

# Improved Implementation of WHO Standard Tuberculosis Guidelines in Indian Health Care Facilities - A Prospective Multicenter Study

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## Abstract:-

### ➤ Background

Quality of TB care is the main aim of WHO TBIC guidelines. But there is an aberration from these standards in TB care resulting in delayed diagnosis, treatment and decreased patient adherence to the therapy. The objective of this study was to check the applicability, identify non-compliance parameters to that of TBIC guidelines and recommend the improvements in health care facilities.

### ➤ Method

This study was a prospective interventional study held at 20 health care facilities offering TB care in Bengaluru. A TBIC checklist was used as a tool to ensure the compliance in the centres towards TB care. The reasons for non-compliance in centres were assessed and recommended for improvement. The centres were re-visited and post-interventional assessment was done.

### ➤ Results

The managerial compliance was the most (97.5%). The overall compliance improvement of the administrative standards after intervention was increased by 11.5% and reached 53.5%. The environmental standards were increased by 9% and reached 34%. Alarming, none of the centres had respiratory facilities and were completely non-complaint during pre and post intervention.

### ➤ Conclusion

WHO TBIC guidelines are much needed in the health care facilities aiding in the quality TB care and to strengthen the health care systems.

**Keywords:-** WHO TBIC, Tuberculosis, Compliance, DOT Centre, India.

## I. INTRODUCTION

Tuberculosis (TB) is among the ten deadliest disease globally [1]. The 2017-18WHO report showed 10.4 million morbidity and 1.7 million mortality estimates globally accounting over 95% in middle and low-income countries. Out of which India(25%), Indonesia (16%) and Nigeria (8%) accounted for large gap between incidence of TB and reported cases which remains a challenge in unregulated

private sectors and weakened health care systems [2,3,4].The TB epidemiology report of India 2017-18estimated that 27.9 lakh people suffered from TB and in the same year 4.23 lakh people died from TB [5,6].Based on WHO recommended strategy of Directly Observed Treatment Short Course (DOTS), Revised National Tuberculosis Policy(RNTCP) was implemented in India in 1997.The Government of India five-year TB National Strategic Plans (NSP) is carried out by RNTCP and serves over a billion people in 632districts. The treatment management is carried out by the meticulous supervision at various levels through a TB unit, at sub-district level [7].

The main epidemiological reasons behind TB in India are poverty, urbanization and HIV epidemic. Quality TB care is essential towards effective diagnosis and treatment of TB, which is also the main aim of the NSP 2012-2017[8]. But there is also an aberration from known quality standards in TB care resulting in delayed diagnosis, treatment with ineffective regimens, and decreased patient adherence to the therapy due to the care providers. Furthermore, published quality improvement projects in resource limited settings tend to describe large scale projects affecting multiple sites at the national or district level. Effectively, TB control measures are limited by the quality of care provided at the primary health care facilities. The current top down approach to improve TB care is through national policies, guidelines and through rigorous implementation of TB infection control (TBIC) and Infection Prevention and Control (IPC) as detailed in the 2009 'WHO Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households' [9-17].

Countries may undertake a national assessment of WHO TBIC policy adaptation and implementation, and thereafter on an annual basis to measure progress over time. Standardized checklist-based assessment tools facilitate efforts to track progress in TBIC implementation. Healthcare facility-level assessment of TBIC checklist should be incorporated into routine supervisory activities. Periodic monitoring and evaluation are crucial for TB program managers, general health services and other relevant stakeholders to ensure WHO global policy on TBIC are adopted and that all health facilities have appropriate TBIC procedures in place [18,19]. Hence, the main objective of this study is to check the applicability, identify the non-compliance parameters to that of WHO

TBIC guidelines and recommend the improvements to the respective health care facilities.

