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Impact of scaling up Xpert® MTB/RIF testing for the detection of rifampicin-resistant TB cases in Karachi, Pakistan

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SUMMARY

SETTING: Pakistan ranks fourth among the countries with a high burden of multidrug-resistant tuberculosis (MDR-TB), with only 19.2% of the 15 000 estimated incident cases being notified. Increasing treatment coverage for MDR-TB is a key priority for Pakistan's National Tuberculosis Programme. The World Health Organization recommends the use of Xpert® MTB/RIF assay as the first-line diagnostic test for individuals with presumed TB.

OBJECTIVE: To describe a multifaceted case finding intervention targeting public and private sector health care facilities that used the Xpert assay as a frontline diagnostic test for individuals with presumptive TB, in Karachi, Pakistan, and its impact on case notifications of MDR-TB.

DESIGN: Cross-sectional study.

RESULTS: A total of 51 168 individuals were tested using Xpert, of whom respectively 7581 and 1534 people were diagnosed with TB in the public sector (reverse public-private mix) and private sector (social business model) arms; 574 (6.3% of all TB cases) were identified as having rifampicin (RMP) resistance. A total of 517 (90.1%) people with RMP-resistant TB (RR-TB) identified through the project were initiated on second-line treatment. The intervention resulted in 194 additional cases of RR-TB, an increase of 43% over the baseline.

CONCLUSION: This project, one of the largest Xpert testing programmes conducted at a city level, resulted in significantly increased detection and treatment of MDR-TB.

KEY WORDS: rifampicin resistance; second-line treatment; private sector

MULTIDRUG-RESISTANT TUBERCULOSIS (MDR-TB) represents a significant threat to the ambitious global targets for ending TB.[1,2] In 2016, of the estimated 490 000 people who developed MDR-TB, only 153 119 (31.2%) were diagnosed and 129 689 (26.4%) were enrolled on second-line treatment and reported.[2] For many years, inadequate diagnostic capacity, particularly the limited availability of sensitive rapid diagnostic tests, has been a key constraint.[3] The World Health Organization (WHO) recommends use of the Xpert® MTB/RIF assay (Cepheid, Sunnyvale, CA, USA) as the first-line diagnostic test for individuals with presumed TB.[4] While South Africa witnessed large increases in the numbers of people detected with drug-resistant TB (DR-TB) using Xpert as the initial diagnostic test,[5] many countries have used restrictive algorithms, primarily due to the high costs relative to those of conventional smear microscopy.[6] Limiting testing to previously treated patients and those with other risk factors misses MDR-TB among the large numbers of incident TB cases.[7]

Pakistan has the fourth highest burden of MDR-TB worldwide.[2] Increasing treatment coverage for MDR-TB forms an integral part of Pakistan's National Strategic Plan for TB.[8] However, of an estimated 15 000 incident MDR-TB cases, only 2881 (19.2%) were enrolled for treatment in 2016,[2] highlighting a significant treatment coverage gap.[2] Up to 90% of the MDR-TB burden is among people without a known history of previous anti-tuberculosis treatment and who are not currently covered by routine drug susceptibility testing (DST).[3] While the absolute number of MDR-TB cases is high, the prevalence of MDR-TB among both new (4.2%) and retreatment cases (16%) in Pakistan is low compared with other high MDR-TB burden countries in Eastern Europe and Central Asia.[2] Pakistan's only drug resistance survey was conducted in 2012–2013. To find additional cases of MDR-TB, testing on a large pool of people is required, which may be resource-

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intensive.[9] Moreover, in Pakistan, three quarters of the population accesses health care through the private sector.[10] However, the contribution of the public-private mix (PPM) to TB case notification in 2016 was 28%;[2] efforts to form linkages with private providers for drug-susceptible TB did not focus on the detection of MDR-TB. Xpert testing in the private sector without donor or government subsidies is prohibitively expensive for most patients.[11]

The Xpert assay was introduced in Pakistan in 2011.[3] However, further experience in scaled implementation of Xpert testing is required to inform its use across the different levels of the health system. The present study describes a multifaceted case-finding intervention targetting the public and private sectors that utilised Xpert as a frontline diagnostic test in Karachi, Pakistan, and its impact on case notifications of DR-TB. We aim to fill the gaps in the literature on the potential constraints in the implementation of Xpert testing in programmatic settings with a high MDR-TB burden.

