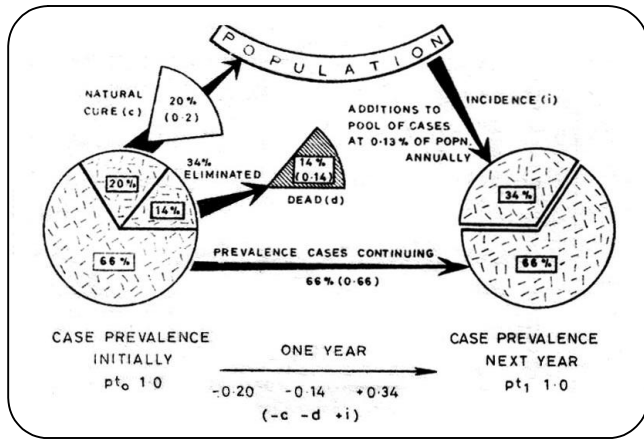


Fig. 2 Pool of tuberculosis cases in the community-natural dynamics: The pool is maintained at the same size (i.e., 1.0) from one year (t_0) to the next (t_1), not considering the population changes. In a year's time, 0.34 proportion of cases get eliminated from the initial pool (death 0.14, cure 0.2), but 0.34 part is added afresh (incidence). Though size of the pool remains 1.0, the addition keeps the pool constantly alive and renewed. It has a sinister significance in view of transmission of infection to a fresh proportion of the uninfected in a community, inspite of no change in case prevalence. The continuance of previous year's prevalence, on the other hand, amounts to failure of the community to reduce the pool through recognition and conversion.

same district in south India, could serve as the database to investigate such a hypothesis.¹⁶

- (vi) It is realised today that tuberculosis mortality rate is not a sensitive enough parameter to represent the tuberculosis situation: mortality rates are coming down in most of the places without reflecting the actual disease trend.¹⁷

In summary, it was not envisaged in 1955-58, when the DTP was being formulated, that there would be a no-change situation in the prevalence rate of tuberculosis after DTP. It was through a series of surveys carried out later in the limited areas of Bangalore, New Delhi, Tumkur and Chingleput that it became clear that no significant reduction in case rates could be expected over a relatively short period of observation.^{6,8,9} The hypothesis underlying the static situation was formulated by the Indian epidemiologists later taking their cue from Grigg's momentous work.^{11,12,13}

In the meantime, the Tuberculosis Surveillance & Research Unit (TSRU), Netherlands established

that it was the annual risk of infection (ARI) which held the key for evaluating the epidemiological trend in a community.¹⁸ The ARI, is the average of incidence rates of infection in an unvaccinated population of same age, calculated over a period of time. It is, by and large, unaffected by the extent of age-sex variations usually observed in general population groups. The rates are statistically derived from the observed prevalence of reactors through tuberculin test surveys conducted repeatedly in a representative sample of the unvaccinated population and following a simple Table.¹⁸ However, ARI could even be calculated from a single infection prevalence survey. The same persons need not be tuberculin tested repeatedly, as required in the incidence studies. ARI could give an estimate of the size of the most recent source of infection from the pool of infection in the community.

The available data from the Longitudinal Survey area of the NTI have recently been used for the calculation of ARI for the area.¹⁹ It has been found to be almost identical with the observed incidence rate of infection during the initial surveys for which the comparison is possible (Fig. 3). Over a period of 23 years, there has been an annual decline in the risk of infection for the area at a rate of 3.2%, on the average, the ARI changing from 1% to 0.6%. One could, then, estimate the incidence of smear positive cases in the community on the basis of the ARI (1% ARI being equivalent to the annual incidence of 50 per 100,000 smear positive cases, being a parametric relationship).²⁰ It could be recalled that at the first survey of the NTI, the incidence of smear positive cases was about 65 per 100,000 (calculated ARI-1%).⁸ In the same area studied 23 years later, the incidence of smear positive cases has been reported to be commensurate with the most recent ARI for the area (ARI - 0.6% : annual incidence of smear positive cases 23 per 100,000).²¹ From a mathematical model, the above actually observed situation has also been found to be consistent with an organised intervention comprising no-programme for five years followed by a programme working with 33% efficiency for 20 years thereafter (Fig. 4).²² It could also be derived from that model (full report unpublished) that programme operation of average 33% efficiency for nearly three decades would give an annual

