Experience and Lessons Learnt on Health Care Personnel Participating In the Implementation of TB Operational Research at (EAPHLNP -OR) Malindi, Kenya

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Summary

INTRODUCTION

Malindi Sub-County Hospital in Kilifi County, is one of Kenya's World Bank (WB) funded East Africa Public Health Laboratories Networking (EAPHLN) Project, Satellite sites, implementing Tuberculosis (TB) Operational Research (OR) protocol. There is Limited literature available in public health journals on the impact of OR studies' implementation on participating health care personnel.

OBJECTIVE

To document experiences, achievements, challenges and lessons learnt by health care personnel participating in the implementation of TB Operational Research (OR) protocol at Malindi Sub-County Hospital a Satellite site in Kenya.

METHODOLOGY

This was a descriptive qualitative study with a purposive data collection method using an in-depth interview guide capturing demographic information. That is, achievements, experiences and challenges of nine health care personnel who participated in the TB OR study from 2013 to 2015. Data transcription was processed using Microsoft word, Open and Auxiliary Coding collected by three investigators. The findings were presented thematically.

RESULTS

Key achievements reported by the respondents include; Refresher courses, Mentorship sessions, Participation in workshop and Seminars. During monitoring and evaluation exercises, participants learnt research skills and experienced knowledge growth through interactions with KEMRI senior scientists. Exposure to OR methodology activities, improved confidence, and work competence to participants.

It was realistic that, GeneXpert test was the most user friendly followed by LED FM microscopy. Participants concurred on challenges encountered during enrolment of study respondents due to heavy workload involving routine and OR activities with inadequate personnel and minimal motivation. However, adherence to protocol for sorting out, routing and triaging coughers with effective referral to laboratories assured collection of quality samples and achievement of high percentage of sample size.

CONCLUSION

Implementing the OR TB study in Malindi Sub-County Hospital was informative experience to the participating health care personnel on appropriate use of existing TB diagnostic tools. Provision of human resource in OR studies is essential to address the challenge of heavy workload that would otherwise disrupt smooth implementation of OR activities.

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Introduction

Malindi Sub - County Hospital in Kilifi County Kenya, is one of the satellite sites under the World Bank (WB) funded East Africa Public Health Laboratories Networking (EAPHLN) Project in Kenya.

The project's main objective was: to establish a network of efficient, high quality, accessible public health laboratory for the diagnosis and surveillance of TB and other communicable diseases.

With Kenya taking lead in integrated disease surveillance, response to operational research and knowledge sharing. Kenya has been selected due to the presence of indigenous populations and hard to reach areas [1].

Malindi Sub-County Hospital is the proposed level five(5) hospital for Kilifi County and it is located in Malindi town. It borders Taita-Taveta County to the west, and the Indian Ocean to the east [2].

The population is estimated to be 432,385 people. Thus, 218,987 Male and 218,398 Female.

Malindi is mainly composed of:

70%), The Mijikendas.
15%), Swahilis / Bajunis.
10% From other counties and nationals.
5% Indigenous people.

The Hospital offers Inpatient and Outpatient Services, Laboratory, and Radiological Diagnostic Services, Medical and Surgical Services that include high dependency New Born and Pediatric Units.

The Malindi Sub-County Hospital (MSCH) is a referral facility for Kilifi, Tana River, and Lamu counties. The hospital has an average monthly In-patient of 726 and average Out-patient of 8,388, with an annual average bed occupancy of 75%. Malindi has an average of 2,378 TB cases per year [2].

Operational Research (OR) may be defined as the search for knowledge on interventions, strategies, or tools that can improve the quality, effectiveness, or coverage of programs in which the research is being done [3].

OR is also defined as an inter-disciplinary branch of applied mathematics or formal science that uses advanced analytic methods to make better decisions. OR is research that provides optimal solutions to complex decision - making [4,5].

Thus, OR in public health is the research into some or all aspects of conducting, or operating a system, or a service, while treating the system as a live entity in its actual, real environment, differentiating itself from research under controlled conditions [6].

It involves research components integrated with analytical methods in routine real-life situations to help improve public health interventions and programs [7] .

Current State of Operational Research

OR in public health has been limited in spite of the fact that it has a rather broader interpretation in global health than in management science. Growing interest among both International and National agencies to invest resources in OR and guide program implementation in public health is evident [8].

However, limited literature is available in public health journals about operational research[8]. This has been attributed partly due to limited trained manpower, capacity and skills to conduct and publish in peer-reviewed journals. Many state governments are now realizing the need for carrying out more OR to answer their health service delivery priority concerns[9].

