Pharmaceutical Management of Life-Saving Commodities: Safeguarding Access and Appropriate Use Now and in the Future
• Life-saving commodities
• Commodity management
• Examples of interventions to improve commodity management
• Transparency and accountability in commodity management
• Data on commodity management
• Prioritization for the Investment Case
“Pharmaceuticals are indispensable to health systems; complementing other types of health care services, they can reduce morbidity and mortality rates and enhance quality of life. Therefore, access to health care and essential medicines is increasingly being viewed as a fundamental human right. Yet the ability of pharmaceuticals to save lives, reduce suffering, and improve health depends on their being of good quality, safe, available, affordable, and properly used.” (WHO GGM)

- Availability of essential medicines in low- and middle-income country (LMIC) surveys averaged
  - 50% in the public sector
  - 67% in the private sector
- WHO estimates that at least 1/3 of the world’s population lacks regular access to essential medicines

Why Worry about Commodity Management?

- Medicines account for the first 3 of the top 10 inefficiencies in health systems (WHR 2010)
  1. Underuse of generics and higher than necessary prices for medicines
  2. Use of substandard and counterfeit medicines
  3. Inappropriate and ineffective use

- Keeps the population safe from harm due to inequitable access, inappropriate use, and unsafe medicines
- Medicine stock-outs can decrease demand for services, increase staff attrition, and ultimately compromise program effectiveness
- Gaps in access to reproductive, maternal, neonatal, child, and adolescent health (RMNCAH) commodities is a barrier to improving the lives of women, adolescents, and children
1. Shaping global market
2. Shaping delivery markets
3. Innovative financing
4. Quality strengthening
5. Regulation efficiency
6. Supply and awareness
7. Demand and awareness
8. Reaching women and children
9. Performance and accountability
10. Product innovation

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<th>Reproductive health</th>
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<td>Oral rehydration salts</td>
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<td>Zinc</td>
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UN Commission on Life-Saving Commodities (UNCoLSC) recommendations support clear objectives for under-utilized, life-saving commodities across the RMNCH continuum of care.
Commodity Management

- More than just procurement and distribution of commodities
- Ensures safety, quality, and cost-effectiveness of medicines as well as access
- Plus access to services that support appropriate and cost-effective use
How Do Medicines Reach Patients?
Complexities of Commodity Management
Dispensing or sale from Drug shops/pharmacies/community health workers (CHWs)/clinics

Key elements
- Product sold/dispensed appropriate to patient needs
- Appropriate packaging to facilitate correct use
- Counseling on use/administration
- Culturally sensitive service delivery
- Report on consumption

Common Bottlenecks
- Product not available
- Product not affordable or more expensive product sold
- Lack of packaging material
- Job aids/SOPs do not exist or not used
- Staff not trained or supervised in dispensing
- No system for reporting consumption or staff not motivated to report
Example of Pilot on Dispensing Aids for Amoxicillin DT for Pneumonia

**Amoxicillin 250mg dispersible tablets (DT)**
Treatment of pneumonia for children from 2 months to 5 years of age

**SUGGESTED DAILY DOSE**
- **2 months up to 12 months**
- **12 months up to 3 years**

**SIDE EFFECTS**
- Amoxicillin can cause the following side effects:
  - Nausea
  - Vomiting
  - Diarrhea
  - Rash
  - Headache

**INFORMATION FOR FAMILIES**
- Store between 15°C and 30°C
- Protect from moisture
- Do not store in or near the refrigerator

**IMPORTANT**
- Keep the dispensing aids out of reach of children
- Do not use if the product is expired
- Disposal: Disposing of the product in a punctured plastic bottle
- Do not mix with other medications

**FOLLOW UP**
- Home visit:
  - Monitor the child's condition
  - Changes to medication
  - Dietary advice
- Telephone visit:
  - Assess the child's response to treatment
  - Adjust dosage if necessary

**AT FOLLOW UPVisit**
- Check the child's:
  - Temperature
  - Breathing rate
  - Cough
  - Appetite
  - Urinary output
- Monitor for:
  - Signs of dehydration
  - Hypoglycemia
  - Anaphylaxis

