USAID
FROM THE AMERICAN PEOPLE

SIAPS
Systems for Improved Access to Pharmaceuticals and Services

Guidance for Planning the Introduction of New Reproductive, Maternal, Newborn, and Child Health Medicines and Supplies

March 2016

Guidance for Planning the Introduction of New Reproductive, Maternal, Newborn, and Child Health Medicines and Supplies

Maheen Malik
Beth Yeager
Suzanne Diarra

March 2016

This document is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

Recommended Citation

Maheen Malik, Beth Yeager, Suzanne Diarra. 2016. *Guidance for Planning the Introduction of New Reproductive, Maternal, Newborn, and Child Health Medicines and Supplies.* Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

Key Words

New products, country introduction, RMNCH products, introduction strategy, steps for new product introduction

Systems for Improved Access to Pharmaceuticals and Services
Pharmaceutical and Health Technologies Group
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: siaps@msh.org
Website: www.siapsprogram.org

CONTENTS

ACRONYMS

ACSM	advocacy communication and social mobilization
BCC	behavior change communication
cGMP	Current Good Manufacturing Practices
DTC	Drug and Therapeutics Committee
DRA	drug regulatory authority
EML	essential medicines list
LMIC	low- and middle-income countries
LMIS	Logistics Management Information System
MDG	Millennium Development Goal
MNCH	maternal, newborn, and child health
MOH	Ministry of Health
MSH	Management Sciences for Health
NDRA	national drug regulatory authority
RMNCH	reproductive, maternal, neonatal, and child health
SDG	sustainable development goals
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SPS	Strengthening Pharmaceutical Services
STG	standard treatment guideline
UN	United Nations
USAID	US Agency for International Development
WHO	World Health Organization

ACKNOWLEDGMENTS

The authors would like to acknowledge the following individuals for their valuable contributions to this document:

Jane Briggs	SIAPS/Management Sciences for Health
Dr. Shekib Arab	Reproductive Health Department, Ministry of Public Health, Afghanistan
Dr. Ajmal Yadgari	Strengthening Pharmaceutical Services (SPS)/Management Sciences for Health

BACKGROUND

Through combined global and in-country efforts, progress has been made in reducing maternal, newborn, and child mortality rates over the past decades. However, the rates remain alarmingly high. A large proportion of these deaths could have been avoided if women and children had access to adequate health services and essential medicines and supplies. A distinct difference in outcomes is seen when the necessary quality medicines and supplies are available along with skilled health providers to attend this vulnerable group. The preventive and curative measures for the major causes of maternal, newborn, and child deaths are well-known, but access to them remains elusive for many.

Global initiatives, including Every Women Every Child,[1] A Promise Renewed,[2] Acting on the Call, A Call to Action[3,4] Every Newborn: An Action Plan to End Preventable Deaths,[5] and Helping Babies Breathe®,[6] are designed with the common goal of improving maternal, neonatal, and child health outcomes. These initiatives aim to make essential maternal, newborn, and child health commodities and services accessible to those women and children who need them and, where they are needed, by providing training, products, and equipment at all levels of the health system. For the post-2015 development agenda, the Sustainable Development Goals (SDG), specifically Goal 3: "Ensure healthy lives and promote well-being for all at all ages," continue to focus attention on reductions in maternal and child mortality. However, within the ambitious context of universal health coverage, active involvement of all stakeholders is required. The vision of the US Agency for International Development (USAID) for "a world where no woman dies from preventable maternal causes and maternal and fetal health are improved" requires USAID to contribute to accelerating reductions in the maternal mortality rate and improving maternal and fetal health targets by 2020.[7]

The Millennium Development Goals (MDG) provided an important framework for development, and significant progress was made in a number of areas. However, progress has been uneven across countries, especially in areas related to maternal, newborn, and child health as well as in reproductive health. The SDG agenda builds on the MDGs and seeks to complete what has not yet been achieved, particularly in reaching the most vulnerable. In the September 2015 United Nations General Assembly meeting, participating countries once again committed to accelerating progress made to date in reducing newborn, child, and maternal mortality by ending all such preventable deaths before 2030.[8]