## II. MATERIALS AND METHODS

### A. Study Design and Site

This study is a prospective multicentre study held at 20 health care facilities recognized as DOTS centres from August 2017 to May 2018. The study sites selected were amongst the urban population of a metropolitan City Corporation, Bengaluru, India. A formal permission from The District Joint Director in-charge of TB activities was obtained. The study sites were picked in such a way that the centres represented from all geographical areas of the city. Health care facilities providing any type of care for people living TB with HIV, as well as those caring for other immunosuppressive conditions (e.g. diabetic clinics, transplant units) were prioritized, as such patients were at higher risk of TB disease if exposed and infected. The centres were further divided into five sub sections which include maternity care, dispensary, referral hospital, general hospital and health care. Under the sub-district level TB units, primary health care centres (PHC) supervised centres were visited for the study.

### B. Study Procedure and Data Collection

The overall study methodology has been depicted in Figure 1. The checklist was selected, and each centre was assessed to know the extent of compliance with four key domains. The required data was obtained from programme staffs in charge of IPC, TB and HIV in DOT centres. The centres were analysed for the compliance with TBIC checklist. The key four domains managerial, administrative, environmental and personal protective equipment (PPE) were primarily focused. The centres which were non-compliant to the various standards were assessed and the various reasons contributing for the non-compliance were justified. These findings of the assessment were communicated to health facility staff and other key stakeholders. After providing feedback, the centres were re-visited and checked. Post -interventional assessment was done and the increases in compliance of the standards were evaluated. The non-compliant areas in terms of interventions were assessed and adequate justification was provided after careful interpretation with the health care workers.

### C. TBIC Checklist

Proper assessment of TBIC requires knowledge of key interventions and strategies. A checklist based on the Health-Care Facilities, Congregate Settings and Household, 2009 WHO Policy on TB Infection Control in is structured around was served as standard tool. It is also aligned with the guidelines that address respiratory infections, 2014 WHO's Infection Prevention and Control (IPC). Managerial activities are essentially policy-level activities and they need to be in place to facilitate the implementation of all the other levels of TB-IC. Administrative controls should be prioritized in all facilities as they are more effective since they have the greatest impact on preventing transmission of TB in health facilities. These measures

prevent droplet nuclei containing *M. tuberculosis* from being spread in the facility, reducing exposure of staff and patients to TB infection. However, it is not possible to eliminate exposure; therefore, environmental measures are required to reduce the concentration of droplet nuclei in the air. Unfortunately, even the combination of administrative and environmental controls can never provide 100% safety; PPE is therefore needed in specific areas and during the performance of specific tasks to create the desired level of safety. It is important to note that environmental and personal respiratory controls will not work in the absence of solid administrative control measures. Each level operates at a different point in enhancing quality TB care.

### D. Assessment of Domain Compliance

The managerial assessment checklist standards from Q1 to Q6 are self-explanatory, and evaluation of documentation (e.g. of an infection control plan or a confidential occupational health record) was done. It was based on a simple interview to the facility staff responsible for TBIC. The administrative assessment checklist included standards from Q7 to Q16. The standards Q7 to Q11 primarily required observation in addition to asking staff about practices. For standards Q12 to Q16 evaluation of a random sample of records (at least 10 files were selected randomly) were assessed for promptness in identification of presumed TB patients, TB investigation and treatment initiation, method of TB diagnosis and HIV testing. As extra pulmonary TB is seldom infectious and diagnostic evaluation can be lengthy, the focus of the sampling for standards Q13 and Q14 were on pulmonary TB. Patient files from within the previous year and preferably within the previous six months (to assess recent practices) were selected and evaluated. The environmental assessment checklist focused primarily on health facilities which relied on natural ventilation (Q17 to Q21). The focus was based on whether simple measures are being taken to reduce risk. In settings where windows are closed or not present, (such as health facilities in cold climates), this checklist was modified to include an assessment of mechanical ventilation and ultraviolet germicidal irradiation. The PPE standards Q22 and Q23, check was done for appropriate particulate respirators (Certified N-95 or FFP2 [or higher]) were available for health-care workers, and that such respirators were being used where indicated.

