Exploring User Acceptability on
New Laboratory TB Diagnostic Tools In Kenya,
East Africa Public Health Laboratories Networking Project
-Operational Research Project Satellite Study Sites

*Kariuki J.[1], Wanzala P.[1], Mwangi M.[1], Orina F.[2], Sang W.[2], Kiptoo M.[4], Karimi M.[3], Kitole B.[5], Too R.[2], Aberi R.[3], Too E.[6], Juma E.[3], Githui W.[3]

1. Center for Public Health Research (CPHR), Kenya Medical Research Institute (KEMRI)
2. Center for Microbiology Research (CMR), KEMRI
3. Center for Respiratory Diseases Research (CRDR), KEMRI
4. South Eastern Kenya University (SEKU)
5. Malindi Sub-County Hospital, Malindi, Kenya
6. Center for Biotechnology Research & Development (CBDR), KEMRI

*** Corresponding Author:** Kariuki J.   *E*mail: jnkaris2005@yahoo.co.uk

Summary

INTRODUCTION

Generally, introduction of new tools is usually done without consultation of the end users. There has been need for evidence to support decision making in regard to acceptance and effective use of the new diagnostic tools.

The East Africa Public Health Laboratories Networking Project through Kenya Medical Research Institute - Operational Research on Tuberculosis, undertook a study to evaluate new diagnostic TB tools which include the Xpert® MTB/RIF (GeneXpert), and the Light Emitting Diodes – Florescence Microscopy (LED-FM). These new tools were introduced in five East Africa Public Health Laboratories Networking - Operating Research Project satellite sites, by the Ministry of Health with support from World Bank since the year 2012.

OBJECTIVE

To document user acceptability of new laboratory tuberculosis (TB) diagnostic tools in the EAPHLNP OR Project Satellite study sites in Kenya.

METHODOLOGY

This was a descriptive study using a cross-sectional design. A non-probabilistic convenient sampling was used to identify laboratory respondents per site. Sixteen laboratory staff who had used the new TB diagnostic tools at the four satellite sites were included in the interviews. A questionnaire was used to collect information on user acceptability to utilize the new tuberculosis diagnostic tools. An in-depth interview guide was included in the discussions with key informants to document the perception of the laboratory staff towards the introduction of new diagnostic tools, infrastructure, procurement, turnround time and their future recommendations.

FINDINGS

It was noted that user acceptability of new TB diagnostic tools revealed varying levels of acceptance for different attributes. All the laboratory staff (100%) indicated that they understood

the concept of GeneXpert compared to 75.0 (95%   CI: 53.8 - 96.2) % for LED-FM. In regard to LED, 9/16 (56.3%) respondents rated the tool as poor compared to GeneXpert. 12/16 (75%) of the respondents reported that LED-FM had a low turnaround time.

A total of 14/16 (87.5%) respondents reported that, there was no clarity on the algorithm for use of GeneXpert. Participants reported that, with regard to safety of equipment, GeneXpert was better than ZN because, users were not exposed to fumes and was easy to operate.

In addition, the staff reported experiencing difficulties in stain preparation for ZN, identification and differentiations of *bacilli* from artifacts. GeneXpert was reported to detect more TB cases than LED and ZN since it was able to amplify low volume / quantities of *bacilli*.

CONCLUSION

GeneXpert was reported to be more preferred diagnostic tool compared to LED-FM. However, both tools have challenges when used independently which can be effectively addressed through argumentation. Quality of service maybe improved when both tools are used.

Intoduction

In sub-Saharan Africa sputum smear microscopy is the cornerstone for tuberculosis (TB) diagnosis especially at peripheral health services.

This method is rapid and inexpensive, highly specific for *Mycobacterium tuberculosis* (MTB) in a high burden setting [1].

Light Emitting Diodes (LEDs) for Florescence Microscopy (FM), commonly referred to as Optimized Sputum Smear Microscopy (OSSM)   have been identified as an alternative to conventional FM for screening of M. tuberculosis [2].

More recently, technological advancement on TB diagnostics has led to the roll out of new and rapid diagnostic tests that are potential for the improved management and control of TB.

These new diagnostic methods are being developed for the detection of TB that includes rapid-culture systems, *antigen* detection, immune-based assays, and nucleic-acid amplification tests.

One such tool is the Xpert® MTB/RIF assay (GeneXpert), which is a rapid molecular diagnostic and automated test that can detect both TB and *rifampicin* resistance, within two hours after starting the test, with minimal hands-on technical time. Due to its ability to detect MTB better than microscopy, the GeneXpert is rapidly being adopted by many countries including Kenya.

