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Unsuccessful Xpert® MTB/RIF results: the Nigerian experience

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Setting: Nigeria, a high tuberculosis (TB) burden country.
Objective: To study the rate, distribution and causes of unsuccessful Xpert® MTB/RIF test outcomes, with the aim of identifying key areas that need to be strengthened for optimal performance of the assay.
Design: This was a retrospective analysis of data uploaded between January and December 2015 from Xpert facilities to the central server using GXAlert.
Result: Of 52 219 test results uploaded from 176 Xpert machines, 22.5% were positive for *Mycobacterium tuberculosis*, 10.8% of which were rifampicin-resistant; 4.7% of the total number of results were invalid, 4.2% had error results and 2.1% no result outcomes. Technical errors were most frequent (69%); these were non-seasonal and occurred in all geopolitical regions and at all health facility levels. Temperature-related errors were more prevalent in the North-West Region, with peaks in April to June. Peak periods for temperature and machine malfunction errors coincided with the periods of low utilisation of the assay.
Conclusion: The key challenge affecting performance was poor adherence to standard operating procedures. Periodic refresher training courses, regular supervision, preventive maintenance of Xpert machines and proper storage of cartridges are strategies that could improve Xpert performance.

Early diagnosis and access to effective treatment remains fundamental to successful tuberculosis (TB) control.[1] TB diagnosis using smear microscopy takes 24–48 h, while solid culture takes 4–8 weeks. This diagnostic delay is an obstacle to achieving early diagnosis.[2,3] The introduction of the Xpert® MTB/RIF assay (Cepheid, Sunnyvale, CA, USA) revolutionised TB diagnosis and gave hope to struggling programmes. Today, diagnostic decisions on both drug-susceptible (DS-TB) and rifampicin (RMP) resistant TB (RR-TB) can be made within 2 h of sample collection, thus significantly reducing the lag time for diagnosis and facilitating prompt clinical decision making, which benefits TB control.[4,5] Following the World Health Organization's (WHO's) endorsement of Xpert, many countries, including Nigeria, embraced this technology with optimism.[6] It is the first simple TB molecular test that is robust enough to be introduced outside conventional laboratory settings.[7] However, the right placement of Xpert machines in the laboratory requires careful consideration of available resources, national capacity building and accessibility of diagnostic testing.[8]

Xpert roll-out

Some key considerations that had to be taken into account when selecting sites for the installation of the Xpert machines included high TB burden sites, current workload of the facility, availability of personnel, adequate infrastructure and the capacity of the appropriate treatment centre. It was thus possible to train a cadre of staff capable of providing technical assistance during the early stages of implementation.

Installation of Xpert machines commenced at national- and state-level laboratories with a relatively stable power supply that would ensure uninterrupted running of the Xpert assay. Setting up of air conditioners, refrigerators and inverters was essential to provide the ambient temperature required to operate the Xpert machines and store the cartridges, and to guarantee an uninterrupted power supply during testing. GxAlert internet data connectivity was also established for the upload of data onto the central server. A 4-day theory and practical training course was provided for laboratory staff and other health care workers at the time of the installation. The supply and distribution of cartridges to facilities was centrally managed by the National Tuberculosis and Leprosy Control Programme (NTBLCP).

At facility level, trained laboratory personnel performed the assay according to the protocol and national standard operating procedures (SOPs). Based on the SOPs, unsuccessful tests showing errors or invalid or incomplete results were repeated. The resolution of error results was dependent on the error codes. Problematic issues that persisted after troubleshooting were reported to the Nigerian Cepheid technical centre for further assistance, either remotely or on-site. Primary concerns about the assay's performance were 'test failures' or unsuccessful test outcomes that cause delay or no diagnosis in some patients. Similar concerns about high rates of error and invalid results were reported by other countries during the early phase of implementation.[9–11] The WHO recommended country-specific operational research, as diagnostic tests that perform well in controlled settings may not always perform optimally in the settings where they are to be used.[12]

We studied the rate, distribution and causes of unsuccessful Xpert test outcomes, with the aim of identifying key areas that need to be strengthened for optimal performance of the assay.

