National Guideline & Operational

Manual for

TB Notification in Bangladesh

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Background:

Being the leading cause of death from a single infectious agent worldwide, Tuberculosis (TB) caused 1.3 million deaths among an estimated number of 10 million infected people in 2017. The South-East Asia Region of the World Health Organization (WHO) had 44% of the estimated cases. In accordance with the Sustainable Development Goals, the WHO has announced an ambitious END TB Strategy. The END TB Strategy calls for 90% reduction in TB incidence by 2035 in comparison to 2015. Globally, the TB mortality rate is falling at about 3% per year. TB incidence is falling at about 2% per year; this needs to improve to 4–5% per year by 2020 to reach the first milestones of the End TB Strategy.

Each year, worldwide around 3.6 million (36%) new cases remain undiagnosed or not reported. In Bangladesh, this number is around 120 thousands. In urban settings of our country, many patients often go to private facilities for seeking health care and the number is believed to be similar (50-80%) to that of the other South Asia countries.

Bangladesh has a huge private health care sector, which is growing at a considerable pace. Private sector dominates health care and has significant involvement in TB treatment, especially in urban area. Large quantities of anti-TB drugs are sold in the pharmacies. Non-standardized prescribing practices among some of the private providers with inappropriate and inadequate regimens and unsupervised treatment continues without proper patient couselling to ensure treatment adherence. This situation together with unrestricted access to anti-TB drugs is threatening to worsen the multi-drug resistant (MDR) TB situation in the coutry. Early diagnosis and complete treatment of TB is

Tuberculosis Control Program (NTP) provides quality assured diagnostic and treatment services to all the TB patients including necessary supportive mechanisms for ensuring treatment adherence and completion. NTP provides mechanisms to ensure treatment adherence support including Directly Observed Therapy (DOT). However, a large number of patients are not benefitted with these program services and leads to non-adherence, incomplete, inadequate treatment leading to MDR TB, despite all the efforts of the program to prevent emergence and spread of drug resistance. If the TB patients diagnosed and treated under all sectors are reported to NTP, the mechanisms available under the program can be extended to these patients to ensure treatment adherence and completion. The potential epidemic of MDR TB can be prevented to a large extent by this intervention.

In order to ensure proper TB diagnosis and case management, reduce TB transmission and limit the spread of drug resistant-TB, it is essential to have complete information of all TB cases. Therefore, the Government of Bangladesh (GoB) declared Tuberculosis a mandatory notifiable disease in January 2014 through a gazette by order of the honorable President of Bangladesh. All public and private health providers should notify TB cases diagnosed and/or treated by them to NTP. Notification gives an opportunity to support private sector for following standard practices. It helps the patients to get right diagnosis, treatment, follow up, chemoprophylaxis & facilitates social support systems. Complete and accurate data obtained from notification will allow continuous evaluation of the trend of the disease with better estimation of burden/impact.

Many of these diagnosed TB cases are referred to NTP linked DOTS facilities by the PPs for treatment initiation and hence been somehow reflected in the national data. However, another portion of the cases buy their anti-TB drugs from the pharmacies under the supervision of their physicians in the private sector and in absence of notification mechanism in current scenario, these cases are not reflected in the national data. Following the declaration from the GoB to notify TB cases mandatorily both from public and private sector, it is now essential to operationalize the notification system.

This is a strategic document¹ that aims to enable TB notification practices by Private Providers and inclusion of missing data towards national reporting.

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¹ Another end user document intended for the end users, i.e. physicians or their assistants or DOTS providers is developed as a Standard Operating Procedure (SOP). This strategic document will be a stable one without frequent revise and the other one will be agile as per modifications of the application.

Goal:

The goal of operationalizing TB notification by health providers to the National Tuberculosis Control Program (NTP) in Bangladesh is to reduce morbidity, mortality and transmission of TB by including missing TB cases for proper management of TB.

Objectives:

- 1. To operationalize mandatory notification (MN) of tuberculosis by private providers (PPs) in the country
- To increase case notification of TB from the PPs by using effective, user-friendly notification tools.
- 3. To extend mechanisms towards proper management of TB patients notified from the private sector
- 4. To help capturing a better picture on TB epidemiology in Bangladesh allowing better evaluation of the trend of the disease for better estimation of burden/impact

Strategy:

Implementation of MN for TB is based on the following approaches that will be gradually adopted to scale up throughout the country:

- Developing a cross platform digital tool that will enable health providers for TB notification to NTP
- Establishing a functional manual/guideline for implementing TB notification using the digital platform for health providers

- Minimizing variability of response on TB notification and mitigate challenges for the purpose
- Optimizing the TB notification system for smooth integration with the national reporting platform (DHIS2), as guided by Directorate General of Health Services (DGHS)

Development of tools for MN in Bangladesh

Since the GoB declaration in January 2014, it became mandatory that all public and private health providers notify TB cases to the government. According to the survey among the private providers in 2016, content of notification for operationalization of mandatory notification of tuberculosis in Bangladesh should be simple and less time consuming to promote user acceptability. Web interface and smart phone app for all platforms will be integrated with NTP web portal to follow the purpose. The private providers will put in following information.

