

Infection control and Revised National TB Control Programme

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Nosocomial Transmission of Tuberculosis is an important concern for all medical personnel in hospital settings^{1, 2}. But infection control is also an important issue at the community level as treatment of TB patients under Revised National Tuberculosis Control Programme (RNTCP) is mainly domiciliary. It is known that most of the transmissions occurs between the onset of cough and initiation of treatment.³ Thus delay in diagnosis affects disease prognosis at the individual level and facilitates disease transmission in the community. In this scenario, the important questions that need to be addressed are –

- How early are we diagnosing our TB patients and initiating them on treatment?
- Is there a mechanism to monitor treatment adherence and outcomes for all TB patients; also for those patients being treated outside the programme?
- How many TB patients are on anti-TB drugs at any point of time and what proportion of those TB patients are treated under RNTCP in our country?

Monitoring and evaluation of infection control measures is operationally easier under programmatic conditions as compared to those outside the programme, thus finding answers to the above questions is pertinent.

The World Health Organization (WHO) has proposed practical and low-cost interventions to reduce nosocomial transmission in settings where resources are limited.⁴ These recommendations emphasize on early diagnosis and rapid treatment of TB rather than expensive technologies, such as isolation rooms and respirators^{4, 5}. These recommendations are important for infection control both in health institutions and community. The present article discusses infection control measures that are already addressed through RNTCP and the areas that need further strengthening / justification.

1. Identification of suspects:

The most recent step towards infection control in RNTCP is the change in definition of TB suspect: from the earlier definition of cough for 3 weeks or more to the present 2 weeks or

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more⁶. This change in definition is expected to decrease the time gap between onset of symptoms and initiation of treatment. For this the programme encourages that - every patient with history of cough, attending any health facility, should be enquired regarding their duration of cough.

RNTCP relies on passive detection of cases, hence it is important to monitor if all symptomatic patients are promptly picked up by the health system. Thus at the Tuberculosis Unit / District level, monitoring the trend of the number of suspects examined per lakh population is important. Similarly at each health facility, monitoring the number of suspects in a month / quarter compared with the number of suspects examined in corresponding month / quarter of the previous years, shows the trend if number of suspect examinations are increasing / decreasing. Comparison with corresponding month / quarters takes care of the seasonal variations in occurrence of TB. Strong administrative commitment to monitor the same is necessary, in all health facilities, so as to ensure that each eligible symptomatic, reaching any health facility, is picked up timely for sputum microscopy.

Although RNTCP relies on passive detection⁷ of cases, it needs to be debated if active detection can be undertaken, atleast in areas like urban slums where population are often not able to access timely diagnosis⁸. Tribal areas are also of concern as there are many tribal districts in the country where the new sputum positive case detection is consistently more than the average for many years and is still increasing / static at higher levels, as reflected in annual RNTCP status reports. Here the concern is - do the tribal patients often reach the health system late for which there is delay in initiation of treatment resulting in greater transmission among them?

Specific measures are being taken within the RNTCP to address the MDR-TB problem through appropriate management of patients and strategies to prevent the propagation and dissemination of MDR-TB.⁹ Recently there is change in definition of MDR-TB suspect under RNTCP. As per the recent definition, any patient who fails a Cat I or III treatment regimen or any Cat II patient who remains smear positive at the end of the fourth month of treatment or later will be identified as “MDR-TB suspect”. But the earlier MDR-TB Suspect definition was restricted only to Category II patients who were smear positive at the end of the four months of treatment or later. This broadening of MDR suspect definition is expected to increase the number of MDR-TB suspect cases; thereby bringing more patients under the framework of DOTS-plus treatment. This step is also expected to decrease the transmission of MDR-TB in the community through early initiation of diagnosis and treatment. In India, the main stay for diagnosis of MDR TB was culture and drug-sensitivity-testing (DST) using LJ media (solid media). But now emphasis is also given on Line Probe Assay (a Multiplex PCR Technique) which can give the results in a week, instead of waiting for 4-6 months using solid media technique. This also facilitates early identification of MDR suspects and their early initiation of treatment. But at present these techniques are yet to reach 100% of our population as the required numbers of laboratories are yet to be established or have not started fully functioning pending the accreditation process.

