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UN COMMISSION ON LIFE-SAVING
COMMODITIES WORKSHOPS:
ASSESSING PROGRESS AND IDENTIFYING GAPS
TO INCREASING ACCESS TO QUALITY-
ASSURED RMNCH MEDICINES
A MIXED-METHODS EXPLORATION

SEPTEMBER 2018

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ACRONYMS

CRP	Collaborative Registration Procedure
DHIS	District Health Information System
DR Congo	Democratic Republic of Congo
EAC	Eastern African Community
ECOWAS	Economic Community of West African States
EML	essential medicines list
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
IDI	In-depth interview
IPM	Informed Push Model
KEMSA	Kenya Medical Supplies Authority
LCS	life-saving commodity
LMIS	logistics management information system
LSC	life-saving commodity
MCH	maternal and child health
MgSO ₄	magnesium sulfate
MOH	Ministry of Health
MSD	Medical Stores Department
NGO	nongovernmental organization
NMRA	national medicines regulatory authority
ONPPC	Office Nationale des Produits Pharmaceutiques et Chimiques [Niger]
ORS	oral rehydration salts
PMS	post-marketing surveillance
PNA	Pharmacie Nationale d'Approvisionnement [Senegal]
PPH	postpartum hemorrhage
QA	quality assurance
RH	reproductive health
RMNCH	reproductive, maternal, newborn, and child health
SADC	South African Development Community

SRA	stringent regulatory authority
STG	standard treatment guideline
SWEDD	Sahel Women’s Empowerment and Demographic Dividend
UNCoLSC	United Nations Commission on Life-Saving Commodities for Women and Children
UNFPA	United Nations Population Fund
UNICEF	United Nations Children’s Fund
USAID	US Agency for International Development
WHO	World Health Organization
WHO CRP	WHO Collaborative Registration Procedure
WHO PQT	WHO Prequalification Team

EXECUTIVE SUMMARY

Introduction

The United Nations Commission on Life-Saving Commodities for Women and Children (UNCoLSC) released a report in 2012 identifying a list of 13 essential drugs and equipment commonly overlooked by program managers, decision makers, and funding agencies. The drugs, labeled *life-saving commodities* (LSCs), included 13 reproductive, maternal, newborn, and child health (RMNCH) commodities, and if more widely available and properly used, could save the lives of more than six million women and children.

In 2015–2016, the World Health Organization (WHO) organized two workshops, in Uganda and Tunisia, under the auspices of the UN Commission. The workshops convened representatives from national ministries of health, regulatory authorities, procurement agencies, central medical stores, international and bilateral partners, and nongovernmental organizations (NGOs) from 14 East and West African countries around the theme of optimizing procurement of quality-assured, affordable life-saving commodities.

Workshop Assessment

As a follow-up to the workshops, Concept Foundation was commissioned by the USAID Global Health Supply Chain Program–Procurement and Supply Management (GHSC-PSM) project to conduct an assessment aimed at deepening the understanding around the practical application of key learnings from the UNCoLSC workshops and the broader challenges that remain.

An assessment was conducted from November 2017 to March 2018 with respondents from Benin, Burkina Faso, Cameroon, DR Congo, Kenya, Malawi, Mali, Niger, Senegal, Tanzania, Tunisia, Uganda, Zambia, and Zimbabwe. The assessment explored the countries' status with regard to eight fundamental thematic areas discussed during the workshops: quality assurance (QA), selection, registration, quantification, procurement, storage and distribution, logistics management information system (LMIS), and regional collaboration.

While the original purpose of the study was to assess how the workshops supported countries toward achieving increased access to quality-assured LSCs, the gap in time between the workshops and the follow-up assessment impeded participant recall and resulted in a loss of participants due to changes in positions/organizations. Drawing clear associations between workshop participation and improved availability and access to LSCs would have required a more robust study design, including baseline and indicators to track and measure progress. However, study participants shared valuable data on the current situation of their respective countries with regard to ensuring access to quality LSCs, including progress made—whether attributed to the workshops or not—and remaining challenges faced. This report assesses, to a lesser extent, the effectiveness of the workshops from the perspective of the respondents, and to a greater extent, countries' status with regard to the eight thematic areas as reported by respondents.

Key Findings

Key findings from the assessment found the **workshops** were useful in supporting countries by providing platforms for experience and knowledge sharing and for regional collaboration strengthening. For future workshops, participants reported they would benefit from a follow-up mechanism.

Progress toward increasing access to quality-assured LSCs was demonstrated in relation to each of the eight

thematic areas explored. However, progress among and within countries was uneven and commodity-specific.

Quality was viewed by participants as being dynamic and dependent on key stages along the supply chain. Countries have adopted multiple strategies to ensure the quality of LSCs throughout the supply chain, but inadequate financial resources and lack of human capacity remain key barriers.

Most countries reported having at least 11 of 13 LSCs included in their **national essential medicines list (EML)**. Although **registered** contraceptive implants, emergency contraceptives, oxytocin, and misoprostol were more likely to be of assured quality compared with other LSCs (see Annexes E and F), inadequate regulatory capacity and funding are the main bottlenecks to testing and post-marketing surveillance (PMS), and contribute to widespread availability of counterfeit LSCs.

Countries reported progress toward strengthening **quantification and procurement** processes; however, data quality, elasticity, timeliness and completeness of information, frequently linked to LMIS and staff capacity, remain key challenges for most countries. Funding gaps severely impact procurement and the supply of quality LSCs. Insufficient funding is leading to the procurement of medicines from local supply channels that may not be of assured quality.

Much attention has been given to improving **storage and distribution** throughout the supply chain, as reflected in the number of initiatives implemented to strengthen these. However, quality of storage at and distribution to lower-level facilities remain inadequate in most countries, which contribute to stockouts and product degradation.

The majority (93 percent) of countries have an **LMIS** in place that captures data on LSCs. However, despite making some progress, not all countries include all 13 LSCs in their LMIS and only one-third introduced an LMIS at all levels of the public health sector. Only 20 percent of countries exclusively capture data electronically.

All countries providing feedback (12 of 14) reported that they were involved in **regional collaboration**, including information sharing, development of a common regulatory framework, and exchange visits.

Recommendations

Recommendations are proposed that highlight a bundle of interventions that focus on broader health system strengthening, increasing collaboration and leveraging country experiences, and continuous advocacy for the procurement of medicines that meet international standards to increase access to quality-assured LSCs. Recommendations pertain to the workshop and each of the eight thematic areas.

To track and measure progress, it is recommended to **conduct workshops with regular frequency** and establish follow-up mechanisms that enable countries to report systematically their progress and challenges.

The assessment further recommends supporting countries toward the **inclusion or expanded indication for all 13 LSCs in national EMLs** and/or the development of a separate list for medical devices according to recommended international standards, with particular consideration given to misoprostol for the treatment of postpartum hemorrhage (PPH) and chlorhexidine for umbilical cord care.

To increase the number of registered LSCs, it is recommended that **countries' regulatory capacity be strengthened** by providing technical support to national laboratories and funding toward earning WHO prequalification or ISO (International Organization for Standardization) certification. Focusing on the supply side, it is recommended to provide manufacturers of quality-assured LSCs with **technical support to**

register more products in more countries.

To improve quantification and supply planning, it is recommended to continue **knowledge transfer efforts and training on revised quantification tools** to strengthen forecasting activities. Additionally, capacity building activities and **training to health care workers on the proper use of LSCs** should be conducted according to standard treatment guidelines (STGs) and international recommendations for the 13 LSCs, with particular focus on misoprostol, magnesium sulfate, and chlorhexidine to ensure appropriate consumption.

Further progress is needed to ensure quality across the supply chain, starting with the **procurement of quality-assured medicines**. Therefore, it is recommended that when feasible, governments procure and donors require that funds are used to procure only RMNCH medicines of assured quality. Increased investments should be prioritized to **support manufacturers toward achieving WHO prequalification or approval by a stringent regulatory authority (SRA)** to increase the available supply of quality-assured LSCs.

Also recommended are increased investments to **improve storage at lower-level facilities** by building more storage warehouses to meet needs and ensure existing facilities are brought up to standards. Investments to support continuous **capacity building of staff** in managing storage and distribution activities should also be prioritized. Support is needed for ongoing initiatives that **advocate that quality oxytocin is kept in the cold chain** throughout the supply chain, including during storage and distribution.

To enable countries to move toward **implementation of an electronic LMIS** that includes all LSCs throughout all levels of the public health system, increased commitments are needed in addition to audits to support countries with the development of action plans to improve efficiencies.

Advocacy for increased **investments to support regional platforms** such as the East African Community (EAC), the South African Development Community (SADC), and Economic Community of West African States (ECOWAS) with training initiatives to support countries in achieving the same level of capacity in order to accelerate implementation of objectives is needed. Regional capacity **initiatives aimed at quality assurance and regulatory harmonization**, including widening the knowledge base, harmonizing registration of quality-assured LSCs, and enhancing laboratory capacity, should be strengthened.

Additional country-specific recommendations based on participant-reported progress and remaining bottlenecks are proposed in Annex G.

Introduction

In 2010, the UN Secretary General's Global Strategy for Women's and Children's Health drew attention to the major public health challenges facing women and children globally as a result of insufficient access and appropriate use of life-saving commodities.¹ The Global Strategy called on the international community to achieve Millennium Development Goals (MDGs) 4 and 5 to reduce child mortality and improve maternal health, which catalyzed the formation of the UN Commission on Life-Saving Commodities for Women's and Children (UNCoLSC).²

The commission was created to increase access to life-saving medicines and health supplies for the world's most vulnerable people. UNCoLSC identified essential drugs and equipment commonly overlooked by program managers, decision makers, and funding agencies. Those drugs were labeled *life-saving commodities*; the list includes 13 RMNCH commodities: female condoms, contraceptive implants, emergency contraception, oxytocin, misoprostol, magnesium sulfate, injectable antibiotics, antenatal corticosteroids, chlorhexidine, resuscitation devices, amoxicillin, oral rehydration salts (ORS), and zinc.³ Product profiles for each commodity are included in Annex A.

To contribute to optimal procurement of affordable and quality-assured life-saving commodities for maternal health, the World Health Organization (WHO) organized two workshops under the auspices of UNCoLSC. In collaboration with Concept Foundation, a workshop was held in Uganda in September 2015. A second workshop was held in Tunisia in July 2016, with Concept Foundation participation. Representatives from 14 East and West African countries—Benin, Burkina Faso, Cameroon, DR Congo, Kenya, Malawi, Mali, Niger, Senegal, Tanzania, Tunisia, Uganda, Zambia, and Zimbabwe—participated in the workshops. Participants were country-level program staff, implementers, and those who are involved in ensuring access to quality-assured, life-saving commodities.

As a follow-up to the workshops, Concept Foundation was commissioned by the USAID GHSC-PSM project to conduct an assessment aimed at deepening the understanding around the practical application of key learnings from the UNCoLSC workshops and the broader challenges that remain.

Although the original purpose of the study was to assess the impact of the workshops on the eight fundamental areas discussed during the workshops (quality assurance, selection, registration, quantification, procurement, storage and distribution, LMIS, and regional collaboration), limited information could be collected on how the workshops directly supported progress toward increased access to quality-assured LSCs. The gap in time between the workshops and the follow-up impeded participant recall and resulted in a loss of participants due to changes in positions/organizations. However, study respondents shared valuable data on the current situation of their respective countries with regard to ensuring access to quality LSCs, including progress made—whether attributed to the workshops or not—and remaining challenges faced.

¹ United Nations Secretary General Ban Ki-moon. 2010. *Global Strategy for Women's and Children's Health*. New York: United Nations.

² Ibid.

³ United Nations. 2012. *Every Woman Every Child: UN Commission on Life-saving Commodities for Women and Children: Commissioners' Report, September 2012*. New York: United Nations.

This report assesses, to a lesser extent, the effectiveness of the workshops from the perspective of the respondents, and to a greater extent, the improvements in ensuring the quality of LSCs in the supply chain made by the countries attending the workshops. For this assessment, workshop participants were invited to complete a questionnaire and participate in in-depth interviews to provide an update on their respective countries in eight thematic areas discussed during the workshops, related to quality of LSCs in the supply chain:

1. Quality assurance
2. Selection
3. Registration
4. Quantification
5. Procurement
6. Storage and distribution
7. LMIS
8. Regional collaboration

The report presents key findings supported by illustrative country experiences for each of the thematic areas. The assessment highlights the challenges remaining in countries and provides recommendations to address bottlenecks and build on reported progress in efforts toward an increased, sustainable supply and access to affordable LSCs of assured quality.

OVERVIEW OF WORKSHOPS

The World Health Organization (WHO) organized two workshops under the auspices of the UN Commission on Life-Saving Commodities for Women and Children. In collaboration with Concept Foundation, the first workshop took place in Uganda in September 2015, and the second was held in Tunisia in July 2016 with Concept Foundation participation.

The workshops brought together a total of 14 countries, which were represented by officials from ministries of health, regulatory authorities, procurement agencies, and central pharmacies and central medical stores, as well as international and bilateral partners, and nongovernmental organizations (NGOs) around the theme of optimizing procurement of quality-assured, affordable life-saving commodities. They allowed for experience sharing among countries and key RMNCH stakeholders.

Eight fundamental thematic areas were covered during the workshops—quality assurance, selection, registration, quantification, procurement, storage and distribution, LMIS, and regional collaboration. The first seven are major components of LSCs supply chain full spectrum and the eighth is supportive of countries' efforts toward ensuring access to quality LSCs.

The objectives of the workshops were to:

- Introduce the revised procurement and quantification tools for life-saving medicines
- Identify common experiences and opportunities to optimize procurement and access to the 13 LSCs with special focus on maternal and child health medicines
- Share experiences and opportunities to optimize quality assurance of UNCoLSC medicines and their supply.

The outputs of the workshops were recommendations for participating countries and the development of synergies to support implementation of prioritized strategic activities to improve access to RMNCH commodities.

BACKGROUND

ASSESSMENT OBJECTIVES AND METHODS

OBJECTIVES

This exploratory and effectiveness assessment was intended to assess and document the progress achieved and the broader challenges that remain to ensuring access to quality-assured UNCoLSC-identified medicines. The effectiveness of the workshops from the perspective of the participants was also assessed. The specific objectives of the assessment were to:

1. Assess the progress achieved toward implementation of strategic activities
2. Assess the broader challenges that remain and identify key areas for targeted support
3. Assess the relevance of the workshops in addressing the common challenges in ensuring access to the life-saving commodities
4. Document lessons for wider use

The assessment was conducted using a sequential explanatory mixed-methods approach. Quantitative data were gathered via an online questionnaire completed by participants. Preliminary analysis of the survey findings was used to develop a key informant interview guide to conduct qualitative in-depth interviews with key informants.

STUDY PARTICIPANTS

The study was undertaken with UNCoLSC workshops participants from 14 countries in the Africa region: Benin, Burkina Faso, Cameroon, DR Congo, Kenya, Malawi, Mali, Niger, Senegal, Tanzania, Tunisia, Uganda, Zambia, and Zimbabwe. Participants were country-level program staff, implementers, and those who are involved in ensuring access to quality-assured life-saving commodities.

All participants gave their written or verbal informed consent prior to participation in the assessment.

PERIOD OF THE ASSESSMENT

The study was conducted from November 2017 to March 2018.

ASSESSMENT DIMENSIONS

The assessment focused on seven dimensions (quality assurance, selection, registration, quantification, procurement, storage and distribution, LMIS) of the supply chain that are critical to ensuring access to the life-saving commodities, as well as on regional collaboration, which was integral to the collaborative structure of the workshops.

Dimension	Description
Quality assurance	A wide-ranging concept that includes all matters that influence the quality of a product. It is the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process from manufacture to delivery. (Quality-assured LSCs that were evaluated for this assessment include products that are prequalified ⁴ by WHO or approved by an SRA, ⁵ or recommended by the WHO Expert Review Panel).
Selection	A national essential medicines list helps guide government in selecting medicines to meet the public health needs of the population.
Registration	Process requiring examination of a product by a national medicines regulatory authority for pre-marketing authorization, market authorization, and post-marketing surveillance to ensure that product are safe and effective for procurement and use. Inclusion of a product in the list permits it to be sold and distributed within a country.
Quantification	Process of determining the cost and quantities required to meet the program or population needs and ensure their timely delivery.

⁴ WHO prequalification of medicines is a service provided by the WHO Prequalification Team (PQT) to assess the quality, safety, and efficacy of medicinal products. Pharmaceutical products found to meet the WHO-recommended quality standards are included in the list of medicines, as manufactured at the specified manufacturing sites, which are considered to be acceptable, in principle, for procurement by UN agencies. WHO prequalification currently covers medicines for treating HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, childhood diarrhea, influenza, and for reproductive health.

