

GFF Country Workshop, 28
January – 1 February 2018

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)¹



- Availability of essential medicines in low- and middle-income country (LMIC) surveys averaged²
 - 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 medicines³

1. Measuring Transparency in the Public Pharmaceutical Sector. Assessment Instrument WHO 2009

2. UN 2012. MDG 8: *The Global Partnership for Development: Making Rhetoric a Reality: MDG Gap Task Force Report 2012*. New York. UN

3. Hogerzeil, H.V., and Z. Mirza. 2011. *The World Medicines Situation 2011: Access to Essential Medicines as Part of the Right to Health*. 3rd ed. Geneva: WHO

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



Life-Saving Commodities for Women 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

Reproductive health

Female condoms
Implants
Emergency contraception

Maternal health

Oxytocin
Misoprostol
Magnesium sulfate

Newborn health

Injectable antibiotics
Antenatal corticosteroid (ANCS)
Chlorhexidine
Resuscitation equip.

Child health

Amoxicillin
Oral rehydration salts
Zinc

Accelerate achievement of MDGs 4 & 5



UN COMMISSION ON
LIFE-SAVING COMMODITIES
FOR WOMEN AND CHILDREN

Commissioners' Report
September 2012



UN Commission on Life-Saving Commodities (UNCoLSC) recommendations support clear objectives for under-utilized, life-saving commodities across the RMNCH continuum of care.

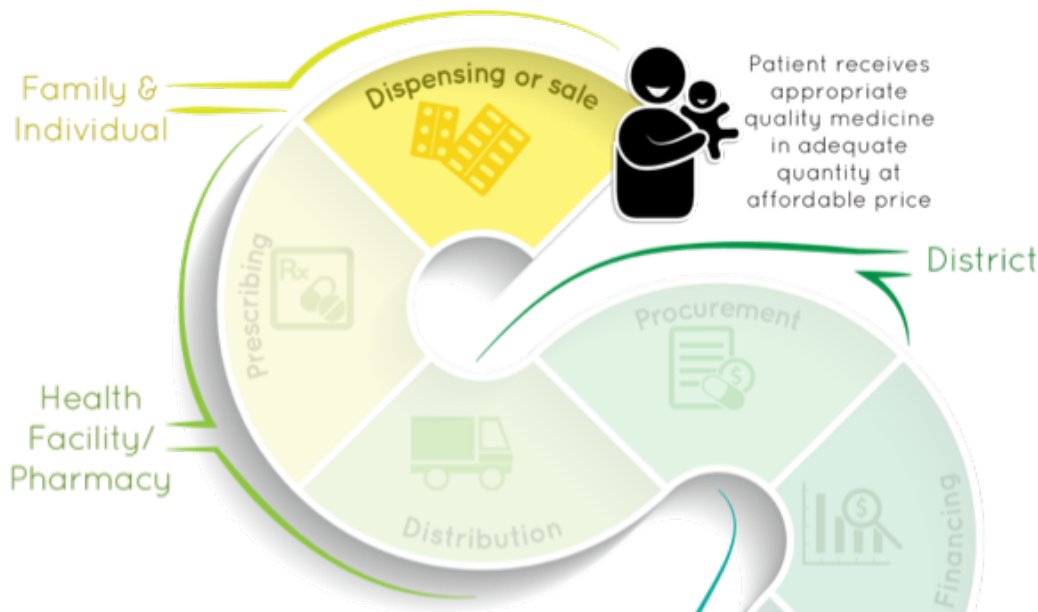
- More than just procurement and distribution of commodities
- Ensures safety, quality, and cost-effectiveness of medicines as well as access
- Plus access to services that support appropriate and cost-effective use



How Do Medicines Reach Patients? Complexities of Commodity Management



Dispensing or sale



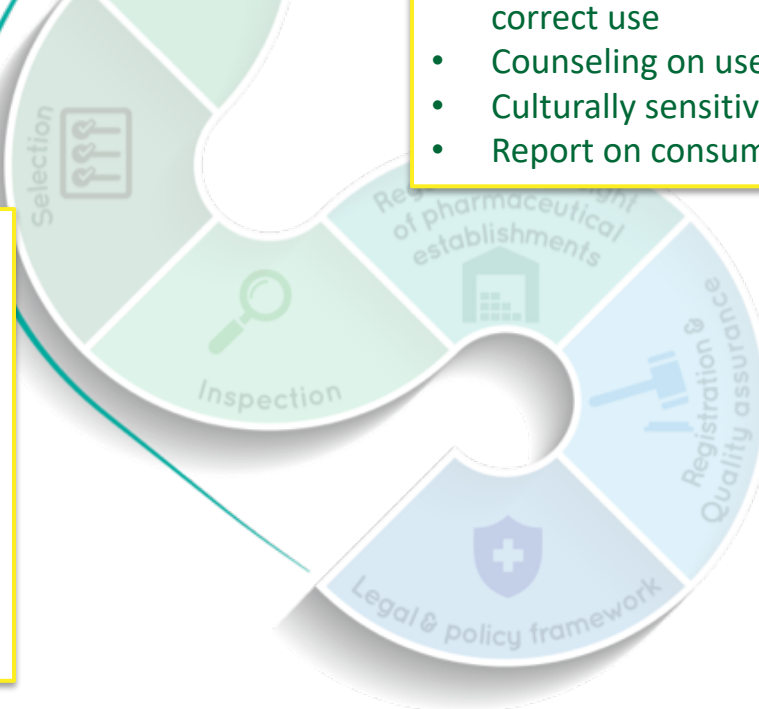
from Drug shops/ pharmacies/community health workers (CHWs)/clinics

Key elements

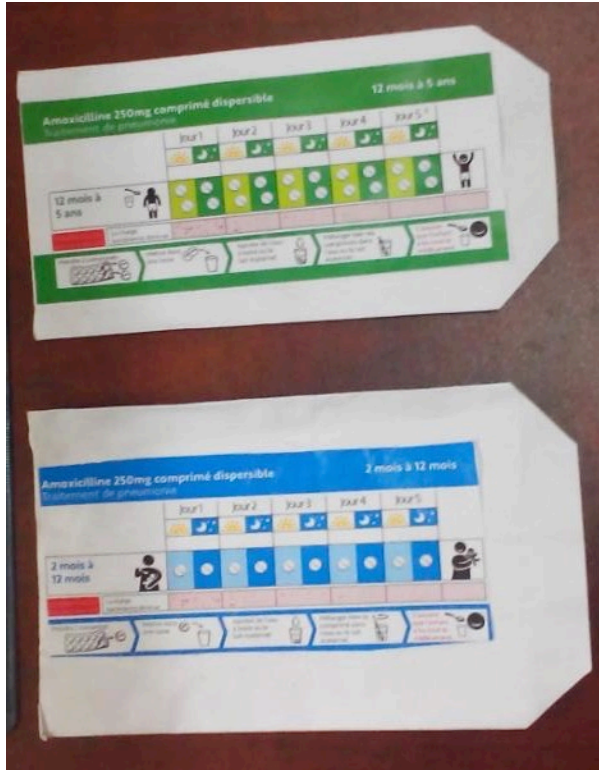
- Product sold/dispensed appropriate to patient needs
- Appropriate packaging to facilitate correct use
- Counseling on use/administration
- Culturally sensitive service delivery
- Report on consumption

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

EVERY BREATH COUNTS

DOING SCHEDULE

- Demonstrate by giving the first dose. Caregiver will watch and learn.
- Give the rest of the medicine to the caregiver to administer to the child at home.
- Instruct caregiver to give medicine twice per day for the full 5 days, even if the child feels better.

	Day 1	Day 2	Day 3	Day 4	Day 5
2 months up to 12 months	☀️	☀️	☀️	☀️	☀️
12 months up to 5 years	☀️	☀️	☀️	☀️	☀️
Complete all days of treatment	■	■	■	■	■
Bacterial load decrease	■	■	■	■	■

Please explain to caregiver: Even if the child feels better, the infection may still remain in their body. ALL of the medication must be given for the bacteria to be killed.

- Wash hands, then take:
- 1 tablet for 2 months up to 12 months.
- 2 tablets for 12 months up to 5 years.
- Put in a small, clean cup.
- Add clean drinking water or breast milk to cover tablet(s) completely. (5mL)
- Mix water and tablet(s) well.
- Make sure the child drinks all the medicine.