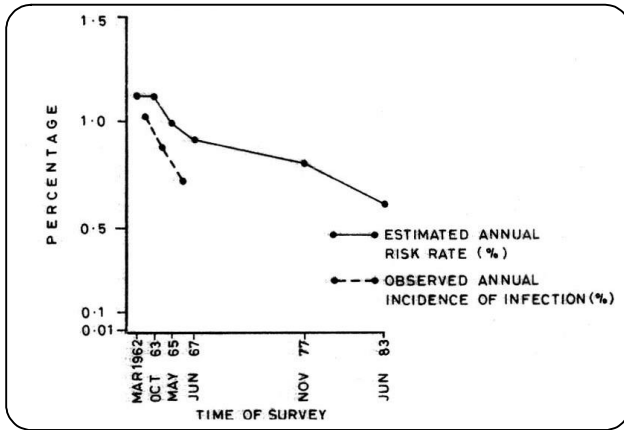


Fig. 3 *Estimated annual risk of infection (ARI) - 23 year trend in Bangalore rural area:* Incidence rate of infection observed between surveys for the same area is also given for the initial years of observation. ARI is a calculated average of incidence, which is very convenient to work out from prevalence data and hence preferred to incidence rates. The curves here show that the observed incidence and calculated ARI give nothing but the same information, as should in any case be obvious!

declining trend to the following extent : 1.4% in case rate (3.89 per 1000, falling to 2.3), 2.0% in smear positive case rate (1.7 per 1000, falling to 0.67) and 3.2% in ARI (1% changing to 0.6%). This could hypothetically be the current epidemiological trend in India : with that average level of programme efficiency. Alternatively, the above trend could also represent the natural dynamics where specific intervention had almost no effect, so close are the two curves in the model (Fig. 4).

It should be understood that the above trend was mathematically worked out on the basis of actual observations in Bangalore area. It is, on the other hand, known from NSS that the tuberculosis situation within India varied from one place to another to an extent (case prevalence rates ranged from 1.54 per 1000 in Delhi as the lower limit of the range to 9.68 in Madanapalle town being the upper limit).² The recent observations of 1% ARI with an annual decline of about 3% around Bangalore and no decline in the Chingleput area near Madras go to show that the tuberculosis situation in India could, in fact, be different in the time dimension as well, if only slightly, as from area to area.^{19,23} **Even then, the likely trend marks India out as a country of high transmission and inadequate decline, a situation in common with other countries of the Indian subcontinent and sub-Saharan Africa**

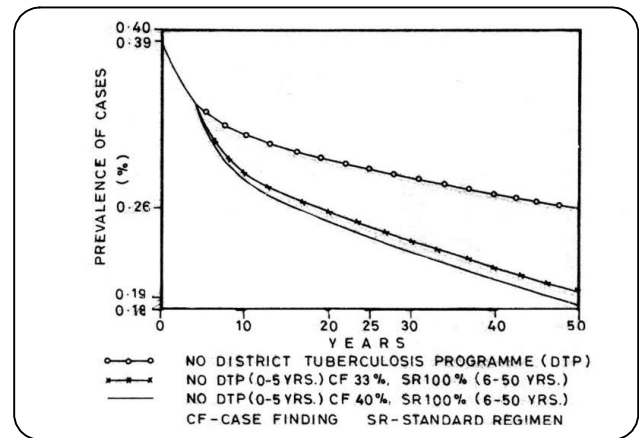


Fig. 4 *Model depicting hypothetical 50 year trend of tuberculosis cases in an Indian community:*

The curve under no-intervention situation is a projection based on the observations in longitudinal survey of NTI, after incorporating likely population changes. However, the projection beyond five years is of theoretical interest only. The middle curve with case-finding efficiency (CF), 33% and all patients on standard chemotherapy regimen (SR) appears to be close to the present Indian reality. Several other options are available in the model (not shown), with variable inputs of resources and efficiency e.g., short course in place of standard chemotherapy, etc. The hypothesis of a slow downward trend hastened by interventions, could be formulated from the model