STUDY POPULATION AND METHODS

Study setting

Karachi is the largest city and economic hub (estimated population 23 million[12]) of Pakistan, with over 60% of the population residing in high-density slums.[10] Approximately 15 private sector facilities are registered as basic management units (BMUs) with the National Tuberculosis Programme, where TB diagnostic and treatment services are available. Karachi has three Programmatic Management for Drug-Resistant TB (PMDT) sites, two in the public sector and one in the private sector, where patients can receive free treatment for MDR-TB.

Project interventions

This project was part of the TBXpert Project, which aims to increase TB case notifications by scaling up Xpert testing. The intervention in Karachi comprised two distinct arms: 1) a reverse PPM arm targeting public sector hospitals and PMDT sites; and 2) a social business model targeting the private sector. A new case was defined as a person who had been previously treated for TB.

Reverse public-private mix model

In this model, TB diagnostics and treatment capacity was strengthened at existing public sector facilities. Xpert machines were installed at the TB laboratories of six public sector hospitals and one private sector PMDT site. The hospitals were provided with additional staff, including an Xpert technician and health workers who screened individuals in the waiting areas of out-patient clinics and other wards of the hospitals for TB symptoms, as per the WHO symptom screen (cough of any duration, fever, haemoptysis, night sweats and unexplained weight loss).[13] The health workers also assisted the TB clinic in collecting sputum samples from other wards, guiding patients in sputum expectoration, data collection, registering and counselling people with TB. Sputum was collected for Xpert testing from all those with presumptive TB who were able to expectorate sputum and who provided consent for the test. The intervention sites were set targets for TB case identification, and compensation for staff was performance-based, with incentives for TB case identification and ensuring high treatment initiation rates. Supervisory visits by managers were carried out to ensure maintenance of equipment, quality assurance of data, troubleshooting and ensuring a supply of Xpert cartridges.

Social business model

TB testing was carried out at three purpose-built TB centres called '*Sehatmand zindagi*' ('healthy life'). This model utilised community-based screeners, placed at 180 private sector clinics (both formal and informal) in the vicinity of the TB centres where they carried out verbal symptomatic screening (according to the WHO symptom screen) of patients and referred them for testing, comprising chest X-ray (CXR) (US$3–5) and free-of-cost Xpert at the centres in case of a positive symptom screen and clinical evaluation by health providers. Individuals who could not pay for CXR were cascaded directly to Xpert, while those who were unable to expectorate sputum for testing were further evaluated by a clinical officer based on clinical symptoms and CXR findings. The social business model (SBM) intervention evolved towards developing a medical detailing team that engaged a network of approximately 600 private providers and encouraged referrals for TB testing. People identified with drug-susceptible TB in the SBM intervention were provided free treatment at the centres registered as BMUs with the Provincial Tuberculosis Programme (PTP). People at reverse PPM sites were registered for treatment at the testing site or at the referral facility. Individuals identified with rifampicin (RMP) resistance were referred to one of the three PMDT sites in the city and initiated on second-line drugs after repeat Xpert testing. Sputum samples were also obtained for culture from all patients registered for treatment for confirmation of RMP resistance.