IMPORTANT

- Check expiration date before giving medicine to caregiver.
- Instruct caregiver to use mixture immediately and do not store for future use.
- Give child any remaining medicine left in cup.
- Instruct caregiver to keep amoxicillin DT out of the reach of children and in a clean, dry place.
- Medicine should not be shared.
- Amoxicillin will not treat a viral infection such as the common cold or flu.

FOLLOW UP

Instruct caregiver

- To continue breastfeeding and give the child more fluids.
- To return immediately if the child:
 - Becomes sicker
 - Is not able to drink or breastfeed
 - Is vomiting everything
 - Develops a fever
 - Continues fast or difficult breathing or wheezing

AT FOLLOW UP VISIT

- Check for danger signs
- Assess child for cough or difficulty breathing
- Ask caregiver:
 - Is the child breathing slower?
 - Is there less fever?
 - Is the child eating better?
- Consider referral if the child is not better.

SIDE EFFECTS

- Amoxicillin can cause the following side effects:
 - Side effects, as with other penicillins, are uncommon and mainly of a mild and transitory nature.



Prescribing



by CHWs/clinics

Key elements

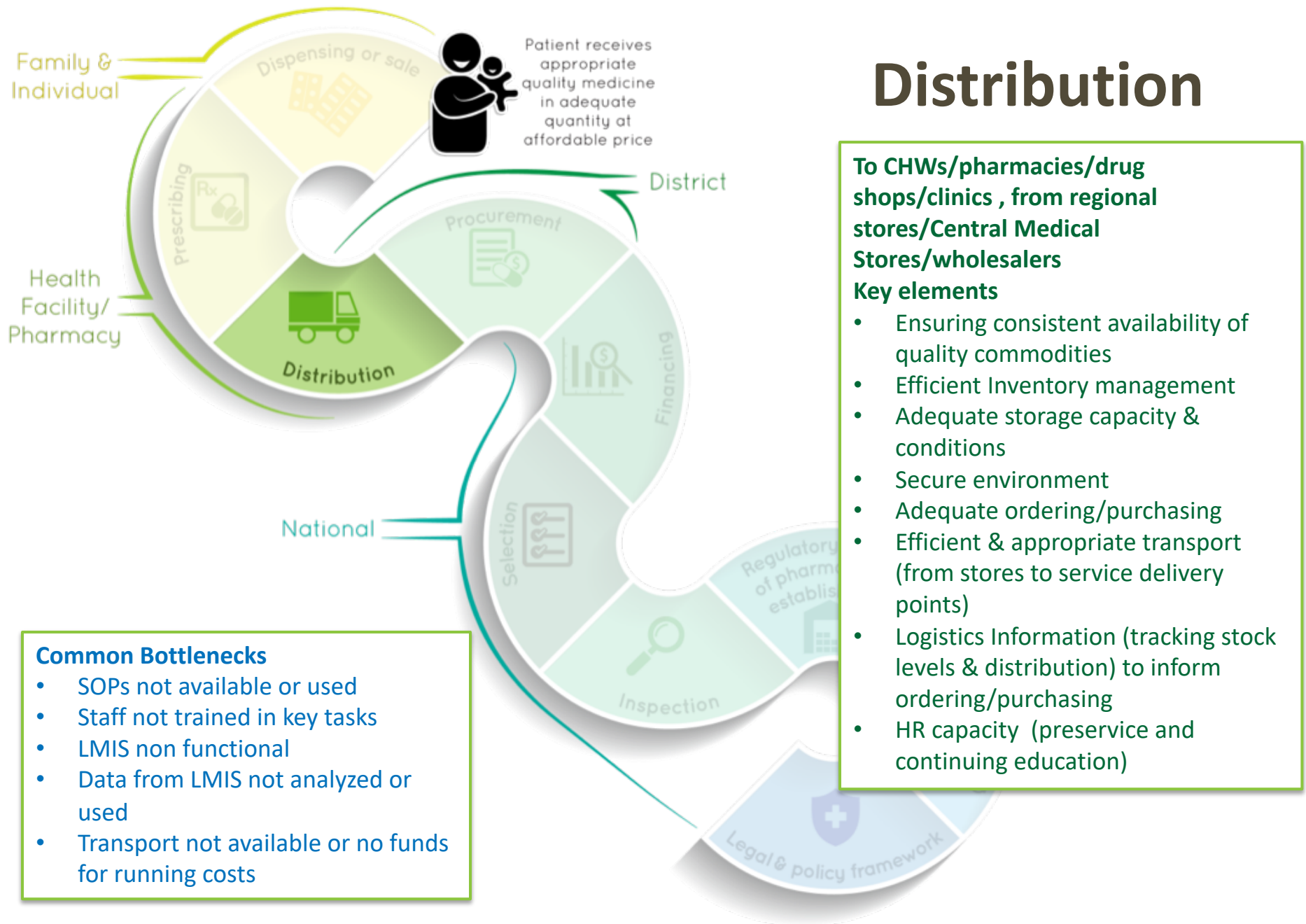
- Appropriate prescribing
- Monitoring and mitigating adverse events of medicine
- Staff capacity (preservice & continuing education)
- Culturally sensitive service delivery
- Control of promotional activities


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



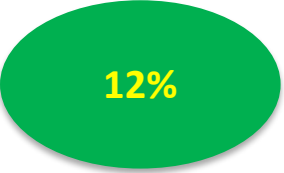


Example – Senegal – Informed Push Model

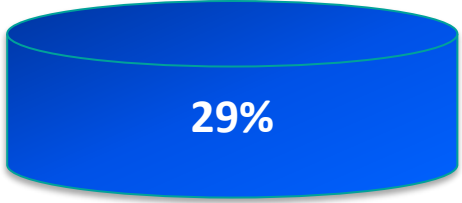


“Yeksi naa”: Context 2012

Contraceptive Prevalence Rate (modern)



Unmet needs (married women)



Stockouts (% public SDPs)



