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Review Article

Does Leprosy Need a Stronger Surveillance System Now? A point of view article

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Multi Drug Therapy (MDT) for leprosy was introduced by WHO in 1982 and the programme has been implemented for more than 3 decades. The main presumption out of the PR based elimination was that with reduction of disease load below 1 per 10000 persons, the transmission of leprosy would be arrested resulting in disappearance of the disease. MDT made the disease description, definition and epidemiological indicators so different that it ceases to be like any other disease. To eliminate the leprosy totally from the country needs following activities : 1. Scaling up of some sentinel sites (SS) to surveillance units (SUs), 2. Source of information, 3. Authentication and standardisation, 4. Generation of own data, 5. Need for a skin smear laboratory, 6. Promoting referral of suspects for DST.

Introduction

Multi Drug Therapy (MDT) for leprosy was introduced by WHO in 1982 and the programme has been implemented for more than 3 decades. Primarily initiated to counter the threat of dapsone resistance, this new tool renewed the enthusiasm among all the stake holders which include workers, patients, programme managers and policy makers. The national programmes were reorganized and strengthened with quick acceptance of the new treatment schedule in all the endemic countries (Lockwood and Suneetha 2005). Wide spread use of MDT reduced the case load so drastically that elimination of leprosy which, by definition was a case load bellow 1 per 10000 population was targeted by 2000 (WHA 1991) and was finally achieved by 2005. Though this was no less an achievement (Richardus and Habbema 2007), there was lack of consensus on the criteria for elimination, as considerable experts preferred incidence rate or its proxy new case detection rate (NCDR) in place of PR (Lockwood and Suneetha 2005, Braber 2004, Fine and Warndorff 1997) and this view was gradually adopted post elimination (WHO 2009a). This important change in the mindset in policy level is expected to remove certain complacency in various circles developed following the declaration of elimination. Another old issue gradually came into light drawing increased attention. Some publications citing the definition of control and elimination, showed that what has

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been achieved in leprosy so far is a good control than elimination and a disease in control needs a effective surveillance system (Dowdle 1998, Richardus and Habbema 2007). Thus a need for a systematic surveillance in the programme became stronger and stronger.

The main presumption out of the PR based elimination was that with reduction of disease load below 1 per 10000 persons, the transmission of leprosy would be arrested resulting in disappearance of the disease (Girdhar 1994, Noordeen 1994). In spite of long years of MDT, the decline of NCDR is not commensurate with that of PR (Smith 1997, Braber 2004) even in districts brought under MDT in the initial years. Added to this in certain pockets rise of new cases has reversed the state of elimination. A WHO workshop held in Hanoi reviewed the updates on the resistance to the components of MDT and emphasized on the preparedness for screening activities at the country level (WHO 2009a). A protocol has also been prepared to initiate the screening process. These are triggers to think for comprehensive surveillance centers in control programme. Facilities for skin smear testing are limited in the programme and there is no way to know the infection pool as well as status of transmission in the community. Some analysis of new case detection rate with its steep decline in some particular years seems to be more due to programme effect rather than the real disease trend (Richardus and Habbema 2007, Declercq 2011). Doubts have been raised as to what extent three decades-MDT is effective in arresting the transmission of leprosy (Richardus and Habbema 2007) ? It is difficult to attribute continuing new cases to 'long incubation period' considering usual incubation period of leprosy being around 5 years. Neither, 'hidden case hypothesis seems to hold good on the backdrop of innumerable awareness campaigns including MLECs, SAPELs. There is a lot of truth in viewing “leprosy as too complicated a disease to expect as a simple elimination paradigm” by Lockwood and Suneetha (2005), who also emphasized need for long surveillance. The proposed sentinel surveillance centers are expected to provide real picture of incidence reflecting status of transmission though from limited areas. It will also guide in standardization of vast and varied field information of the country.

Earlier attempts a system of surveillance

Surveillance is a mechanism of collecting information on specific health events through some selected persons or institutions to analyse and use to improve the programme. In the context of leprosy it is for safeguard against return of the disease. During introduction of MDT, Sample Survey cum Assessment Units (ASSUs) were created for each state in India, to generate information to monitor the progress. The functions these centers mostly remained unsatisfactory. Then leprosy elimination monitoring exercises were introduced in some of the states (WHO 2004) but the system also could not be sustained as expected. New cases continued to appear and recently in some areas increase of new cases even reversed the state of elimination. Setting of sentinel units in NLEP has been recommended in 1994, through a workshop at CJIL Unit, Chennai, India. Outlining the functions, it recommended at least two sentinel units in each state. In addition, it suggested reactivating the dormant SSAUs. There was no action on suggestion of the workshop.

A joint workshop on surveillance was also organised at Chinnai by National Institute of Epidemiology, WHO and Indian Association of Leprologists in 2005 (WHO 2005a). NCDR replacing PR as the crucial indicator was the first recommendation. Encouragingly, post elimination this is being put to practice slowly.

Other recommendations were to: (i) Ascertain the trend of annual incidence of cases along with child case rate and disability rate including gr. 1. (ii) Integrate leprosy in the IDSP. (iii) Follow a standard case definition for surveillance. (iv) Analyse data on variables from basic programme activities in a disaggregated fashion. (v) Utilise present indicators and (vi) dispense with the targets. Some suggested researchable issues were: a. Evaluation of indicators to know the progress expected of elimination. b. Decision on the duration, how long the surveillance should continue? c. Building surveillance mechanism in the community level.

