LFA Training 2019/2020 – Health Product Management Case Studies

1. PUDRs for HIV, TB, and Malaria MoH grants of country X are due for submission in one month.
    a. What information would you request the PR to include with its submission to facilitate your review?
    b. Does this information differ depending on whether it is a PPM or non-PPM PR?
    c. Does this information differ depending on the type of portfolio it is i.e. High Impact, Core, or Focussed?

2. You have recently been appointed as the LFA PSM Expert for country Y where the LFA Team has been in-place for a number of years. There is no specific deliverable required at this time; however, the PUDRs will be submitted for LFA review in the coming 3 months.
    a. What strategies would you use to "get-to-know" the country and portfolio?
    b. What type of information would you prioritize, initially?
    c. Where can this information be sourced?

3. To add value to the CT, the Global Fund expects the LFA (PSM Specialist) to have:
    - A full understanding of the end-to-end HPM system, including stakeholders and partners;
    - The ability to diligently "zoom-in and zoom-out" the Global Fund investments within the country context;
    - A long-term HPM system strengthening mindset;
    - The ability to work with other LFA Team Members to analyze and link PSM information with financial and programmatic data; and
    - The insight to identify the root cause of a problem and propose practical solutions or risk-mitigation measures.

    a. What obstacles do you face in delivering on these expectations?
    b. What would need to change at the Global Fund or the LFA organization to enable you fulfilling these expectations?

1. Review of Malaria Quantification Report

The PR is requesting approval from the CT of the annual quantification for Malaria commodities report, and subsequent procurement. The CT has requested the LFA to review the quantification report and provide a recommendation(s). The request was forwarded from the Team Leader to the PSM Expert on 15 August 2019. The LFA team has been working on this portfolio for a number of years; however, the PSM Expert is relatively new to the team.

The quantification provides information on programmatic data and "consumption" data. The AMC data represents issues to health facility stores and is taken as an indirect measure of stock consumed.

The central level supply chain data shows:

Product	SoH 30.06.19	AMC	MoS	In-transit	MOS with transit	On order	Due date	MoS with order
Artemether + Lumefantrine - 20mg + 120mg (6x1) - Treatment	182,580	38,670	4.72	31,290	5.53	152,445	Sep 19	9.47
Artemether + Lumefantrine - 20mg + 120mg (6x2) - Treatment	8,460	43,170	0.20	155,640	3.80	168,945	Sep 19	7.72
Artemether + Lumefantrine - 20mg + 120mg (6x3) - Treatment	37,290	14,970	2.49	60,960	6.56	68,280	Sep 19	11.12
Artemether + Lumefantrine - 20mg + 120mg (6x4) - Treatment	369,270	305,490	1.21	1,048,740	4.64	1,566,840	Sep 19	9.77
Malaria Rapid Diagnostic – 25 Pack	108'467	27'303	3.97	111,812	8.07	64,795	Sep 19	10.44

The quantification results show a need of:

Item Description	Forecasted 2020	Forecasted 2021
Artemether + Lumefantrine - 20mg + 120mg (6x1) - Treatment	342,005	308,481
Artemether + Lumefantrine - 20mg + 120mg (6x2) - Treatment	387,861	349,842
Artemether + Lumefantrine - 20mg + 120mg (6x3) - Treatment	201,764	181,987
Artemether + Lumefantrine - 20mg + 120mg (6x4) - Treatment	2,889,657	2,606,407
Malaria Rapid Diagnostic – 25 Pack	310,140	324,930

Based on the current supply chain, the quantities of ACTs and mRDTs being requested for procurement are:

Product	Quantity	Delivery date
Artemether + lumefantrine (20 +120) mg 6X1 Treatment	363'180	Starting from Apr, 2020
Artemether + lumefantrine (20 +120) mg 6X2 Treatment	415'020	Starting from Apr, 2020
Artemether + lumefantrine (20 +120) mg Treatment	253'350	Starting from Apr, 2020
Artemether + lumefantrine (20 +120) mg Treatment	2'996'580	Starting from Apr, 2020
Malaria Rapid Diagnostic – 25 Pack	326'580	Starting from Apr, 2020

The central level minimum and maximum stock levels are 6- and 13-months, respectively. The procurement lead-times are 9-12 months from the time the Malaria Program sends the procurement request to the CMS. The PR is putting pressure on the CT to approve the quantities so that they can initiate the procurement process. The CT is under some pressure, internally, to improve grant absorption to avoid funds being decommitted through portfolio optimization.

The PUDR reporting for the past 6-month period indicates:

"M&E-1: Percentage of HMIS or other routine reporting units submitting timely reports according to national guidelines" was 74.6683%.