⁵ Medicines that have earned approval by a stringent regulatory authority are considered quality-assured. An SRA is a regulatory authority that is (a) a member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) prior to October 23, 2015, namely: the US Food and Drug Administration, the European Commission, and the Ministry of Health, Labor and Welfare of Japan (the last also represented by the country's Pharmaceuticals and Medical Devices Agency; or (b) an ICH observer prior to October 23, 2015, namely: the European Free Trade Association, as represented by Swiss-medic and Health Canada; or (c) a regulatory authority associated with an ICH member through a legally binding, mutual recognition agreement valid prior to October 23, 2015, namely: Australia, Iceland, Liechtenstein, and Norway.

Dimension	Description
Procurement	Involves purchasing medicines based on quantified requirements, using appropriate procurement methods and prequalifying suppliers and products.
Storage and distribution	<p>Storage focuses on ensuring products are stored properly according to international recommendations to ensure their quality.</p> <p>Distribution focuses on activities that ensure the quality and integrity of the commodity throughout the distribution channel.</p>
LMIS	Paper-based or computerized system that collects processes and reports supply chain data.
Regional collaboration	Cooperation among countries to solve common issues through information sharing and harmonized approaches.

The workshops were also assessed, as they provided platforms to support country progress with regard to the eight dimensions noted above. However, associating any direct linkages between the workshops and increased access to the 13 priority medicines of quality would have required a more robust design and resources.

SAMPLE SIZE AND SAMPLING STRATEGY

Country-level participants from the workshops were contacted and invited to participate in an online survey. A total of 85 participants were contacted by email and invited to complete the questionnaire. Thirty participants from all 14 countries responded.

Following preliminary analysis of the survey findings, participants were identified and contacted to participate in key informant interviews. Additional study participants were identified through a snowball sampling method. Eighteen respondents participated in in-depth interviews from 10 countries.

The list of participants that contributed to the assessment are included in Annex B.

DEVELOPMENT OF DATA COLLECTION TOOLS

Data collection tools used for the assessment were developed based on the objectives and reports from the workshops. Surveys were conducted through the SurveyMonkey online tool. The survey instrument was pilot-tested and minor adjustments were made before rollout to all participants. The finalized questionnaire is included as Annex C.

A key informant interview guide (Annex D), developed around the eight dimensions detailed above, was used as an organizing framework. The interview guide was developed based on initial preliminary analysis of the survey findings. The interview guide was adapted for each respondent according to their survey responses and functional role in terms of ensuring access to quality-assured LSCs. Key informant interviews were conducted face-to-face in participants' countries. Where this was not feasible, interviews were conducted by telephone.

DATA MANAGEMENT AND ANALYSIS

Quantitative data were examined using SPSS version 23 and Microsoft Excel. Data cleaning was performed prior to analysis. Data collected from francophone countries was translated into English. Descriptive statistics, including measures of central tendency, frequency, and variation, were performed to describe the distribution of study participants by different categories of responses.

Qualitative audio data files were transcribed verbatim into Microsoft Word files. Interviews conducted with participants from francophone countries were translated into English. Transcripts were reviewed, coded, and analyzed using Microsoft Word.

Themes were developed inductively and deductively. Text that identified specific ideas were coded; similar codes were clustered into categories; and categories were examined and grouped into themes. Themes were also developed based on survey findings and from the design of the interview guide as qualitative data were collected to supplement the quantitative findings. The parameters of inclusion were developed and refined along with the themes and category codes using a codebook through an iterative process of coding and analysis. Coded data were reviewed to ensure agreement and consistency among coders.

Results from the qualitative and quantitative data were examined in combination during the interpretation stage of the assessment. This provided richer insights and supported the understanding of the underlying factors affecting progress and barriers.

RESULTS AND DISCUSSION

Results from the assessment are presented as workshop findings (section A), and as countries' status on progress and challenges remaining (sections B to I).

Because direct links between participation in the workshops and progress achieved in recent years could not always be clearly drawn, sections B through I offer an update on the country status with regard to ensuring access to quality LSCs as reported by country-level respondents. The sections are presented using the workshops and thematic areas explored in the questionnaire as a guiding structure:

- A.** Key learnings and synergies developed as a result of the **workshops**
- B.** **Quality** related to the 13 life-saving commodities (LSCs) and quality assurance mechanisms
- C.** **Selection** and inclusion of the LSCs in national essential medicines lists
- D.** **Registration** and regulatory issues
- E.** **Quantification** and findings related to forecasting and supply planning
- F.** **Procurement** of quality-assured LSCs
- G.** **Storage and distribution** practices
- H.** **Logistics management information systems**
- I.** Initiatives for increased **regional collaboration**

Findings presented were reported by participants in surveys or in-depth interviews (external sources were introduced only for section D, *Registration*). Discrepancies between data sources were noted; information presented may not be a comprehensive view of the country situation.

A. WORKSHOPS

The workshops held in Uganda and Tunisia introduced the revised procurement and quantification tools for maternal health medicines and identified common experiences and opportunities to optimize procurement and quality assurance of the 13 LSCs and their supply.

Through the in-depth interviews, respondents shared what they found to be the most useful from the workshops and indicated whether key learnings were applied in any form in their respective countries to improve access to quality-assured LSCs. Overall, the workshops were considered by participants to be efficient tools to support better access to quality-assured LSCs.

ADVOCACY ON QUALITY

First, the workshops advocated effectively for the importance of purchasing quality-assured products and maintaining quality across the supply chain. Several respondents cited the focus on quality as part of the most useful aspects of the workshop. A respondent from Kenya cited learnings about harmonization on LSC specifications. Respondents from Zimbabwe and Tanzania noted the importance of procuring quality-assured products such as WHO-prequalified products, or at least products that were manufactured with minimum Good Manufacturing Practices (GMP) requirements. Participants from Zambia indicated that they had learned during the workshop that oxytocin was actually not stable and

that it had to be kept in the cold chain to maintain its quality. They reported this is now a requirement in their country.

ADVOCACY ON THE 13 LSCs

Second, by relaying the UNCoLSC's message on the importance of the 13 LSCs for the improvement of reproductive, maternal, newborn, and child health, the workshops promoted further use of those commodities in the participating countries. Recommendations were followed by countries, including Kenya, whose participants indicated that, following the workshop, they added chlorhexidine to the country's EML. A respondent from Tanzania indicated that after the workshop, they realized that they needed to understand why their country program had not been using chlorhexidine because the UNCoLSC included it as part of the 13 LSCs. Another respondent from Kenya indicated that the workshop enabled him to better understand misoprostol's indications and advantages.

"The most important change for me was the emphasis and demystification of the misoprostol and removal of my misperception and unnecessary fear. The fear was that the misoprostol was going to be used to manage pregnancies. For me, from the workshop, the advantages of misoprostol outweigh the potential risks."

— In-depth interview (IDI), Kenya

EXPERIENCE/KNOWLEDGE SHARING AND BENCHMARKING SUPPORTING HARMONIZATION OF BEST PRACTICES

Third, the workshops offered a platform for experience and knowledge sharing as well as benchmarking, from which participants indicated that they benefited. Through country presentations, they learned from more advanced countries and took away best practices. Mali participants, for example, indicated that they were inspired by Senegal's reach-the-last-mile experience presented during the workshop when setting up their own last-mile initiative. A respondent from Senegal reported that information and experiences shared during the workshop supported changes to their LMIS and enabled them to develop their country's action plan. Countries could measure their performance against each other and against global standards. They could evaluate areas where they were doing well and those that required further efforts.

"You see, you never know whether what you are doing is right or not until you hear it. So whatever structures and system we have in place (we learned) are appropriate and in line with global standards." — IDI, Kenya

In terms of knowledge gain, many countries cited the session on quantification, during which the RMNCH Quantification Supplement was presented and group exercises were conducted for participants to practice quantification methods. Respondents reported this as a key learning from the workshops and have applied or have continued to apply the methods in their countries, particularly Kenya and Zimbabwe.

"We got training with the quantification documents, which have been very useful in the selection of the different parameters that must be put first to make, for example, the calculations of the quantities to be ordered. [...] A very detailed training with basic documents that we never had the opportunity to access here [in our country]. [...] The documentation that we have received [was quite valuable]. It was less superficial because we worked, there were exercises, we did simulations before and after, and I find this useful."

— IDI, Senegal

Other areas of learning cited included logistics standards and strategies to ensure proper storage of commodities, particularly on those requiring cold chain, as well as supply sources for LSCs.

STRENGTHENING REGIONAL COLLABORATION AND IN-COUNTRY COOPERATION AND COMMITMENT

Fourth, respondents found that the workshops supported regional collaborations and in-country cooperation and commitment.

As reported by a respondent from Tanzania, through discussions shared during the workshop, countries realized that they had similar issues and that they could benefit from exchanging ideas on how make progress in those areas. A participant from Zambia noted, for example, that visits from Malawi have occurred since the workshops.

The workshops also had implications at the country level. They encouraged cooperation between stakeholders involved in access to LSCs as well as commitment from the governments. A respondent from Zimbabwe highlighted that the workshop strengthened partnerships and unity between the different members of her country's delegation as it enabled them to spend time together, and share ideas and experiences. This was echoed by a respondent from Tanzania, who declared that "the workshop was a teamwork. It was a team of government officials and donors. To feel that it is our responsibility to promote access to life-saving commodities. When we sat together, the government and our donors, we all perceived that these commodities are essential. We made a commitment...The workshop has sensitized governments and donors. They became committed."

OPPORTUNITIES FOR FUTURE WORKSHOPS

As above described, the workshops appeared to be valuable and led to positive changes. They were considered to be useful platforms to increasing knowledge and capacity on the different supply chain aspects of the life-saving commodities.

However, it was reported with regret that no system was implemented to enable countries to regularly report back on their progress and challenges after the workshops took place, and to track and support their efforts toward improving access to quality LSCs in a sustainable manner. Respondents indicated that they would benefit from participating in such events at the regional level on a regular basis. This would also support the establishment of a baseline to better measure progress and impact.

B. QUALITY ASSURANCE

Quality assurance throughout the supply chain is vital to ensuring that medicines are safe, efficacious, and meet the standards for proposed use. Quality assurance is wide ranging and incorporates various mechanisms across the spectrum of the supply chain to safeguard the quality of medicines, from manufacturing to registration, procurement, storage, transportation, and distribution, to reach the last mile. Maintaining quality for each of the 13 LSCs depends on product quality, QA approach, and special considerations to technical specifications relevant to the respective the commodity.

For this assessment, survey questions related to quality focused on strategies that have been adopted to optimize the quality of LSCs as well as participants' perceptions around the likelihood that quality-

assured⁶ products are procured and available in their respective countries.

Moreover, thematic areas (i.e., registration and QA mechanisms, procurement, storage and distribution) that served as the framework for the questionnaire and IDIs were explored through the lens of quality. To achieve this, the subject of quality was woven throughout the findings and discussed in relation to the spectrum of the supply chain, from production to the end user. *Quality* was a central theme throughout the assessment.

QUALITY: AN OVERARCHING THEME

Quality was found to be an overarching theme of the assessment and cross-cutting with other main themes. For example, respondents discussed quality of LSCs in various contexts by describing programs, national and donor policies, key stakeholders, and factors that affect access and quality of products. Mechanisms for ensuring quality assurance including product registration, testing, and post-marketing surveillance were discussed in relation to regulatory matters. Proper storage, distribution, and application according to standards were also explored extensively. These findings and links between quality and other thematic areas will be discussed further in subsequent sections of the assessment report.

PARTICIPANTS' PERCEPTIONS OF PROCURED/AVAILABLE QUALITY-ASSURED MEDICINES

The survey examined perceptions around procurement and availability of quality-assured RMNCH medicines. However, IDI discussions revealed varying levels of knowledge around QA mechanisms. Respondents discussed the value of WHO prequalification, but confusion existed about the therapeutic areas that are part of the WHO prequalification program, and which LSCs procured in their countries meet international quality standards.

Overall, the survey results showed that a high percentage of countries, ranging from approximately 60–90 percent across the 13 priority medicines, believe that medicines procured for their country are of assured quality most of the time (always/almost always). Contraceptive implants were the LSC most commonly perceived to be of assured quality. Regional variations demonstrated that francophone countries had a lower percentage of respondents who indicated that quality-assured resuscitation devices and misoprostol are procured. Among anglophone countries, a lower percentage of respondents indicated that quality-assured chlorhexidine, resuscitation devices, antenatal corticosteroids, misoprostol, and magnesium sulfate are procured always/almost always. Variations among survey respondents from the same country were also found.

STRATEGIES TO OPTIMIZE QUALITY

Examination of the strategies that have been implemented to ensure the quality of LSCs throughout the supply chain found that most countries surveyed (79 percent) are implementing a range of strategies. The strategy most frequently reported was registration, followed by capacity building on proper storage of products, increased post-marketing surveillance, ensuring service providers properly handle/transport supplies, and increased collaboration with stakeholders.

CHALLENGES REMAINING

All countries that participated in IDIs acknowledged that further improvements are needed to

⁶ *Quality assured* was defined in the questionnaire as products that have been WHO prequalified, SRA approved or are ERP recommended.

ensure quality across the supply chain. Adequate financial resources and human capacity to ensure a sustainable supply was the most persistent challenge that countries faced.

Other key challenges to quality assurance across the supply chain were mentioned by IDI respondents include poor-quality active pharmaceutical ingredients (APIs) directly impacting the quality of the finished pharmaceutical product, high temperatures affecting proper storage and distribution practices, and issues of counterfeit products entering and circulating in the market.

“In terms of provisions, all have been taken to ensure that health-related products for mothers’ and children’s health are quality products, which are indeed available to the population at all service delivery points. However, the process can be distorted at one level or another due to a lack of material, Financial, and human resources.” — IDI, Senegal

C. SELECTION

A national essential medicines list helps to guide governments to select medicines to meet the public health needs of the population. Medicines included in a national EML are those determined to be priority medicines, which should be accessible at all times in sufficient amounts. The selection of drugs for inclusion in the EML is a process that involves a team of experts, often including the ministry of health, regulatory officials, medical stores, and key stakeholders that review and create a list of critical medicines based on the disease situation, epidemiologic landscape, available data, and public health needs. For the assessment, inclusion of the 13 LSCs in national essential medicines lists and the broader implications to ensuring access to effective and good-quality medicines were examined.

NATIONAL EML STATUS OF LSCs AND PROGRESS TOWARD INCLUSION

Survey respondents from different organizations within the same country had diverse and sometimes limited knowledge about the EML status of the 13 LSCs. Therefore, information gathered from questionnaires was supplemented by IDIs. Still, gaps in information remained.

The workshops reinforced the need for certain medications to be listed in national EMLs. Several IDI participants indicated that revisions have been made in recent years. A respondent from Tanzania reported that the country revised its list in late 2017. The revision was guided by a number of references, including the 13 LSCs and other UN documents and WHO essential models. Kenya, according to a respondent, revised its EML to include chlorhexidine (EML indicates: chlorhexidine gel 4 percent as digluconate 7.1 percent). The respondent reported the indication for misoprostol was expanded to include use for management of PPH. The respondent noted that misoprostol was previously indicated only for treatment of gastric ulcers due to fears around misoprostol and off-label use for abortion. A respondent from Malawi noted that the country recently revised their EML in an effort to include some of the 13 priority drugs. The latest version (5th ed., 2015) includes the addition of chlorhexidine (EML indicates: 7.1 percent chlorhexidine digluconate to cord stump soon after cutting to prevent infection) and antenatal corticosteroids (dexamethasone). For amoxicillin, which was included in the previous EML, a respondent reported that Malawi supported the introduction of amoxicillin in dispersible tablet form for use in children. The respondent indicated that this update led to the addition of amoxicillin dispersible tablets in the national management protocol.

NATIONAL EML LINKED TO COMMODITY PRIORITIZATION AND PROCUREMENT

EML status was reported to be linked to procurement and accessibility of medicines. A participant from Senegal reported, “Its presence in the NEML makes the product essential and a matter of priority. It is compulsory to make [it] available in the country, in a quality generic form, at competitive prices.” A respondent from Tanzania reported that medicines are included in the national EML as a requirement for importation or inclusion under a program. In Kenya, a key informant reported that only LSCs included in the national EML are eligible for procurement.

Medicines included in EMLs may also be prioritized for monitoring of stock availability and quality control. IDIs showed that some countries, such as Mali and Uganda, have a list of “tracer” medicines. The LSCs that are included in the EML and classified as tracer medicines are monitored regularly and included in their logistics management information systems. Mali reported, “The 13 products, except medical devices, misoprostol, and emergency contraceptives, are part of the medicines that the Directorate of Pharmacy and Medicines includes as tracer medicines and that we evaluate, of which we follow the availability through our central purchasing body.”

D. REGISTRATION

Registration is a critical regulatory measure to ensuring quality assurance. Registration, managed by a national medicines regulatory authority (NMRA), is a process in which pharmaceutical products are examined against common standards for pre-marketing authorization, market authorization, and post-marketing surveillance to ensure that products are safe and effective for procurement and use. To better assess access to quality LSCs in the 14 countries, product registration was explored as a key theme during the survey and in-depth interviews. Survey questions focused on LSC product registration and procedures available for accelerated product registration. Through in-depth interviews, the topic of registration was explored further and broader discussions around regulatory issues emerged.