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

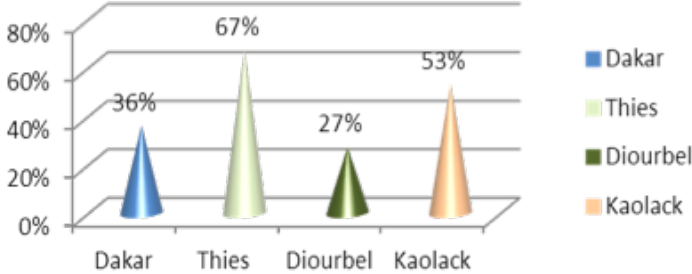
Lack of logistical resources

Remoteness

Inaccessibility

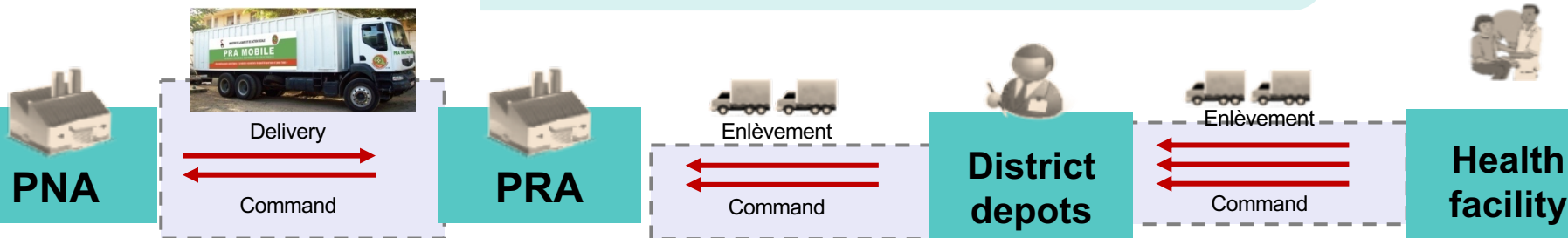


Frequent stockouts at depot districts

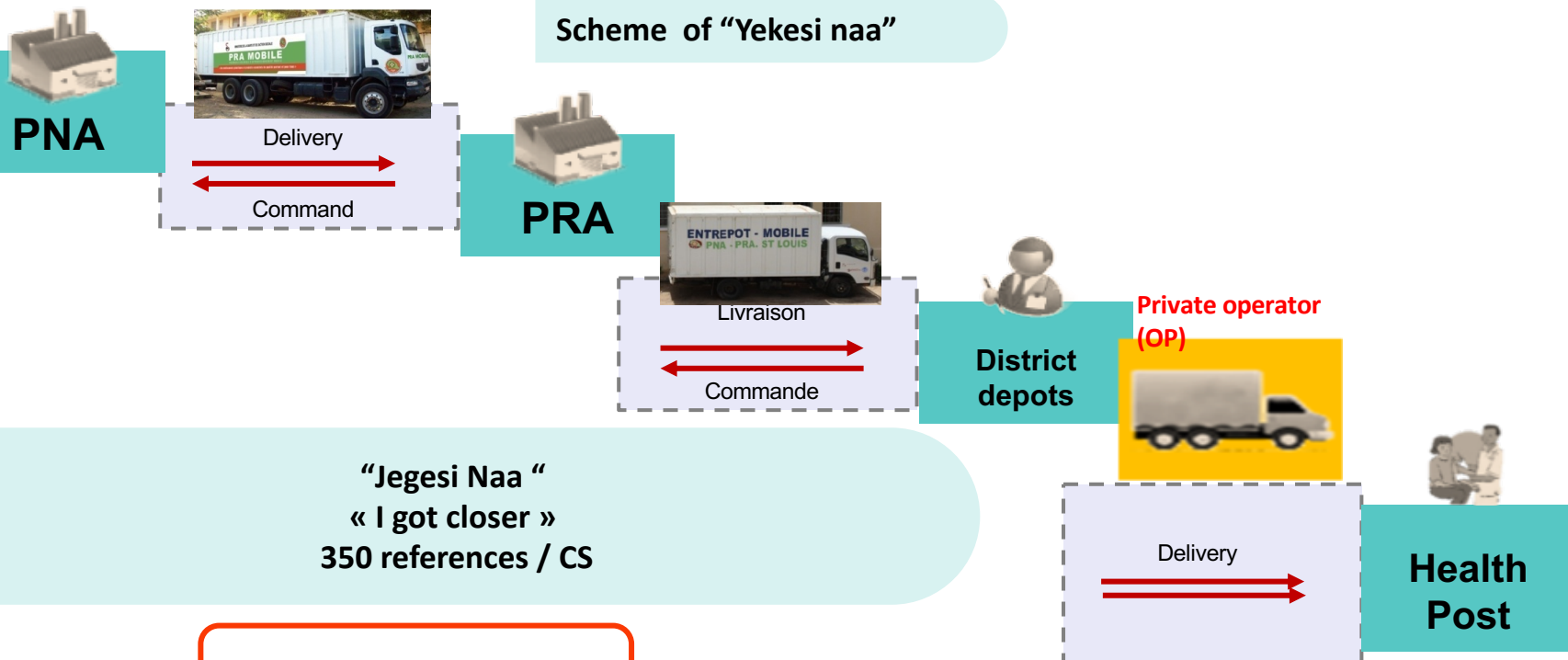


“Yeksi naa”: Description of model

Old scheme before “Yéksi 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

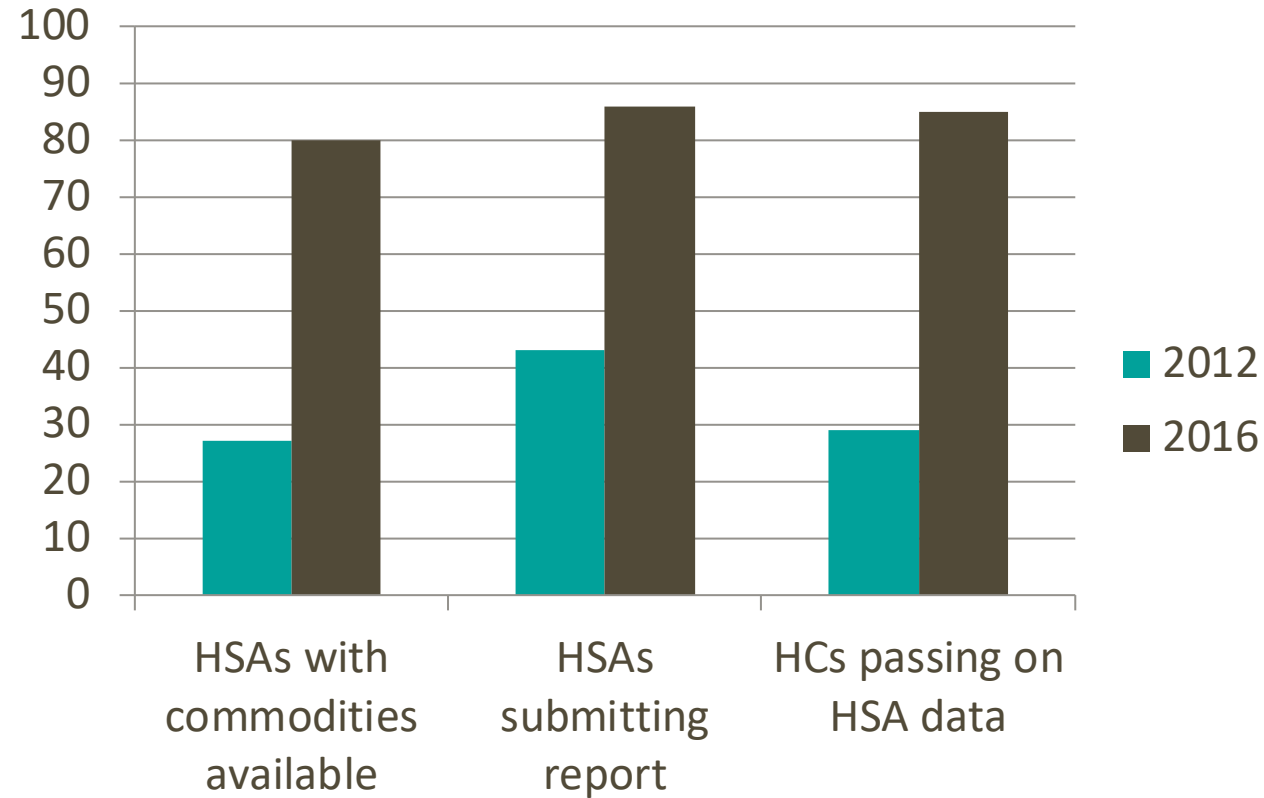


- **Availability of Consumption Data (100%)**
- **Availability of the set of products (75 %)**



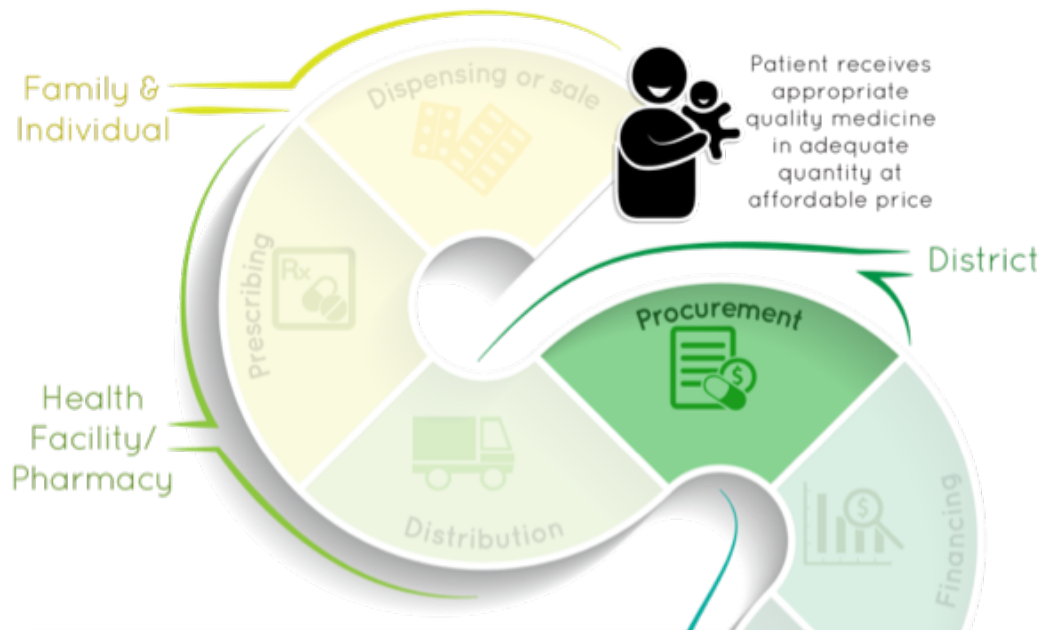
Average stockout rate: 1,88%
(August 2014 – July 2016)