Data analysis

We used de-identified data collected for patient screening and testing indicators, including Xpert log files and summary of laboratory reports from each intervention site, for eight quarters of the intervention from Q3 2013 to Q2 2015. Aggregate summary reports for quarterly patient enrolment and treatment initiation at PMDT sites was obtained to identify the

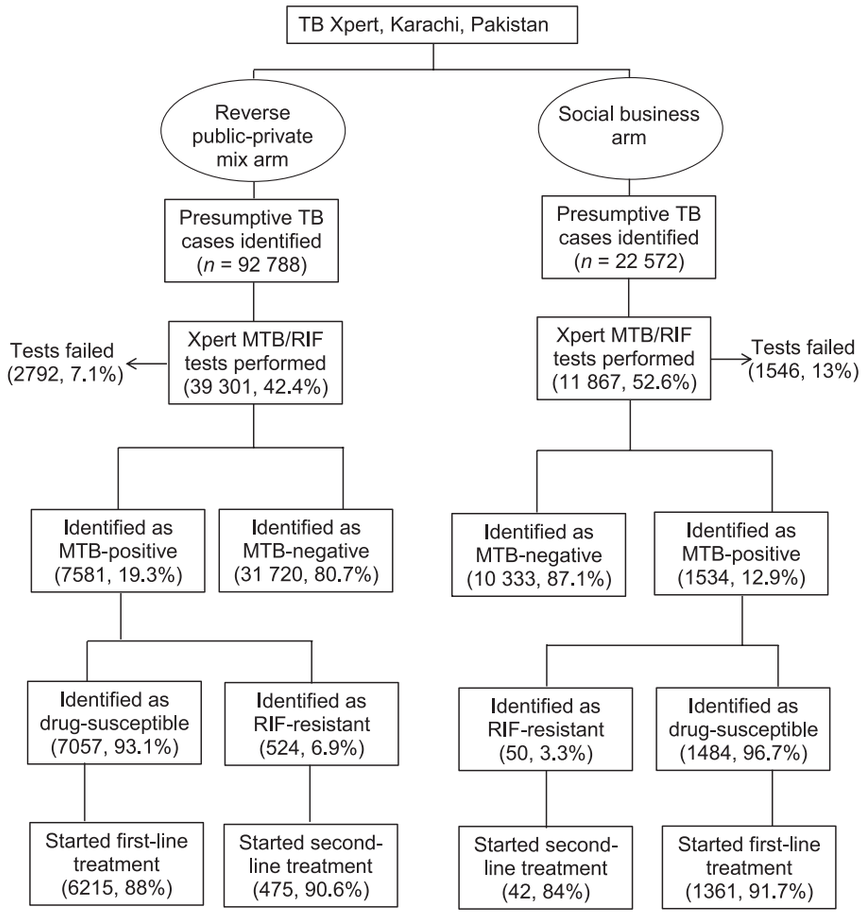

Figure 1 TB screening and Xpert® MTB/RIF testing results. Overview of Xpert MTB/RIF testing and TB case detection as part of the TB Xpert Initiative, Karachi, Pakistan, July 2013–June 2015. TB = tuberculosis; MTB = *Mycobacterium tuberculosis*; RIF = rifampicin.

total number of RMP-resistant TB (RR-TB) cases registered in Karachi.

Summary statistics describing Xpert testing and *Mycobacterium tuberculosis* yield at each intervention site and intervention (SBM and reverse PPM) were determined. The TB REACH methodology for additionality calculations was adapted for DR-TB notifications.[14] This approach allows for more accurate estimation of impact directly attributable to project activities. Briefly, the methodology involves determining the quarterly historical case notifications in the intervention area of the previous 12 quarters before the start of activities. A regression line is fitted to historical notifications and extrapolated to forecast notifications that would have taken place in the absence of any intervention. These are compared with the number of actual notifications that took place during the intervention period to determine the overall additionality of cases. To control any bias resulting from the setup of new PMDT sites outside Karachi, cases known to have residential addresses outside of the city were excluded from the analysis. All data analysis was carried out using Excel™ (MicroSoft, Redmond, WA, USA).