APPROACHES TO ASSESSMENT AND MARKET AUTHORIZATION

Different approaches to registration of LSCs were reported among respondents. Approximately one-third of countries reported in the questionnaire or IDI that a fast-track registration process is applied for LSCs or specific essential medicines. Respondents representing approximately 20 percent of countries (Senegal, Uganda, and Zimbabwe) reported that an abridged approach was applied for products that were SRA-approved or WHO-prequalified.

To avoid delays with procurement, a respondent from Niger reported that registration procedures for medicines in special cases of emergency are now accelerated. Similarly, Senegal is implementing an alternative approach to registration of RMNCH commodities to facilitate procurement and avoid long approval processes. A respondent reported that “many products that are today part of RMNCH program were released on the basis of authorization for temporary use...Why? Because as part of all that is required for the marketing authorization, these products would have been waiting some time, even if they would have complied with quality control, and this would delay the start of the program.”

According to WHO, 11 of the 14 countries (excluding Benin, Niger, and Tunisia) included in this assessment participate in the WHO Collaborative Registration Procedure (CRP).⁷ Although the

⁷ The WHO CRP is a procedure carried out between the WHO PQT and NMRAs to enable more efficient use of resources and accelerate the assessment and registration of WHO-prequalified finished pharmaceutical products. (See the WHO website at:

majority of countries included in the assessment participate in the WHO CRP, survey findings showed that only two countries, Malawi and Uganda, cited it among available fast-track procedures for registration of LSCs.

AVERAGE TIME TO APPROVAL

The estimated time for assessment and marketing authorization varies by regulatory authority. In Uganda, for example, a respondent reported that products are approved in fewer than 12 months on average, and this may be reduced by more than half for RH products. Zambia, as reported by a key informant, has made progress, reducing approval time from more than two years to seven and then nine months. For registration of qualifying LSCs through the WHO CRP in participating countries, the estimated time is fewer than 90 days according to WHO.

The validity period of a registration approval also varies among countries. Interview respondents stated that renewals are often required every four to five years but renewals in some countries are required more frequently. A key informant from Zimbabwe indicated that market authorization renewals are required every year as a revenue-generating mechanism and quality control measure.

LSC PRODUCT REGISTRATION

Surveys gathered information on LSC product registration; however, limited data were provided on product details such as manufacturer, brand, and specifications. Findings are available for 13 of the 14 countries (the exception is Niger), but data are limited for nearly one-half of the countries (Benin, Burkina Faso, DR Congo, Niger, Senegal, and Zimbabwe). Closer examination of some LSCs (i.e., chlorhexidine, amoxicillin, oxytocin, misoprostol, magnesium sulfate, contraceptive implants, and emergency contraceptives; lists of products are included in Annexes E and F) was conducted using registered product information from NMRA sites or shared by respondents. It should be noted that discrepancies between survey results and data sources exist, and dosage and indications for use were not always clear; therefore, information presented may not be a comprehensive or wholly representative view.

Overall, nearly all countries surveyed indicated that at least one product is registered for most of the commodities. The largest gaps in product registration were found for resuscitation devices and female condoms. However, in 29 percent of countries (Benin, Malawi, Niger, and Uganda), respondents made specific mention that medical devices are not required for registration by the NMRA. Moreover, countries may have a separate list for medical devices, but access to this information was limited.

Survey respondents from 11 countries reported that amoxicillin is registered. However, due to the multiple presentations available, amoxicillin in 250-mg dispersible tablet form, suitable for use in children, was registered in fewer than one-half of the countries, according to available published product information. Similarly, at least one respondent from 11 countries indicated that chlorhexidine is registered. But based on published registration lists and the WHO Model List of Essential Medicines for Children (EMLc) recommended presentation for umbilical cord care—7.1 percent chlorhexidine digluconate solution or gel, delivering 4 percent chlorhexidine—the percentage of countries with registered chlorhexidine has decreased to less than 30 percent. As discussed in the *Selection* section of this assessment, chlorhexidine was missing from some national EMLs, or the information included in national EMLs were not suitable for umbilical cord care. This is likely linked to the low number of product registrations found with the

appropriate formulation.

QUALITY OF REGISTERED PRODUCTS

Insufficient data were provided by the majority (63 percent) of survey respondents when asked about registered LSCs, brands, manufacturers, and presentations. Therefore, external registered product data shared by respondents or available from NMRA websites were examined. Data showed that among the 13 LSCs, RH and maternal health products—including contraceptive implants, emergency contraceptives, oxytocin, and misoprostol—had the highest number of registered brands of quality-assured LSCs (Annexes E and F). Limited quality-assured products are available for resuscitation devices, amoxicillin, ORS, zinc, or female condoms. These findings may be attributed in part to data limitations as well as certain LSCs not being eligible for WHO prequalification and/or no products with the recommended WHO presentation having been SRA-approved as shown in Table I. For example, neither amoxicillin 250-mg dispersible tablets nor ORS is not included in the WHO Prequalification Programme and none have been SRA approved (as of February 2018).

TABLE I. AVAILABILITY OF QUALITY-ASSURED LSCs

Both WHO-Prequalified and SRA-Approved*	WHO-Prequalified	SRA-Approved	Not Eligible for WHO Prequalification; None SRA-Approved*
Oxytocin	Zinc	Injectable antibiotics (gentamicin)	Amoxicillin
Misoprostol	**Female condoms	Chlorhexidine	ORS
MgSO ₄		Antenatal corticosteroids	
Contraceptive implants		Resuscitation devices	
Emergency contraception			

*Information based on: Concept Foundation. 2018. *Quality Assurance Manual for Procurement and Supply of Quality-Assured Maternal and Child Health Commodities*. Geneva: Concept Foundation.

** Eligible for prequalification program organized by the United Nations Population Fund (UNFPA) and WHO (not the WHO Prequalification Team).

Examining published registered product data (data unavailable from Niger), one-half of the countries (Benin, Kenya, Malawi, Tanzania, Uganda, Zambia, and Zimbabwe) have at least one and in some cases multiple quality-assured products—either SRA-approved or WHO-prequalified—registered for numerous LSCs. This may be linked to factors such as regulatory capacity, funding, donors, policies, and prioritization of quality-assured RMNCH medicines.

REGISTRATION OF LSCs: PROGRESS AND REMAINING CHALLENGES

IDI participants reported some but limited progress toward increasing the number of registered LSCs. A respondent from Tanzania indicated that the number of registered LSCs has increased. This includes registered amoxicillin and magnesium sulfate; however, examination of registered commodities in the country shows they may not be of assured quality.

Several countries noted a lack of change. In Kenya, an IDI participant attributed this to an existing number of quality LSCs that were already registered. On the other hand, in Senegal and Zambia, lack of

capacity, adherence to policies, and funding shortfalls for quality laboratories, testing, and basic reference standards were cited during interviews as contributing factors. In Malawi, a respondent cited a recent internal study conducted by the Ministry of Health (MOH) that found that 72 percent of products in the market were not registered. The respondent summed the findings as “registration appeared to be a major problem. These are public facilities...so you can imagine what is happening in the private sector.”

REGULATORY MATTERS: PROGRESS AND CHALLENGES REMAINING

Progress Achieved

As part of the survey and in-depth interviews, registration was discussed in the broader context of regulatory matters. Survey respondents reported quality assurance strategies that are being implemented to ensure the quality of LSCs. All countries surveyed indicated that they are registering products and most reported that they conduct audits for Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP), and have increased post-marketing surveillance activities.

Key informants shared additional areas where progress has been achieved in recent years and ongoing challenges. Since attending the workshop, a respondent from Uganda reported that several strides have been made toward strengthening their regulatory capacity: a common technical document has been implemented to help standardize and improve the quality of assessments; a fast-track process for registration has been adopted; the regulatory system has been strengthened as evidenced by WHO prequalification and ISO certification of the national laboratory; and additional funding has supported an increase in the number of assessors from five in 2016 to more than 20, which has improved efficiencies and processing time of applications. Mali has also strengthened its regulatory capacity, facilitating an increase in the number of product registration sessions from two to four per year. In Tanzania, the regulatory authority has implemented additional controls at ports of entry to enhance the surveillance system, leading to a decline in the number of substandard and counterfeit medicines in the market.

Challenges Remaining

Despite progress toward strengthening regulatory mechanisms, countries still face quality issues with products from unreliable sources of LSCs. A respondent from Kenya reported that “sometimes we get companies bringing in commodities. The sample which has been tested for the time of entry, at time of registration. What they’re bringing in, in subsequent batches, may not be as of good quality.” The Uganda respondent referenced a similar case, saying, “Manufacturers will give you good manufactured products for registration but you do not know if they maintain the quality throughout the chain.”

This may be related to survey findings that demonstrated that sample testing as part of pre-authorization and authorization are implemented in only one-half of the countries. Survey respondents from Zambia reported that testing is not being conducted. Discussion with a key informant from the country suggested that additional funding is needed for reference standards tests in order to conduct quality testing. Senegal cited a similar challenge: “Can the country afford three checks over a period of two to three years? That is the problem. It requires a lot of money. It’s why we have a problem of setting up quality controls. Reference substances, [which] are [the] products that we use to compare to products that are sent to us, are extremely expensive and we have a problem of implementation because the state budget is limited.” Testing may also vary across the LSCs, as reported by a respondent from Niger: “If we take misoprostol, oxytocin, amoxicillin, antibiotics such as gentamicin and corticosteroids, they are products that we regularly control in the context of reproductive health. But if you take chlorhexidine, zinc, implants, condoms, et cetera, their quality is not really monitored at the laboratory.”

Challenges around varying QA mechanisms and porous borders were discussed during interviews, in relation to product quality that may be affected by the proliferation of counterfeit medicines. For example, a respondent from Uganda reported challenges with counterfeit medicines, including a recent problem with condoms and emergency contraceptives. Counterfeit medicines, which are unregulated, enter through alternative channels, and are available through parallel supply chains, remain a significant and widespread challenge in Senegal and Niger as well.

“Counterfeit...products do not enter the country through the legal supply chain. It’s really about taking action because these are products that are out of control, that are not of quality, and unfortunately that are used on a large scale.”
— IDI, Senegal

Inadequate regulatory capacity and funding were cited as main barriers to ensuring the quality of commodities. While four of the 14 countries have WHO-prequalified quality control laboratories (QCLs), including Uganda, strengthened capacity and training for assessors is still needed. A respondent from Uganda indicated this will allow them to move away from reliance on WHO and SRAs for technical assistance. In Kenya, despite also having a WHO-prequalified QCL, a respondent indicated that support is needed to enhance the country’s capacity to conduct adequate PMS. The necessary equipment is available, but funding shortages result in outsourcing to an external laboratory for PMS sample testing. Respondents from Mali and Niger also cited a lack of capacity at the national health laboratories. In Mali, regional laboratories have been established in the country, but inefficiencies and the need for increased funding remain. A respondent from Niger stated that support for WHO prequalification or ISO certification of the national quality control laboratory would ensure that quality control practices meet international standards. A respondent from Tanzania stated, “Once the products are in the market, we need to evolve a system of monitoring and safety. We are doing our best to make sure products in the market meet standards, but we have limitations in terms of resources.”

E. QUANTIFICATION

Quantification is critical to maintaining an adequate, uninterrupted supply of the 13 life-saving commodities. It is a process that determines the costs and quantities of commodities required to meet the program or population needs and ensure their timely delivery.⁴ It involves multiple stakeholders, often led by the MOH in collaboration with medical stores, programs, donors, and implementing partners. Therefore, quantification depends on strong coordination among stakeholders as well as reliable data and skilled personnel to ensure proper supply and to avoid wastage.

Quantification was explored in the questionnaire to understand what national forecasting exercises are being performed in countries, the frequency and the type of data/tools used, and the remaining challenges faced. Qualitative interviews further examined the theme, providing additional insight on approaches and country capacity, and further discussion around challenges yet to be met.

NATIONAL FORECASTING FOR LSCs

The majority of the countries surveyed (79 percent) indicated that a national forecasting exercise is being conducted. This is being achieved with donor involvement tied to a specific program or commodity. The United Nations Children’s Fund (UNICEF), the United Nations Population Fund (UNFPA), USAID, the World Bank, and the UK Department for International Development (DFID) were among the donors cited by key informants as key stakeholders participating in technical teams for quantification and resource mobilization efforts.

Countries reported progress toward strengthening quantification and procurement processes. A respondent from Zimbabwe reported that the Ministry of Health has begun efforts to strengthen coordination to avoid past issues of overstock. The respondent detailed that coordination and a clear division of roles between the MOH/pharmacy supplies department and programs has eliminated the duplication of orders. A key informant from Tanzania reported notable progress toward improved accuracy of forecasting and supply planning: “the quantity available in the country is known for many months so we can establish the month of stock and...the planned procurement and shipment, and when they are arriving. We can space data and then you find there is no overstocking and there is good spacing in terms of arrival of goods.”

Respondents reported that national forecasting exercises are not being performed in Kenya, Niger, or Tunisia. Through qualitative discussions, respondents from Kenya and Niger reported that quantification is split by programs. In Niger, quantification is organized by each donor with its own respective logistics and supply chains. Consumption dynamics and stock challenges requiring action at various levels are difficult to accurately monitor. Encouragingly, however, the country informants stated that it is pursuing efforts funded by the World Bank to develop an implementation plan for a single, national quantification and supply chain. Kenya reported that previously the MOH quantified, procured, and distributed medicines but it has since decentralized the process so that counties are responsible for quantifying needs and procuring commodities with their own funds. The Kenya respondent also advised that quantification of LSCs differ by commodity. Certain maternal health commodities, such as oxytocin and magnesium sulfate, are quantified at the district level, whereas family planning commodities are quantified by a family planning (FP) task force, as FP is considered a more well-established structure at local levels. Similar to the findings reported earlier in this assessment in the *Selection and Registration* sections, medical devices and emergency contraceptives were excluded from quantification in some countries.

NATIONAL FORECASTING: FREQUENCY AND METHODS

The frequency at which exercises are performed varies by country, ranging from monthly to biennially; approximately one-third of countries surveyed responded that forecasting exercises are performed annually. However, forecasting may be product-specific. In Benin, for example, survey findings showed that only contraceptive products are forecasted annually. Survey respondents from DR Congo reported that forecasting for contraceptives is performed for less than one-half of the provincial divisions; moreover, quantification for all LSCs in the country are not done systematically.

Countries use a combination of methods to quantify needs. Consumption data constituted the method reported most frequently among survey respondents. Additional data sources used for forecasting include demographic, morbidity, distribution, and service data with consideration given to population growth, standard treatment guidelines, stock availability, and other assumptions. No information on methods was received from DR Congo, Niger, or Tunisia.

CHALLENGES REMAINING

Despite progress and improvements in quantification, countries still face a number of challenges. Data quality, elasticity, timeliness, and completeness of information remain key challenges for many of the countries. Survey findings from Benin indicated that one of its key challenges to increasing access to quality LSCs is the lack of consumption data for forecasting and supply planning exercises. A key informant from Niger indicated that peripheral structures are responsible for collecting and transmitting information to the central level; however, it is not done systematically, resulting in “a lot of data loss.” Uganda reported that the main challenge is the elasticity of information, resulting in

quantified estimates and commodities procured not aligning with consumption data. Unreliable and incomplete information was frequently reported in relation to a lack of skilled and motivated personnel, affecting the accuracy of forecasted data and leaving countries to adjust quantities based on less precise measures.

“Zimbabwe has four levels in the public health system... We don’t have adequate data from the secondary level to quantify needs... There is no real-time data for decision making, so we are relying on reports that come late. Last year... for oxytocin the figures that came out of the quantification were quite huge... These figures look[ed] very weird and we said we can just buy a little bit... and see if we face any shortages. There were no stockouts... but [what we stocked] was significantly fewer [units] than what was actually asked for.” — IDI, Zimbabwe

Data limitations were also directly linked with logistics information management systems. The extent to which an LMIS is implemented at various levels of the health system and its ability to capture accurate information to support quantification, planning, and procurement varied among countries. LMIS will be discussed in more detail in the LMIS section of this assessment report.

Cross-cutting issues of coordination and human capacity were challenges faced by several countries. In Niger, weak coordination was reportedly linked with the lack of a centralized coordinating body and lack of personnel. And while communication and coordination for forecasting have been strengthened in Zimbabwe, a key informant reported that training for health care workers was the responsibility of programs. The respondent referenced two separate cases involving different maternal health commodities and health care personnel who were not properly trained on STGs and the administration of medicines as recommended. Despite forecasting and supply planning exercises, the respondent reported that the lack of human resource capacity is resulting in overstock, wastage, and underuse of essential health commodities. Attrition in the country was also reported to be contributing to the loss of capacity and accuracy of the data being reported.

