The Role of Monitoring and Evaluation in Assessing Progress of Operational Research in the EAPHLNP Study Sites in Kenya

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The East Africa Public Health Laboratory Networking Project (EAPHLNP) is a regional project involving five East African countries, Namely: Burundi, Kenya, Rwanda, Uganda and Tanzania and it is supported by the World Bank.

Summary

INTRODUCTION

Studies on performance of Operational Research (OR) projects have outlined the various enabling factors leading to favorable research outcomes. OR plays a key role in filling the gap between what we know from research and what we do with that knowledge. This has been expressed over time, based on monitoring (progress indicators) and evaluation (performance indicators) results.

OBJECTIVE

To document the performance of OR activities based on Monitoring and Evaluation (M&E) indicators as well as highlighting lessons learned.

METHODOLOGY

M&E framework was developed for the OR studies in three thematic areas; Tuberculosis (TB), malaria enterics as well as components of capacity strengthening and administrative. That was done by KEMRI OR Secretariat in consultation with the East Central Southern African – Health Community (ECSA-HC) Secretariat and the principal investigators of each thematic area from East Africa Community partner states (namely Burundi, Rwanda, Tanzania and Uganda). The framework included outcome indicators for each study, target values defined in accordance with approved protocols. Reporting interval was set at quarterly per year. TB studies had 8 reporting indicators, Enterics had 5 reporting indicators, malaria had 11 indicators, while administrative and capacity building had 15 reporting indicators. The framework was then adopted by the region. In Kenya, the initial roll-out of the research in all three thematic areas was done in February 2013. The first quarter of M&E was conducted in the study sites, as defined in the editorial of this journal, in June 2013 while the second "quarter" was carried out in June 2014.

FINDINGS

Between February 2013 and June 2014, there was little progress in all the three thematic areas. During the first evaluation, the number of enrolled respondents presumed to have TB at the satellite facilities were 185(6.2%) of the expected target number 3,000 persons. Non-satellite sites enrolled 124(8.2%) of the expected 1,520 persons presumed to have TB as well. In the second evaluation, enrollment at the satellite sites was at 13.3% compared to 1.2% in the non-satellite

sites. That represented a two-fold percentage increase in the satellite sites compared to non-satellite sites. Using ZN outcome indicator, there were differences in the number of actual TB cases detected in both sites compared with the target values. Number of TB – cases detected using ZN at satellite sites rose from 7.8% (target of 784 cases) to 11.0% (target of 1725 cases). In the non-satellite sites, there was a decline from 3.1% (target of 508 cases) to 1.1% (target of 1118 cases). In the Enteric Study, there was a marginal decline in the number of patients recruited from 21.6% (target of 1440 patients) as at the first evaluation to 17.2% (target of 1800 patients) in the second evaluation. For malaria study, a total of 333 patients had been enrolled against a targeted of 300 patients into the study representing an over enrollment of 111% from one site. For the administrative indicators, the OR Secretariat had over attained in three target areas namely publication and sharing of OR findings in country and regional bulletins and held OR-Technical working group meetings.

LESSONS LEARNT

Low performance in achieving indicators in both TB and enteric studies was resulted by including; high staff turnover particularly in the non-satellite sites, high workload and breakdown in communication among sites' personnel in regard to participation in research activities. In the satellite sites where study interventions were provided, better performance in achieving indicators was attributed to improved capacity in personnel and other non-financial motivational aspects, such as site exchange visits, refresher courses and frequent attendance of project workshops and meetings. Scientists from KEMRI assisting in patient recruitment, specimen collection and shipment alongside with study site staff resulted to over-attainment of performance indicators. Such was demonstrated in the malaria study. The observed lag time between the various M&E field visits by OR team could have partially contributed to the missed opportunities of identification and correction of any deviations from the project protocols. Changes in leadership especially at the project top management at the Ministry of Health affected the overall performance of OR activitie due to delays in disbursement of funds and delays in obtaining no-objection to incur expenditure on essential activities that were not originally in the approved annual workplans.

CONCLUSION AND RECOMMENDATION

It was established that several factors, some of which could have been augmented if the M&E exercise was conducted in accordance with the framework, affected the achievement of study indicators. M&E component is a crucial activity especially in tracking research progress and should be conducted consistently within the stipulated timeline. This will subsequently provide opportunities of early identification and correction of any deviations from the protocol.

