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FAST Implementation in Bangladesh: High Frequency of Unsuspected Tuberculosis Justifies Challenges of Scale Up

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SUMMARY

Setting—Bangladesh – National Institute of Diseases of the Chest and Hospital, Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders and Chittagong Chest Disease Hospital.

Objective—To present operational data and discuss the challenges of implementing FAST (Find cases Actively, Separate safely and Treat effectively) as a TB transmission control strategy.

Design—FAST was implemented sequentially at three hospitals.

Results—Using Xpert MTB/RIF, 733/6028 (12.2%, 95% CI [11.4,13.0]) patients were diagnosed with unsuspected TB. Patients admitted with other lung diseases with a prior TB history had more than twice the odds of being diagnosed with unsuspected TB as those without a TB history (OR 2.6, 95% CI 2.2–3.0, $p < 0.001$). Unsuspected MDR-TB was diagnosed in 89/1415 (6.3%, 95% CI [5.1,7.7]) patients. Patients with unsuspected TB had nearly five times the odds of being diagnosed with MDR-TB than those admitted with a known TB diagnosis (OR 4.9, 95% CI 3.1–7.6,

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AUTHOR CONTRIBUTIONS:

RRN, PD and EN conceived the idea of the study for publication. PD, AEB, SI, SMMK, MuA, RS, MR and MSH were the field implementation and laboratory team in Bangladesh who implemented FAST. KC and NK provided input into the project design. RRN wrote the initial full draft of the manuscript, PD, AEB, PL, SH, KC, NK, DT and EN contributed critical revisions for intellectual content. All authors gave approval for the manuscript submitted.

p<0.001). Implementation challenges include staff shortages, diagnostic failure, supply-chain issues and reliance on external funding.

Conclusion—FAST implementation revealed a high frequency of unsuspected TB in hospitalized patients in Bangladesh. Patients with a prior TB history have increased risk. Ensuring financial resources, stakeholder engagement and laboratory capacity are important for sustainability and scalability.

Keywords

tuberculosis; nosocomial transmission; FAST; implementation

INTRODUCTION

Bangladesh is one of 22 high TB burden countries, with an incidence of 360 000 reported tuberculosis (TB) cases in 2015¹. Although the Bangladesh National TB Control Programme (NTP) covers 99% of the population and provides free services including TB medications, significant delays in care-seeking, treatment initiation and completion for drug-sensitive and drug-resistant TB remain^{2,3}, despite the roll out of rapid molecular diagnostics such as Xpert® MTB/RIF (Cepheid, Sunnyvale, CA)^{4,5}.

Although the percentage of new cases with multidrug-resistant TB (MDR-TB) is only 1.6% in Bangladesh, the percentage of retreatment cases that have MDR-TB is estimated to be 29%⁶. The first nationwide TB drug resistance survey in Bangladesh in 2011 demonstrated that transmission of MDR-TB may be increasing⁷. Another study demonstrated that patients with MDR-TB were more likely to have been hospitalized for TB-related causes during previous treatment⁸, highlighting delays in diagnosing drug-resistance and the potential for transmission.

Transmitted infection is responsible for more than half of MDR-TB cases; however evidence demonstrates that transmission is not from TB patients on effective treatment but rather from unsuspected cases^{9,10}. TB infection control (TB-IC) in healthcare facilities focuses primarily on patients with known and suspected TB. Active case finding is often lacking. FAST (Find cases Actively, Separate safely and Treat effectively) is a novel, refocused administrative approach to decrease the spread of TB in healthcare facilities¹¹. FAST involves cough screening followed by rapid molecular diagnostic testing for TB and first line drug resistance¹². This enables the prompt initiation of effective treatment, which renders patients non-infectious, probably within days, decreasing onward transmission^{13,14}.

FAST was implemented at three hospital sites in Bangladesh with the aim of decreasing nosocomial TB transmission through the detection of unsuspected and therefore untreated TB disease, including MDR-TB. Here we present the results of FAST implementation and discuss the challenges of implementing this type of comprehensive administrative TB transmission control strategy.

METHODS

The FAST hospital sites were selected on the basis of a high TB prevalence, weak existing administrative controls and Xpert availability. Xpert was the molecular test of choice implemented by the NTP (through the USAID sponsored TB Care II project) given the increased technical complexity and laboratory infrastructure required for other molecular tests such as line probe assays. The primary site for FAST implementation was the National Institute of Diseases of the Chest and Hospital (NIDCH) in Dhaka, which is the largest hospital for TB and respiratory diseases in the country. The other two sites were at Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders (BIRDEM) also in Dhaka and the Chest Disease Hospital in Chittagong. Xpert MTB/RIF was available on-site at NIDCH and BIRDEM but not at Chittagong. All admitted patients at NIDCH and Chittagong and those at BIRDEM with cough or a history of lung disease, including asthma, chronic obstructive pulmonary disease (COPD) and TB, underwent Xpert testing for pulmonary TB (Figure 1). Patients admitted with a confirmed diagnosis of MDR-TB on effective treatment were excluded.