Ethical approval

The study protocol was approved by the Institutional Review Board (IRB), Interactive Research and Development, Karachi. The IRB is registered with the US Department of Health and Human Services, Office for Human Research Protections, Washington DC, USA (IRB#00005148). Verbal consent was provided by participants before conducting Xpert tests.

RESULTS

Tuberculosis screening and Xpert testing

Between July 2013 and June 2015, 115 360 people with presumptive TB were identified, 80.4% through the reverse PPM intervention and 19.6% using the SBM (Figure 1). Of these, 39 301 clients at the reverse PPM sites and 11 867 at the SBM sites underwent Xpert testing (Figure 1). A total of 9115 *M. tuberculosis*-positive cases were detected through the two interventions: respectively 7581 (83.2%)

Table Comparison of Xpert® MTB/RIF testing and TB case detection and MDR-TB treatment initiation between the two project arms, Karachi, Pakistan, July 2013–June 2015

Process indicators	Total *n*	Reverse PPM *n* (%)	SBM *n* (%)	*P* value
Xpert testing performed	51 168	39 301 (76.8)	11 867 (23.2)	<0.0001
Failed Xpert testing	4 338	2 792 (64.4)	1 546 (35.6)	<0.0001
Error	2 881	1 702 (59.1)	1 179 (40.9)	<0.0001
Invalid result	838	838 (73.9)	296 (26.1)	<0.0001
No result	252	252 (78.0)	71 (22.0)	<0.0001
Cases identified as MTB-positive	9 115	7 581 (83.2)	1 534 (16.8)	<0.0001
Cases identified as MTB-positive and RIF-resistant	574	524 (91.3)	50 (8.7)	<0.0001
Patients started on second-line treatment	517	475 (91.9)	42 (8.1)	0.2096

TB = tuberculosis; MDR-TB = multidrug-resistant TB; PPM = public-private mix; SBM = social business model; MTB = *Mycobacterium tuberculosis*; RIF = rifampicin.

and 1534 (16.8%) *M. tuberculosis*-positive cases were identified in the reverse PPM and SBM arms. The yield of bacteriologically positive cases was 19.3% at reverse PPM sites and 12.9% at SBM sites. The Table shows the difference in Xpert testing and cases detected between the two intervention arms.

Drug-resistant tuberculosis treatment coverage

Of all *M. tuberculosis*-positive individuals, 8541 (93.7%) were drug-susceptible, 7576 of whom were started on first-line treatment (88.7% of the total). Among those with an *M. tuberculosis*-positive result, 574 (6.3%), were also RMP-resistant (RMP+/DR-TB): 524 (91.3%) were detected at reverse PPM sites and 50 (8.7%) at SBM sites. The yield of RR-TB was respectively 6.9% and 3.3% for reverse PPM and SBM interventions (Figure 1). Among the RR-TB cases (presumed and confirmed RMP resistance) identified through the project, 517 were initiated on second-line treatment (90.1% of the total yield). A total of 46 (8.5%) individuals were lost to follow-up before treatment, whereas 11 (2.1%) deaths were recorded.

Impact on notified drug-resistant tuberculosis cases in the intervention population (Karachi District)

At the Karachi District level, 642 DR-TB cases were detected during the intervention period, 149 of whom were new diagnoses. This constituted a 43% increase in the identification of DR-TB cases over the baseline trend (Figure 2). The proportion of newly diagnosed cases among all reported DR-TB cases increased from 7% in Q2 2013 to 22% in Q2 2015 during the intervention period (Figure 3).

DISCUSSION

This was the first study to investigate the impact of scaling up Xpert implementation on additional DR-TB case notifications from a programmatic setting in Pakistan. Our intervention targeted both the public and the private sectors through an innovative social business approach, which distinguished it from other studies reported from high MDR-TB burden countries.