---

[1] Every Woman Every Child; http://www.everywomaneverychild.org/
[2] A Promise Renewed; http://www.apromiserenewed.org/.
[3] UNICEF et al. Child Survival Call to Action; http://5thbday.usaid.gov/pages/responsesub/roadmap.pdf
[4] A Call to Action; http://www.unicef.org/ceecis/UNICEF_A_call_to_action_En_Web(1).pdf.
[5] Every Newborn: An Action Plan to End Preventable Deaths; http://www.everynewborn.org/.
[6] Helping Babies Breathe®; http://www.helpingbabiesbreathe.org/.
[7] Ending Preventable Maternal Mortality: USAID Maternal Health Vision for Action Evidence for Strategic Approaches, January 2015; http://www.usaid.gov/sites/default/files/documents/1864/MH%20Strategy_web_red.pdf.
[8] Transforming our world-the 2030 Agenda for Sustainable Development; http://www.un.org/ga/search/view_doc.asp?symbol=A/70/L.1&Lang=E.

In recognition of the need for heightened attention to these issues, in 2014 USAID and the global maternal, newborn, and child health (MNCH) community renewed their commitment to ending preventable child and maternal deaths by 2035. Global targets of an average of fewer than 50 maternal deaths per 100,000 live births and fewer than 20 child deaths per 1,000 live births were set. The achievement of these targets requires a focused, systems-strengthening approach.

In an effort to accelerate progress in the achievement of MDGs 4 and 5, under the UN Commission on Life-Saving Commodities for Women and Children, a number of working groups have been actively working to achieve specific goals. These working groups represent an international collaboration of organizations dedicated to advancing the use of 13 priority commodities. The groups have been actively involved in advocacy efforts at both global and national levels to introduce and increase access to these commodities. The World Health Organization (WHO) has issued revised guidelines on the use of several of these commodities.

As countries are being sensitized to the global activities and interventions under the Every Woman Every Child initiative, they are accelerating efforts to reach the common goal of reducing maternal, neonatal, and child morbidity and mortality in their countries. An initial group of eight pathfinder countries[9] started developing coordinated reproductive, maternal, neonatal, and child health (RMNCH) strategies and country implementation plans, and proceeded to implement plans to scale up access to these commodities. Their work has included assuring that some or all of the 13 priority RMNCH commodities are on their essential medicines lists (EML), and revising standard treatment guidelines (STG) or service delivery protocols to reflect the EML changes. Some of them have moved even further by conducting forecasting exercises for procurement of these commodities, actual procurements, activities to create demand generation, and training of service providers. Recently, more countries have pledged to join the efforts to improve their RMNCH indicators.

However, as many countries embark on these interventions, they often stumble upon common bottlenecks. For example, some commodities are either completely new to the health system or are replacing currently recommended medicines and guidelines. Indeed, in many of the pathfinder countries' implementation plans, coordinated finance and project planning is either weak or entirely absent. To successfully introduce a new commodity, a harmonized plan for its introduction, developed using a step-wise approach and involving concerned stakeholders, is essential. Guidance for program managers ensures that the essential steps are taken and that the steps include two critical components: program planning and financing.

Management Sciences for Health (MSH) works in the design of approaches and interventions for the successful introduction of new technologies and medicines to improve the health and well-being of underserved populations around the world. Benefiting from past work and documents developed, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services program (SIAPS) has been involved in the introduction of new products at the country level. SIAPS prepared this guidance document based on its experience as well as past work undertaken

[9] Uganda, Nigeria, Senegal, Sierra Leone, Malawi, Democratic Republic of the Congo, Tanzania, and Ethiopia.

by MSH[10] to support the introduction of new medicines and commodities to assist countries in their interventions to end preventable child and maternal deaths. This document describes the factors that need to be in place to ensure access to quality RMNCH medicines. It walks the user through each essential step, which may need to be adapted based on an individual country's or program's needs. It helps the user clarify and define key roles and responsibilities to introduce new RMNCH medicines and to strengthen national RMNCH plans, resources, and processes.