DESIGN AND METHODS

The study retrospectively analysed data uploaded between January and December 2015 from Xpert facili-

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KEY WORDS
tuberculosis; diagnosis; implementation; error

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TABLE 1 Proportion of test outcomes by facility level

Level of health facility	Frequency *n* (%)	*M. tuberculosis* detection		RMP resistance (subset of *M. tuberculosis*-positive)			Error *n* (%)	Invalid *n* (%)	No result *n* (%)
		Positive *n* (%)	Negative *n* (%)	Resistant *n* (%)	Susceptible *n* (%)	Indeterminate *n* (%)			
Primary	2036 (3.9)	479 (23.5)	1293 (63.7)	52 (10.8)	419 (87.5)	8 (1.6)	117 (5.7)	98 (4.8)	36 (1.8)
Secondary	29548 (56.6)	6719 (22.7)	19529 (66.0)	668 (9.9)	5872 (87.4)	179 (2.7)	1190 (4.0)	1400 (4.7)	710 (2.4)
Tertiary	20635 (39.5)	4547 (22.0)	13851 (67.1)	543 (11.9)	3839 (84.4)	165 (3.6)	866 (4.2)	971 (4.7)	399 (1.9)
Total	52219 (100)	11745 (22.5)	34673 (66.4)	1264 (10.8)	10130 (86.2)	352 (3.0)	2173 (4.2)	2469 (4.7)	1145 (2.2)

RMP = rifampicin.

ties to the central server using GXAlert. Testing failures on the Xpert assay were classified as 'error', 'invalid' or 'no result'. Identification and grouping of the error codes into categories were guided by the error resolution SOPs provided by the Xpert manufacturer, in which error codes were classified under the causes and the steps to take to resolve problems.[13,14]

By following the SOPs, facility-documented error codes were identified and categorised into five groups based on causes of error (temperature-related, technical problems, cartridge malfunction, electrical connection and machine malfunction errors). Errors due to incorrect temperature, which may be of internal origin or due to external environmental factors, e.g., ambient temperature outside of the acceptable range, dirt on filters due to accumulated dust, faulty fan and malfunctioning heater component, were grouped as Category A errors (codes 1001, 1002, 2014, 1004 and 2022). Category B errors (codes 5006, 5007 and 2008) were related to technical problems, i.e., mostly human errors due to non-adherence to the SOPs during sample processing, such as filling reaction tubes with viscous sputum or incorrect sample volumes, and clogged filters due to the presence of debris in sputum, compromised probe integrity and module failures. Category C errors (error codes 5011 and 2037) were associated with cartridge malfunction, caused mostly by inappropriate storage of the cartridges. Electrical connection issues that resulted in communication loss between the module and the software due to incorrect wiring connections (e.g., poor Ethernet connection between the computer and Xpert, poor connection between gateway and modules, and fluctuation in power supply, with codes 2127, 2126, 1007 and 2122) were classed under Category D. Machine malfunction due to the breakdown of components or module malfunction was grouped under Category E; the associated codes were 2005, 2016, 2032, 2025, 4014 and 4017.

Data cleaning and validation were performed before analysis to improve data quality by exporting GXAlert data to SPSS v16 software (Statistical Package for the Social Sciences, Chicago, IL, USA). Each variable was checked for accuracy and consistency, and frequency tables were generated to check for outliers and errors. Any issue identified was flagged and confirmed using source data.

As this was a retrospective study using anonymous data, ethics approval was not sought.[15]

RESULTS

A total of 52219 tests were performed using 176 Xpert machines. Xpert machines were installed at all health facility levels, with the highest proportion (56.6%) in secondary health care facilities. Approximately 22.5% of the total tests performed were positive for *Mycobacterium tuberculosis*, 10.8% of which were RMP-resistant and 3.0% RMP-indeterminate. Of the total number of tests conducted, 4.7% were invalid, 4.2% had error results and 2.2% had no result outcomes, putting the rate of unsuccessful tests at 11.0%. While invalid and 'no result' outcome rates remained relatively constant across all health care facility levels, error outcomes predominated (5.7%) at the primary health care level (Table 1). Of 2173 error results recorded, only 1736 (79.9%) were documented with codes. About 19.1% of the errors could not be categorised due to lack of information on associated codes.