The World Health Organization (WHO) has championed for the need to a strong and comprehensive evidence based support decision making with regard to the user acceptance of the new and improved diagnostic tools and approaches.

In Kenya and the East Africa region at large, to the best of our knowledge there are no studies on the user-acceptability that have been carried out before.

In partnership with international donors, the Kenya government through the Ministry of Health (MoH) is involved in strengthening the TB control strategy by introducing diagnostic tools ranging from those operating on simple principles to highly advanced automated technologies. [3]

The East African Public Health Laboratories Networking-Operational Research (EAPHLN-OR) Project through the Kenya Medical Research Institute (KEMRI) have been evaluating new diagnostic Tuberculosis (TB) tools. This include, the Xpert® MTB/RIF (GeneXpert) and the Lght Emitting Diodes (LED) microscopy.

These new tools were introduced in five EAPHLNP-OR project satellite study sites by the Ministry of Health through the World Bank support from the year 2012 at various time period.

The laboratory personnel at the sites had an opportunity on onsite refresher training on GeneXpert and LED-FM competence during the M&E and supervision visits by the KEMRI OR Team.

The objective of this study was to document users (Laboratory Staff) acceptability to utilize new TB diagnostic tools introduced in the EAPHLNP OR satellite study sites in Kenya.

Methodology

This was a descriptive study using a cross-sectional design. A non - probabilistic convenient sampling was used to identify laboratory respondents per site.

All the laboratory staff in the four participating satellite sites were targeted for interview. A semi-structured questionnaire consisting of a close - ended (acceptable / not acceptable) questions was used to collect information on user acceptability to utilize the new diagnostic tools.

In total, 16 laboratory staff filled the questionnaire. In addition, purposive sampling was used to identify key informant interview respondents. Six key informant interviews were conducted by the researcher teams.

On average each interview session consisted of 2 participants lasting for about two hours. In total, 8 participants from the laboratory were interviewed.

In addition, secondary sources of information namely site meetings proceeding which were documented during scheduled monitoring and evaluation (M&E) visits by EAPHLNP-OR Project Secretariat were also used.

Content analysis was used to analyze secondary information. Additional analysis was carried out using grounded theory procedures to allow for generalization of emerging themes (referred to as categories), we grouped responses according to five categories:

(1)   Laboratory staff perceptions of introducing new diagnostic tools.

(2)   Infrastructure implications (equipment, laboratory layout & safety installations).

(3)   Procurement implications (reagents, consumables, documentations).

(4)   Implications on sensitivity and turn-a round-time.

(5)   User recommendation of future / new diagnostic tools.

Findings

User acceptability of new TB diagnostic tools revealed varying levels of acceptance for different attributes. All the laboratory staff indicated that they understood the concept of GeneXpert compared to:

75.0 (95% CI 53.8-96.2)%   for LED-FM.

A high proportion of respondents (93.7(81.8-100)%) reported acceptance to functionality (general layout) of GeneXpert compared to;

LED-FM (50.0 (25.5-74.5)%).

User - friendliness (simplicity of operating) GeneXpert was reported by 93.7(81.8-100)% compared to;

69.7(47.2-92.2)% for LED-FM.

Three-quarter of the participants (75.0(53.8-96.2)%) indicated acceptance to GeneXpert on turn-a-round time of results for diagnosing TB, compared to;

37.5(13.8-61.2)%.

Similarly, three-quarter of the participants (75.0(53.8-96.2)%) indicated acceptance to GeneXpert on turnaround time on results for diagnosing MDR-TB.

Close to one-third of the participants (37.5(13.8-61.2)% indicated acceptance GeneXpert on rating of management of specimen workload and using the new platform, compared to;
50.0(25.5-74.5)% on LED-FM.

Over 50% of the participants (56.2%; 95% CI = 31.9% - 80.5%) indicated acceptance to GeneXpert on overall rating compared to other tools, compared to 43.7(19.4%-68.0%) rating on LED-FM.(*see Table 1*).

Table 1: Comparison Of GeneXpert and Led Microscopy Tools Evaluation For User Acceptability Parameters

Parameter / Attributes	GeneXpert (n=16) % (95% CI)	LED Microscopy (n=16) % (95% CI)
Understanding of the concept of the new diagnostic platform (yes / no)	100 (N/A)	75.0 (53.8-96.2)
Functionality (general layout) (acceptable / not-acceptable)	93.7 (81.8-100)	50.0 (25.5-74.5)
User-friendliness (simplicity) of using the new tool (acceptable / not-acceptable)	93.7 (81.8-100)	69.7 (47.2-92.2)
Turnaround time of results for diagnosing TB (acceptable / not-acceptable)	75.0 (53.8-96.2)	37.5 (13.8-61.2)
Turnaround time of results for diagnosing MDR-TB (acceptable / not-acceptable)	75.0 (53.8-96.2)	-
Rating of management of specimen workload and using the new platform (acceptable / not-acceptable)	37.5 (13.8-61.2)	50.0 (25.5-74.5)
Rating of new tool compared to other tools (acceptable / not-acceptable)	56.2 (31.9-80.5)	43.7 (19.4-68.0)

A total of 14(87.5% 95%CI=71.3%-100%) of the respondents reported that they were not conversant with the use of National TB Diagnostic Case Algorithm.