By developing and implementing a systemic strategy, it will be easier for countries to effectively introduce a new product as well as to subsequently evaluate program interventions in a standardized manner and to recommend changes.

[10] SIAPS. *Developing, Implementing, and Monitoring the Use of Standard Treatment Guidelines: A SIAPS How-to Manual*. Arlington, VA: Management Sciences for Health; 2015. http://siapsprogram.org/publication/stg-how-to-manual/.
Essential Medicines Lists and Standard Treatment Guidelines; http://siapsprogram.org/approach/pharmaceutical-services/essential-medicines-lists/.
Maternal and Child Health; http://siapsprogram.org/health_areas/maternal-and-child-health/.

ABOUT THIS GUIDE

Purpose

The purpose of this document is to provide guidance to program managers in ministries of health at national and sub-national levels as well as personnel in other interested organizations on actions to take and factors to consider when expanding access to essential RMNCH commodities. While this document focuses on RMNCH medicines and supplies, it may be used as a guiding document and planning tool for other essential medicines and supplies. This guide addresses several pharmaceutical management issues (pharmaceutical policies, effective medicine management, strengthening regulatory systems, information needs, and product quality and safety practices) that are often overlooked when considering the introduction of new products. Many essential RMNCH medicines and supplies are generic products that are currently widely available in both the public and private sectors. However, these commodities often appear in differing formulations and presentations, and may be of questionable quality. Ensuring access and availability of quality medicines and supplies in-country requires: improving pharmaceutical policy; enforcing compliance with policies and procedures, especially in procurement; and addressing regulatory components of the health system. Likewise, several key RMNCH products are often only authorized for administration by highly skilled providers despite evidence that administration by less skilled providers is both feasible and effective. These types of policies limit the availability of these products to higher-level health facilities as opposed to also having them available at lower-level health facilities or at the community level. The systems strengthening approach described in this document focuses on governance, human resources, information systems, financing, and service delivery, with the provision of medical products cutting across these sub-systems. The goal of this guidance document is to assist managers to systematically plan for the successful introduction of new medicines and supplies by harmonizing and aligning efforts among all stakeholders involved in the process.

The steps in this guide may be tailored according to the stage of implementation in the country. The user should also take into account whether the product is:

- Completely new
- Replacing an existing product for a specific indication
- Being added to be used for an additional indication

For successful implementation, two main components need to be considered in the planning phase:

Programmatic Issues

These include areas of the health system that will undergo changes as a result of the introduction of a new product. They encompass policy or legal changes, modifications in information systems, training of service providers, procurement of the new commodity, distribution planning, and demand generation within the health system and at the community level.

Program planning should be facilitated by the necessary management support. This can be achieved through a well-defined policy and legal framework that supports the introduction of the new product and ensures that there is political commitment.

Financing

Budgeting is essential because without a well-planned budget, the introduction plan developed can fall apart or be left incomplete if the program runs out of funds. It also allows for the prioritization of activities within the overall implementation plan if budget availability is a limiting factor. Budgeting includes the costs of every activity required—from planning to implementation—for the successful introduction of a new product. The next step is to ensure the availability of the funds. A well-established RMNCH commodity security is possible by making the best use of available domestic and external funding.

Intended Audience

This guide is intended for program managers, either within Ministry of Health (MOH) or other organizations that provide RMNCH services, who are responsible for planning the introduction of a new RMNCH medicine or commodity. Ideally, the program manager would be part of a larger team working to plan the introduction of a new product.

Structure

The guide is organized to lead the user through the key areas to consider when planning for the introduction of a new RMNCH medicine or commodity. While we have tried to document the processes and present the activities in a chronological order that may apply to most countries, we recognize that the development of an introduction strategy is an iterative process because many of the activities are interrelated. As such, a few activities may seem to fall under multiple components or the order of the activities may differ depending on which stage of implementation a country is in and/or subject to the regulations of a country.