## III. RESULTS

### A. Descriptive of Study Facilities

This study was primarily focussed on the healthcare facilities providing TB care, irrespective of speciality care providing such as dispensaries, maternity etc. Out of 77 active healthcare centres in the city, 20 centres were enrolled into this study. The lab facilities were not available in 5 centres among the enrolled sites, however they had the privilege to get the samples analysed by the nearest referral and general hospitals. These centres were subjected to assess the various standards of DOT centres as per WHO guideline checklist and with intent to provide feedback for the better-quality TB care. The distribution of these healthcare centres is presented in Table 1 along with

their geographic coordinates. The overall response rate for this study was 100%.

#### *B. Study Facilities Compliance with TBIC WHO Standards Checklist*

The enrolled sites facilities were checked against TBIC WHO standard checklist. During the audit, the key four domains managerial, administrative, environmental and personal protective equipment (PPE) were primarily focused. The data of all the domains has been represented in the supplemental data (Appendix 1). The managerial domain consisted of six factors from Q1 to Q6 and its average compliance was 97.5%. Most of the factors were complied with the standards, out of which factors Q1, Q4, Q5 and Q6 were 100 %, Q2 was 95% and only one factor (Q3) contributed to 85% compliance. Since most of the factors were complaint there was no post interventional improvement in this domain.

In administrative domain there were total of ten factors from Q7 to Q16 and pre-intervention average compliance was 42%. In this domain, a total of six factors including Q7, Q8, Q10, Q11, Q13, Q14 were found to be less than 50% of complaint and two factors (Q9, Q12) being above 50% and two factors (Q15, Q16) being more than 90% compliant to the TBIC WHO standards. The compliance for Q7, which states “fast tracking of patients and guidance on cough etiquette” was 35% (n=7) and post interventional compliance was increased to 70% (n=14). The compliance for Q8, which states “providence of health education material” was 20% (n=4) that was increased to 45% (n=9) post intervention. The compliance for Q9, which states “conductance of patient interviews and observation” the post interventional compliance was increased to 75% (n=15) from 55% (n=11). The compliance for Q10 which states “providence of supplies and proper garbage disposal” was 15% (n=3) and post interventional compliance was increased to 50% (n=10). There were no significant changes in the compliance from Q11 to Q16. The overall compliance improvement of the administrative standards after intervening was increased to 11.5% and reached 53.5% (Table 2).

Five factors (Q17 to Q21) in environmental domain were involved and pre-intervention average compliance was 25%. In this domain, all the factors were less than 50% compliance. Out of which Q17 and Q18 showed post interventional improvement accounting to 9% interventional change. The compliance for Q17, which states “prompt facility design and triage system” was 40% (n=8) and post interventional compliance was increased to 50% (n=10). The compliance for Q18 which states “proper ventilation and display of messages” was 25% (n=5) and post interventional compliance was increased to 60% (n=12). There were no significant changes in the compliance from Q19 to Q21. The overall compliance improvement of the environmental standards after intervening reached 34% (Figure 2). The PPE consisted of two factors (Q22 to Q23) and no post intervention changes could be made. Alarmingly, none of the centres had these

facilities and were completely non-complaint during pre and post intervention.

## **IV. DISCUSSION**

#### *A. Compliance of WHO Managerial Standards*

Facility-level managerial activities include identification and strengthening of local coordinating bodies and development of a facility plan (including human resources) for implementation of TBIC. The plan should also include policies and procedures to ensure proper implementation of the administrative controls, environmental controls and use of particulate respirators. The decrease of compliance in Q3 which stated “being of TB designated person availability at the DOT centre” was due to work shift to attend two centres on the alternative days of a week. The personnel may work in a referral hospital or designated health centre on different days. Rethinking the use of available spaces to optimize the implementation of infection control measures is also crucial. These findings indicate the need for improved isolation guidelines, better staff education and appropriate documentation. As for Q2, one centre had no enough space for establishment of the centre; the reason was not justified aptly.