An increase in the number of DR-TB cases notifications in Karachi was observed relative to the

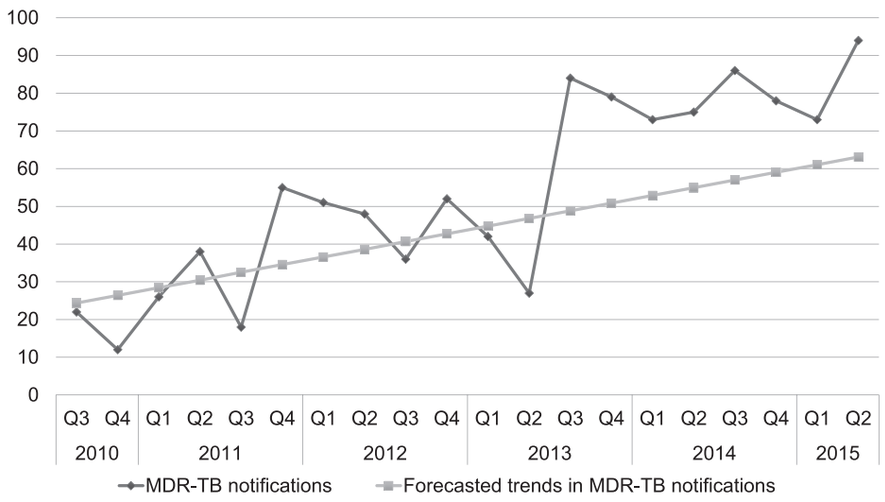

Figure 2 DR-TB case notifications (pre-and post-intervention). Trends in DR-TB case notifications during the intervention period and forecasted baseline trend (in the absence of any intervention), Karachi, Pakistan, July 2013–June 2015. MDR-TB = multidrug-resistant tuberculosis; Q = quarter; DR-TB = drug-resistant TB.

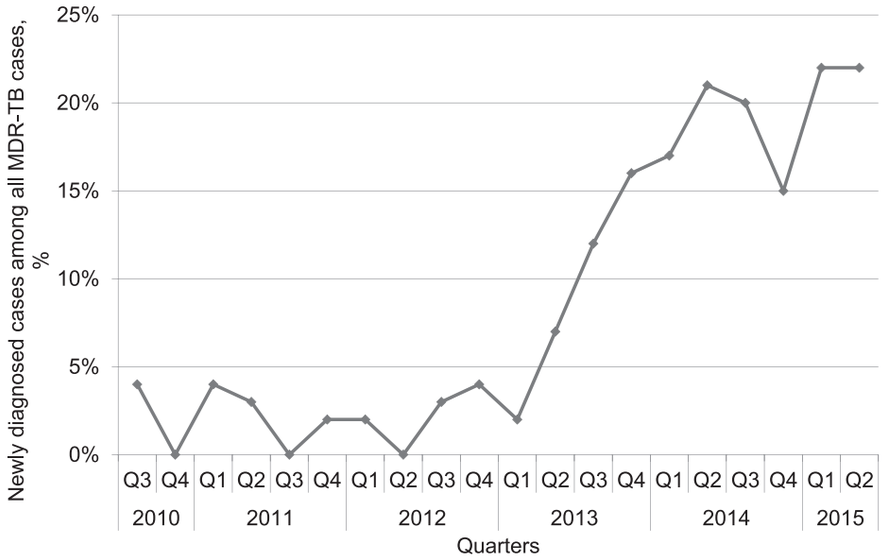

Figure 3 Proportion of newly diagnosed cases among all DR-TB cases. Proportion of newly diagnosed cases among all DR-TB cases, Karachi, Pakistan, July 2013–June 2015. MDR-TB = multidrug-resistant tuberculosis; Q = quarter; DR-TB = drug-resistant TB.

years before the intervention. Our study therefore supports existing evidence from other programmatic settings that have reported up to an eight-fold increase in RR-TB case detection through upfront Xpert testing.[15–19] The latter has increased access to DST in countries such as South Africa, where up to 65% of new cases and 71% of previously treated cases have been tested for RMP resistance,[2] exceeding previous prevalence estimates for the disease in the country.[2]