There is a need to pay more attention to success factors and to draw on a broader range of analytical methods, more interchange with wider OR work.

Nevertheless, the process of OR is not complete without a team trained in OR knowledge and skills. Impossible to perform effectively by a single and inter-disciplinary team is essential for the successful and relevant use of OR techniques.

This gives evidence on the relevance, effectiveness, scalability and improvement of health policies and programs in the most equitable and efficient manner.

There is need to develop workforce trained and proficient in operations research planning, implementation and evaluation. Some of the other challenges for operational research capacity building have been outlined as follows;

(a) Shortage of funding.
(b) Turnover of trained staff.
(c) Difficulty in implementing research skills for program settings.
(d) Reluctance or inability of managers to use findings.
(e) Need to evaluate capacity building procedures.
(f) Length of time needed to achieve maximum trained researchers and consumers.
(g) Need for more consumer-oriented trainings.
(h) Need to improve linkages between researchers and Managers [10-16].

Teamwork spirit is necessary to collectively execute quality OR activities; teams of academicians, policy makers, program managers, epidemiologists, biostatisticians, community health specialists, and health economists need to work together to answer public health system relevant problems and solve them timely [17-20].

OR approaches can inform a range of important process designs and delivery issues. OR can also deal with wide ranging issues in public health:- Health systems, Disease prevention, and Control along with community issues.

The problems of poor coverage of interventions, quality deprived systems, not reaching vulnerable population with services, difficulty in scaling are solved by innovative mechanisms through OR study [17, 19, 2,21-22].

The Kenya Medical Research Institute (KEMRI) was mandated by the Ministry of Health Kenya to spearhead OR activities in Kenya [1].

MSCH was considered as one of the TB intervention satellite sites of the OR TB project [23]. However, most of the staff in MSCH had minimal knowledge and skills in conducting OR studies.

OR activities in MSCH started in 2012 with an initiation of the study protocol that was followed by regular support supervision and scheduled monitoring and evaluation sessions that offered an opportunity to the participants to reflect on their gaps and review on their experiences.

The MSCH OR team had opportunities to share their experiences with OR participants from other sites in Kenya and the East African region in seminars and workshops. These forums enabled participants interact and get feedback from senior scientist from KEMRI and other project member countries.

The exposure enabled the site members to subsequently implement the study with confidence. There is Limited literature available in public health journals on the impact of OR studies implementation on participating health care personnel.

This journal has documented experiences, achievements, challenges and lessons learnt in the implementation of a Tuberculosis Operational Research MSCH project, satellite site. Events encountered in the study period by the laboratory and clinical personnel participating in OR studies are hereby presented as experiences.

While the benefits perceived to have been gained during the study period are documented as achievements. The obstacles that contributed in hindering smooth implementation of the studies are documented as challenges and the new knowledge and skills obtained during implementation of OR activities are the lessons learnt [24].

Objective

To document experiences, achievement, challenges and lessons learnt among health care personnel participating in implementation of TB Operational Research (OR) protocol at MSCH satellite site.

Methodology

TB OR activities in MSCH started in 2012 with the initiation of the study protocol. Followed by regular support supervision, scheduled monitoring and evaluation sessions that offered an opportunity to the participants to reflect on their experiences and review progress.

The MSCH OR team had opportunities to share their experiences with OR participants from other sites in Kenya and the East African region in seminars, workshops and conferences.

These forums enabled participants to interact and get feedback from senior scientist from KEMRI and other project member countries. This exposure enabled the site members to subsequently implement the study activities with confidence.

This was a descriptive qualitative study design with a purposive data collection method using an in-depth interview guide to capture demographic information, achievements, experiences and challenges of nine health care personnel who participated throughout in the TB OR study from 2013 to 2015. They were key informants in this study.

The health workers were clinicians and Laboratory personnel. The clinicians' roles in the OR TB study included consent taking and administration of the study questionnaire. They Performed clinical examinations of the respondents while recording of the clinical findings, referral of the participants to the laboratory, and clinical management of the participants in line with Division of Tuberculosis and Lung Disease (DTLD) guidelines.

The laboratory officers' roles included receiving participants referred by the clinicians, counseling them on sputum sample collection, receiving and logging in of the samples, processing the sputum samples in line with GeneXpert ,LED and ZN laboratory standard operating procedures (SOPs), recording of the sample results and shipment of samples to KEMRI for further analysis.

The health care personnel that participated in the study throughout the years 2013 to 2015 were included as respondents while those that did not participate at all or participated in the study and left were excluded as respondents.