In India, it is estimated that nearly 5% of the TB patients are HIV infected⁸. An HIV positive person also infected with TB bacilli has 50-60% life time risk of developing TB disease, as compared to an HIV negative person who has a 10% life-time risk of developing TB disease¹⁰. Tuberculosis is also one of the earliest opportunistic diseases amongst HIV infected persons. Thus CTD and NACO have developed a standardized cross-referral mechanism for linkages between ICTCs and RNTCP services. This mechanism is applied at all ICTCs nationwide. All

ICTC clients are screened by the ICTC Counsellors for the presence of the symptoms of TB disease (at pre, post, and follow-up counseling) using Ten Point Counselling Tool¹¹. There is also case finding activity at ART Centres and Care and Support Centres. Case finding for TB at all these centres is very important for early suspicion and diagnosis of TB disease, and for the prevention of transmission of TB infection to other clients.

II. During diagnosis:

Once the suspects come for sputum examination there are guidelines regarding the procedure for sputum collection to avoid direct and indirect transmission. The precautions include – the sputum need to be collected in open space, not in closed areas such as toilets and in ill-ventillated rooms, away from other people and laboratory technician should stand behind the patient while supervising sputum collection¹².

While preparing the smears, the laboratory technicians are advised to make smears within six inches around the flame which is considered a sterile zone. If smears are made in the sterile zone, there is less chance of transmission as the aerosol produced during smear preparation coagulates due to heat¹³.

They are also instructed to follow standard operating procedures for disinfection of sputum cups, left over sputum specimen, lids and wooden sticks in foot operated plastic bucket/bin with 5% phenol solution, for atleast 18 hours before final disposal¹².

Monitoring of standard operating procedures (SOPs), during sputum collection, smear preparation and waste disposal have been incorporated in routine quality assurance mechanism protocol, thereby ensuring review of recommended procedures during routine supervisory visits by Senior TB Laboratory Supervisor (STLS) and other supervisory staff.

III. During Treatment:

Most patients with disease due to drug susceptible organisms become non-infectious within several days to weeks after treatment is started¹⁴. To be more specific, it is often quoted that the risk of transmission is greatly reduced if patients are on DOTS for atleast 2-3 weeks¹⁵. Thus early initiation of treatment is an important step for preventing transmission of TB.

Along with early initiation of treatment, the programme also emphasizes on completion of recommended treatment. Ensuring completion or cure of TB patients with appropriate regimens would also decrease the risk of emergence of MDR/ XDR TB. The issue of treatment interruptions or defaults is appropriately addressed by ensuring initial home visits before initiating treatment, counseling and an appropriate monitoring and supervision mechanism to carry out required intervention where necessary.

Available information suggests that the proportion of MDR-TB is relatively low in India. However, this translates into a large absolute number of MDR-TB cases, with an estimated annual incidence of 110,000 cases⁸. Drug resistance levels are higher in areas with a poorly performing DOTS programmes⁹. Thus use of inadequate regimens and inappropriate directly observed treatment (DOT) leads to increase in drug resistance levels in the community. RNTCP

recognises that implementation of a good quality DOTS programme is the first priority for TB control in the country and prevention of emergence of MDR-TB in the community is more imperative rather than its treatment⁹.

Thus for ensuring cure or completion of treatment for all types of TB patients, it would be ideal if 100% of the patients (both in public/ private) are covered under RNTCP. Efforts are being made to improve the quality of TB care in the private sector through better public-private partnerships¹⁶. Although this partnership is gradually improving over the years, still many patients are being prescribed anti-TB drugs outside the programme. Thus we exactly don't know how many TB patients are being treated outside the programme in our country. *Thus it is important to debate if TB needs to be made a notifiable disease through out the country and appropriate mechanism in place to monitor the same.* This would give us a better estimate regarding the quantum of TB patients being treated outside the programme. Thus having notification mechanism in place would ensure better estimates of the incidence and prevalence of TB in our country.

IV. Contact Screening and Preventive Therapy

It is mandatory in the program to **screen all the family members** for symptoms of TB among house hold contacts of sputum positive cases. In the case of family member of sputum positive case, the “suspect” is defined as any individual having cough even for a single day.