Keywords: Operational Research, Monitoring & Evaluation, indicators, targets, performance, factors.

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Introduction

Operational research (OR) plays a key role in filling the gap between what we know from research and what we do with that knowledge i.e. implementation gap. Performance of operational research (OR) was expressed over time, based on monitoring (progress indicators) and evaluation (performance indicators) results with the ultimate relevance in improvement of outcome or influence policy change at the district, national or even international level [1]. In normal programme settings, the operational research team will mainly draw on data that are routinely collected [2]. The collection of routine data was sometimes regarded as a boring and onerous activity for programme staff. Luckly, in operational research that uses, analyses and feed back data to the programme, can provide a convincing alternative view [2].

Use of routine data in research also increases the reliability and accuracy of the information collected which in turn improves the validity of OR [1, 2]. In this article, we adopted the World Bank definition of project monitoring as the collection of data prior to and during the project [3].

The data, when analyzed, pinpoint progress or constraints as early as possible, allowed project managers to adjust project activities as needed. Monitoring also provided the basis for evaluation, which essentially involves two questions: has the project met its objectives and what accounts for its level of performance? Monitoring is a continuous assessment throughout the implementation period, whereas evaluation is periodic, including interim evaluation during implementation, terminal evaluation at the end of the project and impact evaluation some time after the completion of the project [3]. Monitoring and evaluation plans (M & E plan) were based on a suitable management information system.

Operational research (OR) was increasingly taking center stage in generating new knowledge on what works and how well it works. The outcome of the OR activities led to improved programme performance, feasibility assessment of new strategies or interventions as well as advocating for policy / guideline change [4].

In this article, we adopted the definition of OR by Zachariah et al.[5] as the search for knowledge on interventions, strategies, or tools that enhance the quality, effectiveness, or coverage of programmes in which the research is being done. Studies have indicated that for successful implementation of OR projects within organization, among other factors, there was need to establish "critical mass" of dedicated human resources, which should be accompanied by capacity building approaches that are practical output based and regular supervision by partners [6, 7].

Studies on the performance of OR projects had outlined the various enabling factors leading to favourable research outcomes. Key components included the scientific research questions which were generated from within a program context, carried out within existing systems and not done parallel, have competent research officers working alongside programme managers, training, mentorship and on-the-job supervision sustained over time among other factors [5, 8, 9].

That was a descriptive paper which documented the performance of OR activities based on M & E indicators as well as highlighting lessons learned.

Methodology

KEMRI OR Secretariat developed an M&E framework for the OR activities in partnership with the Eastern Central Southern Africa – Health Community (ECSA-HC). The framework was shared and adopted by principal investigators from collaborating partner states namely Republic of Burundi, Republic of Rwanda, Uganda and Tanzania.

The framework had four components, namely TB, malaria, Enterics and administrative. The outcome indicators were defined for each component in consultation with project PIs. The target values and quarterly reporting intervals were deliberated upon and agreed. TB study had 8 reporting indicators namely:

i) Number of TB suspects recruited at satellite facility

(ii) Number of TB suspects recruited at non-satellite facility

(iii) Number of TB cases detected using ZN diagnostic procedure

(iv) Number of TB cases detected using GeneXpert

(v) Number of TB cases detected using OSSMLED

(vi) number of TB cases detected using MGIT

(vii) Average turn-around time using all the study diagnostic tools from presentation of symptoms to initiation of treatment (days)

(viii) number of patients for intra & inter comparisons.

The enterics study had 5 reporting indicators namely:

(i) Number of stool specimens collected from patients presenting with acute diarrheal illness

(ii) Number of specimens identified with *E. coli* pathotypes / using PCR methods

(iii) number of specimens identified with *E. coli* pathotypes / using Vero toxin Assay methods

(iv) Number of bacterial enteric pathogens resistant to commonly used antibiotics at the sites/ using Kirby-Bauer disk diffusion method

(v) Number of specimens identified with bacterial

enteric pathogens / using biochemical media according to standard methods.