During the participants' interview sessions, informed consent was obtained from every participant where confidentially was assured and maintained. The interviews lasted for an average of one hour and were conducted according to practice of qualitative data collecting methods [25]

The interviewer used an in-depth approach to guide the discussion and probe for clarification on emerging issues. Participants from clinical sections were asked to discuss their experience in recruitment of participants, administration of consent and questionnaire.

The laboratory personnel were further probed to discuss their experience in sample collection, reception, handling, processing and shipment, all participants were asked to share their future recommendations, what they liked most and list during the implementation of the study.

Two note takers oriented by the lead investigator on in-depth interview note taking, took notes simultaneously as the interviewer created and maintained an enabling environment for the participants to spontaneously respond to the questions and probes.

After the interview, the note takers and the interviewer shared the notes and performed data transcription using Microsoft Word. The emanating scripts were collated and open-coding was performed. The data obtained from the respondents was reduced, presented thematically and conclusion drawn from the auxiliary coding [26, 27]

Results.

Background Characteristics of The Participants

Nine participants were interviewed , of whom 2 were aged between 20 and 30 years. 3 were aged between 31 and 40. 3 were aged between 41 and 50 and 1 was aged above 51 years. Of the 9 participants, 3 were female and 6 male.

There were 4 diploma holders' Clinical Officers in the clinical sections, 3 degree holders, 1 diploma holder and 1 certificate holder in the laboratory section. Their years of work experience varied; 6 had 2 - 11 years, while 3 had more than 12 years.

Experiences

Supportive Experiences

The participants experienced research skills and knowledge growth through interaction with KEMRI senior scientists mentoring during the monitoring and evaluation visits. Exposure to OR methodology was quite educative, it improved confidence, knowledge and skills in implementing OR activities.

The participants noted that refresher training on sample collection to the laboratory workers was commendable. Five respondents concurred that

"It helped to minimize the issue of insufficient and poor quality samples. After the training, patients were given clear instructions on sputum collection at the Laboratory reception".

Reflecting on their experiences, most respondents anonymously agreed that OR study implementation had helped them in expanding knowledge and skills on quality diagnostics. They noted that in the laboratory, adequate amounts and quality samples were received. This achievedment was through team work between the laboratory and the clinical staff.

Both laboratory and clinical staff gained knowledge on OR implementation processes. Sample reception's (Log in at the lab reception), the respondents from the laboratory section exlpained that patients were guided samples received and examined for quality and quantity.

"New patients came with properly filled requisition forms with study barcodes as identifiers"

The respondents from the laboratory section also expresed that samples were transported in closed specimen holders, smears for ZN and LED-FM microscopy processed in Biosafety Cabinet (BSC) as well as the GeneXpert samples.

The respondents from the laboratory section also reported that, real time PCR GeneXpert equipment is a user friendly machine.

In post analytical experiences (Recording Reporting of results) respondents from the laboratory section reported that samples for shipment were held in the refrigerator at 40^{o}C for at least four days. While the results for the samples processed in the site's laboratory were recorded in the requisition forms and the specific register i.e. TB register.

The participants indicated that GeneXpert was the most user friendly followed by Led Emitting Diodes-Florescent Microscopy (LED-FM). The participating staffs were also able to gain more experience using the LED-FM microscopy which was user friendly and faster compared to Ziehl Neelsen (ZN) microscopy technique in the TB OR.

Participants shared that adherence to protocol for sorting out, routing, triaging coughers and effective referral to laboratory, assured collection of quality samples and achievement of high percentage of sample size.

On the administration of consent form they reported that most patients were willing to sign the consent form; however, one respondent noted that the form was detailed and took time to administer especially to those who could not read and write.

Discussing of their experiences on administration of the questionnaire the participants said it was fair but some respondents did not have phone numbers which posed a challenge.

Three clinicians noted that, patient's instruction for sputum collection was better done in the Laboratory where they received the sputum containers for ease of understanding instructions.

The Laboratory officers also reported that samples were transported in closed specimen holders, smears for ZN and LED-FM microscopy processed in BSC as well as the GeneXpert samples.

The respondents from the laboratory section also confirmed that the real time PCR GeneXpert equipment is a user friendly machine.

In post analytical experiences (Recording Reporting of results), respondents from the laboratory section confirmed samples for shipment were held in the refrigerator at 40^{o}C for at least four days, while the results for the samples processed in the site's laboratory were recorded in the requisition forms and the specific register i.e. TB register.