#### *B. Compliance of WHO Administrative standards*

Administrative standards play a vital role in reduction of transmission of TB among the health care facilities. The prompt identification of people with TB symptoms is of utmost importance depends upon the patient population in the settings. The suspected patients at risk of TB to be separated from other patients and moved to well ventilated areas and adequate counselling on respiratory hygiene and cough etiquette is of priority. Guiding the patients on simple techniques, such as covering the nose or mouth with bend of elbow while sneezing or coughing, which must be cleaned immediately serves as a strong focus on behaviour change. The Q7 factor serves as strong recommendation as per 2009 WHO infection control plan. The reason for non-compliance for Q7 were found to be ‘negligence’ 65% (n=13), even after the post recommendation, the non-compliance 30% was due to the continued negligence of (Health care workers) HCWs.

Adequate materials consisting of information about the infection should be given to the patients. It helps the newly diagnosed patients to understand the disease better and serves as a helpful referral document. However, when patients are not willing to read the education material or illiterates, counselling them on general aspects of the infection and instructing them on the medications, diet etc., helps them in the better understanding of the disease and the stigma reduces. The outcomes, problems associated with treatment and the quality of life of the patient should not only be evaluated by the periodic test results but also by conducting periodic interviews and observation of the patients. The factors dealing with these aspects are Q8 and Q9. The non-compliance for (Q8) was found to be 80% (n=16) where 45% (n=9) was due to non-availability of education material and 35% (n=7) due to the negligence in

providing. Post-counselling compliance change was found to be 25% (n=5) and the non-compliance remained 55% due to the frivolous attitude of the HCWs and the shortage of supplies provided. The non-compliance for Q9 was due to 'negligence' 25% and 'lack of communication' 15% and post-interventional compliance change was found to be 20% (n=4) and the non-compliance remained to be 20% due to non-cooperation.

The usage of surgical masks in coughing patients reduces transmission of droplet nuclei is of conditional recommendation as it not clear whether they make a significant difference and most of them feel stigmatized. However, particularly in patients with serious grade of infection and drug resistance, poor respiratory hygiene and cough etiquette practices; usage of surgical masks serves as a strong recommendation according to the WHO guidelines. Poor management of health care waste disposal in health care centres can cause serious contamination of the surrounding environment and harm public health along with serious threat of spreading infections among the HCW'S and patients. Hence, proper garbage disposal is of high importance in avoiding transmission of the disease and to maintain septic condition among the centres. As concerned to the compliance factor for Q10 "availability of the supplies and garbage disposal of waste", the non-compliance was found to be 85%. The reason for the non-compliance were found to be non-availability of stock (50%) and being nonchalant in carrying out the responsibility (35%). After intervening, post-counselling adherence change was found to be to 35 % (n=7).

There were some factors where there were no significant compliance changes concerned with providence of (Q11A) HIV and (Q11B) TB prophylaxis for the health care officials. It is concerned with the managerial concern where the non-compliance was found to be 95%. But the guidelines suggest it as strong recommendation in centres with high prevalence of TB and weak recommendations for centres with low HIV prevalence out of which one centres (5%) comply with strong recommendation and failed to comply. It is important for the health care workers to undergo periodic testing and to take prophylactic shot when risk is adequate, and they should be educated and encouraged to takes these steps. The additional administrative controls to be implemented along with the above standards include (Q13) rapid screening for TB symptoms and diagnostics and (Q14) treatment initiation after the diagnostic not extending more than a day as per the guidelines. It minimizes the diagnostic delays, ensures rapid use of diagnostics, carrying out investigations and treatment simultaneously and reduces the turnaround time between screening, diagnosis and treatment.