"CM-1a(M): Proportion of suspected malaria cases that receive a parasitological test at public sector health facilities" Non-cumulative 2'784'483/2'809'274 99.1175%

"CM-2a(M): Proportion of confirmed malaria cases that received first-line antimalarial treatment at public sector health facilities" Non-cumulative 638'852/638'852 100.00%

Part 1

a. How does this information provided in the quantification report guide your review?
b. What sources of information could you consider for triangulating this data?
c. Who are the key stakeholders linked to this activity?
d. What other questions can you ask to explore and unpack any underlying causes?
e. What is the short-, medium-, and long-term impact of this situation?
f. What are the possible underlying causes?
g. What are the possible solutions?
h. What would you consider as the recommended actions?

Part 2

The M&E/Programmatic Expert has reviewed the quantification report and provided the following "findings and recommendations" to you:

- The PR recognizes that the most recent programmatic data is of inadequate quality due to the recently rolled-out DHIS2 and, therefore, the TWG has used data from 3-years ago, which is considered – by the PR – as complete and reliable. The M&E Expert believes that data does not reflect the current malaria morbidity burden, especially in the context of increasing coverage of malaria interventions. ***"The LFA advises the PR to make forecasts for shorter time durations, such as one year instead of the suggested two years."***
- According to HMIS 2016 case report adjusted for underreporting, the proportion of *P. falciparum* and *P. vivax* is 77% and 23%, respectively. This assumption has not been triangulated with the 2015 Malaria Indicator Survey (MIS), which is a more robust data source, to give an indication of parasite prevalence. ***"The PR is advised to triangulate data sources which would improve the precision of estimates (e.g. the Malaria Indicator Survey to determine parasite prevalence)."***
- According to the quantification report, single dose Primaquine is recommended after AL treatment for P. falciparum. This assumption needs to be checked to ensure that it is in line with national guidelines. ***"The PR is advised to use assumptions that are based on the current national guidelines."***

a. How would you incorporate this feedback into your review?

2. PMTCT and EID

Access to HIV EID is critical to ensure early detection, treatment initiation, and survival of infected children. Childhood mortality of those infected with HIV in-utero is highest in the first 24-months. In addition, continued exposure during breastfeeding increases the risk of seroconversion.

According to Country X's recent PU, during the last 12-month period, 98% of pregnant women enrolled in antenatal care knew their HIV status and 97% received ART. Of the children exposed to HIV, 81% received a PCR test, but only 67% received a PCR test within 2 months of being born. Of those receiving a PCR test at < 2months, the positivity was 8% compared with 17% in those receiving a PCR test > 2 months and up to 18 months.

Despite improvements in access to early infant diagnosis and expansion of point-of-care PCR machines, coverage is still low at 66% (35% in 2013).

Overall, MTCT in 2018 is 14.97% in children under 1 year.

PART 1:

a. How does this information – found in the Programmatic Reporting sections of the PU – impact on the work that you do for the Procurement section of the PU?
b. What sources of information could you consider for triangulating this data?
c. Who are the key stakeholders linked to this activity?
d. What other questions can you ask to explore and unpack any underlying causes?
e. What is the short-, medium-, and long-term impact of this situation?
f. What are the possible underlying causes?
g. What are the possible solutions?
h. What would you consider as the recommended actions?

PART 2:

a. Discuss creative ways that can be used, for verifications, in the context where visibility on lower level data sources is limited or central level data (e.g. from CMS, laboratory services) is not being shared.

3. TB – up-dates to the WHO's TB diagnostic and treatment guidelines

TB funding represents approximately 16% of the total grant funding available to countries.

Diagnostics

Since 2013, countries have been implementing and scaling up the use of GeneXpert technology. Despite GeneXpert being more effective in detecting the MTB and quickly identifying Rif-resistance, its implementation has revealed challenges – machines and cartridges are more expensive than smear microscopy, the shelf-life of cartridges is relatively short, and poor sputum collection and preparation results in costly errors (e.g. requesting a new sputum sample and re-doing the test). To improve access to rapid detection, most countries have opted for decentralized access to the technology and, with weak laboratory capacity and limited funding, many machines are not receiving the routine calibration, maintenance, and module replacements necessary and monitoring of error rates is not occurring.

Treatment

Over the past 2 years WHO has proposed significant changes to treatment regimens, and countries are still in the process of implementing these. Significantly, Category II treatment has been discontinued, pediatric strengths have changed, and X/MDR-TB regimens "short-course" and "injection-free" have been recommended. In addition to medicines which need to be quarantined and properly disposed of, newer more expensive medicines have to be procured and in-country stocks established to maintain the supply chain. Both these "medicine-activities" have cost implications.

The TB program in Country Z is doing well with drug-sensitive TB detection, treatment, and completion, but struggles with detection, confirmation, and treatment initiation for drug resistant TB largely due to the sample transportation network and the capacity of the laboratory network for culture and DST.

The grant budget for health products and associated costs was 71% of the total budget ($42 million), at grant signing. There are no additional funds available for the TB program from the Global Fund, although the World Bank is financing TB in Country Z. The TB grant absorption is at 52.4% after 18-months of implementation; 43.5% of this is linked to health products.