Our team discussed potential implementation challenges identified through a series of qualitative assessments including staff interviews, focus groups, brainstorming and listing techniques. FAST educational materials were developed and modified after training sessions for physicians, nurses and laboratory technicians. Upon admission, staff were assigned the tasks of cough monitoring and recording. A nurse collected morning sputum specimens from patients, filled out a FAST request form and gave the specimens to a porter. The porter took specimens to the lab and a FAST laboratory test register was completed. The porter returned results to clinical staff on the ward. Patients were broadly divided into two categories: those admitted with a known TB diagnosis made elsewhere (details not recorded) and those who were not known to have TB. Depending on the Xpert results, patients were accordingly separated and moved to the TB or MDR wards if the TB or rifampin resistance probe result was positive. TB treatment, including regimens for MDR-TB, was initiated while the patient was hospitalized. Process indicators relevant to FAST were recorded. 95% confidence intervals and odds ratios were calculated using SAS 9.4. Since FAST was incorporated as part of routine clinical care and the data presented here are operational, no Institutional Review Board or ethics committee approval was required. Governmental approval through the NTP was obtained for all hospital sites.

RESULTS

FAST Outcomes

Results presented here are for FAST implementation at NIDCH (April 2014–September 2015), BIRDEM (October 2014–September 2015) and Chittagong Hospital (April–September 2015). Overall (Table 1 and Figure 1), 6710 patients underwent Xpert testing as part of FAST. Of the 6028 patients who did not present with a known TB diagnosis, 733 (12.2% 95%CI [11.4,13.0]) were found to have unsuspected TB. Patients admitted with other lung diseases with a prior TB history (245/1112, 22.0%, 95%CI [19.6, 24.6]) had a 2.6 fold increase in the odds of being diagnosed with MTB by Xpert, compared to patients with other lung diseases without a prior TB history (488/4916, 10%, 95%CI [9.1, 10.8]) (OR 2.6,

95%CI 2.2–3.0, $p<0.001$). Of the 1415 patients diagnosed with TB (682 admitted with a TB diagnosis made elsewhere and 733 patients diagnosed with unsuspected TB through FAST), 89 (6.3%, 95%CI [5.1,7.7]) were found to have unsuspected MDR-TB. Patients admitted without a known diagnosis of TB who were detected to have TB had a 4.9 fold increase in the odds of being diagnosed with MDR-TB than those presenting with a known TB diagnosis (OR 4.9, 95%CI 3.1–7.6, $p<0.001$). Table 1 lists results by hospital as well as by patient category but since data to explore differences between hospitals were not collected, statistical comparisons by hospital were not made.

FAST Process Indicators

The goal of FAST is to reduce nosocomial transmission through the early detection of infectious TB cases and prompt initiation of effective treatment. The time from sample collection to receiving test results was 3 days (range = 2–4 days). The laboratory processing time for each sputum specimen tested with Xpert was 3 hours. The laboratory operational hours were from Saturday to Thursday for 6 hours/day, which did not represent a change from routine working conditions prior to FAST implementation. The time from test results to treatment initiation was 2 days (range = 1–3 days). 100% of patients diagnosed through FAST were initiated on treatment. Treatment completion and follow up data were not collected as part of this program.

FAST Implementation

We have analyzed FAST implementation according to the Consolidated Framework for Implementation Research (CFIR) and group our observations into its five main categories (Figure 2): characteristics of the intervention, inner setting, outer setting, individuals involved and the implementation process.

Characteristics of the Intervention—Since NIDCH and Chittagong are chest hospitals, all patients there underwent sputum Xpert testing whereas patients with cough were screened and tested at BIRDEM. Ensuring rapid delivery of specimens to the lab, delivery of test results and treatment initiation necessitated task reorganization and shifting. Intense education and training of involved staff was required.

Inner Setting: Hospital—Stakeholder buy-in was a critical feature of the successful implementation of FAST, particularly at NIDCH where the majority of patients were evaluated (Table 1). Other reasons for the lower number of TB cases identified at the other hospitals include a lower case load and bed occupancy (680 beds and 99% occupancy at NIDCH compared to 100 beds and 60% occupancy at Chittagong) and a lower number of patients presenting with respiratory complaints to BIRDEM. Negotiations were required to ensure availability of personal protective equipment (PPE), in particular for staff obtaining sputum specimens. Although there was an Xpert machine at BIRDEM, their laboratory was located further away than the onsite laboratory at NIDCH. There was no onsite Xpert at Chittagong so the logistics for courier delivery of specimens also had to be factored in here.

