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Editorial

LIMITATIONS OF CONDUCTING COMMUNITY SURVEYS TO ASSESS THE EPIDEMIOLOGICAL IMPACT OF TB CONTROL PROGRAMMES ON THE INCIDENCE OF TB

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Tuberculosis (TB) remains a major health problem in India, and accounts for nearly 20-30% of the global TB burden. A comprehensive review[1] in 1993 of the National TB Control Programme (NTP), present in our country for four decades, documented the failure of NTP due to various drawbacks. These included poor management of the TB control programme, over-reliance on X-rays, poor treatment adherence, under-utilization of laboratory services, poor supply of quality drugs, inadequate funding and lack of proper documentation and case reporting. The Revised National Tuberculosis Control Programme (RNTCP), an application of the globally accepted WHO recommended Directly Observed Treatment Short-course (DOTS) strategy, was implemented in 1993 on a pilot basis, rapidly expanded from 1997 and achieved nation-wide coverage in March 2006[2-3]. The DOTS strategy, based mainly on scientific evidence from India, was found to be more cost effective and RNTCP has almost achieved the global target of 85% treatment success and 70% case detection. It should be remembered that this strategy was developed utilizing results from the pioneering studies conducted by the Tuberculosis Chemotherapy Centre, now renamed as the Tuberculosis Research Centre (TRC), Chennai, three to five decades ago which demonstrated the effectiveness of ambulatory treatment of TB, the concept of direct observation of treatment and the efficacy of intermittent treatment regimens[4-6]. Even though the DOTS programme is decentralized in our country and that treatment facilities are free and provided as close as operationally possible to the door step of patients, a large proportion of patients still seek TB care from the private sector and other alternate sources. The private sector, in the initial stages of RNTCP implementation, was not brought into participating in the TB control activities of the country. Now, however, the programme places great emphasis on public-private mix partnership for the provision of TB services.

After the implementation of the DOTS-based RNTCP in Tiruvallur district of south India by the Tamil Nadu Government in 1999, TRC has monitored the programme in one sub-district tuberculosis unit (TU), and has undertaken a series of TB disease prevalence surveys in a representative random sample of population to measure the impact of the implementation of DOTS services under RNTCP on the disease frequency over a period of time. Tiruvallur is a semi-urban area, 40 kms inland from Chennai city, and the study TU had an estimated population of 5,80,000 in 1999. This is the area where the famous ‘Chingelput BCG Trial’ was conducted during 1968-1986 to study the protective efficacy of BCG. This area was under TB surveillance on two more occasions in 1991-1992 and 1994-1996. Hence epidemiological data on TB is available from this area for about three decades. In addition, a good rapport with the local community has been established over the years. The availability of this background information has been very useful for evaluating the impact of the implementation of the DOTS strategy for TB control.

The first disease survey was carried out during 1999 to 2001. All adults aged $\geq$ 15 years included in the survey were first screened for TB by the use of two screening methods, namely elicitation of chest symptoms and chest radiography using MMR (mass miniature radiography). Those who were either

symptomatic and/or had an abnormal chest X-ray suggestive of tuberculosis, underwent sputum examination by smear microscopy and culture. This survey meticulously documented the baseline information on the disease prevalence at the time of implementation of the DOTS strategy in this area[7]. The second survey was carried out in the same population using the same methodology during 2001-2003. This survey has provided the estimates of TB disease prevalence after 2.5 years of implementation of the DOTS strategy.

An analysis of the data for the period 1968 to 1986 showed that there was no decline in the prevalence of sputum smear-positive pulmonary TB (PTB) cases in this area i.e. prior to the use of rifampicin-containing Short-Course Chemotherapy (pre-SCC) regimens[8]. After the introduction of rifampicin-containing SCC regimens (SCC), there was a 4.3% annual decline in prevalence during the period 1987-99. After the implementation of DOTS in this area, the decrease accelerated to 9.0% per annum, with the prevalence of smear-positive PTB cases decreasing from 328 to 259 per 100,000 populations. When the culture-positive cases, irrespective of smear results, were looked at separately, the corresponding rates of decline were 1.4, 2.1 and 11.3% respectively for the three periods of time[9].

TRC has thus demonstrated a substantial annual decline in the prevalence of smear positive (9.0%) and culture positive (11.3%) PTB cases in a sub-district area of Tiruvallur after the introduction of DOTS strategy. If this level of decline can be achieved and sustained across the country, or even a lower annual decline rate of 5%, the RNTCP is likely to meet the United Nations TB-related Millennium Development Goal (MDG) of halving the prevalence of TB by 2015 compared to 1990 levels[10].These results suggest strongly that, in the absence of a large epidemic of Human Immunodeficiency Virus (HIV) infection (<1% of TB patients in the survey area were found to be co-infected with HIV - TRC, unpublished data), DOTS can result in a rapid reduction of TB prevalence. If the results from the third survey, conducted during the period 2004-2006, are considered, the average annual decline over a 5-year period in the smear-positive and culture positive PTB cases is estimated to be 12.5% and 12.6% (TRC, unpublished data). However, the contribution to the documented decline in prevalence from changes in the socio-economic status, status of the HIV epidemic in the community and the intervention due to the active case finding activities attributable to the survey itself, have not been estimated during the analyses. But a substantial annual decline of 6% in the prevalence of tuberculosis infection and in the computed Annual Risk of Tuberculosis Infection (ARTI) has also been demonstrated from three tuberculin surveys conducted in the same area during the period 1999-2005[11].