The quick reference guide in Annex A, which has been adapted from the New Technologies for Tuberculosis Control Framework [11] may be used to guide the development of an introduction strategy, to list the required activities, tentative time lines, and responsible agencies. The framework may be updated as the country progresses with its introduction plan and shared with all stakeholders.

[11] New Technologies for Tuberculosis control; A framework for their adoption, introduction and implementation; http://www.tballiance.org/sites/default/files/child-resources/New%20Tools%20for%20TB%20Control%20Guide%20to%20Adoption%20Introduction%20and%20Implementation.pdf

PART A: Program Planning

Advocacy

- Share global development with in-country partners
- Formation of a national consultative group
- Stakeholder meeting/consultative group meeting

Policy development

- Engage stakeholder's in discussion on inadequacies of the existing health system
- Analyze capacity of the current health system to appropriately manage and use the product
- Develop policy document with input from stakeholder's meeting
- Endorsement by the Ministry of Health

Register product/device

- Determine registration status of the product in the country
- Understand registration requirements
- Inform manufacturer/importer of the registration requirements

Revise essential medicines list

- Identify existing committee that is tasked with the revision of EML
- Determine cost for revision, including printing and dissemination of the revised EML

Demand generation activities

- Develop IEC/ BCC materials
- Develop ACSM activity plan
- Coordinate with stakeholders to get input
- Field test the developed material
- Reach out to all stakeholders so that they can include the revised BCC messages in their ongoing campaigns

Phase out plan for existing recommendation or commodity

- Plan for replacing existing policy/product
- Arrange to liquidate existing stocks of the product that is being replaced by the new product

PART B: Finance Planning

Develop budget components

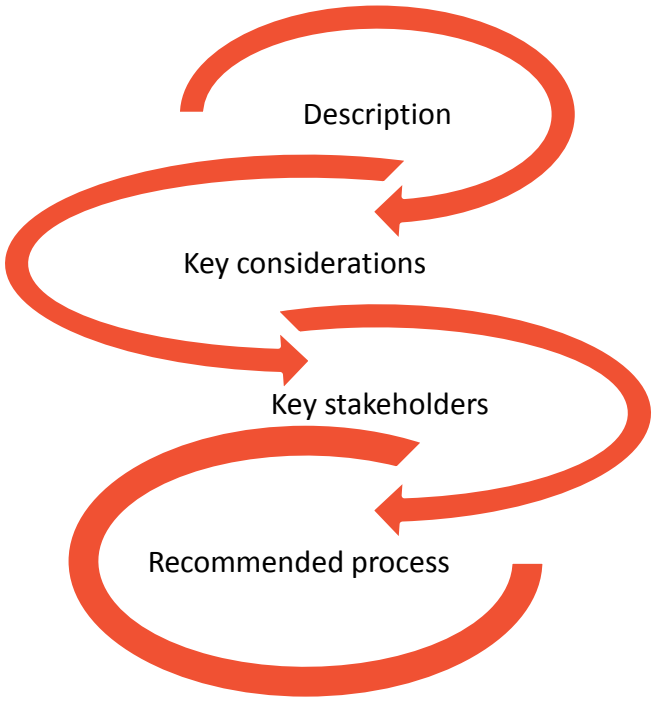
- Ensure budget is allocated for each key component listed under program planning

Identify source of funding

- Discuss with local government stakeholders, donor agencies, and implementing partners and assess funding gaps by comparing existing available funds and the forecasted budget.
- Meet with stakeholders: MOH, donors, implementing partners, private sector
- Update all stakeholders

Establish accountability

For each component of program and finance planning listed above, a description of the component is provided, key considerations that should be addressed are presented, stakeholders that should be consulted are identified, and a recommended process for implementing the step is given.



PART A:
PROGRAM PLANNING

ADVOCACY

Description

An important step in the introduction process is to ensure that in-country stakeholders are apprised of the global development and of any new/revised guidelines related to the new RMNCH product. A consultative group of key stakeholders should be formed, whose purpose would be to discuss the feasibility of introducing the new product and the associated guidelines in the country. Once consensus has been obtained on the need to introduce the new commodity, based on current international recommendations, the other introduction-related activities can be implemented, including the modification of key policy documents to support the new product's introduction. Formation of the consultative group will require a champion to convene it and to facilitate discussions among the stakeholders.