- 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
- Data base calculates resupply quantity
- HSA collects when order is ready
- Supply Chain managers can monitor stock levels and stock outs and respond immediately



- 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



Common Bottlenecks

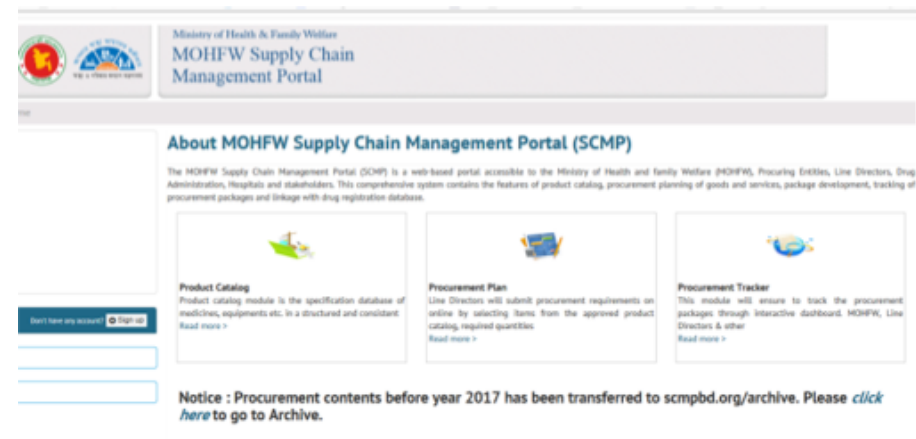
- Lack of (or poor data) for quantification
- LMIS data not used
- Quantification assumptions not validated with stakeholders
- Frequent emergency procurements
- No guidelines on subnational procurement
- Procurement is non-competitive, mismanaged or affected by undue influence
- Poor monitoring of supplier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

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

- 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

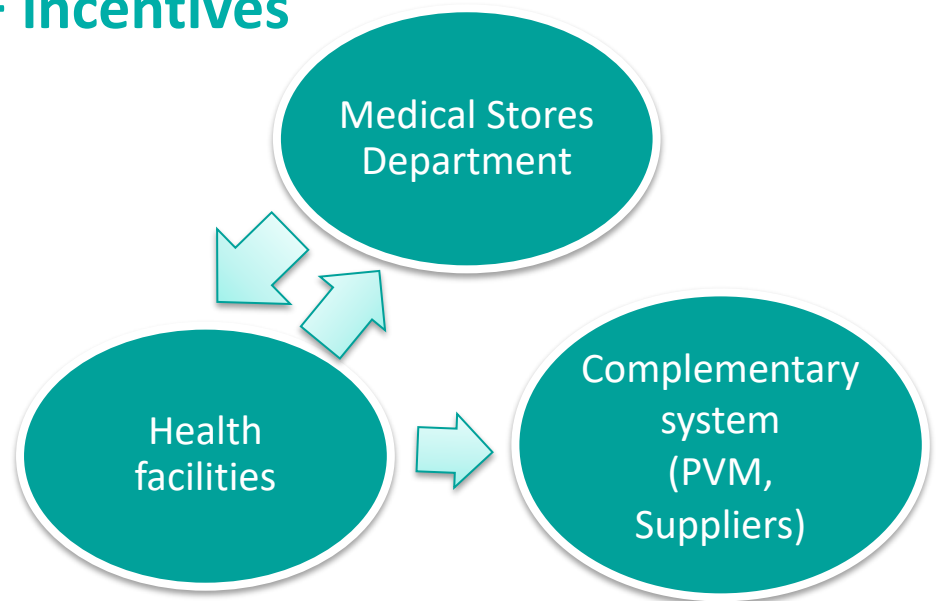
Example: Tanzania – improving commodity availability through Results Based Financing



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.

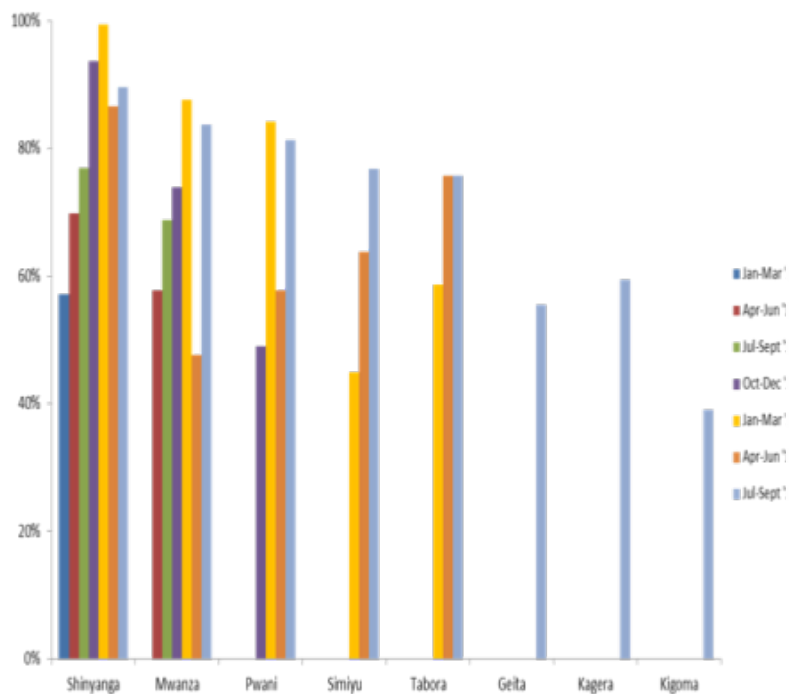
Tanzania's RBF model links payment of cash upon verification of predetermined performance indicators. Currently, the scheme is being implemented in eight regions