The present study provides several lessons that can inform Xpert scale-up in Pakistan and elsewhere. Our study highlights the importance of employing both active case finding approaches and expanded diagnostic algorithms for Xpert testing to bridge the case detection gap in DR-TB. As new cases comprise up to 97% of the total TB cases notified, the burden of DR-TB is overwhelmingly high within this group, which does not receive routine access to DST.[2] In our study, the proportion of newly diagnosed cases among DR-TB cases increased from 7% at baseline to 22%. However, the estimates for MDR-TB among new cases are much higher, and further scale-up of Xpert testing is expected to achieve greater yields.

Treatment initiation in patients diagnosed with RR-TB may be operationally challenging.[20–23] Figure 4 summarises factors that have contributed to low enrolment of patients in the MDR-TB treatment programme in Pakistan. The additional human resources provided at TB centres in private and public sector hospitals that worked to support linkages to PMDT sites, complemented by close collaboration with PTP, resulted in a high proportion RR-TB cases being initiated on treatment, with only 8.5% pre-treatment loss to follow-up in the project. Future scale-ups must invest in data systems, human resource training and strengthening linkages to DR-TB treatment sites to ensure treatment initiation and better outcomes in individuals with DR-TB.

The reverse PPM intervention involved fewer human and infrastructural investments than the private sector intervention. The public sector sites carrying out the project interventions were high-volume tertiary care hospitals providing a large population base to screen from. Four fifths of all Xpert tests were performed through the reverse PPM intervention. A higher *M. tuberculosis*-positive rate compared with SBM was also observed (19.3% vs. 12.9% of all those tested); the reverse PPM intervention also detected >90% of all RR-TB cases in the project. We hypothesise that more individuals with severe illness are found at tertiary care hospitals than in general practitioner clinics, leading to higher *M. tuberculosis*-positive and RR-TB yields at these sites. Our experience therefore supports targeted approaches such as reverse PPM, which leverage existing infrastructure and carry out structural enhancements and process improvements to increase access to DST. The private sector intervention utilised a novel approach to PPM by establishing new health centres and a referral network of private providers through a sustainable SBM. While the SBM approach only detected 16.8% of all *M. tuberculosis*-positive cases and 50 RR-TB cases in the project, the number of referrals and RR-TB cases identified in the private sector increased over the course of the project and were less likely to be detected in the public sector. Comparable trends are experienced in the establishment of any new business, where generating a 'footfall' often takes a long time before reaching