There is also provision in the programme for **screening under 6 years children** in contact with sputum positive TB. On screening, if the child is found to be suffering from TB, he/she needs to be appropriately treated for the same. But if screening is negative for TB, there is provision for child chemoprophylaxis with Isoniazide 5 mg per kg body weight for 6 months; irrespective of the BCG status of the child. But in practice child chemoprophylaxis is weak in many places. The reasons for the same are, difficulty in getting children screened by a doctor in the health centres because of inadequate transport facilities, fixed timings for doctors consultation in Primary Health Centers, long waiting hours for consultation, fear of losing wages, etc. Considering the limitations of our health infrastructure, some innovative strategies have to be formulated for facilitating screening of children - may be allowing screening by trained paramedical personnel instead of religiously following screening by doctors is an alternative. But the decision to go with this alternative runs the risk of increasing emergence of INH resistance.

Preventive therapies for contacts of multidrug-resistant tuberculosis have been suggested by various researchers¹⁷⁻¹⁸ and CDC¹⁹⁻²⁰. But there is no consensus regarding the choice of the drug(s) for the MDR-TB contacts, as per recent DOTS-plus guidelines in India.

Concern is also raised from different quarters regarding preventive therapy with anti-TB drugs for persons infected with HIV as there is increased risk of developing TB among them. But there are no clear guidelines regarding the same in the programme.

V. Involvement of other sectors:

By involving the other sectors, RNTCP can improve the quality of case detection and treatment⁵. Ensuring quality treatment means addressing the issues like treatment interruptions and defaults; thereby increasing cure or completion of treatment for each TB patient. This can indirectly contribute to infection control for TB.

The status of Public-Private Partnership and Public-Public Partnership in RNTCP has gradually matured over the years. This is addressed by coordinating with private, public and corporate sector hospitals, Non-Government Organisations (NGOs) and private practitioners (PP). NGO and Private Practitioner involvement is addressed through various NGO-PP schemes. Involvement of Panchayati Raj Institution (PRI) members is also being encouraged in the programme.

Coordination between Integrated Counseling and Testing Centres (ICTCs) and RNTCP is ensured through the mechanism of Joint framework for TB-HIV coordination. Participation of medical colleges is systematically addressed by having the provision of providing additional staff from the programme, setting-up of core committees in each medical college for streamlining coordination between various departments and through formation of state, zonal and national task forces.

RNTCP does not have any regulatory authority for enforcing implementation. The programmatic approach for involving the other sectors is purely motivational; mainly through sharing information and advocacy. Hence the level of involvement is largely dependent on the perseverance, motivation and leadership qualities of the programme managers. As a result, the level of involvement is not the same in all the states even if the programme has uniform guidelines.

VI. Infection control in health care settings:

In healthcare settings, effective TB infection control is also based on the pillars of early identification and rapidly and effectively treating persons with TB^{21, 22, 23}. As per WHO guidelines⁴, the first priority in infection control is the use of administrative control measures to *prevent generation of infectious droplet nuclei*, thereby reducing the exposure of the Health Care Workers (HCWs) and patients to *M. tuberculosis*. The second priority is environmental control methods that are used to *reduce the concentration of droplet nuclei in the air in high-risk areas* and the third priority is to protect HCWs, via personal respiratory protection, from *inhaling infectious droplets*⁴.

Administrative control measures (to prevent generation of infectious droplet nuclei) include development of an Infection Control Plan, training of HCWs, patient education, sputum collection in optimum environment, evaluation of suspected TB patients in outpatient settings and triage, and reduction of exposure in the laboratories.⁴ According to Blumberg HM²⁴, administrative controls like early detection of TB cases, their isolation and treatment was the most effective components of TB infection control programs in hospital settings in the United States.

Environmental control methods (to *reduce the concentration of droplet nuclei*) range from inexpensive methods such as maximizing natural ventilation and mechanical ventilation, to more costly methods such as ultraviolet germicidal irradiation and HEPA filtration⁴.

Personal protection measures (for preventing inhalation of infectious droplets) like use of Respirators is the other control measure.⁴ Use of Surgical masks prevent the spread of microorganisms from the wearer but do not provide protection to the wearer. Hence, use of surgical masks by HCWs is not recommended but use of the same by patients may be useful⁴. Accordingly, the programme also discourages wearing surgical masks made of cotton wool/ gauze/ paper for personal protection¹².