The non-compliance for Q13 was found to be 90% (n=18) and Q14 was found to be 65% (n=13). No significant interventional changes were made in these factors. Similar studies [20,21] conducted showed the same results indicating greatest delay in diagnosis and initiation of treatment which again indicates insensitivity and non-alertness of Medical officers and field staff. For factors

Q13 and Q14, patients to be contacted and counselling to be provided on the early sample collection and submission. Better co-ordination among the health care workers and the laboratory personnel to decrease the turnover time and for rapid results. To seek management help for the deficient in the supply of stocks. HIV testing and periodic multidrug resistant/ rifampicin resistant test in the mid of the treatment is necessary for enhanced and prompt treatment of the patients. The factors dealing with the above aspects are Q15 "Xpert MTB/RIF done for HIV patients with TB" and Q16 "HIV test provided for TB patients". The compliance for these factors were 90% (n=18) and the non-compliant (10%) was due to the heavy workload of the HCWs. The two centres were heavily populated with patients and few patients were missed on including with these above diagnostics (Table 3).

### C. Compliance of WHO Environmental Standards

Prompt identification of people with TB symptoms (i.e. triage, Q17) is crucial. People suspected of having TB must be separated from other patients must be fast-tracked. The non-compliance was found to be 60%, which after post-counselling recommendation reduced to 50%. This serves as strong recommendation. Adequate ventilation in health-care facilities is essential for preventing transmission of airborne infections and is strongly recommended for controlling spread of TB. The choice of ventilation system will be based on assessment of the facility and informed by local programmatic, climatic and socioeconomic conditions. Any ventilation system (Q18) must be monitored and maintained on a regular schedule. Adequate resources (budget and staffing) for maintenance are critical. The mechanical ventilation and the ultra-germicidal ventilation are done based on the conditional recommendations but natural ventilation being a strong recommendation. The display of messages on cough etiquette (Q18) is also crucial providing guidance to the patients. The noncompliance was 75%, which on post-counselling intervention decreased to 40% (Table 4).

As concerned to the factor on providing guidance on sputum collection (Q20) where the compliance was only 25% due to the negligence as bottles were given to respective patients to collect sample at homes (75%). The isolation of the patients hospitalised (Q21) was not properly done in four referral and one general hospital involved in the study accounting for major non-compliance. The non-compliance being cent percent, which is a strong recommendation. There was no proper isolation due to administrative factors and negligence of the HCWs working with patients. A similar study [22] conducted ascertains the delays involved in isolating subjects.

### D. Compliance of WHO Personal Protective Equipment's

Use of particulate respirators was recommended for health workers when caring for patients or those suspected of having infection. HCWs should use particulate respirators assuring less risk of TB transmission when providing care to infectious MDR-TB and XDR-TB patients or people suspected of having. A comprehensive programme for training health workers in the use of

particulate respirators should be implemented, because correct and continuous use of respirators involves significant behaviour change on the part of the health worker. It serves as a strong recommendation for centres with high MDR/XDR prevalence. Three such centres (15%) were identified. The overall non-compliance was found to be hundred percent.

#### E. Recommendations

The TBIC compliance standards of the four domains can be increased by regular auditing of the centres and continuous training of the healthcare workers in these standards. It was suggested facility level assessment of TBIC standards to be incorporated into supervisory activity. The regular standardized assessment serves as tools to track the progress of the TBIC implementation. Certain areas require better flow of funds and implementation by the managerial and administrative level. It must be often revised with the growing needs of the patients and the centre improvements. Frequently, the findings of the assessment should be communicated with the health care workers and other stakeholders. The feedback from the auditing should be incorporated into revision of the TBIC plan regularly to necessitate a more careful, better and tailored plan.

### V. CONCLUSION

TBIC is a national and sub-national managerial framework which is crucial for the facility level TB care. Lack of TBIC measures will lead to the increased TB transmission and impaired TB care and delayed time to achieve “End TB Strategy”. The above recommendations should be implemented for better facility level controls in health centres which play a basic package of interventions towards the better TB quality care. The prompt implementation of WHO standards helps in aiding better quality care of TB among the health care centres. It helps in minimizing the risks for nosocomial spread of infection among the patients in the centres and improves cordial relationship between the patients and the health care workers. Lastly, improves the standard of care provided to the patients along with broadening the gap between diagnosis and treatment. As clinical pharmacists, not only in the hospitals but their services are much needed in the health care facilities aiding in the quality TB care and to strengthen the health care systems.

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