Key Considerations

- Identify key stakeholders and ensure that they are involved from the beginning.
- Ensure that in-country policy makers and stakeholders are updated on ongoing discussions at the global level.
- Review national policies and regulations to identify potential barriers to implementation.
- Identify stakeholders to form a national consultative group.

Key Stakeholders

- RMNCH program managers from the MOH
- Regulatory agencies
- Procurement agencies
- Implementing partners
- Donor agencies
- Professional associations
- Academics
- Private sector stakeholders
    - Manufacturers
    - Distributors
    - Physician associations
    - Pharmacy associations
    - Nongovernmental and faith-based organizations

Recommended Process

Step 1: Collect technical documentation to facilitate discussions with stakeholders

State-of-the-art technical information should be collected from global or regional sources. For example, recently at the global level, technical experts under the United Nations (UN)

Commission working groups for each recommendation and commodity[12,13,14] with support from participating organizations, have developed advocacy materials to facilitate discussions among MOHs, donor agencies, and implementing partners on the use of the 13 priority life-saving commodities.[15] Available published research from around the world will provide the necessary support for discussions with stakeholders regarding the benefit of introducing the new product and subsequent development of the introduction strategy.

It is equally important to collect available information and documentation on current practices in the country. A review of the current national system, guidelines, and recommendations will help identify gaps in the current health system as well as existing or potential bottlenecks that might pose a threat to the introduction of the new product. The information collected (existing system, gaps, potential areas for improvement, and new recommendations) should be used to inform decision making about introducing a new product and subsequently to develop the revised policy.

In summary, the following documents should be made available to share with stakeholders to initiate advocacy for introducing the new product:

- Global recommendations on the use of the specific commodity/revised WHO guidelines.
- Global/ regional/country evidence on the impact of the new product/introduction of the new guidelines.
- Program implications and feasibility in the specific country context.
- Required funding to implement the new recommendation:
    - Product costs
    - Human resource requirements
    - Preparing the health system

Step 2: Form a national-level working group

For effective implementation, the best way to start the introduction process is to formalize a group of key stakeholders. This working group could be a sub-group of an existing technical working group since many countries have standing technical groups or committees for reproductive health/family planning or MNCH.

Tasks, roles and responsibilities for the consultative group:
The members of the national consultative group will assist policy makers to identify next steps, prepare a plan of action for the introduction of the new product, and facilitate discussions to make the necessary policy changes in the country, including revising STGs, as appropriate, and general advocacy efforts. The group should be willing to meet on a regular basis to move the introduction agenda forward, assume responsibility for moving it forward, and holding

[12] Life Saving Commodities: Recommendations; http://www.lifesavingcommodities.org/about/recommendations/
[13] UN Commission on Life-Saving Commodities Technical Reference Team Briefs; http://www.path.org/publications/detail.php?i=2386.
[14] Healthy Newborn Network; http://www.healthynewbornnetwork.org/topic/chlorhexidine-umbilical-cord-care.
[15] UN Commission on Life-Saving Commodities; http://www.everywomaneverychild.org/networks/life-saving-commodities.

themselves accountable for it. As a starting point, working group participants should assess the strengths and weaknesses of the current health system, determine the additional human resources required to effect the policy change, and also prepare a preliminary calculation of the costs associated with the introduction of the new product.

Identifying stakeholders:
In most low- and middle-income countries, the private sector is an important resource for the provision of health services and products. In many settings, and even when public sector services are the first option for care, clients often seek services from the private sector. The price and quality of products vary greatly in the private sector. To reach the maximum number of beneficiaries and make a quality product available widely, it is very important that the working group involve the private sector from the start of introduction planning. Private sector participants should include pharmaceutical and distribution companies, private sector/faith-based organizations, for-profit and nonprofit organizations, physician's associations, and pharmacist associations.

Depending on the activities, the following agencies/organizations/departments will have vital roles and responsibilities and should be part of the stakeholder group.