In all, 20 different error codes were documented and categorised into five broad groups (Categories A–E). The causes and resolution steps for Categories A and D errors are shown in Table 2. Category B errors, associated with technical issues, were most frequent (69%), and were distributed throughout all geographical regions and at all health facility levels. Whereas errors due to incorrect temperature and poor electrical connections were most frequent in the northern region, errors due to cartridge malfunction predominated in the southern region. It should be noted that errors due to machine malfunction cut across the North and South geographical regions, and were most prevalent in the North-West and South-West (Table 3).

Technical problems occurred throughout the year. Although no temperature-related errors occurred in January, these were recorded from February to December, with a peak in April, May and June. A downward trend was observed from July, with a steady decline to its lowest frequency in September and October, before finally increasingly slightly in November and December. Errors associated with cartridge malfunction and poor electrical connections remained relatively constant in terms of distribution, and occurred throughout the year. Conversely, machine malfunction errors were more prevalent in April, May and June; this, interestingly, coincided with the peak period recorded for temperature-related errors.

DISCUSSION

Findings from this study revealed gross underutilisation of Xpert machines. This is worrisome, as roll-out of the assay was supposed to increase their use, given the high level of automation that makes it user-friendly. During the early phases of implementation, most of the Xpert machines were placed in secondary- and tertiary-level health facilities. The main assumption for this preferential placement was that a stable power supply was more readily available at tertiary- and secondary-level facilities than at the primary level. However, from our findings, it is clear that interruptions in power supply, synonymous with a 'no result' outcome, were evenly distributed among the three facility levels, indicating that an efficient power supply is not dependent on facility level. Greater attention should be paid to sustainability of the back-up power supply to ensure uninterrupted testing, rather than facility-level placement.

TABLE 2 Interpretation and resolution of error codes*

Error type	Error code	Possible cause	Solution
Technically related (Category B)	5006	Probe check failed because: • An incorrect amount of reagent was inserted into the cartridge • The reagent was of compromised quality • Fluid transfer failed	Check if: • Reagent was correctly added to the cartridge • Cartridges were stored correctly Rerun the test using fresh cartridges
	5007	Probe check failed because: • An incorrect amount of reagent was inserted into the cartridge • The reagent was of compromised quality • Fluid transfer failed • The sample was processed incorrectly in the cartridge	Check if: • Reagent was added to the cartridge correctly • Cartridges were stored correctly
	2008	• The filter was clogged • Pressure sensor failed	Use a new cartridge Run a cartridge contacting buffer only
Poor electrical connection (Category D)	2127	Module communication loss was detected because Ethernet cable between computer and Xpert machine was not connected properly	Unplug and replug instrument and Ethernet cable, then restart system
	2126	Module was reset because there was an intermittent power supply failure or power supply cable or connector failure	Restart system
	1007†	The power supply voltage was out of range	Record the information in the error message. If the error recurs in multiple runs, call Cepheid Technical Support
	2122†	Loose or faulty Ethernet cable between the computer and the Xpert machine	Verify that the Ethernet cable between the computer and the Xpert machine is connected properly

*Adapted from Reference 14.
†Explanation provided by Cepheid via e-mail.

In addition to an uninterrupted power supply, the capacity of the health facility to ensure continued operation after installation should also be taken into consideration when selecting sites for Xpert machine placement. This includes maintenance of facility infrastructure such as air conditioners and refrigerators, which has not always been the case in most of the public health facilities selected. The NTBLCP and donors should prioritise the implementation of strategies for improved functionality of Xpert machines over the installation of new machines, to ensure optimal performance at all times. The 22.5% TB detection rate and 10.7% RMP resistance rate recorded, along with the uninterpretable results, was significant. Optimising the functionality of Xpert machines and reducing the number of uninterpretable results may increase the detection of TB and RR-TB. The patient population screened, which comprised presumptive drug-resistant cases and patients with human immunodeficiency virus with TB symptoms, contributed to the high RR-TB detection rate. The main impetus was the timely detection of multidrug-resistant TB,[16–19] as RMP resistance is a surrogate for isoniazid resistance.[20,21]

The key lesson learnt from the Xpert roll-out was that access to diagnosis is not the only indicator for measuring successful implementation; the rate of unsuccessful tests (which add no value to treatment) is also an important indicator of the effectiveness of Xpert implementation over time. Although Xpert was able to de-