The program has requested reprogramming to

- increase the budget for health products (up to 85%),
- increase the budgets for the TB prevalence survey (which is extended by 12-months) and the drug resistance survey (which is new),
- provide opportunities to staff to attend international TB conferences,
- implement meetings to monitor the implementation of PMDT – Programmatic Management Drug Resistant TB,
- update the curriculum for DR-TB trainings, including new drugs and short treatment regimens with appropriate DSM, and
- provide regional training on DR-TB (led by The Union)

Savings have been found from the following activities

- NTRL conduct on site supervision for microscopy and xpert network twice a year in each province – delays in implementing supervision visits
- DR-TB supervision visits to ensure that all presumptive DR-TB patients are tested using GeneXpert MTB/RIF – delays in implementing supervision visits
- Develop guiding documents for the Pharmaceutical Department: Manual to guarantee the quality of pharmaceutical products – this activity has been deprioritized
- National GxAlert Contract to host data, customize reports, license software, as well as modems and WIFI for 76 new GeneXpert machines – this activity has been deprioritized

The grant has completed 18-months of implementation and has 18-months to go. The CT has requested the LFA to review the reprogramming request and provide a recommendation.

a. How would you approach this request?
b. What sources of information would you consider?
c. Who are the key stakeholders linked to this activity?
d. What other questions can you ask to explore and unpack any underlying causes?
e. What is the short-, medium-, and long-term impact of this situation?
f. What are the possible underlying causes?
g. What are the possible solutions?
h. What would you consider as the recommended actions?

4. Sustainability, Transition, and Co-financing (STC)

In-line with the STC policy, country Q is increasing its investments in the HIV Program and has chosen to invest $10 million in health products - $5 million ARVs, $4million HIV RDTs, and $1 million Syphilis RDTs. The NDRA does not, yet, have the capacity to register and ensure the quality of products being supplied in the country. While there is a QC lab, it does not meet the Global Fund's QA Policy requirements. Funding under the grants is allocated to strengthening the NDRA's capacity for pharmacovigilance and post-marketing surveillance. USAID is also funding activities at the NDRA.

The CT has encouraged the MoH to procure the health products through PPM or, at a minimum, to procure products that comply with the Global Fund's QA Policy. The MoH has responded saying that:

- they cannot use PPM for any of the procurement due to the Procurement Law of country Q;
- a manufacturer that has ARVs which are prequalified is establishing a new production facility in country Q; and
- for ARVs, this will improve lead-times and remove the costs associated with shipping and importation and will also allow the CMS to out-source the stock-holding risks.

The MoH has requested that the Global Fund support them in obtaining the lowest possible prices in-line with what PPM achieves.

a. How should the CT respond?
b. What sources of information could the LFA and/or CT consult?
c. What should the CMS consider in making its final decision?
d. Can TGF positively influence this decision, process, and out-come in any way? If yes, how?

5. Condom review – prioritizing

The majority of HIV funding in Country Q goes to ARVs and RDTs. In-country partners fund and provide support for laboratory reagents and consumables, and condoms. The majority of condoms distribution occurs through reproductive health services; distribution through community projects and HIV services is limited. In the coming 12-months funding for condom procurement is decreasing as projects end. The PR is requesting approval to procure condoms with grant resources. The funds being request represent 3% of the budget for health products and associated PSM costs and 1% of the total budget.

The central medical stores (CMS) have storage and distribution capacity constraints. Condom shipments occupies a significant amount of storage space across the supply chain. Distribution from central and provincial levels is often deprioritized as they occupy most of the truck capacity, are considered non-essential, and compete for resources. Distribution of condoms for the HIV program occurs from CMS to the National AIDS Council (NAC) who are responsible for storage and on-ward distribution. Beside the storage and distribution challenges, very little is known about the PSM system for condoms used in HIV prevention programs.

The CT has requested the LFA to review the PR's request the procurement of condoms. The LFA workplan includes LoE for review of quantification and reprogramming but does not include any activities for Condom PSM as this was not foreseen. In addition, based on the current LFA activities, there is limited capacity to take on additional services.

a. What SoW would you cover in your review?
b. What would you exclude and why?
c. How would you balance materiality, LoE, and PSM risks?
d. How could you positively influence the programmatic impact of this intervention?

6. Power generators – for GeneXpert – comprehensive rather than for one technology
   The PR has identified savings in the TB grant and is requesting to use these savings to procure back-up generators for the HIV Load equipment in the central and regional laboratories as well as the POC VL equipment at district and facility level.

   a. According to the Global Fund's policies, is this allowed?
   b. What would you consider in reviewing this request?

1. The following recommendations are taken from recent LFA reports.
    - HIV testing targets are under-achieved for the past 2 reporting periods: “The PR should monitor the performance of implementers to improve testing in the coming 6 months”
    - GeneXpert machine utilization is low: “The PR should improve machine utilization and should strengthen supervision”
    - The LoHP is not aligned with the PF and the budget: “The PR should ensure that the grant documents are aligned”

    In-line with TGF approach to Risk and Assurance, what are the possible Issues, the Root Causes, and the Recommendation(s)?