Inadequate capacity is also causing bottlenecks for maternal health commodities in Uganda and Zambia. In Zambia, a respondent suggested a need for training for nurses and midwives on proper administration of misoprostol and magnesium sulfate. Capacity building to provide health care workers with the correct tools and training to administer magnesium sulfate was also reported as a critical need in Uganda. A respondent from Uganda gave an example of Save Mother, Give Life, a program that has demonstrated the value of funding for both commodities and training initiatives to develop the necessary skills, and commented, “[It is] not only supporting doctors, but midwives, nurses, birth attendants, anesthetic officers, and the mortality rate went down.”

Sociocultural and religious barriers also affect forecasting and supply planning. Women and girls may be less likely to access services in the public sector due to stigma. During interviews, respondents from several countries reflected that certain commodities, such as female condoms and emergency contraceptives are “slow moving.”

F. PROCUREMENT

Quality assurance during procurement is vital to ensuring a safe and efficacious supply of RMNCH medicines. The survey examined approaches to quality assurance and strategies being adopted by countries to safeguard a quality supply of LSCs. Purchasing agents, procurement mechanisms, and the

role of quality in relation to price during procurement of the 13 LSCs were key areas assessed further during qualitative interviews.

APPROACH TO PROCUREMENT OF LSCs

The approach to procurement of LSCs to ensure quality varies among countries. The majority of countries surveyed indicated that they have established a single coordinating body for procurement of LSCs. As highlighted in the previous section *Registration*, Niger has initiated efforts to develop a national quantification and procurement monitoring system. Survey respondents from Kenya indicated the existence of a central coordinating body for procurement; however, during in-depth interviews, it was stated that counties are now responsible for quantification and procurement of commodities.

An IDI participant from Cameroon reflected on a multistep process that is undertaken involving the call for tenders, review of technical and financial dossiers, site visits to verify certification of manufacturing processes, and testing of samples by national or outsourced, certified quality control laboratories. Kenya reported a similar process: a call for bids with specifications for LSCs is launched and only LSCs included in the national EML are eligible for procurement; due diligence of suppliers is conducted; tests on pre-delivery samples are performed; and random batch sampling is conducted after a consignment is received.

Key informants advised that WHO-prequalified medicines may be considered for procurement and consumption without receiving registration approvals. UN agencies may receive an exception from the regulatory authority for registration for procurement of specific LSCs. For example, a Kenyan participant reported that products procured by UN agencies that are not included in the Kenya national EML may be waived for registration under certain circumstances such as the introduction of a new molecule, in the case of an emergency or commodity shortage, or if the product is donated for a specific period and not intended for widespread use. Respondents reported that UNICEF is supporting the procurement of products and receiving waivers for unregistered products in Malawi and Zimbabwe.

In Malawi, the supply of amoxicillin from UNICEF was reported to be the only source of the commodity in the country. However, it is not registered, as it was explained by the informant that product registration is the responsibility of the manufacturer rather than the procurement agent. IDI respondents stated that UNICEF is also procuring amoxicillin dispersible tablets as well as combination ORS and zinc in Zimbabwe through waivers from the Medicines Control Authority of Zimbabwe. Key informants reported that UNFPA is also awarded exceptions for commodities in some countries.

PRIORITIZATION: QUALITY VERSUS PRICE

Many IDI participants reported that countries prioritize quality over price to ensure products are safe and effective for use. For example, it was reported that during the procurement process in Cameroon, technical dossiers are first assessed. After the technical criteria is met, only then is price assessed and compared. A respondent from Uganda stated, “The cost of commodities could contribute to the quality of the product. But the primary thing is that we need quality commodities at whatever cost.”

During discussions on procurement, quality, and price, respondents from Uganda and Kenya reflected on the benefits of economies of scale. Uganda referenced an example of antiretrovirals, stating, “Some of the innovator products are very expensive at the beginning but when the number of the demand required increases, then the prices come down. We don’t believe in the cost determining the quality. We believe in the quality, because at the end of the day, we need to offer good services to the people.” Pooled procurement mechanisms may also have a role in increasing access to quality-assured

LSCs. This mechanism will be discussed in further depth in the *Regional Collaboration* section of this assessment report.

QUALITY LSCs AND THE ROLE OF DONORS

While regulatory mechanisms for quality assurance downstream are viewed among respondents as the responsibility of national medicines regulatory authorities, donors are perceived to have influence over the quality of the product upstream at the procurement level. Among the countries included in the assessment, multiple donors and stakeholders, including UNFPA, UNICEF, and USAID, are involved in the procurement and supply of the 13 priority medicines. Donors are often relied on to fill gaps and shortages in stock, and in some countries, they may be providing the only supply of medicines. The assessment found that—because different donors support various therapeutic areas—funding, procurement, and supply fluctuates across the LSCs.

Product quality was frequently discussed in the context of donor funding and prioritization of medicines. Countries reported procurement through donor channels as mechanisms to ensuring access to quality medicines. But while the supply of medicines procured by donors may often be of assured quality, donor procurement policies vary and do not always guarantee medicines of assured quality. For example, a respondent from Senegal reported that USAID funds have been used to procure products that may fail to meet proper specifications, and therefore, may not be of the same quality as those procured directly by the agency. Moreover, respondents pointed to the fact that commodities procured by donors through waiver mechanisms with the aim of accelerating access to LSCs may not be quality-assured.

“Sometimes there are no registered products and so where there are essential drugs that are needed, drugs are imported through a waiver mechanism. Registration is a voluntary process and certain manufacturers do not get their products registered. This forces us to use the waiver mechanism... Sometimes when these products are analyzed, quality issues can be found.” — IDI, Uganda

Dependency on donors affects the sustainability of the supply. A respondent from Zimbabwe reported that while support from UNFPA and UNICEF is continuing, commitments are decreasing placing additional strains on the country to meet its needs. A key informant shared that Tanzania faces a similar challenge, as most commodities are dependent upon partners. The country is seeking to address the problem by mobilizing government resources for procurement of LSCs. Donor dependency is also a challenge in Uganda, where “procurement of many of these commodities...are entirely relying on government partners.”

PROGRESS TOWARD OPTIMIZED PROCUREMENT

When examining recommendations for technical specifications that have been adopted to enhance procurement of quality-assured LSCs, only one-half of the countries surveyed replied but a varied range of responses were provided. A respondent from Uganda reported awareness of technical specifications for oxytocin and the requirement for cold chain. Survey findings from Zambia reported that the country procures only WHO-prequalified oxytocin. During an in-depth interview, a respondent from Tanzania stated that in addition to the supply purchased by donors, medical stores are now procuring WHO-prequalified LSCs. Cameroon reported they have strengthened their stock availability that includes magnesium sulfate for the prevention and treatment of pre-eclampsia/eclampsia.

CHALLENGES REMAINING

While many countries have a centralized procurement body and various measures are being implemented to improve access, countries still face supply challenges related to low awareness, inadequate funding, poor coordination, and multiple procurement channels for LSCs. Awareness around quality is impacting prioritization and procurement of quality-assured LSCs. A respondent from Tanzania stated that universities are training students *not* to invest in WHO-prequalified and SRA-approved medicines. Zimbabwe also raised the role for potential collaboration with academia to promote sustainability and knowledge transfer by training and building the capacity of the next generation of the workforce.

Insufficient funding was reported as a major challenge to increasing access and supply of quality-assured LSCs. A Zimbabwe informant reported that “I actually think access may have decreased because of the economic challenge and the decrease in funding.” Based on survey findings, funding is also a top need in Mali. Tanzania reported the existence of both an internal and external funding gap, impacting access and availability of LSCs. A respondent reported that in Cameroon, public health priority programs—HIV/AIDS, tuberculosis, and malaria—are processed for payment prior to other program areas in the country. Consequently, this has affected the supply planning and procurement of other essential commodities.

In Zambia, a key informant reported that poor coordination of multiple stakeholders has led to the overstock of condoms. Condoms are being purchased by USAID, MOH, and at the local level, all from different suppliers with different quality standards.

Local procurement of commodities in Kenya is leading to concerns over the quality of the medicines. An IDI respondent from the country reported that shortages of commodities in public health facilities are resulting in counties sourcing products from local, private pharmacies that may not be up to quality standards. The respondent reported that “[counties] may be buying counterfeit but without knowing because it’s cheap and they don’t have the capacity.” A key informant from Niger reported that the lack of resources and capacity of a national pharmaceutical purchasing body has caused state structures to purchase essential medicines from the private sector, where the quality of medicines may be substandard.

G. STORAGE AND DISTRIBUTION

Storage and distribution are important components of the supply chain, as products pass through these steps before being used in the service delivery points. Therefore, it is essential that they are managed in a way that ensures a product’s integrity until it reaches the final user.

Questions included in the survey and the interview guide related to storage and distribution aimed to determine if the 13 LSCs were stored and distributed in the countries in a way that ensures their quality, and to identify the strategies that were in place to maintain the products’ quality along the supply chain.

The rich feedback received on this subject indicates that these two areas are given much attention, both because efforts have been made to improve them and because important challenges are still being encountered.

NATIONAL BODY IN CHARGE OF PRODUCTS DISTRIBUTION TO THE PUBLIC HEALTH SECTOR

What first emerged from the responses received is that, in terms of process and organization, most countries tend to have a national body in charge of the distribution of medical products to the public health sector that will also, when possible, try to integrate products received from international partners in order to avoid multiple distribution systems. This is the case in Kenya, for example, where the Kenya Medical Supplies Authority (KEMSA) also distributes products imported by UNFPA, and in Zimbabwe, where NATPHARM (National Pharmaceutical Company) also distributes products coming from UNFPA and UNICEF. Those bodies are equipped with medical stores (usually at the central level and in regions and districts) for storage of products before delivering them to the service delivery points.

In terms of the distribution model applied, three countries (Kenya, Tanzania, and Zimbabwe) indicated that they had evolved toward a pull distribution system, in which the health care facilities order products according to their demand or consumption. In Tanzania, a push system is still in place but only for new commodities—and only for the first consignment of a new commodity. Kenya has a push system that applies only to commodities like family planning products procured by partners. In Zimbabwe, an “assisted pull” system is in place, in which “the facility staff are assisted in filling in the forms that will then trigger the order by a district pharmacist.” The other countries did not share this information.

STRATEGIES AND MEASURES IMPLEMENTED TO ENSURE QUALITY DURING STORAGE AND DISTRIBUTION

What also emerged from the responses received is that countries are aware of the impact storage and distribution have on the quality of the products and that these are integral parts of the quality assurance process.

“A quality-assured product for me is a product that is availed to the users after it has passed through the proper steps from production, its storage and distribution—all the different steps of getting the product has to be fulfilled.” — IDI, Malawi

Therefore, much effort has been made to strengthen those two areas. Each of the surveyed countries (except DR Congo, which provided no feedback on this subject) reported having implemented measures to enable appropriate storage and distribution of medical products, whether they had been set up before or after the workshop (it was not always clearly stated in the responses received). It is noted that international organizations are highly involved in the storage and distribution improvement process of some countries, such as WHO in Tunisia, UNICEF in Zimbabwe and Uganda, USAID in Cameroon, Gavi in Uganda, the Global Fund in Cameroon, Tanzania, and Zimbabwe, for example.

As for the areas targeted by those measures, they are varied. First, it was reported that much effort has been made to improve the cold chain during storage and distribution. For example, a respondent shared that in Tunisia, a project called OPTIMIZE was set up in 2000 by WHO to improve the cold chain for the products received at PCT (Tunisia's Central Pharmacy) from PCT throughout their distribution to the public health facilities. In Uganda, in order to maintain cold chain, products requiring refrigeration are reported to have been integrated into the vaccine supply chain and stored in the refrigerators for vaccines in instances when other refrigerators were unavailable or broken down. This was reported to function well and has not impacted the quality of vaccines. Moreover, four new cold chain delivery

trucks were provided by Gavi and the government. In Niger, participants indicated that cold chain is also ensured up to the district level and sometimes even to the peripheral centers thanks to the refrigerators set up by the vaccination project. Senegal and Zimbabwe respondents reported that the cold chain is monitored throughout distribution using data loggers. Senegal also set up a cold chain monitoring system at the service delivery points through temperature monitoring sheets.

Improvement of the storage space is a second area where several countries made progress. For example, a respondent from Cameroon reported that, with the support of partners such as the Global Fund and USAID, the country is opening an additional regional store, which will increase their storage capacity, tackling an area of major challenge in the country. In Zambia, challenges were reported with storage of condoms as they are received in very large quantities, but country respondents have reported that they now have stores in provinces where they are trying to relocate them in order to avoid storing all supplies at the central level.

Third, several countries reported that measures were implemented to improve the overall storage standards and transport means across the supply chain. For example, Mali built prefabricated warehouses complying with standards as part of the strategic plan of the central medical store. In Senegal, it was reported that significant efforts were made by the National Supply Pharmacy (PNA, the leading public distributor) to bring premises up to standards. In Zimbabwe, with the support of UNICEF, the National Medical Stores were provided with trucks, and storage conditions in a number of health facilities have reportedly improved.

Fourth, another quality assurance mechanism applied by many countries in order to ensure proper distribution of products is GDP audits. Such a mechanism was cited by 13 countries (all excluding DR Congo) in the survey as being a strategy implemented to ensure the quality of LSCs throughout the supply chain.

Fifth, two countries also mentioned the existence of initiatives aimed at improving distribution of the products to the last mile. The two respondents from Senegal referred to their last-mile projects, called “Yegesi naa” and “Yeksi naa,” and the respondent from Mali mentioned the country’s “reach the last mile” initiative that they implemented in two regions.

Finally, capacity building for staff on proper handling, storage, and transportation of products is also among the measures implemented in most countries. A respondent from Cameroon indicated that the “capacity of the staff handling this activity is a main challenge.” The country is currently being supported by the Global Fund in this area.

CHALLENGES REMAINING

Although numerous measures have been implemented and much progress has been made in terms of product storage and distribution, significant challenges remain and difficulties in securing funding was cited as a major barrier limiting progress. Two countries, Uganda and Zimbabwe even cited inadequate storage and/or distribution as being one of three main challenges that remain and that limits access to quality-assured LSCs.

A major remaining issue impairing optimal storage and distribution of LSCs in most of the surveyed countries is the lack of homogeneity of storage and distribution quality throughout the country. Respondents from different countries reported discrepancies between the quality of storage at and distribution from the national distribution and storage entities (mainly at the central level), where it seems to be satisfactory, and at lower levels (especially at the facility level), where it is not fully

adequate. This is the case in Malawi; a respondent indicated that the distribution and storage from the national to the district level are good but that below the district level quality varies. In Niger, storage is reportedly better managed at the level of the central purchasing body (the National Office of Pharmaceuticals and Chemicals [ONPPC]) rather than at the lower levels, in peripheral structures. A respondent from this country shared that in 2018, an assessment conducted by the government to evaluate the storage capacity of the health care structures across their districts revealed that more than 90 percent of them did not comply with storage standards. They lack, for example, ventilation or air-conditioning systems, and storage rooms are sometimes simple office rooms, not fit for purpose. Moreover, in Niger, it was reported that the product transportation system in place between the health districts and lower levels, which requires lower-level facilities to pick their product stock directly from the district distributor level, is not optimal and creates issues such as stockouts. A Senegal respondent indicated that the cold chain was ensured at the level of the PNA and PRAs (regional respondents of PNA), but not fully ensured at the service delivery points, where the premises for storage were not satisfactory. A respondent from Zimbabwe reported that the storage capacity at the facility level was not sufficient.

“It is a product [oxytocin] that must be transported under certain conditions. The problem is at the local level. If it comes to the service delivery point, under what conditions will they keep [it]? If they don’t all have UNICEF’s cool boxes? If they have a refrigerator like we find in every house where you keep milk and stuff, can it also [be used to] keep oxytocin? Because we are part of the integrated logistics supervision, when we go to certain areas, it is not satisfactory in terms of storage. The implementation of the oxytocin program has suffered much more in terms of storage at the service delivery points level than in the cold chain that is provided from its arrival at the airport to the distribution in the service delivery points.” — IDI, Senegal

Tanzania is reportedly affected by similar issues. The central level (Medical Stores Department [MSD]) seems to be well equipped, whereas facilities, especially in rural areas, sometimes lack adequate storage equipment such as refrigeration systems or even electricity. A Kenya respondent mentioned that in certain parts of the country, the cold chain was not easy to maintain, and the capacity of the warehouses was low.

Secondly, some challenges at the central level were also reported to persist in Niger and Cameroon. A respondent from Niger mentioned that ONPPC was facing human resource issues, as well as managerial challenges and logistics weaknesses (lacking transport equipment within the store, for example); a respondent from Cameroon indicated that the storage space at the central level was insufficient.

Finally, confusion on the oxytocin storage requirements remains. Respondents from two countries (Cameroon and Kenya) indicated that in order to remedy the cold chain issues they face, they were procuring oxytocin products that were stable in ambient conditions and therefore would not require refrigeration, despite WHO’s recommendation always to store oxytocin between 2 and 8°C.