- MOH
- Drug regulatory authority (DRA)
- Supply and quantification department in the MOH
- Central Medical Stores
- Champions in reproductive health, family planning, maternal and neonatal health (leading professors) from the public sector
- Donor agencies
- Implementing partners working on RMNCH
- Private sector representatives

Step 3: Convene a stakeholder meeting/national consultative group meeting

The group should decide which other entities could play a potential role in ensuring the timely and effective introduction of a new product. Depending on the stage of introduction in any given country, a two- to four-day consultative meeting of stakeholders may be convened to discuss key considerations for a successful introduction and scale up. The working group should decide on a wider audience to invite to the consultative meeting. The objective of the meeting is to think through the elements that need to be considered in the introduction plan, and allow the wider group to debate and voice their concerns and/or opinions.

During this meeting, the most current scientific information is presented and discussed, and in consideration of the country context. At the conclusion of the meeting, next steps in the development of the introduction strategy should be determined as well as the individuals or organizations responsible for completing them, and with timelines to accomplish the activities.

The most important issues for consideration and approval are:

- Policy change
- Registration of the product
- Mechanisms for procurement, storage, and distribution
- Quality assurance of the product procured
- Curriculum development and training of service providers
- Demand generation

- Gather all related available technical documents from global, regional, and country sources to guide the process.
- Engage all possible key stakeholders from the beginning of the process to ensure their participation and buy-in.

POLICY DEVELOPMENT

Description

A country's national health policy ensures the delivery of quality health services. It defines the priority areas for the government, civil society, donor agencies, and implementing partners to achieve better health outcomes and in relation to the population's health needs. A policy should include all components that are vital for successful health program implementation, which ranges from preparing the health system to assuring the availability and delivery of health care services.

Since a new product is new to the health system, it should be incorporated into the country's current health policy as an amendment to the current policy to obtain the attention of policy makers and implementers. If the health policy in a country is due for revision, then this policy change can be part of the revised/newly developed policy.

Key considerations

- Assess implications of the new product introduction on current health policy in the country.
- Assess and analyze capacity of the health care system to absorb the changes.
- Involve key stakeholders to ensure that any queries raised by policy makers can be answered effectively.
- Share draft revised policy with all stakeholders.
- Get the policy endorsed and disseminated to all stakeholders.

Key Stakeholders

- Members of the consultative working group
- Policy makers from all related departments of the MOH, planning commission, and finance

Recommended Process

Step 1: Draft a national introduction plan/strategy

Ideally, the MOH takes the lead role. Under the leadership of the MOH, an introduction strategy should be drafted with input from all members of the national consultative working group. The working group can follow the stepwise approach outlined in this document to guide the development of the introduction strategy. A draft strategy, with tentative roles, responsibilities, and timelines should be available as an outcome of the national consultative group meeting. Using this information, a formal introduction strategy with clearer activities and steps to follow should be designed and shared with policy makers for approval.

Step 2: Approval and dissemination of the policy

The group should follow up to ensure that the draft policy is approved by concerned authorities and is disseminated to all concerned.

- Revised policy should be compatible with the health system.
- Willingness of all stakeholders to accept the roles and responsibilities assigned to them.
- Approve and disseminate the policy to all concerned.

REGISTER PRODUCT/DEVICE

Description

To ensure harmonization, the technical requirements and specifications (presentation, dosage, and strength) of the new product to be registered should be clearly defined. Everyone, including the DRA, manufacturers/importers, and last but not least, end users/patients and/or service providers will benefit from the standardization as it will ensure product safety, uniformity, and ease of availability and administration.

Key Considerations

- Is the product already registered for use in the country – in a different strength/ for a different indication?
- How many products are already registered for the same indication as the new product?
- Is the product registered in the country for an intended RMNCH-related use?