Procurement practices with RBF incentives



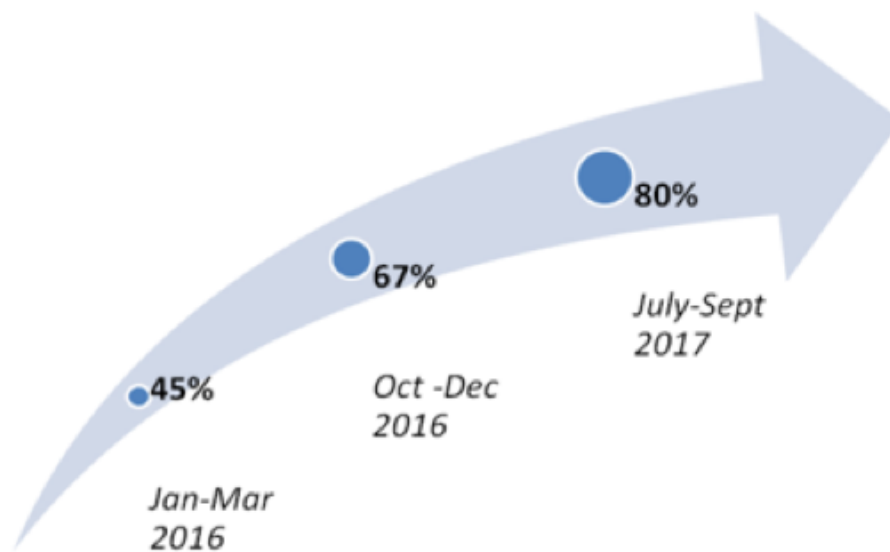
Tanzania Results

Quality of care

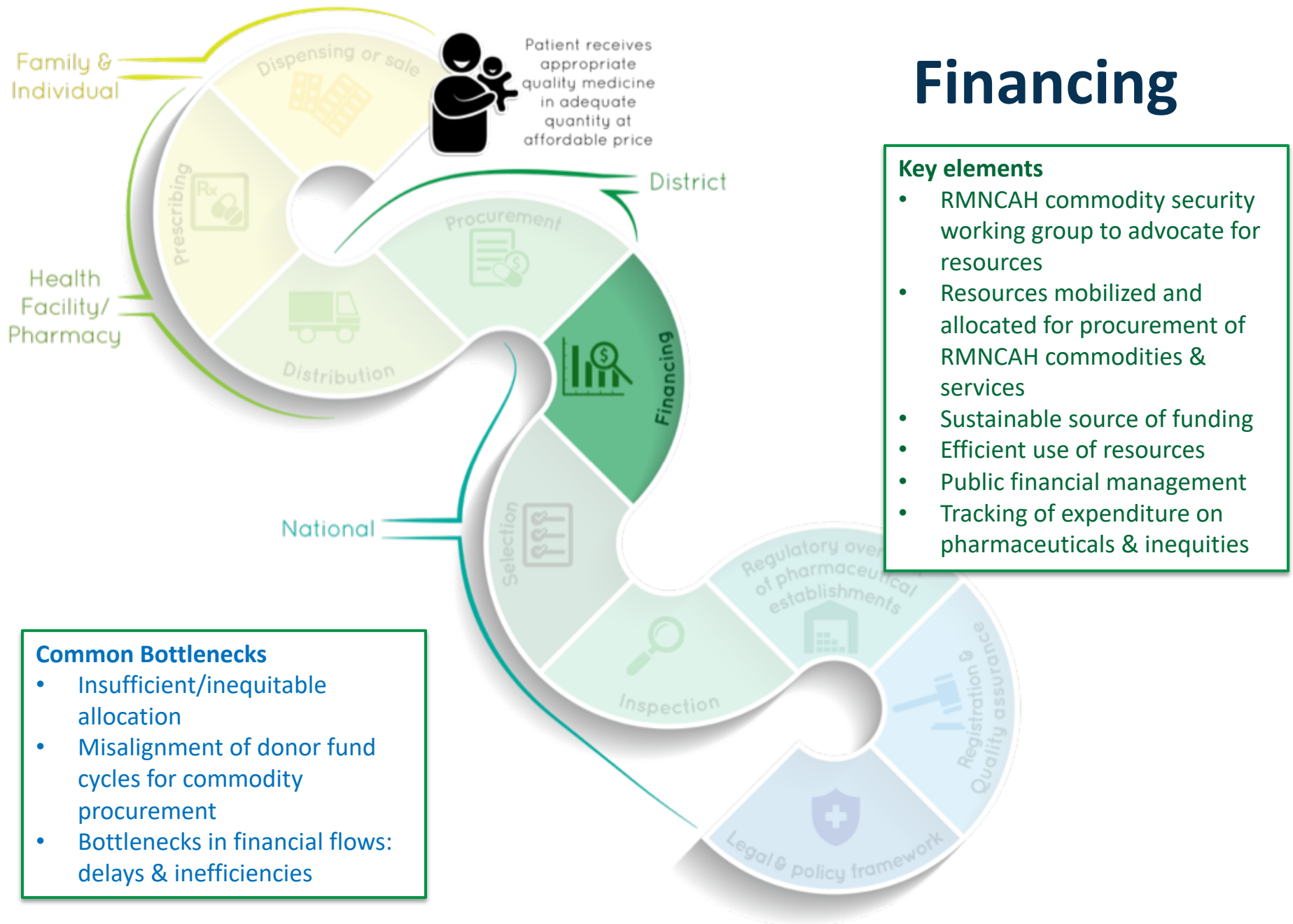


Dispensaries and health centers

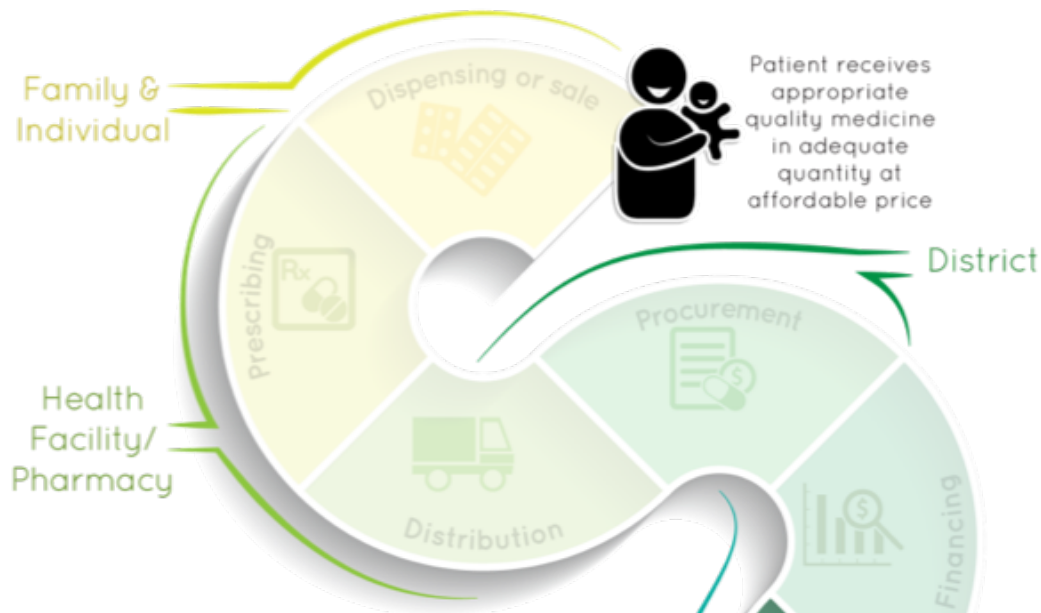
Availability of tracer commodities



Financing



Selection



Key elements

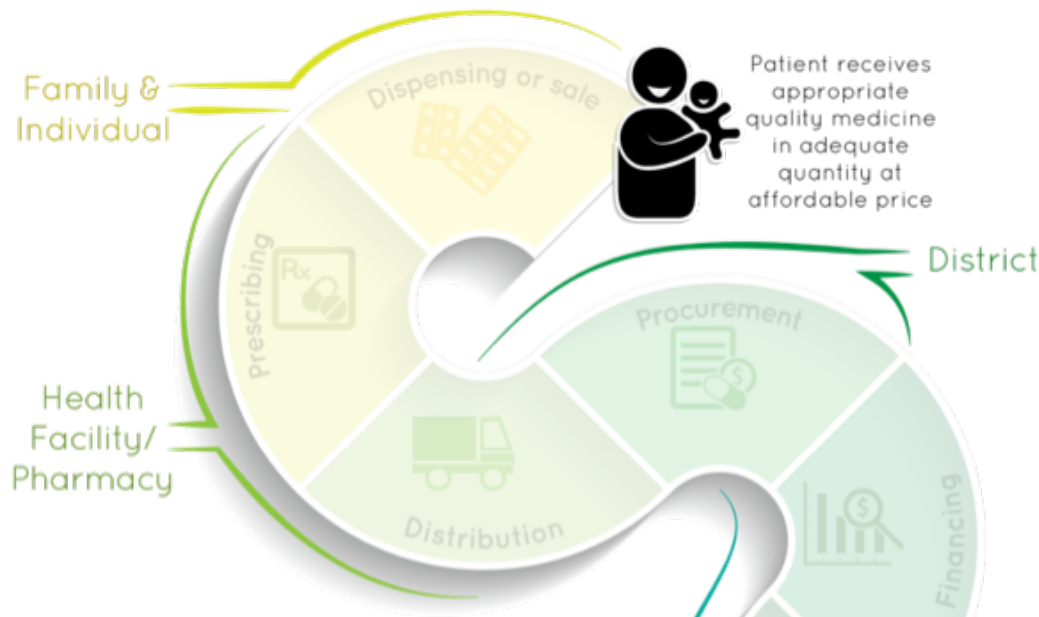
- Selection of appropriate products
 - Essential Medicines List
 - Standard treatment Guidelines
- Selection of appropriate dosage forms
- Determine which commodities should be available at which level
- Insurance reimbursement lists