Malaria study had 11 reporting indicators namely :

(i) Number of outpatients enrolled at the site's facilities
(ii) Number of patients with absence of parasitaemia / using in vivo method
(iii) Number of patients with ETF using in vivo method
(iv) Number of patients with LTF / using in vivo method
(v) Number of patients cured in vivo method after PCR correction using CoArtem® or dihydroartemisin-piperaquine
(vi) Number of patients with adverse events
(vii Genotype in recurrent parasites i. PF MDR1 gene – 86, 1042, and 2
(viii) Genotype in recurrent parasites ii. PFCRT 76
(ix) Genotype in recurrent parasites
(x) Gametocyte carriage rates
(xi) Capacity Building.

The administrative aspects had 11 reporting indicators as shown in ***Table 4***.

The M&E reporting periods were set to commence with the rolling out of the research studies in the various sites. In Kenya, the first quarter of monitoring was conducted 5 months into the study (February to June 2013), while the second quarter was carried out after 16 months for the period July 2013 to June 2014.

During the supervision visits, the M & E team examined copies of the consent forms, patient questionnaires, and specimen request forms for assessing data completeness. Barcodes label sheet in the recruitment clinics and those from the laboratory were matched for consistency checking. The team held discussions with site teams to clarify issues. A feedback session to the hospital teams and administrators was conducted at the end of each supervision visit. Copies of minutes and activity reports were used to monitor the progress of OR secretariat who were the overall project administrative coordinators. After field visits, data collation was done in order to assess project progress and performance. The evaluation was done following the indicators outlined in the M & E framework.

Findings

During the period under review (between February 2013 and June 2014) TB study reported on 6 indicators out of a total of 8 indicators. Two indicators which involved combination of different TB detection diagnostic techniques could not be reported on since they were scheduled for year 3 and 4 of the research phase as they were overtaken by events. During the first evaluation, the number of persons presumed to have TB enrolled at the satellite facilities were 185. This was equivalent to 6.2% of the expected target number (3,000 persons). During the same period, non-satellite enrolled 124 persons presumed to have TB (8.2%) of the expected 1,520 suspects.

In the second evaluation, enrollment at the satellite sites was at 13.3% compared to 1.2% in the non-satellite sites. This represents a two-fold percentage increase in the enrolment in the satellite compared to non-satellite which reported nearly an eightfold percentage decline. Using ZN outcome indicators, there were differences in terms of diagnostic tool performance between satellite and non-satellite facilities. Number of TB cases detected positive using ZN outcome indicators at satellite sites rose from 7.8% (target of 784 cases) to 11.0% (target of 1725 cases). In the non-satellite facilities, there was a decline from 3.1% (target of 508 cases) to 1.1% (target of 1118 cases).

Inter and intra clinical comparisons by clinicians in the satellite facilities reported a threefold increase in terms of the number of forms filled for the comparison moving from 29.8% (target = 104 forms) to 73.4% (target of 168 forms) at 1st evaluation and the 2nd evaluation respectively. In the non-satellite facilities, there was a marginal decline of 3.6% from 11.5% (target of 104 forms) to 7.9% (target of 229 forms) during the same period. *Tables 1a,b* profile the progress of the TB study.

Enteric Study had a total of 5 indicators of which one indicator (number of specimens identified with *E. coli pathotypes* / using Vero toxin Assay methods) could not be reported on as the research was ongoing.

In terms of patient recruitment, there was a marginal decline in the number of patients enrolled from 21.6% (target of 1440 patients)as at the 1st evaluation to 17.2% (target of 1800 patients) in the 2nd evaluation. However, due to several interventions at some of

Table 1a and b: *TB study progress*

Indicators	Study site	Description	1st evaluation (February – June 2013)			2nd evaluation (July 2013 - May 2014)			Cumulative (February 2013 to May 2014)		
			Target	Actual	% Progress	Target	Actual	% Progress	Target	Actual	% Progress
1: Number of Persons presumed to have TB enrolled at satellite facility (number)			300	185	6.2	6600	879	13.3	9600	1064	11.1
2: Number of Persons presumed to have TB enrolled at non-satellite facility (number)			1520	124	8.2	5280	64	1.2	6800	188	2.8
3: Number of TB cases detected using ZN diagnostic procedure at the site (number)											
4: Number of TB cases detected (number)	Satellite sites	ZN procedure positive	784	61	7.8	1725	189	11.0	2509	250	10.0
		ZN (negative cases tested using **GeneXpert** procedure	1569	10	0.6	3432	43	1.3	5001	570	11.4
	Non-satellite sites	ZN procedure	508	16	3..1	1118	12	1.1	1626	28	1.7
5: Average turnaround time from presentation of symptoms to initiation of treatment (days)	Satellite sites	ZN procedure	4	3		4	3		4	3	
		GeneXpert procedure	15	5		15	5		15	5	
		OSSM procedure									
	Non-satellite sites	MGT procedure.									
		ZN procedure	4	3		4	3		4	3	
6: No. of patients (for intra & inter comparisons) – 50 patients per site per year	Satellite sites		104	31	29.8	229	168	73.4	333	199	59.8
	Non-satellite sites		104	12	11.5	229	18	7.9	333	30	9.0