(ARI : 1.0% to 2.5% and annual decline 0% to 3%). Alternatively, and by an optimistic estimate, it could be in a league with the countries of East and South East Asia (ARI : 1.0% to 2.5% with annual decline less than 5%).²⁴

While epidemiologists generally accept the study of ARI for following the epidemiological time trend, it would be useful to study other pertinent data. In spite of the obvious difficulty in interpreting the very small likely change in the case prevalence rates, one could form a hypothesis from available data on the distribution and nature of the problem in the community. For example, the relative no-change situation in the disease rate taken along with equal urban and rural prevalence rates and the wide margins between infection, disease and mortality rates (infection rate 38%, case rate 0.4%, mortality rate 84/100,000) would seem to suggest that the tuberculosis situation in the country is somewhere on the downward or low

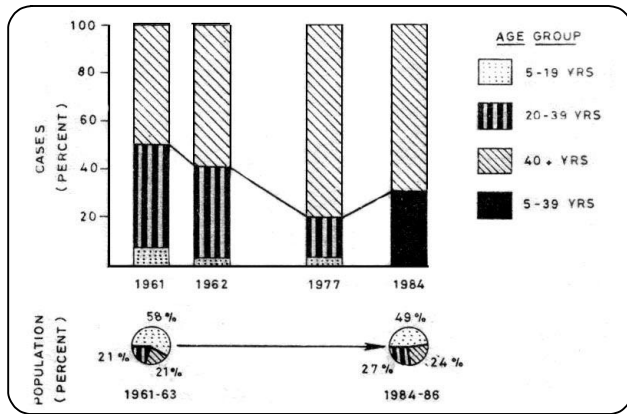


Fig. 5 *The proportional distribution of bacteriologically positive cases in the community:* The distributions from National Sample Survey and Longitudinal Survey of NTI, show a relative concentration in the age group 40+. In 1961 NTI survey, as much as 58% of the community in age 5-19 years would contain only about 5% - 7% of total cases. About 20% of total population, who were in 40+ age, would contain about 50% of cases. This, in itself, is epidemiological evidence in support of ageing of cases. During subsequent periods between 1977-78 and 1984-86, still fewer cases could be detected in younger age groups. Of the total cases, 80% were concentrated in those aged 40+, constituting 24% of population. Substantial shift of cases towards higher age groups is all too evident.

endemic phase of the disease.^{12,13} Other epidemiological observations in this context are the distribution of cases by age and sex and the proportion of smear positivity among the prevalence cases. In the earlier surveys carried out by the NTI in Bangalore district rural areas, over 50% of the cases were distributed in the age group 40 years and over.⁸ However, in the recently

reported surveys from the same area, between 70% and 80% of the cases were found to be in this age group.^{21,25} Over a period of time, cases have shifted more and more to the higher age ranges, sparing those in the below 20 years range, which constitutes half the total population (Fig. 5). Prevalence rates continue to be higher in the males than in females, especially with the increase in age.⁸ Further, the proportion of smear positive cases, which could be taken as comparatively late and more advanced cases, show a decline in relation to culture positive cases (Table 1). The above findings appear to be meaningful when considered in conjunction with the general observation of paediatricians that miliary, meningeal and other disseminated forms of tuberculosis in children are waning throughout the country.^{11,26} In some pockets and among those residing in distant and hilly regions as well as among tribal populations, in whom tuberculinisation may not have taken place to the extent as in the relatively "urbanized" areas, the situation could be different. The occurrence of glandular and other forms of childhood tuberculosis and even pulmonary tuberculosis is considerably higher in these, as is evident from community surveys carried out in Car Nicobar and Bangalore City areas.^{27,28} In all the 6,125 children aged 0-14 years, resident in Car Nicobar Island, 27 (4.4 per 1000) had histopathologically confirmed glandular tuberculosis with prevalence rate of all forms of tuberculosis being 6.2 per 1000. Compared to this, none had glandular tuberculosis among the 1,537 children aged 0-14 in a Bangalore slum and the prevalence of all forms was 3.5 per 1000. A similar prevalence rate was also observed in the Bangalore rural area.²⁹