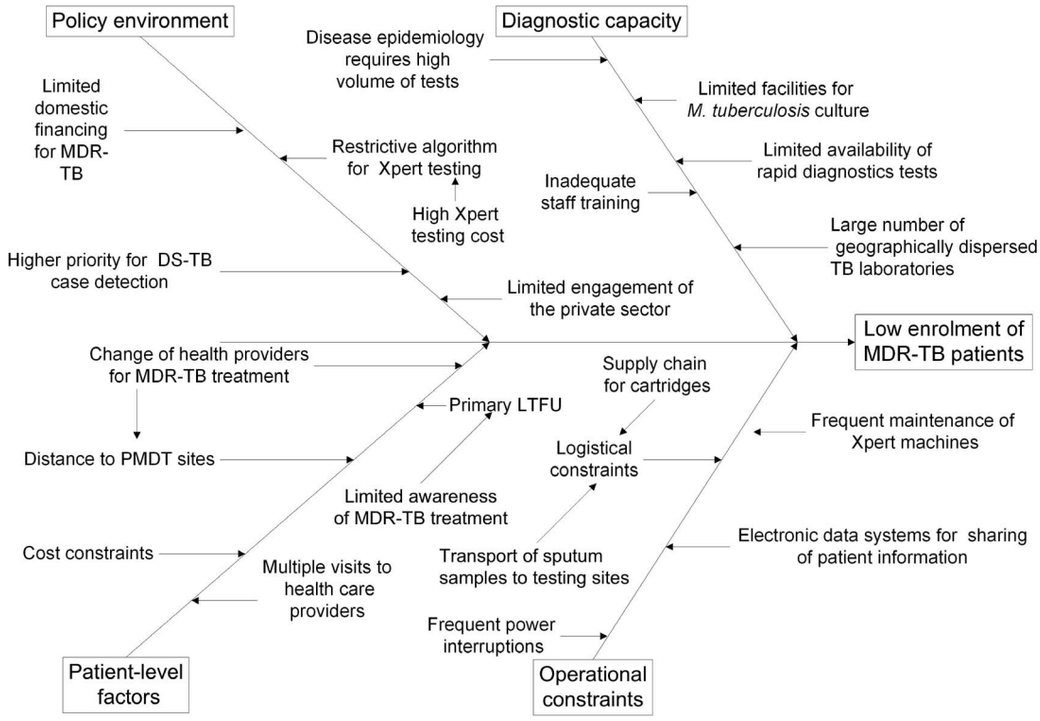

Figure 4 Factors contributing to low enrolment of MDR-TB patients in treatment programmes. Illustration of the factors that have historically contributed to low enrolment of MDR-TB patients in treatment programmes in Pakistan. MDR-TB = multidrug-resistant tuberculosis; PMDT = Programmatic Management for Drug-Resistant TB.

maturity.[23] Similar strategies may be considered in countries with a rampant private health sector, particularly in South Asia and Africa. While about three quarters of all health services are availed in the private sector in Pakistan,[10,11] only 28% of all TB cases were notified through private facilities.[2] During the study period, the PPM contribution to TB case notifications was 15–20% in Pakistan and 13–17% in India and about 55% in China.[2] Increased engagement with the private sector is therefore necessary, despite lower yields and higher costs to identify additional cases that would likely have otherwise remained undiagnosed.[1,2]

The potential options for diagnostic algorithms and case finding strategies need to be carefully appraised and measured against cost implications for each setting. Of the 48 high-burden countries, at least 15 have adopted national guidelines based on testing of all presumptive TB cases using Xpert.[2] This may not be feasible in resource-constrained settings, including for countries with donor support for TB programmes. However, testing algorithms focused on presumptive drug-resistant cases only may limit case detection, as a significant number of MDR-TB cases are among new TB cases. Pakistan's first national anti-tuberculosis drug resistance survey reported RMP resistance in 4.4% (95% confidence interval 2.4–4.9) of new cases.[24] Application of novel screening tools such as digital CXR with computer-aided detection could save Xpert cartridges and therefore lower costs.[25,26]

In our study, Xpert testing could only be performed on less than half of people identified as needing testing. Support was provided for expectoration through nebulisers and mucolytic agents, which incurred additional costs and patient counselling efforts. Similar challenges may be encountered in other active case-finding programmes. Our experience with technical issues and equipment malfunctions is consistent with those reported by early Xpert implementers elsewhere.[11,27,28] The costs of equipment maintenance, biomedical support, module re-calibrations and back-up power supplies need to be incorporated within programme budgets. Ensuring appropriate supply chains of cartridges and transport of patient sputum samples to Xpert testing sites are also probable challenges for large-scale implementers.

An important limitation of the study was that we could not determine what proportion of the additionality in DR-TB cases was attributable to implementation of Xpert testing relative to the active case-finding efforts in the project. As laboratory-level data were unavailable, we could not ascertain the additional increase in testing for Xpert through active case finding or analyse the differences in yield of RMP resistance in new vs. retreatment cases. As the study was conducted in a major urban centre, it may not be

generalisable to rural settings, where yield may be lower due to lower patient volumes and underdeveloped laboratory facilities.