Outer Setting: NTP—The main barrier to obtaining stakeholder buy-in at the NTP level related to costs. Since no extra staff were hired for the project, the costs for FAST were

primarily related to the costs of the Xpert cartridges (USD 9.50 subsidized price set by the Global Fund), which were supplied by the TB Care II grant from USAID, along with associated laboratory labour costs. Reliance on external funding and subsidized pricing for molecular tests such as Xpert remains a challenge for FAST and raises the need for a rapid triage test as part of this sort of active case finding algorithm. Of note, the increased costs for TB and MDR-TB treatment incurred by the NTP due to enhanced case detection through FAST must be mentioned, however cost-effectiveness is not evaluated here.

Individuals Involved—NTP approval was required for FAST implementation. Staff in the TB Care II implementation team at NIDCH led coordination of the overall FAST strategy there, whereas FAST implementation at BIRDEM and Chittagong was supervised distantly. New staff were not recruited for this project and so tasks such as cough monitoring and specimen transport were distributed among existing staff. Nursing staff, in particular, represent the backbone of FAST and were a key population to engage; however shortages of ancillary and laboratory staff were also noted challenges.

Implementation Process—Several strategies were employed to improve the turnaround time for the delivery of specimens, Xpert results, and treatment initiation. These strategies required involvement of staff across the care cascade (doctors and nurses from the hospitals, laboratory personnel, hospital administrators and NTP staff) during the FAST algorithm development stage. Consultation meetings were held with staff members to understand the goals of the project, expected benefits and their individual roles and relationships within the team. The implementation team undertook negotiations with the hospital administration to provide salary increases for staff with greater responsibilities due to task shifting. Implementation barriers related to laboratory capacity included lack of experience using Xpert and frequent module failure of Xpert (approximately 25%), compounded by an inadequate supply-chain including replacement of failed modules. Dedicated implementation team efforts were also required to simplify recording and reporting using a patient register managed on the ward and a laboratory register managed separately in the laboratory. Having a 16-cartridge Xpert machine (standard is 4-cartridge) at NIDCH was critical for ensuring the rapidity of the results turnaround time. Incentives such as measuring and comparing FAST process indicators between wards and having a FAST nurse of the week were useful tools.

DISCUSSION

FAST implementation at three hospitals in Bangladesh revealed a high frequency of hospitalized patients with unsuspected TB, including MDR-TB. This finding is conspicuous given that the majority of patients were cared for in a national chest hospital serving as a TB referral center. Patients presenting with other respiratory diseases with a prior history of TB were more than twice as likely to be diagnosed with active TB than those without a prior history of TB (OR 2.6, $p<0.001$). An increased risk of TB in patients with a prior TB history has been previously described^{15,16}. As the screening strategy for FAST is optimized, one approach may be to prioritize patients with a prior history of TB for Xpert testing. Patients with unsuspected TB were more than five times as likely to be diagnosed with MDR-TB than those admitted with a known TB diagnosis (OR 4.9, $p<0.001$), highlighting the

importance of rapid molecular drug susceptibility testing for all patients being evaluated for TB. The reason for the lower rate of MDR-TB (6.3%) demonstrated here in comparison to other studies at NIDCH that demonstrated higher rates of MDR-TB patients (>60%)^{17,18} is unclear, although those studies only evaluated smear positive patients and one specifically evaluated patients with risk factors for MDR-TB¹⁷.

Healthcare facility administrators have an ethical responsibility to provide a safe environment for healthcare workers and patients. Administrative TB-IC measures such as FAST are central to decrease TB transmission, through rapid detection of unsuspected or inadequately treated TB and prompt initiation of effective therapy. In the hierarchy of TB transmission control, administrative measures are thus recommended as the first line of defense and should be prioritized¹⁹. Ideally all facilities would adopt a comprehensive TB-IC approach that incorporates a detailed assessment to determine how environmental controls such as maximizing natural ventilation and germicidal ultraviolet air disinfection can be used as well as PPE (surgical masks for potentially infectious patients and N95 respirators for healthcare workers), which represent the second and third lines of defense, alongside administrative control approaches. Engaging healthcare workers as agents of change can help to drive and sustain necessary system changes^{20,21}.