Table 1 Proportion of Smear Positive Cases from Survey to Survey in Bangalore Rural Area (1961-84)²¹

| Survey | Year Initiated | Cases (No.) | Smear Positive | Prevalence Rate of Smear Positive Case (Per 100,000) |
|--------|----------------|-------------|----------------|--|
| I | 1961 | 178 | 47.0 | 189 |
| II | 1962 | 151 | 47.0 | 175 |
| III | 1964 | 136 | 44.8 | 151 |
| IV* | 1966 | 162 | 58.6 | 230 |
| Latest | 1984 | 96 | 15.6 | 68 |

* **Note :** Temporary reversal of trend in survey IV was ascribed to drought and deprivation. It was reflected in all the related rates, e.g., population emigration, prevalence and incidence of infection, cases, etc (not presented)

It could be inferred that both the urban and rural areas of Bangalore district were in a favourable situation compared to Car Nicobar where the process of tuberculinisation was not advanced and tuberculosis services had just started. Other areas within the country having similar socio-economic and demographic situation as obtaining in Bangalore district may be assumed to be having a similar tuberculosis epidemic situation. It could also be surmised that the situation in Car Nicobar now could have been the likely situation in Bangalore several decades back. These findings, in general, on the urban-rural and age, sex distribution of cases as well as the form and severity of the disease are consistent with the declining epidemiological trend as shown by Grigg.¹¹

Epidemiological assessment of the situation through a repeat survey has been a contentious issue in this country for sometime. For technical as well as operational reasons enunciated earlier, it has been considered appropriate to carry out well planned repeat studies only in certain areas with a view to judge the epidemiological trend in the country as a whole by extrapolation through mathematical models.^{10,22} However, some still prefer repeated countrywide sample surveys. It is true that the NSS was carried out as far back as 1955-58² and the future course of action from time to time needs to be related to the epidemiological situation. It has to be appreciated that a repeat survey could reveal three likely epidemiological situation : of no decline, slight decline, or slight rise of the prevalence rates. What plans do we have of changes to be made in the programme appropriate to the epidemiological picture emerging from the repeat all India survey? In case there is no agenda for changing the programme, a repeat national sample survey-even as it is conducted at a considerable expense - will not be action related but of academic interest. **Simply to understand the current epidemiological situation in the country as a whole, is it advisable to undertake expensive repeat surveys when it is not possible to observe a single time trend for the country as a whole because of several variables affecting the trend differently from area to area?** It is to be realised that the dynamics of tuberculosis are related to variable demographic and living situations, different health efficiency situations, in general,

and levels of coverage and delivery of anti-tuberculosis measures, in particular. Besides, there are myriads of social, political and cultural variables which are yet undefined from region to region that impinge on the epidemic curve. Only very complicated standardisation procedures could satisfy the sampling needs of a representative national repeat survey, especially because information on some essential variables is hard to come by, making stratification a difficult exercise indeed. Hence, it appears, that the study of an all India sample, looking for quantification of change with time, is beyond the scope of observational studies. The nearest approximation can only be attempted through mathematical models. The latter approach would, no doubt, suffer from a measure of oversimplification but could, at least, provide a likely picture, at a fraction of the resources and within the bounds of feasibility.

The mathematical model recently constructed at the NTI by our group is an attempt to weave together some of the mentioned variables at play (Fig. 4).^{22,30} The model has its drawbacks in the sense that it is not a stochastic but deterministic model : it is not capable of showing changes in the changing trend with time, nor does it incorporate the social and educational imponderables in its fabric. However, it provides an expectation to the programme planners over a 50 year period under variable efficiency situations, patient behaviour patterns represented by compliance, and input of resources in the form of regimen variability and coverage by services. Thus, the results of variable degrees of intervention interwoven with population response could be obtained from the model. Observational studies, if possible in some areas, could be matched with the expectations from this model. Alternatively, a hypothetical projection of the epidemiological situation for an area could be made from the mathematical construct, provided the efficiency of the health services could be known, from the monitoring of the programme in the area. It could be derived from the model that given the current efficiency of the programme and the resultant trend, there will be a slow decline in tuberculosis upto 50 years, the decline in later years being almost marginal (Fig. 4).²² **Therefore, when the efficiency of the case-finding programme is about 33%, treatment efficiency thereabout or lower, and the rise in population considerable, it is futile to**