Key Stakeholders

- National DRA
- Manufacturers
- Importers
- Physicians
- MOH
- Implementing partners
- Donors

Recommended Process

Step 1: Determine registration status of the product

Review the current list of registered products to assess whether the product is already registered in the country for:

- A different indication
- In a different concentration
- In the recommended formulation and concentration

Step 2: Understand the registration requirements for the new product

The DRA should be contacted to collect information on the new product registration and also to register a new product in other formulations/concentrations if it is already registered in the country. Most DRAs require a set of documents to be included with the registration application, such as:

- Drug safety test report
- Available research studies conducted in other countries
- Documents to establish product safety, efficacy, and quality
- Clinical trials conducted
- Information about the manufacturer's plant
- Copy of GMP inspection certification from the foreign manufacturer in the event the product will be imported

All such documents should be made available in a timely manner and submitted with the application to avoid delay in the registration process.

Some countries have the option of fast-track registration. If such an option exists, it should be explored to avoid delay in product availability once program implementation starts. Also, DRAs sometimes allow an unregistered product to be brought into a country as a donation so long as it is not sold in the open market. However, the registration application should be submitted in good time to allow follow-on procurement to proceed promptly to avoid stock-outs. Product registration is the primary responsibility of either the manufacturer or the importer that brings the product into the country. Members of the national working group should engage with interested manufacturers/importers and support them in gathering information from the DRA and as well as available global information.

Step 3: Work with manufacturers or importers to secure registration of the product

The first step may be to advertise an expression of interest so that interested manufacturers may be contacted to get information on the new product (formulation, percentage of active ingredient, source for getting the active ingredient if it is not already locally available, any improvement in the manufacturing plant infrastructure) to prepare themselves to formally apply for product registration with the DRA when the time comes. As mentioned in the previous step, the working group can facilitate the medicine registration process by linking interested manufacturers to the national DRA (NDRA).

- Understand the registration process in the country.
- Timely submission of the application with all required documentation.
- Use fast-track service, where available.
- Receive exemption certification, where applicable, e.g., initial product coming into the country as a donation.

REVISE ESSENTIAL MEDICINES LIST

Description

Another key policy document for the national health system is the EML. The national EML should be updated as soon as possible following product registration to incorporate the new product. The EML is important because the list is often used to guide public sector procurement decisions.

Key Considerations

- What are the specific uses of the new product? (first-line management/second-line management)
- What is the recommended formulation of the product? (gel/liquid, tablet, syrup, powder, ampule, and size, in the case of a device)
- What are the product specifications for the intended use?

Key Stakeholders

- MOH EML Drug and Therapeutics Committee/ multidisciplinary expert committee
- Members of the stakeholder's working group
- Champions in the RMNCH field
- International agencies: WHO, UNICEF, USAID, representatives from relevant global working groups
- Staff from purchasing department of the MOH
- Representatives from health facilities

Recommended Process

WHO's expert committee on the selection and use of essential medicines meets every two years to review and update the existing EML. Most countries also update their EML every two year. However, in most instances, by the time a new WHO recommendation is released, chances are that countries may have either just finished revising their national EML, or in a few selected cases, have just distributed them for use by health care providers. In such cases, the countries may decide to either issue an addendum or consider revisiting the entire EML. This is very important as the procurement departments in the MOH strictly follow the EML in their procurement planning and also some insurance companies follow the national EML as a guide for creating lists of medicines covered under an insurance scheme. Once the product in on the EML for a specific indication, it will lead to rational use and improved supply planning.

Many countries require additional documentation before a medicine can be included on the national EML. For example:

- Summaries of clinical guidelines on use and effectiveness
- Quality assurance standards

- WHO revised guidelines
- Capacity of health staff to deliver the product

All such documentation should be available before the product is presented for approval to be included in the national EML.

A Drug and Therapeutics Committee usually exists in most countries. Members of the national working group should reach out to the committee to get information on requirements for a medicine to be included on the EML.

Key steps to add a medicine to the list include:

- Indicating the disease/condition for the use of the medicine.
- Indicating the level of health care provider who will be allowed to administer the product.
- Indicating the level of service delivery outlet where the product will be introduced.
- Adding the product to the EML.

The revised EML should be disseminated to all relevant stakeholders so that they can ensure that the new product is included on the list of medicines to be procured and used.