Qualitative Findings

From the in-depth interviews, the staff reported experiencing difficulties in stain preparation, identification and differentiations of bacilli from artifacts while using conventional methods of TB diagnostic.

"The GeneXpert has made our work easy. All TB samples are analyzed using this machine..."
Participant #1, Kitale.

"...sometimes some people can get confused when identifying artifacts and bacilli.
They look the same and one needs time which we do not have since we have a lot of work.....
" Participant #2, Kitale.

GeneXpert was reported to be better than ZN because users were not exposed to fumes and easy to operate. Thus it was safe to use and does not required expansive physical to setup.

> *"I like GeneXpert,*
> *it has made my work simple.*
> *The bench is clean,*
> *one does not have to*
> *do staining and mounting of*
> *slides under the hood.....*"
> Participant #1, Malindi.

In some sites, they reported they had no storage space in the laboratory for storing the GeneXpert cartridge which required large cabinets. Some Sites experienced irregular supply of reagents for both GeneXpert and LED-FM.

> *"... last week, PCU brought us*
> *a lot of cartridges from Nairobi.*
> *That is why you see these supplies still*
> *on table and on that shelve........*
> "* Participant #1, Kitale.

Out of the 16 respondents, 12 of them reported that LED-FM had a low turn-around time. GeneXpert detected more TB cases than LED and ZN since it was able to amplify low volume / quantities of bacilli.

> *"Most of us see LED-FM as a*
> *user-friendly tool,*
> *but has chances of errors*
> *associated with*
> *user capacity*
> *may lead to its unreliability.*
> *However, in a high workload facility like ours,*
> *we prefer to use GeneXpert*
> *since it can amplify low volume of TB bacilli."*
> Participant #2, Malindi.

GeneXpert tool was used as the first diagnostic test for all tuberculosis suspects. Respondents viewed the continuation of GeneXpert as a first line of TB diagnosis as very likely and very positive about it.

> *"We were informed by the National Programme*
> *that all patients in chest clinics,*
> *should have their sputum tests done*
> *using GeneXpert as*
> *a first line of diagnostic test.*
> "* Participant # 1, Busia

Discussion

This study has elicited new user perception on new TB diagnostic tools in field-setting. GeneXpert tool was the preferred TB diagnostic tool compared to LED-FM microscopy on different attributes. The rationale and adaption of the new tools in laboratories was said to be due to ease of operation and high turnaround time.

These attributes may have contributed to GeneXpert becoming more acceptable compared to other technologies.

In addition, revised national TB diagnostic guidelines indicate that, GeneXpert was to be the first line tool for TB diagnostic.

Barriers towards using GeneXpert include equipment breakdown, calibration schedule not being followed, occasional stock-outs of reagents and low throughput that may have resulted to high workload.

However, due to high workload LED-FM was preferred over GeneXpert. In both cases, these new tools were preferred over other tools not included in this study such as ZN which was used as the benchmark for the validation of the new diagnostic tool in the TB study at the study site (Githui, 2014). Majority of the respondents reported they understood the working principles of the GeneXpert.

This represents a positive experience in terms of operational knowledge of new technologies. Which noting that, adaption of new tools and procedures were partially associated with the presence of well-qualified and experienced personnel in laboratories at any one time [4].

Challenges associated with use of LED-FM include low turnaround time. This study did not probe for specific reasons why the low turnaround time. LED-FM was rated poor by 9/16 (56.2%) respondents compared to newer diagnostic tools.

They reported experiencing difficulties in identification of *bacilli* as well as differentiating *bacilli* from artifacts and preparation of stains. In addition, they reported that, LED-FM was not user - friendly and they felt uncomfortable with the general layout of that equipment.

These challenges could be overcome by laboratories augmenting multiple diagnostic methods at their use and would obtain near accuracy and comparable results to improve quality of service [5]

Conclusion

GeneXpert was reported to be more preferred diagnostic tool compared to LED-FM.

However, both tools have challenges when used independently which can be effectively addressed through argumentation.

Implications for Practice

Quality of service maybe improved when both tools are used.

Acknowledgement

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