End user information requirement for TB notification

- 1. TB Case name
- 2. Age
- 3. Sex
- 4. Active mobile number
- 5. Address of TB case
- 6. Address of Suggestive DOTS
- 7. Anatomical site of disease: Pulmonary TB / Extra-pulmonary TB
- 8. Previous treatment history: New / Relapse / Treatment after failure / Treatment after loss to follow-up/default (OPTIONAL)
- 9. Bacteriological status: Bacteriologically confirmed TB case / Clinically diagnosed TB case (OPTIONAL)

- 10. Rifampicin susceptibility: Resistant / Sensitive / Not available (OPTIONAL)
- 11. GoB-issued personal unique identification number: Birth Certificate,
 National Identity Card (NID), Passport, Driving License etc.
 (OPTIONAL)

Value of TB notification

- Inclusion of the estimated number of missing TB cases currently not reported
- Ensuring free treatment and proper follow-up for the notified TB cases
- Supporting all physicians to adhere standard practices according to national guideline
- Providing complete information of all TB cases to the National Tuberculosis Program (NTP)
- Allowing better evaluation of the trend of the disease with better estimation of burden/impact

Case Definitions for TB notification

Site of disease

<u>Pulmonary TB case</u> – Pulmonary TB refers to disease affecting the lung parenchyma.

<u>Extra-pulmonary TB case</u> – Extra-pulmonary TB refers to tuberculosis of organs other than the lungs. TB may affect any organ or tissue. Examples are: mediastinal and/or hilar lymph nodes, larynx, cervical lymph nodes, pleura, meninges, central nervous system, spine, bones and joints, kidneys, pericardium, intestines, peritoneum and skin. Patients diagnosed with both pulmonary and extra-pulmonary TB should be classified as pulmonary TB.

Bacteriological status:

<u>A bacteriologically confirmed TB case</u> is one from whom a biological specimen is positive by smear microscopy, culture or WRD (WHO approved Rapid Diagnostic tool such as Xpert MTB/RIF). All such cases should be notified, regardless of whether TB treatment has started.

A clinically diagnosed TB case is one who does not fulfill the criteria for bacteriological confirmation but has been diagnosed with active TB by a clinician or other graduate medical practitioner who has decided to give the patient a full course of TB treatment. This definition includes the cases diagnosed on the basis of Xray abnormalities or suggestive histology and extrapulmonary cases without laboratory confirmation.

Previous treatment history:

<u>New</u> – A patient who has never received anti-TB drugs; OR A patient who received anti-TB drugs for less than one month.

<u>Relapse</u> – Relapse patients have previously been treated for TB, were declared cured or treatment completed at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection).

<u>Treatment after failure</u> – Treatment after failure patients are those who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.

<u>Treatment after loss to follow-up</u> – Treatment after loss to follow-up patients have previously been treated for TB and were declared lost to follow-up at the end of their most recent course of treatment. (These were previously known as treatment after default patients).

Other(s) – previously treated patients are those who have previously been treated for TB but outcome after their most recent course of treatment in known or undocumented.

Rifampicin susceptibility:

<u>Rifampicin resistant</u> – Patient with a drug resistance test result from a NTP-accredited laboratory report showing resistance to rifampicin.

<u>Rifampicin sensitive</u> – Patient with a drug resistance test result from a NTP- accredited laboratory report showing sensitivity to rifampicin.

<u>Not available</u> – Patient without a drug resistance test result from a NTP-accredited laboratory test report.

Potential features for TB notification system

- 1. Submission of information for TB Notification using registered mobile/web users:
 - by mobile platform (android & iOS)
 - by web interface
 - o by SMS²
 - by USSD (Unstructured Supplementary Service Data) *
 - by IVR (Interactive Voice Response)*
 - o by Mobile phone call *

(*Potential options to be incorporated in future)

- 2. Information uploaded/stored in the dedicated server³
- 3. Dedicated technical support for troubleshooting & feedback.
- 4. Periodic report generation, automated or customized⁴
- 5. Aggregated data outputs for NTP dashboard
- 6. Integration of aggregated data to national reporting through DHIS2.

² This requires a sophisticated system and authentication from BTRC, subjected to endorsement from NTP and may take a considerable time to commence

³ Primarily hosted at icddr,b, subjected to uptake of the system & server by NTP

⁴ Any format not yet specified, subjected to requirement of/discussion with NTP

Steps following notification of TB cases by PPs

- 1. Notification of TB patient into database with auto generated unique ID based on geo-codes introduced by Bangladesh Bureau of Statistics (BBS) and year followed by serial number. For example: a unique ID can be 302614-18-0001, which consists of Division Code [30], District Code [26], Upazilla Code [14], Year [18] & Serial Number [0001]
- 2. Automatic push sms to the patient reminding her/him to register for treatment at nearest DOTS
- 3. Follow up of treatment registration of the notified patient by DOTS personnel, getting automatic push sms with notified patient contact details
- 4. Update any missing information into the database by DOTS personnel
- 5. Entering the treatment registration number of the patient into the database by DOTS personnel
- 6. Automated feedback sms to the referring PP regarding successful treatment registration of the notified patient
- 7. Entry of follow up/treatment outcome information by concerned DOTS personnel*
- 8. Automated feedback sms to the PPs regarding treatment outcome*
- 9. Data preserved in dedicated server