Alternative methods of reporting of all diagnosed new TB cases have to be developed to enable better measurement of the “true” incidence of PTB. The incidence of PTB was measured in India in earlier longitudinal surveys through repeat surveys at fixed intervals which varied from 1 to 5 years. However, at that time, the programme efficiency was poor and the duration of treatment was longer (12 to18 months). Because of these factors, the duration of illness was usually about 3 years and this allowed for the detection of new cases occurring between two surveys. With the introduction of SCC, the duration of treatment was reduced to 6 to 8 months. The implementation of DOTS strategy under RNTCP has further shortened the duration of the sputum positivity among the new cases to 2 to 3 months. In this scenario, the earlier method of detecting new cases by repeat surveys at 2.5 year intervals will result in under-reporting of incidence.

Incidence changes as a result of the changes in the transmission of the disease in the community. Estimating incident cases from two community based disease prevalence surveys using X-ray as a screening tool for detection of cases with a mechanism to identify the new cases in between the surveys is very expensive, time consuming and requires enormous technical inputs that would be difficult to contemplate outside the context of a special study. All cases identified in the first survey conducted during 1999-2001 were prevalent cases. The new cases identified in the second survey (2001-2003) were incident cases and

the total cases, irrespective of new or treated, identified in the second survey were prevalent cases. However, there was no follow-up of the survey population in the period between the two surveys. TRC has made an attempt to correctly estimate the incidence of new PTB smear-positive cases by tracing out the new cases that developed between the first two surveys. We used the TB register maintained in the TU of the area, in order to identify the new smear-positive cases that reported from the survey area in the period between the surveys to health facilities for chest symptoms and were diagnosed as PTB, to the total of new cases detected by the second disease survey. Addresses of patients were collected from the TB Register and they were visited by the field staff and their identity confirmed. Definition of cases included as incident cases remained to the same. The incidence in those aged 15 years and above from the first two disease surveys (including the new cases from the routine programme) was estimated to be 126 per 100000 populations[12]. However, this estimated incidence is likely to be an underestimate of the "true" incidence due to a proportion of incident cases being missed by the surveys if diagnosed and treated in between surveys and/or if treated in the private sector.

An easier method would be to measure incidence and impact of the implementation of DOTS through routine case notifications under the programme provided all new cases are notified. The number of new smear-positive PTB cases notified annually to the health facilities in the study TU from mid-May 1999 to 2003 were 188, 386, 443, 464 and 455 respectively, and the corresponding annual notification rates, measured as the number of cases per 100,000 adult populations, were 69.5, 95.1, 109.1, 114.3 and 112.1 respectively. There was thus an increase in the notification rates seen in the early years but this seemed to have plateaued in the later years. Importantly, therefore, the routine notification rates here are found to be even much below the incidence rate estimated from the disease survey results, which itself may be an underestimate of the "true" incidence rate in the study population.

The primary aim of any TB control programme is to prevent the transmission of TB infection by treating all active TB cases to a complete cure. For this, all new cases should be notified properly to the RNTCP to reflect the "true" incidence of TB disease in the community. In India, a substantial proportion of TB patients, however, seek care from private practitioners and these cases treated by the private sector are generally not notified to the RNTCP[13]. These practitioners must however have a significant amount of information about their patients, their diagnosis, treatment and outcome. The data at such sources needs to be made available to the RNTCP to enable better use of this data in order to improve the quality and completeness of the TB control programme's reporting. All TB cases will be notified in a situation where there is a good surveillance system like that of a universal birth and death registration system. Unfortunately India, with its weak surveillance systems, will take a long time to achieve this goal. Therefore, a good networking system for notifying TB cases by all practitioners needs to be developed and implemented. Mandatory notification to the system of all TB cases could be considered, if practical.

The following are pre-requisites for a good notification system:

1. All TB cases attending either a private or public sector health facility should have an unique identification (ID) number along with other details of the patient such as age, sex, residential address, mode of diagnosis, type of TB, regimen prescribed, etc.
2. All TB cases should be notified to a central place in the district from where a summary report should be sent to the State level and to the Central TB Division, Ministry of Health and Family Welfare, Government of India in Delhi after amalgamation of the data.
3. The system should have an inbuilt mechanism of removing any duplicate reporting that arises when a patient seeks TB care from more than one provider.
4. Private sector should also use the same standard method of diagnosis and tratment as practiced by the public sector.

Unless and until the notification system is strengthened, the notification data will not reflect the epidemiological situation of TB to any high degree of accuracy. An increase in the notification rate does not necessarily indicate a worsening of the TB situation. Rather, it may well simply indicate an improvement in diagnostic and reporting activities. However in the long run, trends in the notification rate should reflect the actual trends in incidence in the respective community.

Alternatively incidence of TB disease can be estimated using Styblo's equation[14] between incidence of new smear PTB cases and ARTI rates. However the incidence estimates derived using this equation are uncertain because of the imprecise nature of the ARTI rates computed from prevalence of TB infection derived from tuberculin surveys conducted using different methodologies. This imprecision is magnified when an effective TB control programme and/or an on-going HIV epidemic are in existence. As a consequence, the case detection rates, measuring the proportion of the estimated incident cases of new smear-positive disease detected by the programme, are not very reliable.

Hence, to conclude the most appropriate long term solution is to have in place a strong routine notification system which over time will reflect the trends in the incident cases in the community and will measure the progress towards the MDG of halting and reversing the incidence of TB disease by 2015.

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