TABLE 3 Distribution of different categories of error by geographic region and health facility level

		Error type categorised					
	Tests performed *n* (%)	A (temperature-related) *n* (%)	B (technically related) *n* (%)	C (cartridge malfunction) *n* (%)	D (poor electrical connection) *n* (%)	E (machine malfunction) *n* (%)	Total *n*
Geographic region							
South-South	8138 (15.6)	1 (0.5)	155 (73.8)	32 (15.2)	18 (8.6)	4 (1.9)	210
South-East	8013 (15.3)	4 (1.5)	212 (80.9)	16 (6.1)	24 (9.2)	6 (2.3)	262
South-West	9288 (17.8)	24 (8.1)	169 (56.9)	54 (18.2)	31 (10.4)	19 (6.4)	297
North-Central	13891 (26.6)	14 (2.9)	373 (76.6)	53 (10.9)	40 (8.2)	7 (1.4)	487
North-East	3871 (7.4)	2 (1.3)	95 (62.5)	9 (5.9)	43 (28.3)	3 (2.0)	
North-West	9018 (17.3)	41 (12.5)	187 (57.0)	24 (7.3)	57 (17.4)	19 (5.8)	328
Total	52219 (100)	86 (5)	1191 (68.6)	188 (10.8)	213 (12.3)	58 (3.3)	1736
Facility level							
Primary		6 (6.9)	52 (59.8)	3 (3.4)	24 (27.6)	2 (2.3)	87
Secondary		25 (2.5)	709 (70.5)	95 (9.5)	145 (14.4)	31 (3.1)	1005
Tertiary		55 (8.5)	430 (66.8)	90 (14)	44 (6.8)	25 (3.9)	644
Total		86 (5)	1191 (68.6)	188 (10.8)	213 (12.3)	58 (3.3)	1736

tect a good number of TB cases, the high rate of unsuccessful test results clearly showed that early diagnosis, which is fundamental to TB control, may not be achieved in many individuals if Xpert is not properly managed.

According to the Xpert manufacturer, a cumulative error rate of >5% is unacceptable and should be investigated and resolved immediately. The 5.7% error rate recorded in the primary health-level facilities in our study indicates suboptimal performance; strategies identified for the resolution of these errors should therefore be intensified at the primary level.

In view of the above, we went a step further and studied the distribution of error categories by geographic region and month. A high percentage (19.1%) of the errors were not coded, which suggests that most facilities do not make use of the error resolution SOPs for troubleshooting. A similar observation was made in a previous article.[22] Most errors involved technical issues and originated from incorrect sample processing or poor sample quality. It is to be noted that the high rate of technical errors was among the issues discussed at the Xpert Early Implementers Meeting held in France in 2012.[23] Most of the errors recorded by early implementers, such as South Africa, were linked to improper procedures used in specimen collection and sample preparation, as well as faulty modules and cartridges. The fact that Category B errors cut across geographic regions and facility levels shows that all cadre of staff working at Xpert sites are implicated. This can be attributed to the high rate of staff attrition in the health sector, whereby experienced staff leave in high numbers and are replaced by new personnel without technical experience. The introduction of planned capacity building schemes—which include training, supervision, mentoring and proficiency testing—by the NTBLCP for staff at Xpert facilities will facilitate skill acquisition and continued quality improvement. To reduce Category C errors, the storage temperature for cartridges should be carefully monitored and maintained from the time of landing at the port until the cartridges arrive at the warehouse, to their final destination at Xpert facilities. This also includes maintaining the correct temperature during transportation.

Category A errors were more frequent in the Northern region due to its characteristic hot, dry, dusty climate. In addition to the installation of air conditioners, special attention should be paid to routine maintenance of the equipment, such as monthly cleaning of exhaust fan filters. Raizada et al. reported that most temperature-associated errors were related to clogging of exhaust fan filters by dust or the inappropriate positioning of equipment.[12] It is therefore recommended that Xpert operators, especially those in the Northern region, routinely clean the filters, monitor and chart ambient room temperature, and check the machine's internal temperature whenever a Category A error is flagged. This confirms the source of the error and facilitates fast and accurate troubleshooting. Maintaining a clearance space of 10 cm between the Xpert machine and the wall and other equipment will go a long way to ensure that the warm air generated during testing is expelled properly from the machine. The seasonal variations in the errors indicate that temperature-related errors were most prevalent from March to June. This is to be expected, given the high temperatures associated with these months.