Table 2* Population required for Repeat Surveys to validate Case Prevalence Rates derived from Epidemic Model under some Input Variables of Intervention (Given Initial Case Prevalence Rate 0.389%) (For Confidence Level 95%, One Sided Test, Power 80%)

| Year of observation | Input Variables of Intervention | | | | | |
|---------------------|--|--|--|--|--|--|
| | a | | b | | c | |
| | Case prevalence rate estimate from model (%) | Population required in a survey for validation | Case prevalence rate estimate from model (%) | Population required in a survey for validation | Case prevalence rate estimate from model (%) | Population required in a survey for validation |
| 10 | 0.312 | 89,748 | 0.281 | 43,609 | 0.281 | 43,609 |
| 25 | 0.286 | 48,302 | 0.239 | 21,194 | 0.238 | 20,881 |
| 50 | 0.255 | 27,232 | 0.190 | 11,104 | 0.175 | 9,354 |

Input Variable of Intervention :

- (a) No intervention - 50 years.
- (b) No intervention - 5 years; 33% case-finding efficiency (CF) and all cases on standard regimen (SR) for 6 - 50 years.
- (c) No intervention - 5 years; 33% CF and all cases on SR for 6 - 25 years; 33% CF - 20% cases on SCC; 80% on SR for 26 - 35 years; 40% CF - 40% on SCC and 60% on SR for 36 - 50 years.

* Calculated on declining prevalence rates of cases (initially by 3.8% per year) decelerating with time, as per model²² (Also see Fig.4).

Source of Data : Balasangameshwara et al,²² Appendix

talk of epidemiological assessment through repeated nationwide surveys.

From the foregoing discussion, therefore, it would seem reasonable not to consider a repeat nationwide survey to be one of the priorities at this time. **The stress should rather be on action to raise the efficiency of the DTP to as near the critical level of efficiency as possible, wherein almost all of cases reporting on their own are detected and all of them are put on short course chemotherapy.**³⁰ Only when monitoring through management information system starts showing an efficiency of this level should one consider the situation ripe for epidemiological assessment. Till then, the attempt should be to get high service coverage to obtain deliberately controlled case-finding and treatment efficiency. Additionally, there should be nationwide surveillance through ARI. Repeat surveys in some areas could, however, be carried out to provide inputs into the model and to validate the findings of the model with time. If such validations are carried out at

relatively long intervals, the population size for repeat studies may not be prohibitively large, as seen from the projections of Balasangameshwara and Chakraborty (Table 2).²²

One may wonder whether the epidemiologists are right in expecting the control programme to bring in epidemiological returns in a relatively short time. It is possible that with the kind of social and economic development in countries like India, our main aim should only be to meet the demands of the people, rather than achieve a technical breakthrough in tuberculosis control, as is being attempted in some of the developed countries.³¹ For countries like India with the current annual incidence of about 750 smear positive cases in the average district of 1.5 million, the task of reducing it is altogether different compared to, say, a country like the Netherlands, with the present incidence of only 12-15 smear positive cases in a million population (Table 3). To set an epidemiological goal for the programme, therefore, may not be the right concern for the health planners, especially when enormous

Table 3 Indian situation set against that in the epidemiologically advanced countries heading towards the goal of 'elimination'

| Country | Epidemiological Situation | | | |
|----------------|--|--------------------------------------|--|--------------------------------------|
| | Present | | Qualification for 'close to Elimination' Status | |
| | Incidence of smear positive cases per million/year | Prevalence of infection all ages (%) | Incidence of smear positive cases per million/year | Prevalence of infection all ages (%) |
| Most Advanced* | 12-15 | 15 | 1.0 | 1.0 |
| India** | 500 (750) | 40 | (1.2) | |