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

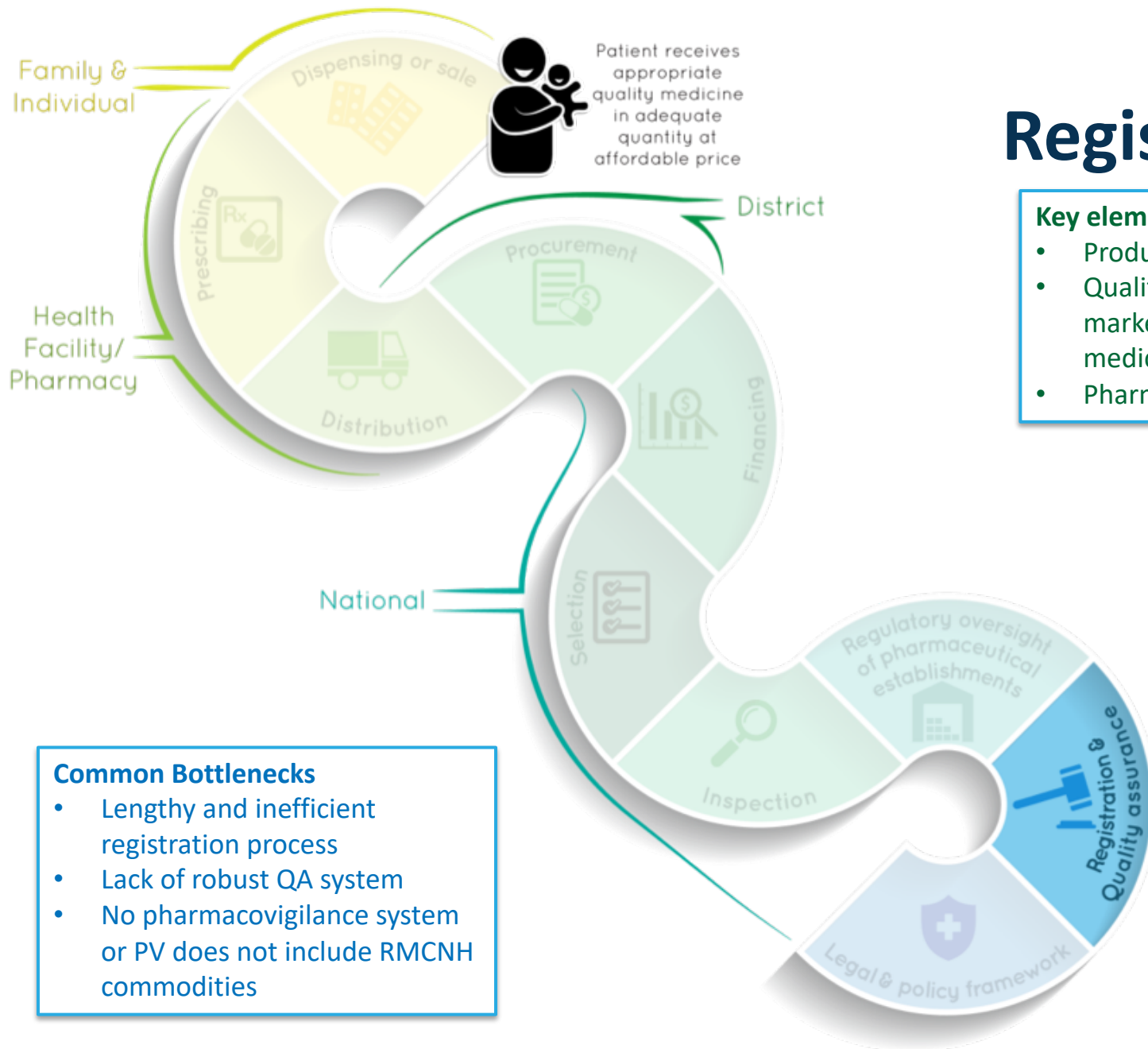
- Lack of pharmacy standards by which to inspect
- Lack of HR capacity to inspect and enforce
- Weak decentralized inspection
- Lack of information on which shops are licensed, which have been inspected and when and what the results were
- Weak enforcement of provider registration



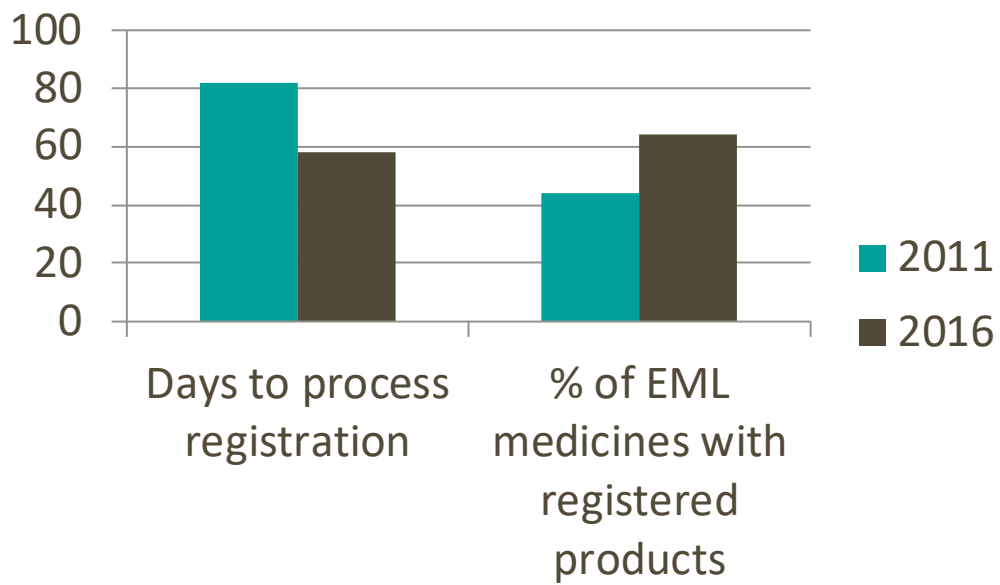
Registration

Key elements

- Product registration
- Quality assurance- post marketing surveillance of medicines
- Pharmacovigilance