H. LOGISTICS MANAGEMENT INFORMATION SYSTEMS

Logistics management information systems (LMISs) are essential tools for ensuring uninterrupted supply of commodities as the data they capture on product consumption informs proper quantification and procurement as well as supports appropriate stock management.

The aim of the questions included in the survey and the interview guide related to LMIS was to determine if the countries all had a LMIS, its type (paper-based or electronic), the number of LSCs included, and where it was implemented, as well as to highlight any specific initiatives implemented to

improve LMIS and identify any remaining challenges.

CURRENT STATUS OF THE COUNTRIES WITH REGARD TO THEIR LMIS

Information shared by the respondents is summarized in Table 2. It was difficult to obtain a clear picture for some countries, as interviewees' reports were sometimes conflicting. Overall, however, what emerged from the responses received, is that all countries (except DR Congo, which did not provide feedback on this subject) seem to have a LMIS that captures data on LSCs.

However, only five countries (36 percent) reported that they included all the LSCs in their LMIS, while the other countries' LMIS include only some of the LSCs. Contraceptives are most commonly included, and resuscitation devices, chlorhexidine, and misoprostol are the commodities most frequently cited as being omitted. In Mali, the reason given for not including misoprostol in the LMIS was the fact that this product is not part of the supply program for the public health sector (misoprostol is only available in the private market). As for chlorhexidine in Tanzania, a respondent from this country indicated that the commodity is absent from the LMIS as it is not used in their program.

Table 2. Data Collected on LMIS, by Country

Country	Existence of LMIS/Data Captured in LMIS	LSCs Included	LMIS Type (Paper-Based and/or Electronic)	Inclusion at All Levels of the Public Health System	Electronic Tool Name Cited by Respondents	Date LMIS Created
Benin	Yes*	Oxytocin, magnesium sulfate, contraceptive products (female condoms, contraceptive implants, emergency contraception), ORS	Both paper-based and electronic†	Yes/no‡	DHIS2	
Burkina Faso	Yes	Contraceptives, oxytocin	Both paper-based and electronic	Yes		
Cameroon	Yes	All	Both paper-based and electronic§	Yes/no**		2015/2016
DR Congo	No information provided on LMIS					
Kenya	Yes	All commodities except misoprostol, devices and chlorhexidine††	Both paper-based and electronic	Yes/no5‡‡	ERPS§§ used by KEMSA departments, DHIS2*** used by counties, districts and a few hospitals	
Malawi	Yes	All	Both paper-based and electronic†††	Yes	SEE-Stock	

* Conflicting information received: Two survey respondents from Benin indicated the existence of an LMIS capturing data on LSCs, whereas a third respondent mentioned that there was none. However, as the first two then described the LSCs included in the LMIS, their responses were taken into account; they were thought to more knowledgeable on this subject than the third respondent.

† Conflicting information received: One respondent from Benin indicated that the LMIS was electronic while the second person mentioned it was both paper-based and electronic, adding that the health workers filled in the paper-based LMIS, and that data were then entered in an Excel file and exported to DHIS2.

‡ Conflicting information received: One respondent from Benin responded that the LMIS had been introduced at all levels of the public system, but a second respondent said the contrary.

§ Conflicting information received: One respondent from Cameroon indicated that the LMIS was electronic, but the second person described it as both paper-based and electronic.

** Conflicting information received: One respondent from Cameroon responded that the LMIS had been introduced at all levels of the public systems, but a second person said the contrary.

†† Conflicting information received: Three respondents from Kenya provided divergent information. One indicated that the LMIS included all LSCs; a second said that it comprised only contraceptives and a third stated that it included all commodities except misoprostol, resuscitation devices, and chlorhexidine.

‡‡ Conflicting information received: Two respondents from Kenya advised that the LMIS had been introduced at all levels of the public health system, but a third reported to the contrary.

§§ ERPS stands for Enterprise Resource Planning System.

*** DHIS2 stands for District Health Information System 2.

††† Conflicting information received: One respondent from Malawi indicated that the LMIS was paper-based; two described it as both paper-based and electronic.

Country	Existence of LMIS/ Data Captured in LMIS	LSCs Included	LMIS Type (Paper-Based and/or Electronic)	Inclusion at All Levels of the Public Health System	Electronic Tool Name Cited by Respondents	Date LMIS Created
Mali	Yes	Contraceptives excluding emergency contraception, life-saving maternal and child health tracer products (excluding misoprostol)	Both paper-based and electronic	No (everywhere except in the north)		1995 with tools review in 2006
Niger	Yes	Oxytocin, misoprostol, injectable antibiotics (gentamicin), antenatal corticosteroids, resuscitation devices, amoxicillin, contraceptive implants	Both paper-based and electronic*	No	Channel 1, Channel 2	
Senegal	Yes	All	Paper-based	Yes [†]	DHIS2 being tested	
Tanzania	Yes	All except chlorhexidine [‡]	Both paper-based and electronic [§]	Yes/no ^{**}	ILS Gateway ^{††} , DHIS2	Electronic LMIS launched in 2013
Tunisia	Yes	All	Electronic	No		
Uganda	Yes	All except resuscitation devices	Electronic	No	DHIS2	
Zambia	Yes	No information provided	Electronic	Yes		
Zimbabwe	Yes	All	Both paper-based and electronic	Yes ^{‡‡}	Auto-DRV ^{§§}	

* A respondent from Niger indicated that the information is collected on paper up to the district level.

[†] Although a respondent indicated that the LMIS was introduced at all levels of the public health care system, a second confided that getting consumption data from the facilities was challenging.

[‡] Conflicting information received: The two survey respondents from Tanzania provided slightly different information; one indicated that all the LSCs were included in the LMIS while the second excluded chlorhexidine.

[§] A respondent from Tanzania indicated that the paper-based system is used by facilities that lack electricity (mainly in rural areas). As for those that have electricity, computers, and wi-fi, the staff enter the data through computers and the electronic forms.

^{**} Conflicting information received: One respondent from Tanzania responded that the LMIS had been introduced at all levels of the public system; a second reported to the contrary.

^{††} ILS stands for Integrated Logistics System.

^{‡‡} Although the LMIS was reported to be included at all levels of the public health system, it was mentioned that a robust LMIS was existent mainly at the primary health care level and at the national drug supplier level but that the system was not as effective at the secondary, tertiary, and quaternary levels.

^{§§} DRV stands for Delivery Receipt Voucher.

With regard to method of data capture, most countries (64 percent) reported both electronic and paper-based. Tunisia, Uganda, and Zambia capture data only electronically whereas Senegal reported exclusively collecting data on paper.

Regarding whether or not the LMIS has been implemented at all levels of the public health system, the responses are divided. Only five countries said yes (Burkina Faso, Malawi, Senegal, Zambia, Zimbabwe). Four countries said no (Mali, Niger, Tunisia, Uganda). As for the other countries, the different respondents provided conflicting information. Through the IDIs, some countries indicated the levels where the LMIS was missing or deficient. Mali reported, for example, that the LMIS was introduced at all levels of the public health system everywhere in the country except in the north, due to the ongoing crisis. In Senegal, although it was reported that the LMIS was introduced at all levels of the public health care system, a respondent confided that getting consumption data from the health centers can sometimes be challenging. In Zimbabwe, NATPHARM (National Pharmaceutical Company, the national drug supplier) and the primary health care level seem to have a robust LMIS, whereas the system is not as efficient at the secondary, tertiary, and quaternary levels.

SPECIFIC INITIATIVES IMPLEMENTED TO IMPROVE LMIS

A few countries specified initiatives implemented to improve their LMIS. In Senegal, for example, the USAID-funded program Informed Push Model (IPM) has been running for the last four years. As explained by a Senegal respondent, IPM project's aim is to distribute products (including LSCs) and provide feedback on the real consumption data coming from the facilities they serve. This program is very successful in providing the reliable consumption data that was missing from the health facilities before its implementation. The project will end in June, and collaboration between IPM and PNA is in progress to ensure continuity. In Tanzania, the electronic LMIS was launched in 2013 and since then has been rolled out gradually across the country. In 2017, hospitals were included in the LMIS, so their data on consumption is now available through this system. Respondents from Tanzania can really see the benefits of the electronic method, with one saying it was “[a] more efficient method because if you are using paper based it requires physically taking papers from one place to another. But electronic system, someone is sitting somewhere, in your office you can send information...And they can process your order. You can receive your order without making extra movement, without going physically to this, the central MSD.” Through the World Bank-funded project SWEDD (Sahel Women's Empowerment and Demographic Dividend) and the Global Fund, a respondent from Niger shared that the country is working on the elaboration of a manual aimed at “defining stakeholders' distinct responsibilities and identifying the information to be collected” as clear guidance on the use of the LMIS is currently missing.

CHALLENGES REMAINING

Despite positive initiatives and progress made, reports indicated that LMIS remains an area requiring much further improvement. LMIS are not fully functional in numerous countries and therefore do not allow those countries to get the timely and accurate data needed to inform proper quantification and procurement decisions and adequately manage stocks. Respondents cited the lack of guidance to and training of staff managing stock data; lack of connections between the different LMIS used within a country (some countries have different software programs in place that are not linked, or have electronic tools and manual systems that therefore need to be reconciled); lack of funding to establish electronic LMIS that would enable the collection of better and more timely data than manual LMIS; and lack of widespread implementation of LMIS at all levels across the country, which precludes obtaining a comprehensive picture of the product consumption in the country as some of

the reasons for the overall inadequacy of LMIS.

For example, a respondent from Niger mentioned that, at the peripheral structures, data were not collected on a daily basis, and therefore a lot of data were lost.

“Peripheral structures are those which conduct the activities, implement, and those which will have to collect information on a daily basis and transmit it centrally. The information is sometimes not collected on a daily basis, which means that some information is missing.” — IDI, Niger

A respondent from Zimbabwe shared that their electronic system (auto-DRV), which collects consumption data at the facility level, is not connected to the Central Medical Stores system, which results in manual input into the system and delays with the availability of the data.

A respondent from Mali raised the issues of social marketing NGOs, at the peripheral level, that do not all transmit their logistics data.

The inadequacy of LMIS currently in place to properly capture data was actually cited by about one-half of the countries (Benin, Burkina Faso, Cameroon, Kenya, Mali, and Zimbabwe) as being one of the three main remaining challenges that limits access to quality LSCs in their respective countries.

I. REGIONAL COLLABORATION

During the workshops, regional collaboration was cited as a useful mechanism for helping countries solve common issues, and therefore it was much encouraged.

The aim of the questions included in the survey and the interview guide around this topic was to determine if the countries were taking part in any kind of regional collaborations to improve access to quality LSCs.

Overall, what emerged from the responses received is that regional collaboration is perceived as a strong tool for increasing access by pooling resources and knowledge, harmonizing strategies to overcome common challenges, and facilitating economies of scale and stock management. As presented in Table 3, all countries reported being involved in regional collaboration initiatives except Tunisia and DR Congo, which provided no feedback on this theme.

AREAS OF REGIONAL COLLABORATION

Information sharing among countries was cited by nearly all countries as being an area of regional collaboration. A respondent from Niger indicated that sharing knowledge enables less experienced countries to learn from more experienced ones, and thereby avoid repeating the same mistakes. Burkina Faso noted that through the SWEDD project the country is part of as a platform that allows sharing of experiences with the five other participating countries (Chad, Côte d'Ivoire, Mali, Mauritania, Niger). NEPAD (New Partnership for Africa's Development) was also cited as a useful platform for experience sharing. Sharing information on stock levels was mentioned—for example, by Tanzania—as being an efficient measure to sell overstock of products to a country that is facing stockouts.

Another area reported as being productive in terms of regional collaboration is the development of a common regulatory framework (cited by 10 countries). Through the Eastern African Community (EAC)—which includes Kenya, Tanzania, and Uganda—respondents from Uganda and Tanzania mentioned the work being undertaken on the harmonization of requirements in terms of registration and Good Manufacturing Practice. They are, for example, working on the development

of a common technical document for product registration that should be used by all members of this community. As for Zambia, which is part of another regional collaboration platform called South African Development Community (SADC)—together with DR Congo, Malawi, Tanzania, and Zimbabwe—they reported being in discussion with Kenya, Tanzania, Uganda, and Zimbabwe to have one common laboratory to test all products. A respondent from Senegal mentioned that the Economic Community of West African States (ECOWAS)—of which Senegal is part, together with Benin, Burkina Faso, Mali, and Niger along with another 10 countries which did not participate in the workshops—also tends to harmonize pharmaceuticals registration for its member states so that when a product is registered in a member state, it automatically obtains marketing authorization in Senegal.

More than one-half of the countries surveyed reported they are engaging in regional collaboration through exchange visits to learn and share best practices. For example, public sector staff Niger and DR Congo conducted a visit to Mali to learn from their experience with LMIS.

Another field of collaboration, which countries can benefit from in terms of economies of scale and stock management, that was mentioned by approximately one-third of the countries is pooled/bulk

procurement. Cameroon cited, for example, ACAME (Association Africaine des Centrales d'Achats de Médicaments Essentiels, the central purchasing body of West Africa for essential medicines), whose objective is bulk purchasing of the 13 LSCs, and of which Cameroon is a member. A respondent from Uganda indicated that the EAC is working to create a regional pooled procurement platform.

Finally, harmonized quantification and harmonization approaches for malpractice were cited less frequently but are also areas of regional collaboration among the countries.

CHALLENGES REMAINING

Several respondents also pointed out some challenges that limit regional collaboration. Tanzania shared that all countries within the same community, such as EAC, have not reached yet the same level of capacity. This delays, for example, the implementation of mutual recognition in terms of product registration, whereby a product registered in a member country would automatically be registered in the others.

“We developed a common technical document. Some countries are not yet using it. We want to use the document which we jointly developed and agreed as guidelines. Each country should now start using that document. We needed to work together in workshops, do joint evaluation, joint GMP inspections so that we build the skill. We should have same skills in each member country. Once that is reached, it is easier to recognize when one country registers that others can recognize.” — IDI, Tanzania

Funding was another barrier cited to regional collaboration. A respondent from Senegal reported that, to collaborate with other countries, travel is required, and this is costly. Given the country's budget constraints, they would prefer to use the money to solve immediate issues in their structure. A respondent from Uganda explained that, for an initiative such as EAC to be fully functional, funding—particularly for training—is needed.

Challenges faced in individual countries are also barriers to regional collaboration. A respondent from Senegal indicated, for example, that after the workshop he kept in touch with some participants from Burkina Faso and Mali, but he noted that “it has not gone further than that. People went back to their countries, these countries have so many problems in situ. It is very difficult.”

Furthermore, regional collaboration on harmonized registration may impact national regulatory revenue-generating mechanisms. A respondent from Uganda indicated that initiatives to fast-track registration as part of EAC are lagging because some NMRA are concerned that they will lose this source of income if such initiatives are implemented.

Table 3. Areas of Collaboration at Regional Levels in Which Countries Are Involved

Country	Regulatory Framework	Harmonization Approaches for Malpractices (i.e., Penalties for Theft, Counterfeit Drugs)	Harmonized Quantification	Pooled/Bulk Procurement	Information Sharing	Exchange Visits to Learn Best Practices	No Collaboration
Benin	X	X			X	X	X ¹
Burkina Faso	X		X	X	X	X	
Cameroon			X	X	X	X	
DR Congo							
Kenya			X		X		
Malawi	X		X	X	X	X	
Mali	X				X	X	
Niger	X			X	X	X	
Senegal	X				X	X	
Tanzania	X			X ²	X		
Tunisia							
Uganda	X				X	X	
Zambia	X	X			X		
Zimbabwe	X				X		

¹ Conflicting information was shared in the survey by respondents from Benin. One indicated that there was no regional collaboration in place, but a second cited several instances.

² A respondent from Tanzania indicated that pooled procurement was an area of regional collaboration but that it had not yet been implemented for contraceptive implants.

LIMITATIONS OF THE ASSESSMENT

- › The assessment was conducted two to three years following the UNCoLSC workshops in Uganda in 2015 and Tunisia in 2016, since earlier there was no funding available for this assessment and follow-up. This naturally affected participants' abilities to accurately reflect upon and recall information about the workshop. The study tried to address this through the use of a mixed-methods approach to gather richer information through qualitative interviews; however, this limitation remained.
- › Another challenge was that, because a number of the original participants at the workshops in had in the meantime changed jobs and positions, they were either no longer available to participate or were no longer fully aware of possible changes that had taken place. In these cases, a snowball technique was used to identify alternative respondents.
- › There was no systematic baseline was conducted at the time of the workshops or milestones/indicators developed to measure progress for the purposes of this assessment. To address this gap, questions in the assessment were framed in relation to the period since the workshops took place and findings were assessed with caution.
- › The study tools were designed to elicit information from workshop participants from multiple countries, examining country status in relation to the full spectrum of the supply chain, quality assurance, and progress toward and obstacles hindering increased access to all 13 life-saving commodities. Data collected from respondents was self-reported, and therefore, sometimes incomplete and difficult to validate. Moreover, approximately only one to two participants in a country representing different areas of the supply chain participated in IDIs, limiting the completeness of information that could be gathered. County assessments could enable a more focused examination of the situation and build on the findings of this report.