Notes:* ***Monitoring (progress)=Actual/ Sample size *100%*

the study sites, the number of patients enrolled rose significantly from 309 to a cumulative of 685 patients (35.7%). Three types of bacterial enteric pathogens were identified using biochemical media according to standard methods namely *E.Coli, Shigella spp* and *Salmonella spp.* A total of five (5) *E. coli pathotypes* were identified using PCR methods. ***Table 2*** profiles the progress of the enteric study.

Table 2: *Progress of The Enteric Study*

Indicators		1st evaluation (February - June 2013)			2nd evaluation (July 2013 - May 2014)			Cumulative (February 2013 to May 2014)		
		Target	Actual	% Progress	Target	Actual	% Progress	Target	Actual	% Progress
EN#1: Number of stool specimens collected from patients presenting with acute diarrheal illness (i.e. number of patients) – in all the site		1440	311	21.6	1,800	309	17.2	1920	685	35.7
EN#2: Number of specimens identified with bacterial enteric pathogens / using biochemical media according to standard methods (cumulative number) – [Assume a prevalence rate at the rate of 50%].	***Pathogenic E.Coli***	250	0	0	420	55	13.1	420	55	13.1
	Shigella spp.	250	0	0	420	32	7.6	420	32	7.6
	Salmonella spp.	50	0	0	420	74	17.6	420	74	17.6
EN#3: Number of specimens identified with E. coli pathotypes/ using PCR methods(cumulative numbers) [Assumes aprevalence rate of 9% of the 17% of **EN#2** above]	**ETEC strain**	5	0	0	40	7	5.7	55	15	27.3
	EPEC	5	0	0	40	4	10.0	55	18	32.7
	EIEC strain	5	0	0	40	1	2.5	55	4	7.3
	E.agg	5	0	0	40	1	2.5	55	15	27.3
	STEC	5	0	0	40	0	0	55	3	5.5
EN#4: Number of bacterial enteric pathogens resistant to commonly used antibiotics at the sites/ using Kirby-Bauer disk diffusion method (numbers) [Assumes a prevalence rate of 11%]	***Pathogenic E.Coli***	15	0	0	55	49	89.1	55	49	89.1
	Shigella spp	10	0	0	32	5	14.3	32	5	14.3
	Salmonella	10	0	0	74	10	14%	74	10	14

***Notes:** Monitoring (progress)=Actual/ Sample size *100%*

Table 3: *Malaria Study Patient Recruitment Summary between February 2013 and May 2014*

Indicators	Target Value	Actual Values	Achievement (%)
1. Number of potential subjects requesting for malaria diagnostic services	-	1,616 participants	-
2. Number of screened patients testing positive for malaria parasites	300 patients	476 patients	158.7
3. Number of patients consented	300 patients	427 patients	142.3
4. Number of patients enrolled into the study	300 patients	333 patients	111.0

Malaria study was designed to match high prevalence seasonality data from the national malaria unit.

Malaria Study had 12 indicators

Only 4 indicators could be reported from the one in Msambweni study site since the study was on-going. A total of 333 patients had been enrolled against a targeted number of 300 patients into the study. That represented an over enrollment of 111%. ***Table 3*** summaries the performance of the Msambweni study site.

The OR Secretariat had 11 administrative indicators. From the results displayed in ***Table 4,*** the secretariat had over attained in three target areas namely publication and sharing of OR findings in the country and regional bulletin, short term training / skills development and holding of OR-Technical working group meetings.

Reasons for non-attainment in the three indicators was attributed to heavy workload by the OR secretariat, changes in the PCU priorities concerns, budgetary allocation and time constrains since there was a phased roll-out of research studies.