CONCLUSION

We described a multifaceted scale-up of Xpert testing in public and private sectors in Karachi. An increase in case notifications for DR-TB was observed relative to historical trends supporting existing evidence from other programmatic settings in high DR-TB burden countries. A high proportion of those identified with RR-TB were initiated on second-line treatment under this project. Further scale-up of Xpert testing needs to take into account the most appropriate diagnostic algorithms weighed against cost implications, and ensure appropriate technical and operational support for effective programme delivery.

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Conflicts of interest: none declared.

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RÉSUMÉ

CONTEXTE : Le Pakistan est au quatrième rang des pays durement touchés par la tuberculose multirésistante (TB-MDR) avec seulement 19,2% des 15 000 cas nouveaux estimés qui sont notifiés. Accroître la couverture du traitement de la TB-MDR est une priorité majeure pour le Programme National Tuberculose du Pakistan. L'Organisation Mondiale de la Santé recommande le recours au test Xpert® MTB/RIF comme test de diagnostic de première ligne pour les individus présumés tuberculeux.

OBJECTIF : Décrire une intervention à multiples facettes de recherche des cas ciblant les secteurs public et privé qui ont utilisé le Xpert comme test de diagnostic de première ligne pour les individus présumés tuberculeux, à Karachi, Pakistan, et son impact sur les notifications de cas de TB-MDR.

SCHÉMA : Etude transversale

RÉSULTATS : Un total de 51 168 patients ont eu un test Xpert, parmi lesquels 7581 et 1534 ont eu un diagnostic de TB dans les bras secteur public (mix public-privé inversé) et secteur privé (modèle d'entreprise sociale) respectivement ; 574 (6,3% de tous les cas de TB) ont été identifiés comme résistants à la rifampicine (RMP). Un total de 517 (90,1%) personnes atteintes de TB résistante à la RMP (TB-RR), identifiées grâce au projet, ont été mises sous traitement de deuxième ligne. L'intervention a abouti à 194 cas supplémentaires de TB-RR, soit une augmentation de 43% par rapport au départ.

CONCLUSION : Ce projet, un des plus vastes programmes de test Xpert réalisés au niveau d'une ville, a abouti à une augmentation significative de la détection et du traitement de la TB-MDR.

RESUMEN

MARCO DE REFERENCIA: Paquistán ocupa el cuarto lugar en los países con más alta carga de morbilidad por tuberculosis multirresistente (TB-MDR), con una notificación de solo 19,2% de los 15 000 casos nuevos estimados. La ampliación de la cobertura de tratamiento de la TB-MDR constituye una prioridad del Programa Nacional contra la TB de Paquistán. La Organización Mundial de la Salud recomienda la utilización de la prueba Xpert® MTB/RIF como prueba diagnóstica inicial en las personas con presunción de TB.

OBJETIVO: Describir una intervención multifacética de búsqueda de casos dirigida a los sectores público y privado que utilizaba la prueba Xpert como método diagnóstico de primera línea en las personas con presunción de TB en Karachi y definir su repercusión en las notificaciones de casos de TB-MDR.

MÉTODO: Fue este un estudio transversal.

RESULTADOS: De las 51 168 personas examinadas con la prueba Xpert, se diagnosticó TB en 7581 personas en la rama del sector público (estrategia inversa de colaboración público privada) y en 1534 en el grupo del sector privado (modelo de empresa social) y se detectó la resistencia a rifampicina (RMP) en 574 casos (6,3% de todos los casos de TB). De las personas detectadas en el proyecto con TB resistente a RMP (TB-RR), 517 (90,1%) comenzaron un tratamiento con fármacos de segunda línea. La intervención tuvo como resultado el diagnóstico de 194 casos adicionales de TB-RR, es decir un aumento de 43% con respecto al nivel de referencia.

CONCLUSIÓN: El presente proyecto, uno de los programas más extensos de detección con la prueba Xpert realizado a escala de una ciudad, dio lugar a un aumento notable de la detección y el tratamiento de casos de TB-MDR.

Queries for jtld-22-08-18

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