**SIDE EFFECTS**
- Nausea
- Vomiting
- Diarrhea
- Rash
- Headache
Prescribing by CHWs/clinics

Key elements
- Appropriate prescribing
- Monitoring and mitigating adverse events of medicine
- Staff capacity (preservice & continuing education)
- Culturally sensitive service delivery
- Control of promotional activities

Common Bottlenecks
- Treatment guidelines do not exist, not disseminated, or not adhered to
- Best practices not included in STGs
- Staff not trained or supervised in prescribing
- Weak controls on medicine promotion
  - Inaccurate, misleading information
Distribution

To CHWs/pharmacies/drug shops/clinics, from regional stores/Central Medical Stores/wholesalers

Key elements
• Ensuring consistent availability of quality commodities
• Efficient Inventory management
• Adequate storage capacity & conditions
• Secure environment
• Adequate ordering/purchasing
• Efficient & appropriate transport (from stores to service delivery points)
• Logistics Information (tracking stock levels & distribution) to inform ordering/purchasing
• HR capacity (preservice and continuing education)

Common Bottlenecks
• SOPs not available or used
• Staff not trained in key tasks
• LMIS non functional
• Data from LMIS not analyzed or used
• Transport not available or no funds for running costs
Example – Senegal – Informed Push Model
“Yeksi naa”: Context 2012

Contraceptive Prevalence Rate (modern)

Unmet needs (married women)

12% 29%

Stockouts (% public SDPs)

44% Without full range of RH commodities

80% Stock outs

Results basic studies carried out

- WHO, 2011: 30% of beneficiaries reported having unmet needs for modern contraceptives
- McKinsey, 2013: 44% of facilities did not have the full range of essential reproductive health products. 80% of facilities experienced stock outs. 60% of facilities stock outs occurred even though products were available at PNA

Lack of financial resources
No control of consumption data
Lack of quantification of needs
Lack of logistical resources
Remoteness
Inaccessibility

Frequent stockouts at depot districts
“Yeksi naa”: Description of model

Old scheme before “Yeksi naa” launch

Scheme of “Yekesi naa”

“Jegesi Naa“
« I got closer »
350 references / CS

Integration of all program products

“Yeksi naa” «I arrived»
118 references
“YEKSI NAA”: RESULTS OBTAINED

- Availability of Consumption Data (100%)
- Availability of the set of products (75%)

Average stockout rate: 1.88%  
(August 2014 – July 2016)
Example Malawi - cStock

- Problems in availability of products and reporting by the community health agents (HSAs)
- Most HSAs had mobile phones
- Set up an intervention to improve flow of data and products using cStock through SMS of mobile phones and analysis by the District Product Availability team
- Health facility resupplies HSAs on receipt of stock levels by SMS
- Database calculates resupply quantity
- HSA collects when order is ready
- Supply Chain managers can monitor stock levels and stock outs and respond immediately
Results from Malawi

- Nationwide scale up by 2012 over 3700 HSAs
- Other products added to package eg FP and EPI
- DHIS 2 integration under m health platform
Procurement

By CMS/pharmacies/drug shops/clinics

Key elements
- Central and subnational procurement
- Ensure quality products-
  - WHO prequalified commodities
  - registered commodities
  - Use of approved suppliers or registered wholesalers
- Ensure reasonable prices
  - Tax waivers on essential commodities
  - Competitive transparent process
  - Large volume procurement
- Quantification: forecast and supply plan
- Tender management

Common Bottlenecks
- Lack of (or poor data) for quantification
- LMIS data not used
- Quantification assumptions not validated with stakeholders
- Frequent emergency procurements
- No guidelines on subnational procurement
- Procurement is non-competitive, mismanaged or affected by undue influence
- Poor monitoring of supplier and procurement performance
Procurement in Bangladesh

- Problem: Lengthy procurement lead times, delayed donor procurement approvals, incomplete and inaccurate data
- Coordination: Established a Procurement and Logistics Management Cell at ministry level, Forecasting Working Group at directorate level, and supply chain coordination forum
- Procurement reform: Guidelines, operations manual, and streamlined processes

- Information system: Increased visibility and use of data through Supply Chain Management Portal
• Procurement lead time decreased from 78 weeks to 33 weeks (FP) and 52 weeks (MNCH)
• Savings of USD 6.38m as of 2015 through improved quantification and oversight, thereby preventing unneeded procurements
• e.g., in FY 2012-2013, anticipated procurement of 65,000 implants was cancelled leading to a cost saving of USD 1.38 million
• In 2014-2015, procurement for 410,000 implants cancelled = cost-saving of USD 4.1 million
Example: Tanzania – improving commodity availability through Results Based Financing
The Government of Tanzania has been applying Results-based Financing (RBF) approaches to improve the quality and utilization of health services in primary care facilities. Tanzania’s RBF model links payment of cash upon verification of predetermined performance indicators. Currently, the scheme is being implemented in eight regions.