SUMMARY OF KEY FINDINGS AND CONCLUSION

Overall, progress toward increasing access to quality-assured LSCs was demonstrated in relation to each of thematic areas explored in the assessment of quality-assured LSCs; however, at the country level progress was uneven and commodity-specific. Major challenges reported were health system–related bottlenecks, donor prioritization, and inadequate investments. This assessment highlights that increased access to quality-assured LSCs is dependent on a bundle of interventions that draw upon a broader health systems strengthening approach.

The following is a summary of the key findings from the assessment arranged by thematic area with consideration to linkages between commodity quality, the supply chain, and barriers to access.

Workshops

- › The participants unanimously found the workshops to be useful to support them toward the goal of optimal access to quality LSCs, mainly by bringing the agenda of LSCs' quality to the forefront, and by serving as platforms for experience and knowledge sharing and for regional collaboration strengthening.
- › For future workshops, participants would benefit from a follow-up mechanism to enable them to systematically track and report back on progress and challenges to support their efforts in a sustainable manner.

Quality

- › Workshop participants view LSC quality as dynamic, and dependent on key stages along the supply chain.
- › Participants perceive that LSCs of assured quality are procured most of the time. However, confusion around internationally recognized quality assurance mechanisms—WHO prequalification and SRA approval—remains.
- › Countries have adopted multiple strategies to ensure the quality of LSCs throughout the supply chain but inadequate financial resources and lack of human capacity remain key barriers.

Selection

- › Most countries have at least 11 of the 13 LSCs included in their national EML.

Registration

- › The majority of the countries (79 percent) participate in the WHO CRP, which can reduce significantly registration approval time but registration through this channel may be underutilized.
- › Registered contraceptive implants, emergency contraceptives, oxytocin, and misoprostol were more likely to be of assured quality compared with other LSCs.

- › Inadequate regulatory capacity and funding are the main barriers to testing and PMS, and contribute to widespread availability of counterfeit medicines.

Quantification

- › Data quality, elasticity, timeliness, and completeness of information, frequently linked to LMIS and staff capacity, remain a key challenge for most countries.
- › The lack of trained and skilled health care workers to administer medicines—including misoprostol and magnesium sulfate—according to recommendations and STGs, is a key challenge to forecasting and supply planning, which has resulted in some countries in overstock, wastage, and underuse of essential health commodities.
- › Quantification is affected by the uptake of certain LSCs, including female condoms and emergency contraceptives due to sociocultural and religious barriers.

Procurement

- › The quality of LSCs is often dependent on donor policies and procurement practices.
- › Waiver mechanisms can accelerate access to LSCs but remove key regulatory measures; the quality of commodities cannot always be guaranteed.
- › Internal (government) and external (donor) funding gaps severely impact procurement and the supply of quality LSCs.
- › Insufficient funding is resulting in the procurement of medicines from local supply channels that may not be of assured quality.

Storage and Distribution

- › Significant attention is given to improving storage and distribution throughout the supply chain, as reflected in the number of initiatives implemented to strengthen them.
- › Quality of storage at and distribution to lower-level facilities are still inadequate in most countries, which contribute to stockouts and product degradation.
- › Oxytocin is still not kept in the cold chain in all countries.

LMIS

- › Ninety-three percent of countries have an LMIS in place that captures data on LSCs.
- › However, despite some progress made, not all countries include all 13 LSCs in their LMIS and only one-third introduced it at all levels of the public health sector. Only 20 percent of countries exclusively capture data electronically.

Regional Collaboration

- › All countries that provided feedback (12 of 14) reported being involved in regional collaboration initiatives including mainly information sharing, development of a common regulatory framework, and exchange visits.
- › Despite limited funding or varying levels of capacity across countries, those initiatives were reported to effectively support their efforts toward access to quality LSCs. This happened by

pooling resources and knowledge, harmonizing strategies to overcome common challenges, and facilitating economies of scale and stock management.

RECOMMENDATIONS

Workshops

- › Conduct workshops with regular frequency and establish follow-up mechanisms that will enable countries to track and report systematically their progress and challenges.

Quality

- › Governments should procure only RMNCH medicines of assured quality whenever feasible.
- › Donors should require that funds are used to procure only RMNCH medicines of assured quality whenever feasible.

Selection

- › Support countries toward the inclusion or expanded indication for all 13 LSCs in national EMLs and/or the development of a separate list for medical devices according to recommended international standards, with particular consideration to misoprostol for the treatment of PPH and chlorhexidine for umbilical cord care.

Registration

- › Promote the use of WHO CRP to accelerate registration of LSCs to avoid reliance on alternative mechanisms including waivers or temporary authorizations.
- › Strengthen countries' national laboratories by providing technical support and funding toward earning WHO prequalification or ISO certification.
- › Provide technical support to manufacturers of quality-assured LSCs that meet WHO recommended specifications to register products in more countries.
- › Support manufacturers of LSCs, particularly chlorhexidine, ORS, and amoxicillin toward SRA approval (not eligible for WHO prequalification).

Quantification

- › Continue knowledge transfer efforts and training on revised quantification tools to strengthen forecasting activities.
- › Conduct capacity building activities and training for health care workers on the proper use of LSCs according to STGs and international recommendations for the 13 LSCs, with particular focus on misoprostol, magnesium sulfate, and chlorhexidine.
- › Increase advocacy for the use of quality-assured LSCs, including misoprostol for the management of PPH, female condoms, and emergency contraceptives to mitigate stigma and low awareness.

Procurement

- › Waivered medicines should be permitted only for those that meet international quality assurance standards.
- › Support manufacturers toward WHO prequalification or SRA approval to increase the available supply of quality-assured LSCs.
- › Strengthen collaboration with academia for long-term training purposes.

Storage and Distribution

- › Increase funding to improve storage at lower-level facilities by building more storage warehouses to meet needs, and by ensuring existing facilities are brought up to standards.
- › Support continuous capacity building of staff who manage storage and distribution activities.
- › Support ongoing initiatives that advocate for quality oxytocin to be kept in the cold chain throughout the supply chain, including during storage and distribution.
- › Conduct audits in each country to identify causes of storage and distribution issues, to improve the situation in a sustainable manner.

LMIS

- › Support countries to secure funding to move toward implementation of an electronic LMIS that includes all LSCs throughout all levels of the public health system.
- › Provide continuous training for staff handling data collection and input.
- › Conduct audits to support countries with the development of action plans to improve efficiencies.

Regional Collaboration

- › Advocate for investments to support regional platforms such as EAC, SADC, ECOWAS with training initiatives to support countries to achieve the same level of capacity in order to accelerate implementation of objectives.
- › Strengthen regional capacity and collaboration for quality assurance and regulatory harmonization, including widening the knowledge base, harmonizing registration of quality-assured LSCs, and enhancing laboratory capacity.
- › Examine pooled procurement or other strategies to achieve more optimal pricing of quality-assured products.

ANNEXES

ANNEX A. PRODUCT PROFILES OF THE 13 LIFE-SAVING COMMODITIES

13 UN COMMISSION LIFE-SAVING COMMODITIES

The Life-Saving Commodities Practitioners' Network (<http://lifesavingcommodities.org/>) includes information on the product profiles and associated diseases/health conditions to be tackled through the 13 life-saving commodities.

Reproductive Health

1. *Female Condoms*

They are the only female-initiated method available that offer dual protection from pregnancy and sexually transmitted infections (STIs)/HIV.

2. *Contraceptive Implants*

Implants are a highly effective and popular method of long-lasting and reversible contraception, offering multiyear protection.

3. *Emergency Contraception*

Emergency contraception is a unique method, offering women an important second chance to prevent unintended pregnancy if a method fails, is not used, or sex is forced.

Maternal Health

4. *Oxytocin*

WHO recommends oxytocin as the uterotonic of choice for prevention and management of postpartum hemorrhage. In settings where skilled birth attendants are not present and oxytocin is unavailable, misoprostol (600 micrograms orally) is recommended.

5. *Misoprostol*

In low-resource settings where oxytocin and a skilled birth attendant may not be available, misoprostol may be used to prevent and treat postpartum hemorrhage (PPH).

6. *Magnesium Sulfate*

WHO recommends magnesium sulfate (MgSO₄) as the most effective treatment for women with eclampsia and severe pre-eclampsia.

Newborn Health

1. *Injectable Antibiotics*

WHO lists three injectable antibiotics for the treatment of neonatal sepsis on the Essential Medicines List for Children: procaine benzylpenicillin, gentamicin, and ceftriaxone.

2. *Antenatal corticosteroids (ANCS)*

ANCS injection for women at risk of preterm delivery is the most effective intervention to reduce the risk of respiratory distress syndrome for preterm babies and is the standard of care in most high-income countries.

3. *Chlorhexidine*

Chlorhexidine digluconate (7.1 percent chlorhexidine digluconate aqueous solution or gel, delivering 4 percent chlorhexidine for umbilical cord care) is a low-cost antiseptic effective against major agents of neonatal infection.

4. *Resuscitation Devices*

One of the leading causes of neonatal and infant mortality is asphyxia, defined as the failure to initiate and sustain breathing at birth. Resuscitation devices are indicated for management of asphyxia and other respiratory ailments.

Child Health:

5. *Amoxicillin*

Amoxicillin is an antibiotic that is used to treat pneumonia in children under five. Amoxicillin is prepared in 250-mg scored, dispersible tablet in a blister pack.

6. *Oral Rehydration Salts*

ORS is a glucose-electrolyte solution given orally to prevent dehydration from diarrhea. It is packaged in sachets of powder to be diluted in 200 mL, 500 mL, or 1 L of fluid, prepared to an appropriate flavor. Replenishment with zinc can reduce the duration and severity of diarrheal episodes. Zinc is prepared either in 20-mg scored, taste-masked, dispersible tablets or oral solutions at concentration of 10 mg/5 mL.

7. *Zinc*

Zinc can help prevent and reduce the severity/duration of diarrhea. Zinc is prepared either in 20-mg scored, taste-masked, dispersible tablets or oral solutions at concentration of 10 mg/5 mL.

ANNEX B. LIST OF SURVEY AND IDI PARTICIPANTS

S. no.	Organization	Country	Survey Participant	IDI Participant
1.	Ministry of Health	Benin	Yes	—
2.	UNICEF	Benin	Yes	—
3.	—	Benin	Yes	—
4.	Central Purchasing Body for Essential Medicines and Medical Consumables	Benin	Yes	—
5.	Currently Pharmacy ABBY in Bobo Dioulasso, Burkina Faso	Burkina Faso	Yes	—
6.	National Drug Quality Control and Valuation Laboratory	Cameroon	—	—
7.	Ministry of Public Health	Cameroon	Yes	—
8.	CENAME (National Supply Center for Essential Drugs and Medical Consumables)	Cameroon	—	Yes
9.	DPM/MSP—Directorate of Pharmacy and Medicines/Ministry of Public Health	DR Congo	Yes	—
10.	National Program for Reproductive Health—Ministry of Public Health	DR Congo	Yes	—
11.	Ministry of Health	Kenya	Yes	—
12.	UNFPA	Kenya	Yes	Yes
13.	Ministry of Health	Kenya	Yes	-
14.	Kenya Medical Supplies Authority	Kenya	—	Yes
15.	UNFPA	Malawi	Yes	—
16.	World Health Organization	Malawi	Yes	—
17.	UNICEF	Malawi	Yes	Yes
18.	Gika Community Medical Clinic	Malawi	Yes	Yes
19.	Directorate of Pharmacy and Medicines	Mali	Yes	Yes
20.	MSP/DPH/MT— Ministry of Public Health/Directorate of Pharmacy and Traditional Medicine	Niger	Yes	Yes

21.	Ministry of Public Health	Niger	Yes	Yes
22.	National Supply Pharmacy	Senegal	Yes	Yes
23.	National Drug Control Laboratory	Senegal	—	Yes
24.	USAID	Tanzania	Yes	—
25.	Ministry of Health	Tanzania	Yes	Yes
26.	Tanzania Food and Drugs Authority	Tanzania	—	Yes
27.	Tanzania Food and Drugs Authority	Tanzania	—	Yes
28.	Directorate of Pharmacy and Medicines (Ministry of Health)	Tunisia	Yes	—
29.	National Drug Authority	Uganda	Yes	—
30.	National Medical Stores	Uganda	Yes	—
31.	Ministry of Health	Uganda	Yes	—
32.	Ministry of Health	Uganda	—	Yes
33.	National Drug Authority	Uganda	—	Yes
34.	Medical Stores Limited	Zambia	Yes	Yes
35.	Zambia Medicines Regulatory Authority	Zambia	Yes	—
36.	Ministry of Health and Child Care	Zimbabwe	Yes	Yes
37.	Medicines Control Authority of Zimbabwe	Zimbabwe	Yes	—
38.	UNICEF	Zimbabwe	—	Yes

ANNEX C. SURVEY QUESTIONNAIRE

UN Commission on Life-Saving Commodities' Workshops: Assessing Progress and Identifying Gaps to Increasing Availability to Quality-Assured Maternal, Newborn, and Child Health Commodities

Thank you for participating in the survey "UN Commission on Life-Saving Commodities' Workshops: Assessing Progress and Identifying Gaps to Increasing Availability to Quality-Assured Maternal, Newborn, and Child Health Commodities," a follow-up to the workshop you attended in Uganda in 2015.

As part of the project Initiatives to Increase Supply of Quality-Assured Maternal and Child Health (MCH) Commodities, funded by the USAID GHSC-PSM project, Concept Foundation* aims to deepen the understanding around the practical application of key learnings from the UNCoLSC workshops that were held in Uganda in September 2015 and Tunis in July 2016, and the broader challenges that remain.

The results of this survey will generate a clearer understanding of key areas requiring further action to support increased access to quality-assured** maternal and child health medicines.

We understand you may not have answers to all questions and encourage you to consult with colleagues as needed. Your support in completing this questionnaire as fully as possible is much appreciated!

Instructions: Please answer each question with reference to the context of any actions or strategies implemented following participation in the UNCoLSC workshop held in Uganda in September 2015. Questions presented in the questionnaire are in reference to the UN Commission's list of 13 life-saving commodities: oxytocin, misoprostol, magnesium sulfate, injectable antibiotics, antenatal corticosteroids, chlorhexidine, resuscitation devices, amoxicillin, oral rehydration salts, zinc, female condoms, contraceptive implants, and emergency contraception.

*Concept Foundation is an international nonprofit organization dedicated to ensuring access to quality and affordable sexual and reproductive health medicines.

**Quality-assured is defined in the questionnaire as products that are WHO-prequalified, SRA-Approved, or ERP-recommended.

I hereby consent that Concept Foundation may disclose the information contained in this questionnaire in publications relating to its project Initiatives to Increase Supply of Quality-Assured Maternal and Child Health (MCH) Commodities.

☐ Yes

☐ No

☐ Partly (please indicate which information should not be disseminated)

Today's date: _____

Respondent's professional details

*Full name

*Job title

*Organization

Address of organization

City/town

State/province

ZIP/postal code

*Country

* Email address

I. Which of the 13 UN Life-Saving Commodities (**LSCs**) are included on the national **Essential Medicines List** (EML)? (check all that apply)

- ☐ Injectable antibiotics (gentamicin)
- ☐ Antenatal corticosteroids (betamethasone and/or dexamethasone)
- ☐ Chlorhexidine
- ☐ Resuscitation devices
- ☐ Amoxicillin (i.e., dispersible tablets, pediatric formulations)
- ☐ Oral rehydration salts
- ☐ Zinc
- ☐ Oxytocin
- ☐ Misoprostol
- ☐ Magnesium sulfate
- ☐ Female condoms
- ☐ Contraceptive implants
- ☐ Emergency contraception

2. Please list any of the above-mentioned **LSC products that are currently registered** in your country (please indicate brand, manufacturer, and presentation where possible):

Injectable antibiotics (gentamicin): _____

Antenatal corticosteroids (betamethasone and/or dexamethasone): _____

Chlorhexidine: _____

Resuscitation devices: _____

Amoxicillin (i.e., dispersible tablets, pediatric formulations): _____
 Oral rehydration salts _____
 Zinc: _____
 Oxytocin: _____

3. During the workshop, several **quality assurance strategies** were presented. What strategies are your organization implementing to ensure the quality of LSCs throughout the supply chain? (check all that apply)

- ☐ GMP audits
- ☐ Testing of samples before registration
- ☐ Registration of products
- ☐ Random sample testing of registered products before distribution
- ☐ GDP audits
- ☐ Ensuring service providers properly handle/transport supplies
- ☐ Increased post-marketing surveillance
- ☐ Capacity building on proper storage of products
- ☐ Increased collaboration with stakeholders
- ☐ Unsure
- ☐ Other (please specify): _____

4. Since the workshop, has there been **collaboration at the regional level** to increase access to quality-assured LSCs on:

- ☐ Regulatory framework
- ☐ Harmonization approaches for malpractices (i.e., penalties for theft, counterfeit drugs)
- ☐ Harmonized quantification
- ☐ Pooled procurement of WHO-prequalified/SRA-approved products
- ☐ Information sharing
- ☐ Exchange visits to learn best practices
- ☐ No collaboration
- ☐ Other (please specify): _

5. What are the three **major challenges that remain** that limit access to quality-assured LSCs?

Thank you for completing the survey!