Most of the participants acknowledged that the questionnaire was instrumental in helping to trace respondents who did not bring the second sputum sample Most of them reported that the OR activities enlightened prospective researchers as more knowledge was acquired on patient triaging, processing of samples and triple packaging.

The participants explained that ;

"it was useful in bringing together
multi-disciplinary team members
to work together towards achieving
a common goal, in terms of patient triaging,
processing of samples,
packaging and shipping".

The participants shared experiences and lessons learnt has reminded us that, we have been sitting on a lot of data which we can use to analyze share and make policy.

The participants wished the support given to the data collector at the site should be reviewed, to enable motivation of staff on the ground.

"Boosting the morale and motivation
of the research assistants
collecting data
on the ground is crucial,
since it is that data collect,
which the PI will present
to change policy"
most of the participants expressed.

Challenging Experiences

Sharing their experiences, all clinicians interviewed concurred that recruitment of study participants was challenging at times because not all patients who met the study's inclusion criteria passed through the TB clinic where the enrolment took place.

Achievements

Key achievements reported by the respondents include;

(i). Most participants had an opportunity to attend to more than five refresher trainings.
(ii). All the nine participants reported to have participated in three mentorship sessions.
(iii). Six respondents who participated in three workshops observed that, knowledge gained in those sessions is tremendously non - comparable.

Among other achievements reported by the participants, was, the recruitment and effective laboratory referral of the study participants. MSCH laboratory, in the year 2013 to 2015. There were 11,595 patients whose samples were analyzed with LED-FM and ZN staining methods of which 918 were smear positive giving a positivity rate of 7.9%.

A Total of 1,352 patients were enrolled in the OR study between 2013 and 2015 of whom, 176 were TB positive. Giving a positivity rate of 13.0%. Out of the 1352 samples collected 1004 were shipped to KEMRI in Nairobi.

All patients were offered an equal opportunity to participate in the study. Despite available data showing that, 10,243 patients were not recruited into the study.

Participants reported that, the good study coordination strengthened the relationship between the laboratory staff and the clinicians. In addition to patient cooperation, it resulted in almost all patients who were offered the opportunity to participate in the study signing the consent form.

The also recommented MSCH satellite site as the best TB OR study patient recruitment site amongst other satellite sites since inception.

They suggested that, the achievements were possible through appropriate identification of the patients', collection of adequate samples, processing and shipping of the samples to KEMRI in accordance to the standard operating procedures (SOPs).

That resulted in more than 70% of the coughers being recruited into the study. This contributed to this site being ranked the best TB sample collecting site in the region. MSCH satellite site had a target of 1156 respondents, but recruited only 995 giving a performance of 86.1% as the affirmed participants.

The respondents also clarified that MSCH laboratory as one of the Satellite sites selected to participate in evaluation of the diagnostic tools benefited through acquiring a new GeneXpert and LED-FM microscope for the purpose of conducting the study.

They further noted that MSCH OR team has benefited through interacting with senior scientist,

during the regular monitoring and evaluation cum mentorship sessions, exchanging ideas with other study sites from other countries in workshops and seminars. This enabled the team to come up with new research concepts that are under development.

Challenges

The participants discussed the challenges they went through when implementing the study Participants concurred on challenges encountered during enrolment of study participants due to heavy workload involving routine and OR activities with inadequate personnel and minimal motivation.

Among the challenges, they reiterated, that some patients not passing through the TB clinic, others not bringing the second sputum sample and the questionnaire being out of stock, were among the major challenges experienced. However, two participants felt that the questionnaire was long while some patients were too sick to understand the instructions.

It was also reported that, it was not easy to demonstrate sample collection in the clinic since the sample collection falcon tubes are provided in the laboratory and the congestion nature of the clinic.

Moreover, the participants agreed that, it was not easy to monitor patients producing samples during sample collection due to lack of properly designated place for sputum sample collection.

The respondents from the laboratory section reported that, weekly laboratory staff rotation / turnover compromises quality and complicates the process of patient instruction. Secondly, with high workload and congestion, this necessitates close supervision and reorientation of staff from time to time.

Failure of identifying OR respondents at the reception resulted to lose of study subjects. Each time new staff was sent to reception was necessary to be oriented that was a challenge to the staff at the processing bench which led sometimes getting insufficient samples.

The respondents from the laboratory section also reported that, some patient were not able to follow instruction due to being very sick to comprehend or just being non-cooporative. The respondents reported that staff devoted themselves to the OR activities but there was no direct motivation to the staff to compensate on the extra work / over time utilized at bench work and sample shipment preparation was demoralizing.