Procurement practices with RBF incentives
Tanzania Results

Quality of care

Dispensaries and health centers

Availability of tracer commodities

- Jan-Mar 2016: 45%
- Oct-Dec 2016: 67%
- July-Sept 2017: 80%
Financing

Key elements
- RMNCAH commodity security working group to advocate for resources
- Resources mobilized and allocated for procurement of RMNCAH commodities & services
- Sustainable source of funding
- Efficient use of resources
- Public financial management
- Tracking of expenditure on pharmaceuticals & inequities

Common Bottlenecks
- Insufficient/inequitable allocation
- Misalignment of donor fund cycles for commodity procurement
- Bottlenecks in financial flows: delays & inefficiencies
**Selection**

**Key elements**
- Selection of appropriate products
  - Essential Medicines List
  - Standard treatment Guidelines
- Selection of appropriate dosage forms
- Determine which commodities should be available at which level
- Insurance reimbursement lists

**Common Bottlenecks**
- EML not updated and aligned with treatment guidelines
- EML not widely disseminated
- Limited stakeholder involvement in review of EML and STGs
- No documented review process
- Lack of transparency; use of evidence or defined criteria for decision making
- Conflicts of interests not declared, reported and/or appropriately managed
Regulatory oversight & inspection

Key elements
- Licensing and inspection of pharmacies, drug stores, wholesalers & manufacturers
- Enforcement
- Provider registration

Common Bottlenecks
- Lack of pharmacy standards by which to inspect
- Lack of HR capacity to inspect and enforce
- Weak decentralized inspection
- Lack of information on which shops are licensed, which have been inspected and when and what the results were
- Weak enforcement of provider registration
Registration

Key elements
• Product registration
• Quality assurance - post marketing surveillance of medicines
• Pharmacovigilance

Common Bottlenecks
• Lengthy and inefficient registration process
• Lack of robust QA system
• No pharmacovigilance system or PV does not include RMCNH commodities
Strengthened Registration in DRC

- Weak regulatory capacity to manage registration and approval of new medicines
  - Large number of unregistered, substandard, and falsified medicines circulating
- Weaknesses in the registration process
  - No written procedures
  - No registration committee
  - No mechanism existed for tracking decision making
  - No official register of approved medicines
- Intervention
  - SOPs and guidelines for product registration
  - Staff training
  - National registration committee formed, schedule for quarterly meetings established
  - Database of registered products created
  - Set up systems for publishing and posting of the registered medicines list
More products were registered in the database (400 in 2011 to 4,606 in 2016)
1,392 products were deregistered in 2015-2016
Customs officers and inspectors are better equipped to identify and confiscate unregistered medicines at the border and in circulation in DRC
MOH has the capacity to systematically and transparently evaluate and approve medicines for registration, in a timely manner
Policy and legal framework

Key elements
- National Medicine Policy
- Policy on user fees and exemptions
- Legislation to regulate activities in public and private sectors
- Legal dispensing of medicines

Common Bottlenecks
- Misalignment of policy with strategies eg CHWs
- Legislation outdated or not enforceable
• To improve efficiencies and reduce wastage and mismanagement

• Coordination committees & quantification committees to increase participation and transparency, reduce wastage, analyze funding gaps, and minimize inconsistency and undue influence
  ➢ e.g., Swaziland TWG coordinated supply planning allowed UNFPA to cancel an unnecessary procurement of 12,000 sets of Jadelle implants, saving USD 102,000.