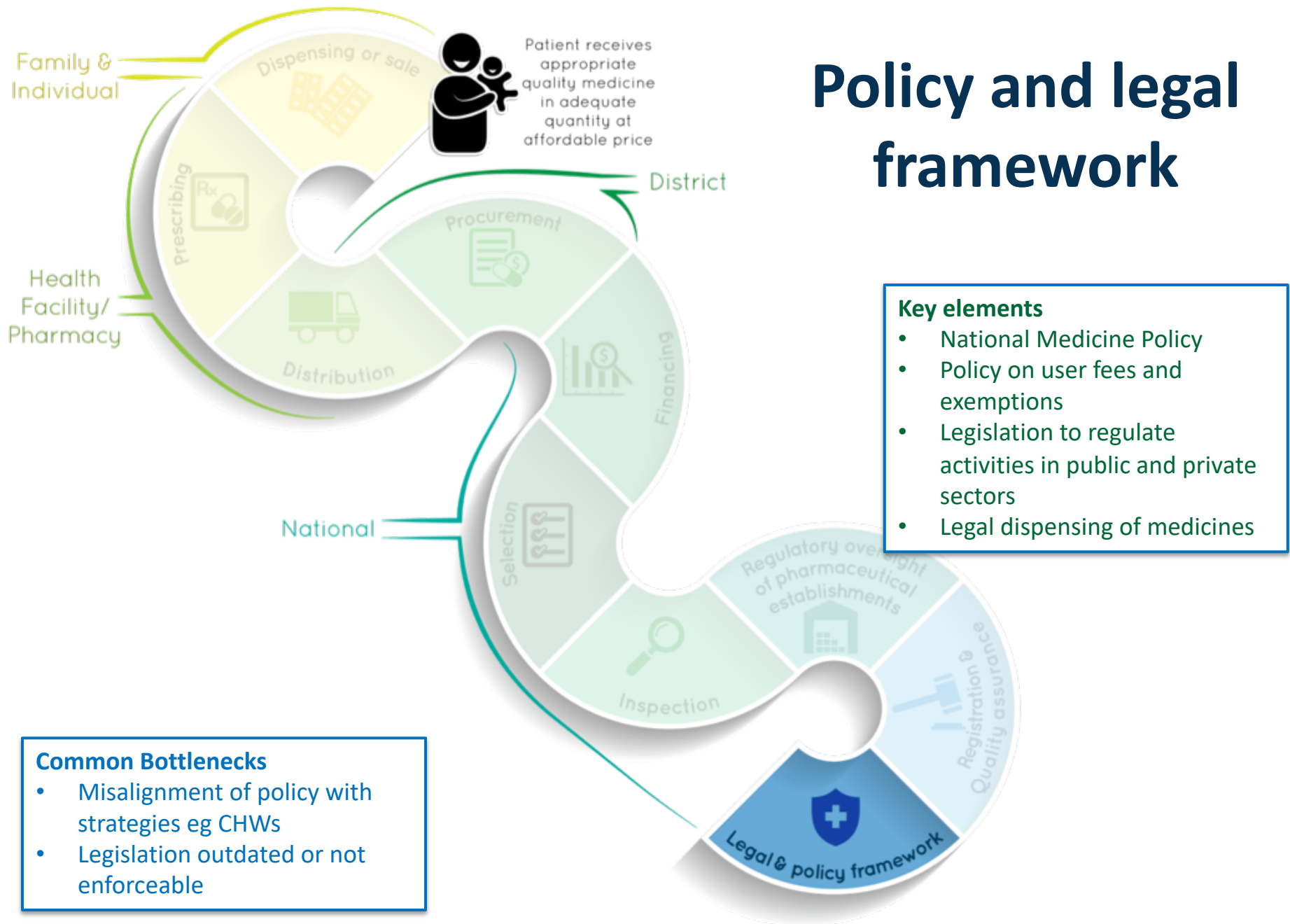


- Weak regulatory capacity to manage registration and approval of new medicines
 - Large number of unregistered, substandard, and falsified medicines circulating
- Weaknesses in the registration process
 - No written procedures
 - No registration committee
 - No mechanism existed for tracking decision 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



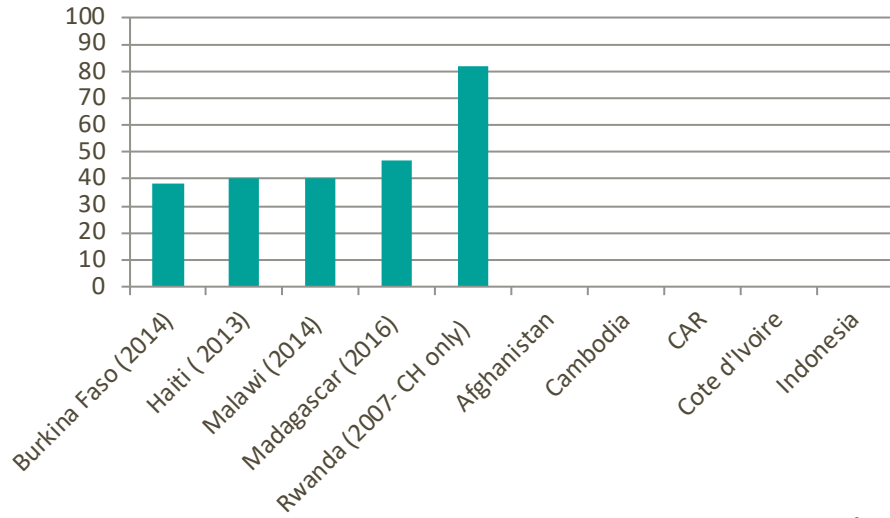
- **To improve efficiencies and reduce wastage and mismanagement**
- **Coordination committees & quantification committees to increase participation and transparency, reduce wastage, analyze funding gaps, and minimize inconsistency and undue influence**
 - e.g., Swaziland TWG coordinated supply planning 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**



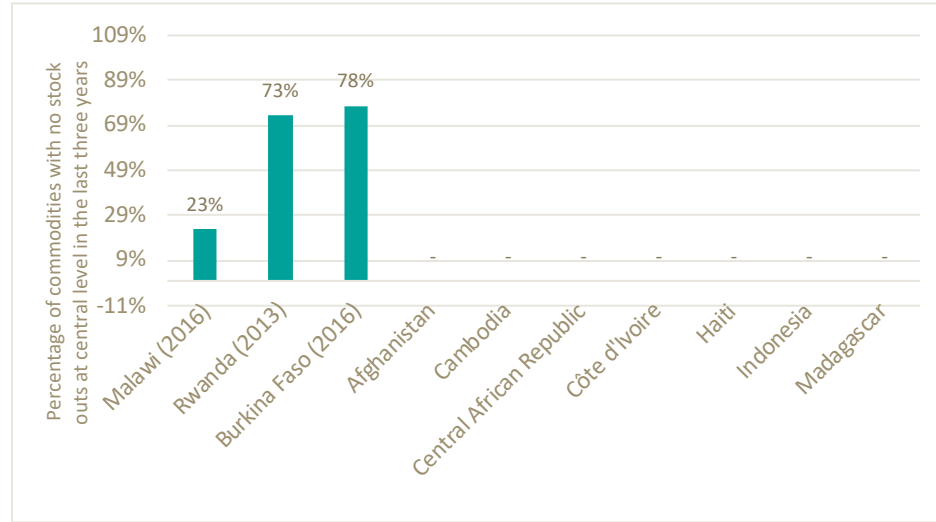
What do we know about commodity management in these 10 new GFF countries?

Availability: scarce and or outdated data

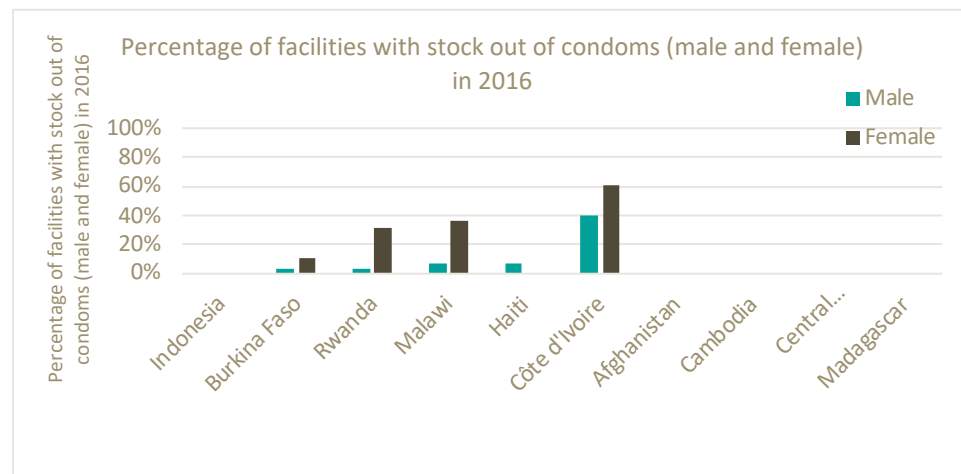
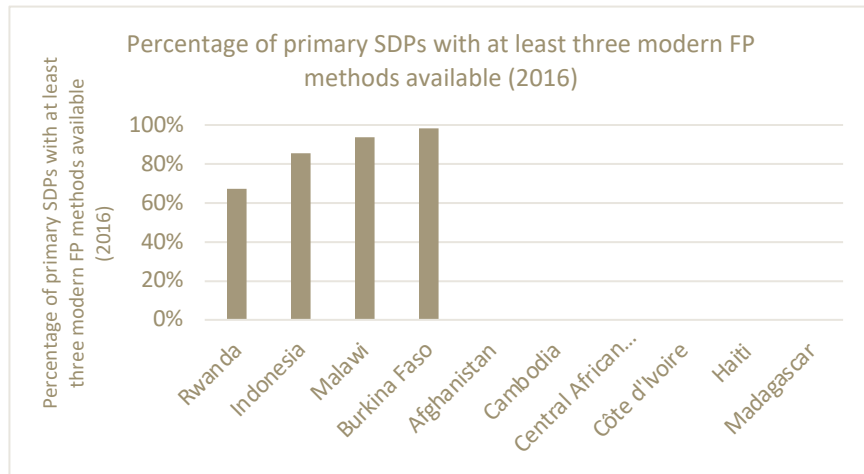
Availability of a set of essential medicines (%)