ANNEX D. INTERVIEW GUIDE

INTERVIEW GUIDE: UN COMMISSION ON LIFE-SAVING COMMODITIES' WORKSHOPS: ASSESSING PROGRESS AND IDENTIFYING GAPS TO INCREASING AVAILABILITY TO QUALITY-ASSURED MATERNAL, NEWBORN, AND CHILD HEALTH COMMODITIES

INTERVIEW INFORMATION

Interviewer: _____

Country: _____

Date of interview: ____/____/____
Month / Day / Year

Time of interview: ____/____
Hr / Min

Method of interview: ☐ In person ☐ Telephone

INTRODUCTION (INTERVIEWER AND CONCEPT FOUNDATION):

My name is [NAME]. I am working for Concept Foundation and will be doing this interview. Concept Foundation is an international nonprofit organization dedicated to ensuring access to quality and affordable sexual and reproductive health medicines.

PURPOSE OF THE INTERVIEW AND FORMAT

Thank you for dedicating some time to speak with me today. Concept Foundation is grateful for your willingness to participate in this interview.

The interview is part of the project that Concept Foundation is leading, "Initiatives to Increase Supply of Quality-Assured Maternal and Child Health (MCH) Commodities," funded by the USAID Global Health Supply Chain–Procurement and Supply Management project. It is in follow-up to the questionnaire that was submitted to you in late 2017. It aims to deepen our understanding around the practical application of key learnings from the UN Commission on Life-Saving Commodities workshops that were held in Uganda in September 2015 and Tunisia in July 2016.

Through the interview we would like to gather as much information as possible on the current situation/status of your country with regard to ensuring access to quality maternal, newborn, and child health commodities and how the workshop supported you in this regard. What we learn from this discussion will enable us to generate a clearer understanding of progress achieved and key areas requiring further action.

The thematic areas in the interview will follow those covered in the questionnaire. You are not obligated to respond to all questions, participation is completely voluntary. If, during the interview, you have any questions or require any clarification, please don't hesitate to ask.

We will record the conversation to facilitate note taking. We will transcribe the interview and then conduct analysis to identify themes and learn from what has been shared.

The duration of the interview should not exceed 1.5 hours.

CONSENT

I agree to participate in the interview.

NAME:

DATE:

With regard to being quoted, please initial next to the statement that you agree with:

	I agree to be quoted directly.
	I agree to be quoted directly if my name is not published.
	I do not agree to be quoted.

QUESTIONS

BACKGROUND

Let's start by having you please describe your current role and what you do.

- How long have you served in your current position?
- Could you tell me about your involvement with ensuring access to quality RMNCH products?
- Do you remember the UN Commission on Life-Saving Commodities workshop held in Uganda/Tunisia?

QUALITY/QUALITY ASSURANCE

In regards to quality, in your opinion, what is a quality-assured reproductive, maternal, newborn, or child health product?

- Do you think that the measures that are currently in place in your country in terms of quality assurance ensure the quality of the 13 LSCs along the spectrum of the supply chain, from registration to use?
- What are some challenges your organization continues to face when it comes to quality assurance of LSCs?
- Were there any lessons from the workshop which could improve quality? Have the lesson(s) been used?

SELECTION

Let's talk about your country's national essential medicines list (EML). How does EML status affect access to these essential medicines in your country?

- Prioritization for registration? Procurement? Price controls?

Can you talk about any of the 13 life-saving commodities that are yet to be included in your country's national EML?

[13 LSCs: injectable antibiotics (gentamicin), antenatal corticosteroids (betamethasone and/or dexamethasone), chlorhexidine, resuscitation devices, amoxicillin dispersible tablets or pediatric formulations, oral rehydration salts, zinc, oxytocin, misoprostol, magnesium sulfate, female condoms, contraceptive implants, and emergency contraception.]

When was the EML revised last? Were there any revisions made to ensure inclusion of any of the above 13 commodities?

REGISTRATION

Have you noted any change in the number of quality LSC products that are registered and available?

- Since when have you observed a change? Why do you think it has changed? Tell me about the registration process in general? Do you have fast track registration? Have there been any efforts to register LSCs using a fast-track process?
- Specific to any particular LSCs? Specific fast-track processes or exemption processes? Do you think these fast track processes affect access to quality medicines for women and children?

QUANTIFICATION AND PROCUREMENT

Let's hear about how quantification and forecasting for LSCs is done.

Did anything presented during the workshop affect the way quantification/forecasting is being done?

- Is what is being currently quantified and forecasted fulfilling the real needs and demand?
- What is needed to ensure quantification is in line with the real needs?

When it comes to procurement of LSCs, does selection criteria used for procurement differ among LSCs (i.e., contraceptives vs. medical devices vs. misoprostol)?

- How can the right balance between price and quality be assured?

Can you tell me about any organizations providing funding/procuring 13 LSCs in your country?

- How does that affect access to quality assured LSCs? Certain LSCs?

STORAGE AND DISTRIBUTION

Do you think that the 13 LSCs are currently stored and distributed in a way that ensures their quality?

- If yes, what is being put in place that ensures proper storage and distribution?
- If not, what is missing? What are the problems that you identify?
- Were there any storage and distribution-related lessons you took away from the workshop? If yes, which ones were the main lessons?
- Have those lessons been used in any way to improve storage and distribution?

INFORMATION SYSTEMS

Let's hear about your logistics management information system. When was it started? Where is it implemented and does this affect availability and access to quality LSCs?

Was there anything presented or discussed during the workshop that supported changes to your country's LMIS?

REGIONAL COLLABORATION

During the workshop, there was much discussion around regional collaboration and experiences from different countries were shared.

Do you think that regional collaboration can help improve access to quality LSCs in your country? Are you aware of any initiatives for increased regional collaboration?

- Did the workshop have any effect on regional collaboration in your country?
- What has been prioritized? Who is involved?

Was the workshop useful for networking? Can you tell me about your personal experience?

CHALLENGES/OPPORTUNITIES

From the workshops, what did you find most useful?

- Have these takeaways and learning been applied in any form in your country?

In the last years since attending the workshop, has access to quality-assured LSCs in your country changed?

- For any improvements, can you elaborate by theme and priority?
- What got the initiatives started? Can you describe anything that needed to be addressed along the way?
- If no improvement, what barriers have stalled better access to quality life-saving commodities?

Are there any (other) areas for improvement that you and your organization have interest and need?

- Is there anything (resources, tools, etc.) that your organization currently lacks in order to meet your goals—quality assurance, registration, selection, procurement, and distribution?
- Among these, which strategies do you think have the greatest impact at increasing access to quality-assured LSCs?
- In general, do you think such workshops have a role in improving access?
- What are the best ways to ensure application of the lessons learned from such workshops?

Are there any topics we have not discussed that you would like to share that are important to understanding the current status of the LSCs in your country?

CLOSING

Next steps: We will be continuing to collect data during the next months and will plan to share with you, other workshop participants, and the broader maternal and child health community the results from the follow-up assessment in mid-2018.

Thank you for your generous time and participation in the interview. Your feedback is very helpful in gaining a better understanding of the progress achieved and further opportunities to increasing access to quality LSCs in your country.

ANNEX E. LIST OF REGISTERED CHLORHEXIDINE, AMOXICILLIN, OXYTOCIN, AND MISOPROSTOL

COUNTRY	LSC COMMODITY ^a			
	Chlorhexidine	Amoxicillin (i.e., dispersible tablets, pediatric formulations)	Oxytocin	Misoprostol
Benin	Dermobacter (5% and 20% digluconate)	Amoxicillin (dispersible tablet form not available)	Synthocinon, Oxytocine Botis	Cytotec
Burkina Faso	Unknown	Clamoxyl, 1-g dispersible tablet, by GlaxoSmithKline West and Central Africa; amoxicillin products available in other forms	Syntocinon, by Novartis Pharma, 5 IU/mL, injectable solution	Misoclear, by MSI, 200 mcg, tablet
Cameroon	Chlorhexidine (brand/manufacturer unknown)	Amoxicillin powder (brand/manufacturer unknown)	Oxytocin 10 IU/mL, 1 mL (brand/manufacturer unknown)	Misoprostol 200 mcg (brand/manufacturer unknown)
DR Congo	Chlorhexidine (gel 7.1% digluconate not available)	Ospamox 1,000 dispersible tablet Bte/12 and Ospasmox 500 DT Bte/13, by Sandoz GmbH, Austria	Syntocinon 5 IU, by Novartis; oxytocin solution inj. IM/IV B/100 ampoule, 1 mL, by Chengshi Manufacture	Cytomon 200-mcg tablet B/28, by Kaushik Therapeutics Ltd., China; Kontrac 200, 200 mg, by Fourrts Laboratories; Miso 200, by Famy Care Ltd., India; Misoptol, by Lincoln; Misotec, by Nirma Ltd.; Mistrovix 20 mg, by Mepro Pharmaceuticals, India; Sagatec 200 mcg, by Modhike Private Ltd., India
Kenya	Chlorhexidine gluconate 7.1% gel, by Universal Corporation Ltd.	Unknown	Oxytocin (10 IU), by Laborate Pharmaceuticals Ltd., India; Sytocinon 5 IU/mL and 10 IU/mL inj., by Novartis; Evatocin 10 IU, by M/s.Neon Laboratories Ltd.; oxytocin 5 IU, by Rotexmedica GmbH Arzneimittelwerk; oxytocin 10 IU inj., by Umedica Laboratories; Unitocin 10 IU/mL inj., by Medisel; oxytocin 10 IU, by United Pharma	Kontrac 200, by Fourrts Laboratories, India; Cytotec, by Pfizer; Misoclear, by Pharm Access Africa Ltd.; Misopro, by Naari; Misoprost, by Cipla Ltd.; Isovent, by Square Pharmaceuticals Ltd.
Malawi	Chlorhexidine 5% w/v, by Mission Pharma	Amoxicillin_dt 250-mg dispersible tablet, by Medreich Ltd; Spamox_250dt 250-mg dispersible tablet, by Sparsh Bio-Tech Pvt. Ltd.; amoxicillin 125-mg dispersible tablet, by Micro Labs Ltd.; Miloxy_250_dt 250-mg dispersible tablet, by Milan Laboratories, India	Oxytocin 10 IU/mL inj., by Onali Pharmaceuticals; oxytocin 10 IU/mL inj., by Ciron Drugs & Pharmaceuticals; oxytocin 10 IU/mL inj., by Bharat Parenterals Ltd.; oxytocin 10 IU/mL inj., by Strides Arcolab Ltd.; oxytocin 10 IU/mL inj., by Scanpharm; Syntocinon 5 IU/mL and 10 IU/mL, by Novartis; oxytocin 10 IU/mL, by Pharmamed; oxytocin 10 IU/mL, by Umedica Laboratories; oxytocin 10 IU/mL, by International Dispensary Association; oxytocin 10 IU/mL, by Techfab International; oxytocin 10 IU/mL, by Worldwide Pharmaceuticals	Misoclear, by Acme Formulation Pvt. Ltd.; Misoprost 25 mcg and 200 mcg, by Cipla Ltd.; Isovent, by Square Pharmaceuticals; Misoclear, by Cipla Ltd.; Kontrac, by Fourrts Laboratories, India

^a The information listed for each of these commodities was made available by national sources in each country.

Mali	Chlorhexidine (gel 7.1% digluconate not available)	Amoxicillin (dispersible tablet form not available)	Unknown	Misoclear, by Acme Formulation Pvt. Ltd.
Niger	Unknown	Unknown	Unknown	Unknown
Senegal^b	Unknown	Numerous amoxicillin products available in other forms	Delivrex 5 UI/mL, injectable ampoule, by BDA Pharma Pvt. Ltd.; Oxytroy 5 UI, by Troikaa Pharmaceuticals Ltd.;	Cytotec, 20-mcg tablet, by Pfizer Holding, France; Misoclear, 200-mg, tablet, by Acme Formulation Pvt. Ltd., India
Tanzania	Umbipro, by GlaxoSmithKline Consumer Healthcare S.A., South Africa, 7.1% gel	Medomox 125 DT, by Medopharm Pvt. Ltd., India, 125-mg dispersible tablet; numerous amoxicillin products available in other forms	Vitocin, 5 IU/mL injection, by Vital Healthcare Pvt. Ltd., India; Oxytroy, 10 IU/mL, by Nirma Ltd., India,	Misoprost 200, by Cipla Ltd., India; Vagiprost, by Egyptian Co. for Chemicals & Pharmaceuticals SAE, Egypt, 40 mcg/mL tablet; Misoclear, by Acme Formulation Pvt. Ltd., India; Misopro, by Naari Pharma, India; Cytotec, by Piramal Healthcare Ltd. (Pfizer), UK; Ace Miso, by Acme Formulation Pvt. Ltd., India
Tunisia^c	Unknown	Novamox, by Adwya Tunisia, 1 g or 500 mg for dispersible tablet; Amoxicilline Zentiva, by Winthrop Pharma, Tunisia, 1-g dispersible scored tablet; Amoxal, by Medicef Tunisia, 500-mg and-g dispersible tablet; Clamoxyl, 500-mg and 1-g dispersible tablet, by Adwya Tunisia; numerous amoxicillin products available in other forms	Oxytocine Phanpharma, Rotexmedica GmbH, 5 UI/mL, injectable solution in ampoule; Oxytocin Grindex, by As Grindeks (Latvia), HBM Pharma S.R.O. (Slovenia), and Uab Santonika Latvia (Latvia), 5 UI/mL, injectable solution in ampoule	Unknown
Uganda	Galscrub, by Galentic Pharma, India, 4% w/v topical liquid	Agoxin 125 DT, by Milan Laboratories, India, 125-mg dispersible tablet; numerous amoxicillin products available in other forms	Evatocin, by Neon Laboratories Ltd., India, 10 IU/mL; oxytocin, by Gland Pharma, India (listed twice by different license holders); oxytocin, by Dahongying Pharmaceutical Co. Ltd., China, 10 IU/mL; oxytocin, by Zhejiang Ruixin Pharmaceutical Co. Ltd., China, 10 IU/mL; Syntocinon 5 IU/mL and 10 IU/mL, by Novartis Pharma, Switzerland	Cytotec, by Piramal Healthcare Ltd., UK, 200 mcg; Kontrac 200, by Fourrts Laboratories Pvt. Ltd., India, 200 mcg; Misoclear, by Acme Formulation Pvt. Ltd., India, 200 mcg; Misopro, by Jagsonpal Pharmaceuticals Ltd., India, 200 mcg; Misoprost 200, by Cipla Ltd., India, 200 mcg
Zambia	Hibiscrub topical solution and Hibitane 5% concentrate, by SSL International, England; Chlorxy-G gel (chlorhexidine digluconate 7.1%)	Spamox dispersible tablets, by Sparsh Biotech Pvt. Ltd., India	Oxytocin 10 IU, by North China Pharmaceutical Group International Corporation; oxytocin, by Scanpharm Denmark; oxytocin, by Shanghai Pharmateq; oxytocin, by Wuhan Grand Pharmaceutical Group; oxytocin, by Yashika Pharmaceuticals; oxytocin, by CSPC Ouyi Pharmaceuticals	Misoprostol, by Zizhu; Misoprost, 25/200, by Cipla Ltd.; Celprotec, by Cospharm Investments; L-Pill, by Lincoln Pharmaceuticals; Misotac, by Sigma Pharmaceuticals Ltd., Egypt; Yashiprostol, by Yashika Pharmaceuticals; Misoclear, by Acme Formulation Pvt. Ltd.
Zimbabwe	Chlorhexidine (gel 7.1% digluconate form not available)	Amoxicillin (dispersible tablet form not available)	Oxytocin, by Rotexmedica; oxytocin, by Gland Pharma, India; Syntocinon 10 IU/mL and 5 IU, by Novartis Pharma/USA	Celprotec, by Acme Formulation Pvt. Ltd.; Cytotec, by Searle & Co., UK; Misoclear, by Acme Formulation Pvt. Ltd.; Misoprost, by Cipla Ltd.

^b Including commodities registered in the last five years, as survey respondent indicated that marketing authorizations are valid for five years. (Note: Published information also showed commodities registered more than five years ago.)

^c Information was provided by survey respondent and where possible validated by data published on the website of the Directorate of Pharmacy and Medicines.