• Civil society participation and monitoring of service delivery, e.g., CSOs in Mali participated in national quantification workshops

• Strengthen information systems to generate reliable data that can be analyzed and used

• HR systems and processes fair and transparent
What do we know about commodity management in these 10 new GFF countries?
Availability: scarce and or outdated data

Availability of a set of essential medicines (%)

% of commodities with no stock outs at central level in 3 years

Reproductive Health

Percentage of primary SDPs with at least three modern FP methods available (2016)

Percentage of facilities with stock out of condoms (male and female) in 2016
### Guidelines, Policies and Systems

#### System policy factor

<table>
<thead>
<tr>
<th>System policy factor</th>
<th>Afghanistan</th>
<th>Burkina Faso</th>
<th>CAR</th>
<th>Côte d’Ivoire</th>
<th>Haiti</th>
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<td>Guidelines include ORS for management of diarrhea</td>
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<td>LMIS system</td>
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#### Percentage of 13 RMNCH LSC commodities on EML (2017)

- Afghanistan: 80%
- Burkina Faso: 80%
- Cambodia: 60%
- CAR: 40%
- Côte d’Ivoire: 60%
- Haiti: 80%
- Indonesia: 80%
- Madagascar: 80%
- Malawi: 80%

#### Percentage of RMNCH commodities that have at least one product registered (2013)

- Afghanistan: 73%
- Cambodia: 80%
- CAR: 80%
- Côte d’Ivoire: 80%
How to Prioritize what to include in the IC

• Identify bottlenecks in management of commodities
• Options for situational analysis
  – RMNCH landscape synthesis
  – Global Fund supply chain capacity maturity model
  – USAID supply chain assessments
  – WHO regulatory system benchmarks assessment
18 countries in sub-Saharan Africa and Asia conducted RMNCH Landscape Synthesis, including six (6) with multiple rounds (2013-2016)

- Conducted first round
- Multiple rounds conducted

Landscape Countries
- Bangladesh *
- Benin
- Burkina Faso
- Cameroon
- DRC
- Ethiopia
- Kenya *
- Malawi
- Mali
- Mozambique
- Niger
- Nigeria
- Pakistan
- Sierra Leone
- Senegal
- Tanzania
- Uganda
- Zambia

* Enumeration assisted by USAID
Country situational analysis

MALAWI

RMNCH Landscape Synthesis Summary Report 2016

Overview

This report summarizes the RMNCH Landscape Synthesis results, which reviews the state of commodity manufacturing, import, procurement, regulation, quality control, supply and utilization to help identify barriers to accessing life-saving RMNCH commodities and services. The RMNCH Landscape Synthesis brings together data from established information sources (including MoH documents, health facility assessments, and health management information systems, and household surveys). This is complemented by semi-structured interviews with MoH officials, procurement and regulatory agencies, and in-country partners. Based on this information, indicators were given a performance rating (weakest “1” to “5” strongest) and presented in the tables below.

In Malawi, the RMNCH Landscape Synthesis was conducted during February 2016 and involved a collaboration of in-country UN agencies, MoH personnel and partners.

Using the Summary Report

This report summarizes information on commodity-related bottlenecks and barriers to accessing life-saving RMNCH commodities and services. Identification of barriers can begin the conversation amongst government and partners to address these barriers and build sustainable solutions. Teams are encouraged to:

- Share this information with partners to examine bottlenecks and cultivate potential solutions
- Identify ways to integrate the solutions into country plans
- Share this information with stakeholders to advocate for solutions, raise resources, and foster accountability

Afghanistan (pending), Burkina Faso (2016), Malawi (2013, 2015, 2016)
Prioritization for investment case

- Barriers to access and availability of commodities include lack of information on financing, procurement, weak supply chains, inadequate regulatory capacity, and lack of coordination across stakeholders.
- Situational analysis to identify key bottlenecks
- Synergy with other donor efforts
- Involve all key stakeholders, including those with technical expertise in commodities, in determining bottlenecks and defining areas to intervene
- Look for most critical bottlenecks
Commodities are an essential piece of RMNCAH interventions.

Ensuring the safety, quality, availability, and appropriate use of commodities is paramount.

Procurement and distribution are not the only challenges.

Prioritizing key bottlenecks in commodity management can result in cost savings through improving efficiency.

Strengthening pharmaceutical systems takes time, and needs commitment, funding, and coordination, but is essential for sustainable improvements in access to medicines to meet needs of population now and in the future.

Consider key commodity management bottlenecks among priorities for Investment Case.
Learn More

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