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



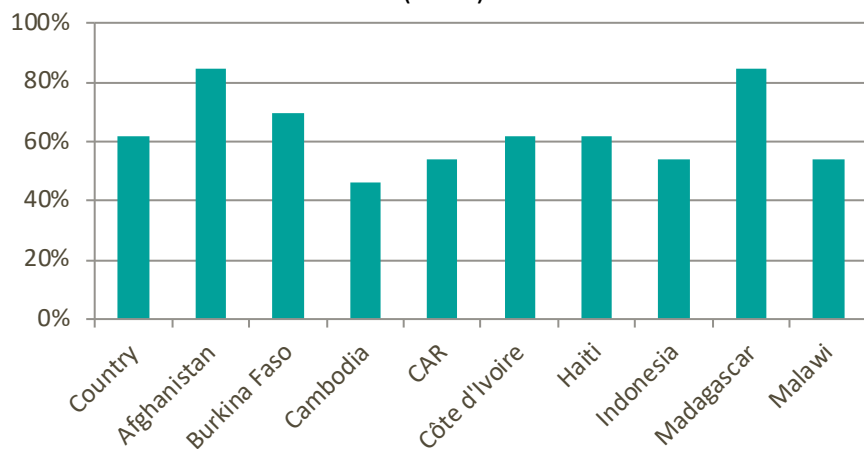
Reproductive Health



Guidelines, Policies and Systems

System policy factor	Afghanistan	Burkina Faso	Cambodia	CAR	Côte d'Ivoire	Haiti	Indonesia	Madagascar	Malawi	Rwanda
EML up to date *	2014	2014		2009	2013	2012	2011	2008		2010
Guidelines include ORS for management of diarrhea										
Guidelines include zinc for management of diarrhea										
Guidelines include oxytocin for mngmt of 3rd stage of labor										
Guidelines include magnesium sulphate for eclampsia										
Policy for community case management of diarrhea										
Policy for community case management of pneumonia										
LMIS system										
Quality problems reported (pharmacovigilance)										
Products sampled for quality testing										

Percentage of 13 RMNCH LSC commodities on EML (2017)

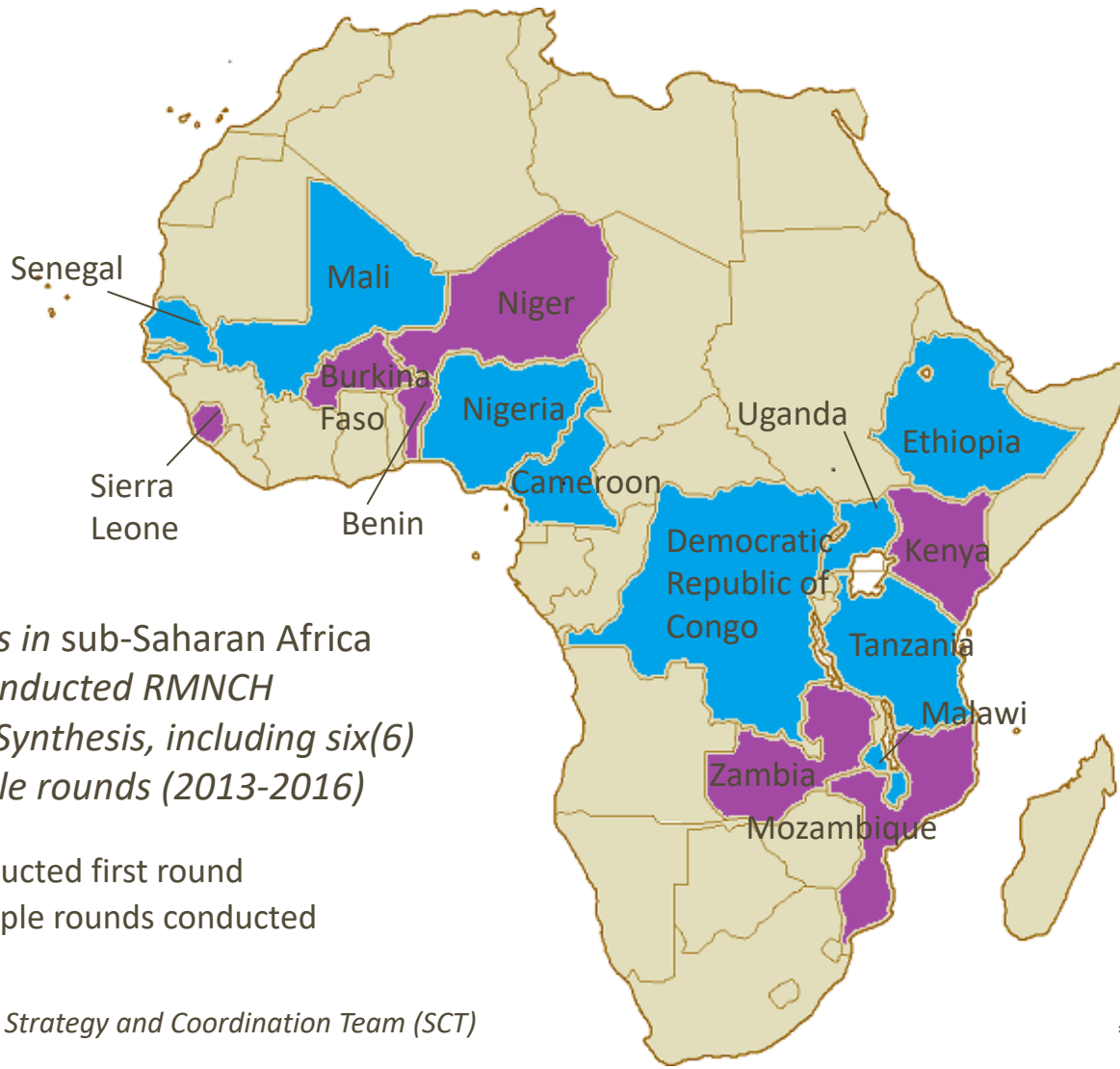


Percentage of RMNCH commodities that have at least one product registered (2013)



- 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

Situational Analysis using the RMNCH Landscape Synthesis Tool



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

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

Slide from RMNCH Strategy and Coordination Team (SCT)

* Enumeration assisted by USAID

Country situational analysis

Select Country Single-Country Dashboard: Burkina Faso Download PDF
Download XLS

Commodity Specific Reset ● Very Weak ● Weak ● Moderate ● Strong ● Very Strong ○ Missing Data ⊗ Not Applicable

		Regulatory				Supply			Performance				Demand & Access		
		National EML	National Treatment Guidelines	Registered In-Country	Prescription Authority	Tracked in eLMIS	National stock-outs	Percent of FOC with stock available	Training Curriculum developed (National)	% facilities with trained personnel	Job-aids / Checklists developed (National)	% facilities with job-aids / checklists	Policy against user fees	Service utilization routinely tracked	Coverage rate
REPRODUCTIVE	Female condom	5	3	3	5	5	5	90%	5	88%	3	55%	1	5	2%
	Implants	5	3	3	5	5	5	91%	5	85%	3	55%	1	5	12%
	Emergency contra.	5	1	3	1	3	3	15%	5	85%	3	55%	1	1	3
MATERNAL	Oxytocin	5	5	3	5	5	1	90%	5	80%	3	72%	5	1	3
	Misoprostol	5	5	3	5	5	3	1%	5	80%	3	72%	5	1	3
	Magnesium sulfate	5	5	3	5	5	5	24%	5	80%	3	72%	5	3	3
NEW BORN	Injectable antibiotics	5	5	3	5	5	5	92%	3	53%	3	99%	5	1	3
	Anfenatal corticosteroids	5	5	3	1	5	1	72%	3	53%	3	99%	5	1	3
	Chlorhexidine	1	1	3	1	3	3	3	53%	3	99%	5	1	3	
CHILD	Neonatal resuscitation	3	5	3	3	3	3	3	53%	3	99%	5	1	3	
	Amoxicillin	5	5	3	5	5	5	89%	3	83%	3	5	3	41%	
	ORS	5	5	3	5	5	5	82%	3	83%	3	5	3	21%	
	Zinc	5	5	3	5	5	5	72%	3	83%	3	5	3	0%	

Systemic

	Coordination			Innovative financing		Quality			Supply		Demand & Access
	Coordination mechanism	RMNCH plan coded and budgeted	Commodity security strategy	Results-based financing mechanism	Procurement from GMP- accredited manufacturers	National medicines control lab	Monitoring quality and safety of medicines	Forecasting tools	Comprehensive national eLMIS	Supply chain training to districts	Demand generation
Burkina Faso	3	3	5	3	5	3	5	4	3	5	5

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, health and logistic 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)² 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 partners³.

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

- 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

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