(*Potential options to be incorporated in future)

Role of NTP^{5,6}

- Disseminate information regarding TB Notification to all PPs and the professional associations
- Ensure environment, option & feedback for orientation/registration of PPs
- Provide the platform, e.g. mobile app, web interface, sms etc. for TB
 Notification and link for registration to all PPs
- Ensure that all TB cases notified by the PPs are registered for proper managment immediately after (no later than two weeks from) notification
- Ensure that the notifying PP is informed of the treatment registration of his/her patient
- Ensure that all PPs notifying from different facilities are registered using Unique ID
- Maintain the list of PPs with details and IDs
- Encourage PPs to notify TB cases on timely manner
- Capacity building of the PP assistants to undertake responsibility for the TB cases notified

⁵ A program focal person and an ICT technical focal person also need to be identified

⁶ During piloting & then scale up of the TB notification system, most of the roles would be handled by icddr,b with support from the donor(s) and as endorsed by NTP

- Routinely review the progress in TB notification by PPs
- Collect, collate and upward submit the TB Notification reports submitted by the PPs
- Ensure proper documentation to enable treatment adherence & completion

Transition after piloting TB notification system⁷

Followed by piloting and learning from this experience, the TB notification system will be scaled up including major areas covering more PPs within and outside Dhaka.

Role of Providers/Private Practitioners

- Registering themselves in the NTP developed TB notification system
- Ensure accuracy and completeness of information during registration process
- Facilitate understanding and requirement about TB Notification for the assistants
- Ensure that all TB cases to be notified are entered in for TB notification by self or the assistant
- Ensure proper referral to DOTS for TB patients notified and

⁷ Primary communication on this next step has already been discussed with a potential donor & will be shared to NTP in MN taskforce meeting so that the TB notification system goes well developed & risk free.

recommend treatment & follow up:

- o Counselling of TB patients including promotion of treatment adherence & follow up to ensure treatment completion
- TB Contact tracing, screening for symptoms and referral for evaluation if any TB symptomatic is found amongst the TB contacts
- o Offering INH chemoprophylaxis to eligible child contacts
- o Family members' counselling

Monitoring

Monitoring is the routine tracking of programs using input, process, and outcome data that are collected on a regular, ongoing basis. Monitoring is used to assess whether or not planned activities are carried out according to schedule. Monitoring activities reveal the extent to which the program is progressing towards identified targets and services are being utilized. An abrupt or unexpected change in monitoring data may trigger the need for a more formal evaluation of the activities.

Data source for monitoring

- Database on facilities including location and key relevant information
- List PPs/PP assistants per facilities
- Inputs in MN app on TB cases diagnosed by PPs
- Enumeration of DOTS facilities according to different areas

Indicators for monitoring

- No. of registered Facilities/PPs/PP assistants reached
- No. of registered Facilities/PPs/PP assistants notifying TB patients
- No. of TB patients notified fortnightly
- No. of TB patients enrolled to DOT among notified patients

Recording & Reporting of TB notification⁸

Routine tracking of recording of the notified TB cases will be done by a Data Management Assistant (DMA) for completeness of the entered information for Facility/Provider/Patient. Any subsequent follow up information or any observed error in any of the data will also be tracked and addressed by the same person.

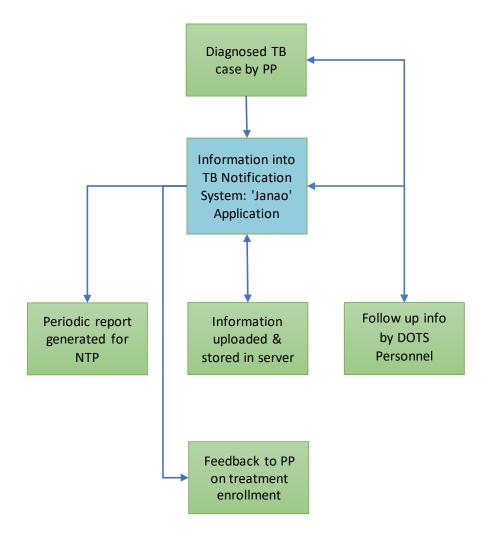
As part of the TB notification system, a real time dashboard will show the basic summaries on some basic indicators over time. Data for the notified TB cases and other info can also be exported and reports can be generated as required.

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⁸ Once the TB notification system is established after piloting & scale up, other than recording & reporting, NTP will not have any additional responsibility to deal on a routine basis.

Annexure9

Flow of notification information



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⁹ The Standing Operating Procedure (SOP) is based on direct operating steps of the TB notification system for the registered users. That is subjected to be a standalone document for the user, especially the end users, i.e. Private Providers & their assignees. The SOP may be an addition to this Operational Manual as an annexure.