* Norway, Netheralands, etc.: (ARI 0.1 to 0.01%, 10% Annual Decline, 'Close to Elimination Status' projected to be achieved by 2025 A.D.).³¹

** Figures based on NTI Survey.⁸

() Calculated for 1.5 million population i.e., an average Indian district.

sustained efforts are needed to bring about marginal returns in epidemiological terms. However, even partly agreeing with the above standpoint, one may still wonder as to the way out of the present "epidemiological mess" as described by Grzybowski and others.¹ The situation surely merits concern, wherein the already diagnosed cases continue to constitute a major proportion of the prevalence (2/3rd), year after year (Fig.2).^{1,8} Low treatment efficiency as the reason for the unfortunate situation of previous cases forming a major proportion of the overall pool long after they were diagnosed, it is argued, forces us to settle for long time frame of tuberculosis control. To some, this may seem strange enough, in the context of a rather high coverage of the population by health services.

The issue is more management related than technical in nature. The basic scientific management of any system, applied judiciously and in a sustained manner has to play its role usefully in the tuberculosis programme as well. Nevertheless, the programme managers are well advised to identify shortfalls from the inbuilt monitoring system and apply corrective measures in an ongoing manner.³² **Unfortunately, the level of management expertise in itself is related to the social and economic development. Its lack in the field of health is as pervading as in social and economic areas in developing countries. It would not do to expect managerial miracles overnight.**

In this context, it is worthwhile to recall that while the annual incidence of smear positive cases in an average Indian district amounts to about 750, as mentioned above, nearly 660 cases are being diagnosed under DTP with the average case-finding efficiency of 33% of all cases reporting at PHIs.³⁰ The efficiency of finding the smear positive incidence cases cannot, therefore, be so poor (88%). A lot can be achieved under the circumstances by raising the treatment efficiency, since smear positive incidence cases form the crucial group of transmitters of infection. Readjustment of priorities following appropriate operations research towards achieving this goal is called for:

The challenge has certainly increased with AIDS already threatening to compound the problem of tuberculosis, as is happening in some of the developing countries of Africa. In so far as this country is concerned, persons infected with tubercle bacilli constitute close to 40% of the community at large.⁸ As long as tubercle bacilli lurk in them, eradication/elimination can not be considered as the goal under the programme.¹² Further, with the introduction of HIV infection the persons infected with tubercle bacilli are additionally exposed to the risk. **It is true that the additional risk is not enough to offset the epidemiological balance in a big way as in the case of the industrialised countries with a low infection rate in the relatively vulnerable group aged 20-50 years.**³³ The availability of almost

unlimited resources could perhaps take care of any possible aberration in the epidemiological curve of tuberculosis there. However, for the countries of sub-Saharan Africa and Asia with their high risk of transmission of tuberculosis, there is every possibility of an escalation of the epidemiological situation. India does not have, as yet, the data on how the epidemiological situation will affect the Indian sub-continent. It is also not geared to meet the result of interaction of the twin problems. One should plan to meet that eventuality from now on.

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Appendix : Hypothesis test for population proportions in repeat surveys :

1. Initial prevalence rate - take lower value of the estimated range for 95% confidence limit, calculated as follows.³⁴

$P - 1.96 p(1-p)/n$ where p = Case proportion; n = Population sample

2. Impute the expected rate of annual decline to the lower value of the range and calculate subsequent prevalence, yearwise (1% decline in case prevalence rate used in this paper).
3. Population to be subsequently screened for 95% confidence limit ($Z_{1-\alpha}$) and 80% power ($Z_{1-\beta}$) for a one sided test.³⁵

$$n = \{Z_{1-\alpha} [2P(1-P)] + Z_{1-\beta} [P_1(1-P_1) + P_2(1-P_2)]\}^2 / (P_1 - P_2)^2$$

Where P_1 = Initial Prevalence

P_2 = Subsequent Prevalence

& $P_1 > P_2$

$$P = (P_1 + P_2)/2$$

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