Molecular epidemiology studies have demonstrated nosocomial TB transmission in high TB burden countries^{22–24}. Although it would seem that the principles of FAST merely represent optimal clinical practice, active TB case finding in healthcare facilities has not been the standard of care in most high TB burden countries²⁵. In 2014, almost 10% of MDR-TB detected in Bangladesh was by FAST (2014 NTP data, personal communication-P. Daru). Our data suggest that strategies such as task shifting through consensus building with existing staff can enable the implementation of a labour-intensive strategy like FAST. However, increased resources to hire dedicated staff, ensure access to onsite Xpert testing and implement electronic data collection systems are needed to improve and sustain the success of FAST as a transmission control strategy.

Our data point to the need for the routine collection of FAST-specific process indicators to provide evidence of efficacy of the intervention. These indicators include the time taken to generate and deliver diagnostic results and initiate effective therapy. Additional data including the total number of patients who were eligible for screening and the number of patients presenting with a known TB diagnosis who are confirmed to have TB by Xpert should be collected. These data were not recorded as part of the operational data set presented here, which limit our ability to understand the incremental benefit of a strategy like FAST compared to the prior standard of care.

Ideally healthcare facilities would assign a dedicated implementation team for FAST but at minimum a person or team should be responsible for assessing the relative importance and feasibility of different measures within the hierarchy of TB-IC. Although typically cross-sectional in nature, stakeholder analysis can be a useful tool to facilitate complex multidisciplinary interventions like FAST²⁶. Strengthening laboratory capacity is paramount. The higher than expected rates of Xpert module failure (25%) demonstrated in this field setting are concerning when compared to other studies that reported lower rates of Xpert

failures²⁷. Gaps in training personnel to perform Xpert and maintenance and supply-chain issues are recognized implementation barriers that must be overcome²⁸.

By refocusing TB-IC on early detection and treatment, the principles of FAST are fundamental to TB control. Although resource-intensive, FAST is a feasible and effective TB-IC approach that may have an important impact on decreasing nosocomial TB transmission. Sustainability remains an ongoing challenge and is primarily compromised by inadequate dedicated financial resources and the difficulty of creating long-term cultural change. Conceptual frameworks can facilitate the integration of disease-specific interventions into health systems²⁹. Further dissemination of operational research from other FAST implementation sites as well as cost-effectiveness data from an ongoing study of FAST in Peru³⁰ will be critical for guiding practice and policy recommendations.

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Figure 1. FAST Algorithm at Hospital sites in Bangladesh

*All patients admitted to NIDCH and Chittagong Chest Hospital were eligible (since these are respiratory disease hospitals) and underwent Xpert testing as part of FAST. At BIRDEM, patients were screened for cough and underwent Xpert testing through FAST if cough was reported.

Figure 2.

FAST implementation analyzed using the Consolidated Framework for Implementation Research (CFIR).

Table 1

Results of Xpert MTB/RIF Testing from FAST Implementation by Patient Category

	Patients with known TB diagnosis (%), [95%CI]	Total number tested	Patients without known TB diagnosis (n=6028)				Odds ratio (95% CI)	p value
			Patients with other lung diseases (%), [95%CI]	Total number tested	Patients with other lung diseases with a prior TB history (%), [95%CI]	Total number tested		
Previously undetected TB cases diagnosed through FAST using Xpert (n=733)								
- NIDCH	N/R	-	488 (9.9, [9.1, 10.8])	4916	245 (22.0, [19.6, 24.6])	1112	2.6 (2.2–3.0)	p<0.001
- BIRDEM	N/R	-	457 (9.7, [8.9, 10.6])	4711	241 (23.0, [20.4, 25.6])	1050	-	-
- Chittagong	N/R	-	31 (15.9, [11.1, 21.8])	195	1 (2.0, [0.05, 11.1])	48	-	-
Previously undetected RIF resistance diagnosed through FAST using Xpert (n=89)								
- NIDCH	31 (4.5, [3.1, 6.4])	682	42 (8.6, [6.3, 11.5])	488	16 (6.5, [3.8, 10.4])	245	4.9* (3.1–7.6)	p<0.001*
- BIRDEM	29 (4.6, [3.1, 6.5])	635	41 (9.0, [6.5, 12.0])	457	16 (6.6, [3.8, 10.6])	241	-	-
- Chittagong	0	0	1 (0.3, [0.08, 16.7])	31	0	1	-	-
	2 (4.3, [0.5, 14.5])	47	0	0	0	3	-	-

N/R denotes not recorded.

* The comparison groups for this statistical comparison are patients admitted with a known TB diagnosis who had detectable RIF resistance on Xpert testing versus all patients without a known TB diagnosis who had detectable RIF resistance on Xpert testing.

Statistical comparisons between hospitals were not made given that other data with which these findings could be explored were not collected.