CONCLUSION

The performance of the Xpert assay is dependent on adherence to SOPs by programme personnel. Xpert roll-out should be followed by quality supervision and mentoring to improve staff competence in test procedures and routine maintenance of the machine. The significant rate of unsuccessful tests observed in this study shows that evaluations of the assay should not be based on the case detection rate alone. Performance, in terms of the number of interpretable results that informed the patient's treatment regimen, is also an indicator that should be assessed and monitored for improved test outcomes. Finally, Xpert machines should be installed in those facilities (private or public) where patients prefer to seek medical help, and where the machines can be better managed, maintained and utilised.

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Contexte : Le Nigeria, pays lourdement frappé par la tuberculose.
Objectif : Etudier le taux, la distribution et les causes de mauvais résultats du test Xpert dans le but d'identifier les domaines clés qui doivent être renforcés pour une performance optimale du test.
Schéma : Analyse rétrospective des données téléchargées entre janvier et décembre 2015 depuis les structures équipées de Xpert vers le serveur central à travers le GXAlert.
Résultats : Sur 52 219 tests téléchargés à partir de 176 machines, 22,5% ont été positifs pour *Mycobacterium tuberculosis*, dont 10,8% ont été résistants à la rifampicine ; globalement, 4,7% ont été invalides, 4,2% ont eu des résultats erronés et 2,1% n'ont eu aucun résultat. Les erreurs d'origine technique ont été les plus fréquentes, à 69%, n'ont pas eu de variation saisonnière et sont survenues dans toutes les zones géopolitiques et à tous les niveaux des structures de santé. Les erreurs liées à la température ont été prévalentes dans la région nord-ouest, avec des pics d'avril à juin. Les périodes de pic en termes de température et de dysfonction des machines ont coïncidé avec les périodes de faible utilisation du test.
Conclusion : Le problème principal qui a affecté la performance du test a été l'adhérence médiocre aux procédures opératoires standardisées. Des révisions périodiques de la formation, une supervision régulière, une maintenance préventive de la machine à Xpert et un stockage approprié des cartouches constituent des stratégies susceptibles d'améliorer la performance du Xpert.

Marco de referencia: Nigeria, un país con alta carga de morbilidad por tuberculosis.
Objetivo: Estudiar la tasa de resultados fallidos de la prueba Xpert, su distribución y sus causas con el objeto de reconocer las esferas prioritarias que precisan fortalecimiento, a fin de obtener un funcionamiento óptimo de la prueba.
Método: Fue este un análisis retrospectivo de los datos enviados al servidor central por los establecimientos que practican la prueba Xpert, mediante el sistema GXAlert, de enero a diciembre del 2015.
Resultados: De 52 219 pruebas realizadas en 176 dispositivos y subidas al sistema, 22,5% fueron positivas para *Mycobacterium tuberculosis* y de ellas el 10,8% presentó resistencia a rifampicina; de todos los resultados, 4,7% fueron inválidos, 4,2% exhibieron error y 2,1% de las pruebas no comportaban un resultado. El error más frecuente fue el de tipo técnico (69%), el cual no siguió un carácter estacional y ocurrió en todas las regiones geopolíticas y en establecimientos de salud de todos los niveles. Los errores debidos a la temperatura predominaron en la región noroeste, con períodos de mayor frecuencia de abril a junio. Los períodos de mayor frecuencia de errores causados por la temperatura o el disfuncionamiento de los dispositivos coincidieron con épocas de baja utilización de la prueba.
Conclusión: El principal problema que interfirió con el buen funcionamiento de la prueba fue el incumplimiento de los procedimientos normalizados de trabajo. Se podría mejorar la eficacia de la prueba Xpert mediante estrategias como los cursos periódicos de actualización, la supervisión constante y el mantenimiento preventivo de los dispositivos, además del almacenamiento adecuado de los cartuchos de la prueba.

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