In India, of all the recommended interventions, implementing administrative control is the most feasible strategy⁵. Implementing the engineering control measures (e.g., negative-pressure isolation rooms) may not be feasible in most health care facilities because of high costs⁵. Personal respiratory protection measures (e.g., N95 respirators) are also relatively costly to implement and are of limited effectiveness in high-incidence, resource-limited settings²⁵.

As per RNTCP, the key to reduce the risk of tuberculosis transmission at health facilities is early diagnosis and prompt initiation of RNTCP treatment regimens until cure. Infectious TB patients also become rapidly non-infectious once they are started on directly observed treatment under RNTCP¹². Considering the feasibility in Indian set-up and evidence of successful infection control in other countries, it can be concluded that more emphasis on administrative measures in India, may be the most practical approach to infection control.

But there are few issues which also need to be considered, like - Who should design and implement TB infection control programs in India? This is a complicated issue because of the variability of health care systems in India (e.g., public, private, corporate, non-governmental and alternative medical systems) and because the private sector is dominant, diverse, and largely unregulated¹⁶. The other important concern, that is appropriately raised by Pai M et al⁵, is that there is no national accrediting body in India and thus there is no pressure on healthcare facilities to get accredited.

The RNTCP has already taken an initiative to formulate the - Needs assessment for airborne infection control measures and National Airborne Infection Control Committee has been constituted²⁶. The objective is to develop and support implementation of technical and operational guidelines on airborne infection control in health care facilities. All large health care facilities need to have an infection control plan (including air-borne infection control) and a team for ensuring implementation of the control measures⁸. This is in line with the Joint Monitoring Mission (JMM) report, 2006, which recommended that infection control in inpatient facilities needs to be improved and guidelines for the same need to be formulated by the national programme to promote local implementation of basic infection control measures²⁷.

Role of Infection control committees in each health care setting^{28, 29, 30}

This infection control committee can monitor adherence to infection control recommendations in various health care settings. In **out-patient department** it can ensure if there is proper natural ventilation, sputum collection area is an open space away from registration or waiting area,

ICTC/ART centers and DOT centre don't share common space, TB patient examination rooms are spacious and well ventilated, there is optimal practice of cough hygiene and there is a mechanism of fast tracking of chest symptomatics. In the **in-patient wards**, certain facilities can be ensured like adequate bed spacing, good cross ventilation, appropriate health education of admitted patients by staff (nurses, doctors), restriction on visitors (especially children), discouraging usage of surgical masks by health care workers, cough hygiene by the patients given due emphasis, appropriate disinfection of nebulization units for TB patients, confirmed HIV patients don't share rooms with open TB cases, etc. In **high risk areas**, like ICU, Bronchoscopy unit, Operation Theatre, if personal protective measures for health care workers are adequately available and optimally used.

VII. Summary and Debate points:

To summarize, few issues that need further discussion/ debate are as follows:

- a) Can it be ensured that certain history is taken for each patient before initiating diagnosis/ treatment like – (a) How many days/ weeks are you coughing? (for increasing suspect examination) (b) Is there anybody in your house with similar symptoms? (for increasing suspect examination) (c) Have you ever been treated with TB anytime in the past? (for ensuring correct categorization) (d) Do you have any children less than 6 years in your house? (for screening for TB and for advising treatment / chemoprophylaxis) (Question 'b' and 'd' is especially important for sputum positive TB patients)
- b) Can we ensure monitoring regarding adequacy of suspect referral from all health facilities?
- c) Should TB be made a notifiable disease so that each patient, whether treated in public/ private, is accounted for and adequately monitored?
- d) Can we stop sale of anti-TB drugs over the counter, especially the 2nd line drugs, so as to prevent emergence of MDR-TB? This is expected to reduce treatment interruptions, defaults and inappropriate regimens.
- e) Should we encourage active case detection, atleast in the priority areas, if we can ensure quality laboratory diagnosis, drug supply and adequate supervision? This is to reduce transmission of infection.
- f) Can we have adequate infrastructure to ensure fast tracking of patients to decrease nosocomial transmission?
- g) Can we make it mandatory that there has to be an Infection Control Committee in each health care facility and it really functions?

All these concerns may not need extra resources but what is required is genuine concern and necessary leadership qualities to provide supportive supervision to make this a reality.

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