Table 4: *OR Secretariat Administrative Indicators Attainment Between February 2013 To May 2014*

Indicators	- June 2013)			- May 2014)- cumulative		
	Target	Actual	% Progress	Target	Actual	% Progress
1: Regional OR-TWG meetings (numbers)	3	1	33	3	4	133
2: In-country research protocol development workshops (numbers)	6	0	0	4	0	0
3: Secretariat progress / review meetings – regular meeting (numbers)	24	9	38	12	11	92
4: In-country OR-TWG meetings (numbers)	3	1	33	3	2	67
5: Training (short term capacity building / skill strengthening) for regional secretariat (numbers)	1	0	0	1	2	200
6: Operation Research (OR) trainings held for satellite laboratory managers / staff (numbers)	1	0	0	1	0	0
7: In-country research protocol approved	1	0	0	3	0	0
8: Operation research (OR) "off-shoot" proposals developed, approved and funded (number). At least one -proposal from each satellite site	0	0	0	5	4	80
9: Publication and sharing of OR findings in country and regional bulletin (numbers)	0	0	0	3	32	1067
10: Publications in peer reviewed Journals (numbers)	0	0	0	3	0	0
11: Participation in scientific conferences (number of conferences)	0	0	0	3	2	67

Discussion

Generally, there was little progress in all the three thematic areas. Overall, in both the TB and enteric studies, the desired target levels were not attained. The main reasons for the low performance were similar in both satellite and non-satellite sites for both enteric and TB studies. This was probably due to a combination of factors affecting progress such as high staff turnover, breakdown of communication between site personnel regarding research activities as well as changes in the overall project management were some of the common issues observed. The reasons for the low progress in the TB and Enterics studies are summarized in Box 1.

Box 1: *Reasons For The Low Progress in Both The TB and Enteric*

- Delay in the conceptualization of the research protocols by the site clinicians slowed recruitment.
- High staff turn-over in all the sites creating a challenge in continuity of the project in most of the sites.
- Breakdown in communication between the site personnel.
- Adult patients inability to produce stool specimens at the time of recruitment in the enteric study.
- Negative attitude by laboratory and clinicians towards the project.
- Changes in overall project logistic such as delay in supplies and disbursement of funds.
- Insufficient hospital administrative support in fast tracking research activities.
- Delay in rolling-out research in some sites.
- High workload at the clinical and laboratory settings within constrained staffing.
- Decentralization of TB treatment centres limited recruitment at the study sites.
- For enterics study, patients who were consented did not present at the laboratory to provide the specimens.
- Lack of staff motivation at the non-satellite sites resulted in low recruitment.

Malaria over-attained in the four indicators. This could be attributed to the fact that it was purely a clinical trial and Masambweni Sub-county Hospital is an established center for previous malaria studies. In addition, the presence of a research teams at the station throughout the study duration to supervise and mentor the site study team. In regard to the performance of the administrative component, the high attainment in most indicators was as a result of putting in place strategic actions such as guided presentations for the 4th KEMRI Annual Scientific & Health (KASH) Conference held in February 2014. A total of 32 publications were presented and published in the symposium book of abstracts and proceedings for wider circulation.

Lessons Learnt

There was more progress in terms of project performance indicators for TB and enterics studies in the satellite sites than non-satellite sites. This was as a result of more research activities that were on-going in satellite sites than non-satellite sites which acted as a motivation to the staff.

This aspect is consistent with various studies which argue that research should be carried out within existing systems and not done parallel or have competent research officers working alongside programme managers, training, mentorship and on-the-job supervision sustained over time among other factors [5, 8, 9].

Initially, the M & E field visits were staggered over a period of 4 months interval. However, only 2 visits were conducted instead of the anticipated 5 visits covering the 14 months time frame. The observed lag time between the various M & E field visits by OR Secretariat could have partially contributed to the missed preparation of scientific abstracts and opportunities of identification and correction of any deviations from the original project proposal. Levison and Madzorera [10] noted that the primary value of any monitoring in project management is an opportunity to address implementation problems as quickly as they arise.

Conclusions & Recommendation

Generally, it was established that several factors, some of which could have been augmented if the M&E exercise was conducted in accordance with the framework, affected the achievement of study indicators. M&E component is thus a critical activity especially in tracking research progress and should be conducted consistently and within the stipulated timeline. This will subsequently provide opportunities of early identification and correction of any deviations from the protocol. Consent and participation in the study.

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