"This seems like the researchers are more interested to get the data but less sensitive to the plight of those collecting the data on the ground" the participants reported.

Moreover, there were no regular results from KEMRI Laboratories to the satellite for comparison purpose as way of External Quality Assessment (EQA) as it was stated before the research began [28].

Other challenges experienced by the participants were heavy work load as one staff had to ran GeneXpert, perform cultures, and do sputum microscopy for both ZN and LED-FM. Equipment brakedown, where two modules were error prone >5% thus leading to being disabled.

The equipment has not been calibrated for >2years, while computer power supply was defective. Some patients were not able to bring two samples, some sample containers were not properly screwed of which some were leaking or were soiled.

Realized Value Of Participating In OR Study

From their experience all of the respondents said ,they would be interested to participate in another OR study because by doing so, they utilize the data generated in their place of work on daily basis to inform policy on health management in the country and in the region at large.

The innovative nature of OR necessitated the creation of a sputum reception window behind the laboratory that was instrumental in isolating coughers from other patients and quarantining TB samples.

This also improved specimen traceability from the main laboratory register to bench work sheet, TB register to monthly summaries. All coughers and OR respondents were properly identified and logged in, through proper patient counseling the number of insufficient samples reduced.

Lesson learnt

The participants recommended that, all coughers be referred to the TB clinic for clinical examination and be followed up to the Lab to make sure that they reach the Laboratory where they get supervised during coughing for quality sample collection.

They expressed that understanding of the consent forms by the patients helped in questionnaire administration and recruitment while the consent enabled patients to feel privileged and respected. Upon proper instruction to the patients' quality samples were obtained. OR study implementation was instrumental in improvement of quality diagnostic services in the laboratory. Hence, such should be performed regularly.

The participants also learnt that GeneXpert equipment is a powerful diagnostic tool for both Mycobacterium Tuberculosis (MTB) and Rifampicin resistance with proper use of SOPs, samples handling and analysis. With adequate supplies samples are analyzed and results released within turnaround time of 24 hours while with good documentation it is easy to calculate workload.

The strict adherence to standard operating procedures contributed to timely processing of specimen and patients getting their results within 24 hours.

The diagnostic tool GeneXpert made it possible to diagnose TB and Rifampicin resistance within 2 hours in HIV positive smear negative individuals. In comparison, it was noted that LED-FM microscopy was more user friendly than ZN, at the site.

Samples which could not be shipped on the collection day were stored in the refrigerator at 40ºC for 4 days. A designated isolated area where the samples were placed in a locked specimen holder as a Bio-Safety precaution during sample holding was identified.

Discussion

While implementing the study there were a number of issues that came into focus such as the gap on patient sample flow was noted that necessitated the creation of a special sputum sample window to streamline the sample processing system. This is in line with Naidoo *et al* who affirmed that operational research examines a system and agrees with [29].

The International Union Against TB and Lung Disease definition of OR

*"research into strategies, interventions, tools or knowledge that can enhance the quality, coverage, effectiveness or performance of the health system or program in which the research is being conduct"*3.

The shared experiences of the research participants

"the researchers were more interested to get the data but less sensitive to the plight of those collecting the data"

this is in agreement with *Creswell, et al* when he argued that researchers were always concerned with data ownership [30].

The minimal incentive to the data collectors was reported as challenge as *Naidoo et al* argues that appropriate external sources of support – financial, technical and research mentoring – must be in place at all stages of planning and implementation of the research [29].

The study being conducted within existing systems and not done in parallel, O.R. was viewed as a scientific approach to solving problems; in agreement with Rajgop that competent research officer worked alongside the research assistants during the training mentorship, and on-the-job supervision sessions [31].

The challenge of quality of sample necessitates the development of other studies to investigate at what extent the quality of sample affects the results. This is in agreement with Young-A Lee] that monitoring the results of implementing one set of research findings may lead to new research questions [32.

There was no direct motivation to the staff apart from facility support. This made them wish to see it done differently in future.

Conclusion

Implementing the OR TB study in Malindi Hospital was an informative experience to the participating health care personnel on appropriate use of existing TB diagnostic tools. Provision of human resource in OR studies is essential to address the challenge of high work load that would otherwise disrupt smooth implementation of OR activities.

Recommendation

Implementation of OR TB study require provision of trained human resource for its success.

KEMRI - OR team, Nairobi
OR Team - Malindi
Hospital administration- Malindi Sub-county Hospital.
G4S courier services - Malindi office
Kilifi County Government
ECSA

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