ANNEX F. LIST OF REGISTERED MAGNESIUM SULFATE, CONTRACEPTIVE IMPLANTS, AND EMERGENCY CONTRACEPTION

COUNTRY	LSC COMMODITY ¹		
	Magnesium Sulfate	Contraceptive Implants	Emergency Contraception (Levonorgestrel)
Benin	Unknown	Norplant	Unknown
Burkina Faso	Unknown	Jadelle Sans Inserteur implant, by Bayer East Africa Ltd., 75-mg implant	Levopreg, by Medical Pharmaceutique, 1.5-mg tablet; Norvel-72, by Mednext Pharma Pvt. Ltd., 0.75-mg tablet; Secufem 1.5, by Elea S.A.C.I.F & A., 1.5-mg tablet
Cameroon	MgSO ₄ 10-mL injectable (brand/manufacturer unknown)	Jadelle levonorgestrel implant 75 mg; Implanon NXT, etonogestrel 68 mg	Norlevo, levonorgestrel 1.5-mg tablet
DR Congo	Unknown	Femplant 75 mg B/I 0 x 2 implants, by Shanghai Dampla, China; Implanon NXT, by NV Organon; Jadelle Sine 2 x 75-mg implant, by Bayer Finland; Jadelle 75-mg subdermal implant, B/I x 10, by Bayer Germany	Planfam 1.5-mg, B/I, by GDD, India; Revoke 1.5, B/I x 1, by Famy Care Ltd.; Revoke 72, B/I x 2, by Famy Care Ltd., India; Levo-BD 1.5 mg, B/I, by M/S Pharmasia Ltd., India
Kenya	Magneon injection, by M/s Neon Laboratories Ltd.; Nalepsin injection, by Beximco Pharmaceuticals Ltd.; magnesium sulfate injection 50% w/v, by Aurum Pharmaceuticals Ltd.	Zarin implants, by Pharm Access Africa Ltd.; Implanon NXT, by NV Organon BV; Jadelle, by Bayer	Levonorgestrel tablets BP, by Par Laboratories; Ecee 2 tablets, by Cadila Healthcare Ltd.; Depo Progestin and Famydepo, both by Mylan Laboratories Ltd.-Women's Health Care; Revoke 72, by Mylan Laboratories Ltd.-Women's Health Care; Pill 72, by Cipla Ltd.; Option-2, by Dawa Ltd; L-Gest tablets, by Strides Shasun Ltd.; Rydgona-72, by Mankind Pharma; Levo 72 One Step tablets, by West-Coast Pharmaceutical Works
Malawi	Unknown	Zarin 150 mg (75 mg/rod) implant, by Pharm Access Africa Ltd; Implanon 68-mg/rod implant, by Schering-Plough; Implanon NXT 68 mg/15 mg/rod radiopaque, by Merck; Norplant 36-mg subdermal implant, by Bayer Pharma; Norplant 6 x 36-mg subdermal implants, by XXX; Jadelle 75-mg implant, by Bayer Pharma	Pill-72 0.75-mg tablet and I-Pill 1.5-mg tablet, by Cipla Ltd.; Today Pill 0.75-mg tablet, by Bliss Gvs Pharma; Escinor-1.5 1.5-mg tablet, by Famy Care Ltd.; Safeplan ECP 1.5-mg tablet, by PSI Malawi; Preventol 0.75-mg tablet and Uni-Pill 1.5-mg tablet, by HLL Lifecare Ltd.; Back Up 1.5-mg tablet, by Acme Formulation Pvt. Ltd., India; Option-2 0.75-mg tablet, by Dawa Ltd.; Unosure 72 1.5 mg-tablet, by Unosource Pharma
Mali	Unknown	Implanon 68-mg implant, by Merck; Jadelle Sine 2 x 75-mg implant, by Bayer; Zoladex 3.6-mg injectable implant, by Astra Zeneca, UK	Unknown
Niger	Unknown	Unknown	Unknown
Senegal^a	Unknown	Implanton NXT 68-mg implant, Merck Sharp & Dohme, France	Ipill 1.5-mg tablet, by Cipla Ltd., India; Norvel-72 0.75-mg tablet, by Mednext Pharma Pvt. Ltd., India; Protect Pill 1.5-mg tablet, by MSR Lab, France
Tanzania	Magnesium sulfate, by Pharmaceutical Solution Industry, Saudi Arabia, 50% w/v solution	Unknown	Emerginor, by Nanjing Baijingu Pharmaceutical, China, 0.75-mg tablet; Pill 72, by Cipla Ltd., India, 0.75-mg tablet; Revoke 72, by Jai Pharma Ltd., India, 750-mcg tablet; Depregdina, by Acme Formulation Pvt. Ltd., India, 1.5-mg tablet; Hyan, by Jai Pharma Ltd.,

¹ The information listed for each of these commodities was made available by national sources in each country.

^a Including commodities registered in the last five years, as survey respondent indicated that marketing authorizations are valid for five years. (Note: Published information also showed commodities registered more than five years ago.)

			India; Revoke 1.5, by Jai Pharma Ltd., India, 1.5-mg tablet; P2, by Jai Pharma Ltd., India; Trust Daisy 2, by Jai Pharma Ltd., India, 750-mcg tablet; Trust Daisy 1, by Jai Pharma, India, 1.5-mg tablet
Tunisia^b	Sulfate de magnesium Proamp, by Aguettant France, Demo SA, Greece, 15 g/100 mL, injectable solution in ampoule	Implanon, NV Organon, Netherlands, 68-mg implant	Norlevo, by Osny Pharma S.A.S., France, 0.75-mg/cp, tablet B/2, 1.5-mg tablet; Delpharm, France, 1.5-mg tablet B/I
Uganda	Gelcid, by Lincoln Parenteral Ltd., India, 50% w/v injectable solution, 10 mL ampoules; magnesium sulfate, by Gland Pharma Ltd., India, 50 mg/mL solution for injection/5-mL ampoules; magnesium sulfate injection, by Martindale Pharmaceuticals, UK, 50%w/v solution for injection, 10-mL ampoules	Jadelle Sine, by Bayer Pharma, Finland, 2 x 75-mg implant; Zarin, by Shanghai Dahua Pharmaceutical Co. Ltd., China, 75-mg implant	Fasile-One, by Jagsonpal Pharmaceuticals Ltd, 1.5-mg tablet; I-Pill, by Cipla Ltd., India, 1.5-mg tablet; Pill 72, by Cipla Ltd., India, 0.75-mg tablet; Pregnon, by Famy Care Ltd., India, 0.75-mg tablet; Revoke 1.5, by Famy Care Ltd., India, 1.5-mg tablet; Revoke 72, by Famy Care Ltd., India, 750-mcg tablet
Zambia	Magnesium sulfate, by CSPC Ouyi Pharmaceuticals Co.; magnesium sulfate, by North China Pharmaceutical Group International Corporation; magnesium sulfate, by Tejay Pharmaceuticals Ltd.	Indoplant, by Jai Pharma, India; Implanon implant and Implanon NXT implant, by Merck	Microlut tablet, by Bayer; Pill 72, by Cipla Ltd., India; Revoke-72, by Jai Pharma, India
Zimbabwe	—	Jadelle Sine, by Bayer Finland; Levoplant, by Shadong Jingang Biological Pharmaceutical Co., China	Hyan, by Mylan Laboratories Ltd.-Women's Health Care; I Pill, by Cipla Ltd., India; Microlut, by Schering AG, Germany; Pill 72, by Cipla Ltd., India; Postinor, by Chemical Works o Gedeon Richter Ltd., Hungary; Pregnon / Revoke 1.5 / Revoke 72 / Secure-L, by Mylan Laboratories Ltd.-Women's Health Care

^b Information was provided by survey respondent and where possible validated by data published on the website of the Directorate of Pharmacy and Medicines.

ANNEX G. EXAMPLES OF REPORTED COUNTRY PROGRESS AND KEY RECOMMENDATIONS

Examples of country progress reported by participants through the use of surveys and/or in-depth interviews conducted from November 2017 to March 2018 are presented below. Recommendations are based on reported progress and remaining bottlenecks.

COUNTRY	PROGRESS ACHIEVED	RECOMMENDATIONS
Benin¹	<ul style="list-style-type: none"> Reported to be implementing strategies such as product registration, GDP and GMP audits, and capacity building on proper storage of products to ensure quality of LSCs. Collaborates at the regional level on different areas such as a regulatory framework and harmonization approaches for malpractice. The country also collaborates with other territories, sharing information and organizing exchange visits to learn best practices. 	<ul style="list-style-type: none"> Support MOH toward national quantification of all LSCs annually. Expand the reach of the LMIS to capture more accurate consumption data throughout the country.
Burkina Faso¹	<ul style="list-style-type: none"> Developing an integrated LMIS that could include all reproductive health products. Collaborates at the regional level in different areas such as a regulatory framework, harmonized quantification, and pooled procurement of WHO-prequalified/SRA-approved products. The country also collaborates with other territories, sharing information and organizing exchange visits to learn best practices. 	<ul style="list-style-type: none"> Strengthen coordination among partners to improve quantification exercises. Support CAMEG to deliver medical products as per schedule.
Cameroon	<ul style="list-style-type: none"> Reported that products are registered using the WHO CRP mechanism. Plans to strengthen storage capacity through the addition of a regional store. Working toward building the capacity of staff on proper handling, storage, and transport of products. Reported that all LSCs are included in the LMIS. 	<ul style="list-style-type: none"> Increase investments to ensure perennial funding for procurement of RMNCH supplies. Strengthen price controls of LSCs to improve affordability and access. Support country to strengthen its LMIS: extend LMIS to the peripheral level and improve capacity of the staff working with the LMIS.

¹ Information is based on survey responses only as no participants from the country took part in the in-depth interviews.

DR Congo^{1,a}	<ul style="list-style-type: none"> Reported having registered EMA-approved chlorhexidine using a fast-track registration process for quality-assured medicines. 	<ul style="list-style-type: none"> Support MOH toward national, systematic quantification of all LSCs. Support collection of consumption data to inform quantification (as opposed to the demographic data currently used for this exercise). Support capacity building of the staff using the LMIS (DHIS2).
Kenya	<ul style="list-style-type: none"> Revised EML to include chlorhexidine for umbilical cord care and misoprostol for the management of PPH. Implemented a pull distribution system for FP commodities. 	<ul style="list-style-type: none"> Increase investments to enhance the capacity of Kenya's WHO Prequalified QCL to conduct adequate post-marketing surveillance rather than outsource testing needs. Conduct awareness generation activities to address stigma and sociocultural barriers related to contraceptive use. Improve supply planning at the county level and advocate for procurement of only quality-assured medicines from trusted sources to avoid issues related to poor-quality and counterfeit medicines procured from local sources.
Malawi	<ul style="list-style-type: none"> Revised EML to include chlorhexidine for umbilical cord care, antenatal corticosteroids (dexamethasone), and expanded amoxicillin for child formulation. Reported that products are registered using the WHO CRP mechanism. Reported that all LSCs are included in the LMIS. 	<ul style="list-style-type: none"> Strengthen regulatory capacity to reduce the reported percentage (75%) of unregistered products. Encourage registration of magnesium sulfate and female condoms of assured quality. Support "last mile" initiatives to ensure reach, storage capacity, and capacity of health care workers in remote areas.
Mali	<ul style="list-style-type: none"> Improved regulatory capacity demonstrated by an increased number of product registration sessions from two to four each year. Increased the number of warehouses to expand storage capacity to support the central medical store. Implemented "last mile" initiatives to enable reach of LSCs to end users. Procuring refrigerated trucks in 2018 to enable cold chain during transport. 	<ul style="list-style-type: none"> Increase investments to enhance the capacity of regional laboratories. Conduct a market assessment to determine the registration and availability of LSCs of assured quality. Improve availability and quality of consumption data to better quantify needs.

^a Survey participants provided limited information on country progress.

Niger	<ul style="list-style-type: none"> • Working toward the implementation of a national quantification exercise and supply chain. • Ensures cold chain for products requiring refrigeration up to the district level and sometimes the peripheral centers through integration into the vaccine supply chain. • Developing manual to provide guidance on use of LMIS. 	<ul style="list-style-type: none"> • Strengthen regulatory capacity: <ul style="list-style-type: none"> ○ To test and monitor chlorhexidine, zinc, and contraceptive implants. ○ To reduce the proliferation of counterfeit medicines, and examine regional mechanisms as it is a cross-border issue. • Increase investment in enhancing the capacity of Niger's national laboratory toward earning WHO prequalification or ISO certification. • Strengthen the capacity of peripheral structures to collect and transmit data to the central level to support forecasting and supply planning.
Senegal	<ul style="list-style-type: none"> • Adopted abridged registration procedure for SRA-approved and WHO-prequalified medicines. • Established a cold chain monitoring system using temperature monitoring sheets at service delivery points. Products requiring cold chain are monitored during distribution with the use of data loggers. • Implemented "last mile" initiatives to enable reach of LSCs to end users. • Reported that all LSCs are included in the LMIS. • Implemented USAID-funded Inform Push Model to strengthen the quality of consumption data. 	<ul style="list-style-type: none"> • Conduct a market assessment to determine the registration and availability of LSCs of assured quality. • Strengthen regulatory capacity: <ul style="list-style-type: none"> ○ To procure and use reference substances for quality control. ○ To reduce the proliferation of counterfeit medicines, and examine regional mechanisms as it remains a cross-border issue. • Strengthen cold chain storage for oxytocin at the service delivery level.
Tanzania	<ul style="list-style-type: none"> • Improved surveillance system at ports of entry, which has led to a decline in the number of substandard and counterfeit medicines. • Improved accuracy of forecasting and supply planning, which has reduced overstock. • Medical stores procuring WHO-prequalified LSCs, adding to the supply received from donors. • Launched an electronic LMIS in 2013; since then, it has been gradually rolled out across the country, including to hospitals in 2017. 	<ul style="list-style-type: none"> • Conduct awareness generation activities to address stigma and sociocultural barriers related to female condom and emergency contraceptive use from the public sector. • Strengthen collaboration with academia and knowledge around best practices related to quality assurance and procurement of quality-assured LSCs. • Build capacity of managers at the ministry level to increase knowledge around key recommendations and issues related to LSCs for quantification, procurement, and supply chain management.
Tunisia¹	<ul style="list-style-type: none"> • Since 2000, with the support of WHO, launched OPTIMIZE to work toward improving its cold chain for distribution to public health facilities. • Implemented an electronic-based LMIS. • Reported that all LSCs are included in the LMIS. 	<ul style="list-style-type: none"> • Provide support to expand inclusion of all 13 LSCs in the national EML. • Support the MOH toward establishing national forecasting exercises for RMNCH commodities.

	<ul style="list-style-type: none"> Centralized the procurement of medicines to enable quality of the products throughout the supply chain. 	<ul style="list-style-type: none"> Support Ministry of Health to accelerate marketing authorization procedures for LSCs.
Uganda	<ul style="list-style-type: none"> Strengthened regulatory capacity: <ul style="list-style-type: none"> Developed and implemented a common technical document. Adopted a fast-track registration procedure for SRA products and participates in the WHO CRP. National laboratory earned WHO prequalification and ISO certification. Increased the number of assessors from five in 2016 to 20 in 2018. Have integrated products requiring refrigeration (i.e., oxytocin) into the vaccine supply chain to maintain cold chain during transport and storage. Implemented an electronic-based LMIS. 	<ul style="list-style-type: none"> Strengthen post-marketing surveillance to reduce the number of counterfeit medicines. Increase investments in surveillance mechanisms such as handheld field devices for part of entry product testing. Support training initiatives to build the capacity of health care workers on the standard treatment guidelines for magnesium sulfate to ensure the proper administration and use of procured supplies to reduce overstock, wastage, and under-utilization of LSCs.
Zambia	<ul style="list-style-type: none"> Expanding storage capacity to meet supply needs for condoms. Implemented an electronic-based LMIS. Applied learnings from workshop by requiring oxytocin to be kept in the cold chain. 	<ul style="list-style-type: none"> Strengthen regulatory capacity and investments: <ul style="list-style-type: none"> To procure and use reference standards to conduct quality testing. To conduct sample testing as part of preauthorization and authorization. Provide training to nurses and midwives on treatment guidelines for magnesium sulfate and misoprostol to ensure proper administration and use of procured supplies to reduce overstock, wastage, and under-utilization of LSCs. Strengthen coordination among stakeholders to avoid duplication of procurement of condoms that may result in overstock.
Zimbabwe	<ul style="list-style-type: none"> Adopted an abridged registration procedure for SRA-approved and WHO-prequalified medicines. Products requiring cold chain are monitored during distribution with the use of data loggers. Implemented an assisted pull distribution system for commodities. Reported that all LSCs are included in the LMIS. 	<ul style="list-style-type: none"> Provide training to health care workers at peripheral clinics on treatment guidelines for magnesium sulfate and oxytocin to ensure proper administration and use of procured supplies to reduce overstock, wastage, and under-utilization of LSCs. Strengthen collaboration with academia and knowledge around best practices related to quality assurance and procurement of quality-assured LSCs. Identify tools to support linkages between LMIS (auto-DRV) and the Medical Store Department system.