Proposed activities

Scaling up of some sentinel sites (SS) to surveillance units (SUs): Amongst the causes of relapse in leprosy, resistance to rifampicin is most crucial. It is the 'back bone' of MDT and there is no substitute for it. It is encouraging that at the global level this risk has been realised and protocol for testing rifampicin resistance already designed in a WHO sponsored workshop held at Hanoi in 2008 (WHO 2009b). Accordingly India has already initiated the process in collaboration with 4 state-of-the art laboratories to cater the needs of 12 states to start with (DGHS 2009). Each state has four/five sentinel sites entrusting a clinician to select suspected relapse case to refer to their respective drug sensitivity testing (DST) laboratories. At least one of the sentinel sites in each state can be scaled up to sentinel center (SC) by attaching a survey unit to the already existing clinical section and supplementing with an epidemiological and a skin smear testing facility. The latter two can be managed by a data-entry operator and a smear technician respectively (even part time).

Source of information: Both the data of specified areas available in the district and data generated by the active survey by the SC need to be analysed. Presently such combined data is said to be ideal for Public health surveillance. Though programme prefers voluntary reporting of cases, active survey is preferable for reasons stated below. Information on present indicators collected for the purpose of routine MIS will be enough for surveillance purpose also. But the available data require to be filtered and authenticated for consistency by the epidemiology section of the SC.

Authentication and standardisation: Filtration means, to discard, investigate and correct inconsistent and erratic values in the periodic reports. In the Central Leprosy Division (CLD) indicators are analysed and certain feedbacks are given back to the state (CLD –DGHS 2013) This is a welcoming step but subsequent chain of activities up to sub-district level seems weak. It is not out of the place to present some examples of how averaging the value of indicators becomes non-representative. A comparison of annual report of India of year 2012-13 with that of 2008-09 shows change in NCDR from 11.1 to 10.8; PR from 0.74 to 0.73; child rate from 10.1 to 99%. In the year 2013-14, D N Havelli reported 386 new cases with NCDR 98 & child rate 26%; Arunachal Pradesh with 48 new cases; reported a child rate of 25% and Sikkim with 19 new case reported child rate as 15%. These are some small states and UTs of India. None of these reports are wrong. Averaging failed to reflect the high and low performance of individual states. Segregated analysis is required and attempts are being made with support from ILEP to categorise the districts on the basis of performance. The main objective is for providing more attention to low performing districts. The surveillance units filtering the data at district level will contribute refining of statistics at the state and the CLD level.

Generation of own data: SCs will generate their own data from the defined area. By active survey

all incident cases will be recorded to get the real incidence of 12 months. This can be compared with what is available from new cases registered by voluntary reporting. Extrapolation will provide result for a larger area. No special drive for case detection will be undertaken in these areas. This will also provide early case detection (at least within a year) and get rid of two important proxies- ANCDR and percentage of Gr. 2 disability. The latter indicator primarily introduced to indicate late cases, has now assumed a more crucial indicator for overall success of the leprosy control programme (WHO 2009a).

Need for a skin smear laboratory: A skin smear laboratory is must for SCs. Presently smear labs are not adequately functional to refer right cases to the DST laboratories. This is a crucial step in the process. Cases are being lost in the process of waiting of referral to a far of place. This gap will be filled by a readily available skin smear support. It will test the smear of cases detected in the process of sentinel survey and provide clue on infection pool in the area. Lack of any information on infection and transmission is a crucial gap in the control of an infectious disease. In Lymphatic filariasis, need of Mass Drug Administration (MDA) in an area is decided on the basis of the microfilaria rate in the night blood smear (a procedure more cumbersome than skin smear testing) and absence of antigenemia through immunochromatographic test (WHO 2005b). In tuberculosis two skin smear tests are mandatory to know the infectious cases in the community and declaring cure latter. With this logic, leprosy programme whose strategy is stated to have been borrowed from that of RNTCP (RNTCP 2005, Giridhar 1994) deserves revival of skin smear test at least for the surveillance purpose. Regarding diagnostic value an estimated about 30% MB cases are missed (ILA 2002) due to lack of skin smear testing. The DST labs are not getting enough cases partly due to lack of both interest and the facility at the sentinel site levels.

Promoting referral of suspects for DST: The unit will be instrumental to develop a network of institutions particularly the dermatology clinics and referral centers and other potential sources of suspects. Cases of the area who seek retreatment also constitute a potential group. Similar to retreatment group in TB, they deserve through investigation to exclude relapse. SC will be watchful to mobilize suspects from the above units and after completing the formalities refer the cases. A registry of simple clinical relapse is the first step. Workshop suggested function of SCs under the guidance of pioneer leprosy institutions for some time. The ILEP members may support developing at least one SC in the state they are supporting.

Does leprosy continues as any other disease?

Leprosy as a public health problem should not drift from what is in the text book. MDT made the disease description, definition and epidemiological indicators so different that it ceases to be like any other disease. What to speak of other disease, it differs so much with its close cousin-tuberculosis. What was wrong with simplified information system ? The robust achievement, elimination has been reached by SIS. Every workshop comes with something new. Why the denominators were so different ? 10,000 for PR, one lakh for child rate and one million for disability rate and none of them is accompanied with a note of reason or rationale for the change. Values of indicators in decimal dilute the severity of the problem which is not good for the programme.

NB: A skeletal form on this issue was presented in Biannial Conference of IAL, at Chandigarh in March 2014.

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