- Understand the process for the revision of the EML in the country.
- Present all relevant documents.
- The revised and approved list should be disseminated to all stakeholders.

UPDATE STANDARD TREATMENT GUIDELINES/SERVICE DELIVERY PROTOCOLS

Description

Standard treatment guidelines are systematically developed statements that help practitioners and prescribers make decision about appropriate treatment for specific clinical conditions. These exist for various levels of health care facilities and providers.[16] To ensure the rationale use of the newly registered product, it is very important to engage a sub-group of the existing Drug and Therapeutics committee responsible for updating the STGs and service delivery protocols in the country. The committee may decide to include use of the new medicine in service delivery guidelines for health care providers as well as in the pre-service delivery training curriculum. This is vital to ensure quality health care at all levels of service delivery. Several documents are available on the importance of and process needed to update STGs.[17]

Relevant STGs/service delivery protocols should be updated to include information on the recommended use of the new product. The revised STGs should include complete information on:

- Cadre of provider that is authorized to administer the new product
- Recommended dosage and duration of treatment
- Mode of application/administration

A second important consideration is to determine which level of service delivery will be involved in the provision of the specific commodity:

- Facility
    - Hospital
    - Health center
    - Health post
- Community

[16] *Managing Access to Medicines and Health Technologies* MDS-3; http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf.

[17] *Producing national drug and therapeutic information: The Malawi approach to developing standard treatment guidelines*; http://apps.who.int/medicinedocs/pdf/whozip24e/whozip24e.pdf.
Field MJ, Lohr KN, Editors. *Clinical Practice Guidelines: Directions for a New Program*. Washington, DC: National Academy Press; 1990. http://www.nap.edu/openbook.php?record_id=1626.
Field MJ. Lohr KN, Editors. *Guidelines for Clinical Practice: From Development to Use*. Washington, DC: National Academy Press; 1992. http://www.nap.edu/openbook.php?record_id=1863.
Strengthening Pharmaceutical Systems. *Pharmaceuticals and the Public Interest: The Importance of Good Governance*. Arlington, VA: Management Sciences for Health; 2011. http://projects.msh.org/projects/sps/SPS-Documents/upload/sps_governance_pub_final_2011.pdf.
IMS Institute for Healthcare Informatics. *Understanding the Role and Use of Essential Medicines Lists*. Parsippany, NJ: IMS Institute for Healthcare Informatics; 2015. https://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/IIHI_Essential_Medicines_Report_2015.pdf.

Key Considerations

- What level of provider is currently authorized to administer the new product or similar products?
- At which facility level(s) will the new product be available?
- What is the recommended use of the new product?

Key Stakeholders

- RMNCH program managers
- Drug and Therapeutics Committee (DTC)
- Clinicians
- Procurement unit in the MOH

Recommended Process

Step 1:

Engage with the committee responsible for revising the treatment guidelines to address the development and/or revision of the STGs, depending on whether the product is completely replacing an existing recommendation or if the product will now be the recommended treatment. A sub-group of the DTC may take responsibility for this task, and/or establish the guidelines.

Step 2:

Develop an overall plan for updating the guidelines. A comprehensive plan, with well-defined time frames is necessary to ensure that the inclusion of the product in the STGs is started and finished within a reasonable period of time.

Step 3:

Identify the disease/condition that the revision will cover.

Step 4:

Determine the appropriate treatment options. This is a critical step. Evidenced-based information should be used to identify appropriate treatment guidelines, where possible, using information from WHO global recommendations. Experts and clinical specialists should be consulted to confirm proposed treatment options. The revised guidelines should be consistent with national formularies, recommendations, and guidelines.

Step 5:

Identify first-, second-, and third-line medicines, when appropriate, and if the product is replacing an existing first-line treatment medicine, it should be documented.

Step 6:

Provide dose and duration, contraindications, and side effects.

Step 7:

Determine what information should be included in the STGs. Information provided in the STGs can vary widely.

Step 8:

Draft the STGs for comments and pilot testing.

Step 9:

Publish and disseminate. After completion and approval of the final draft, the document should be published and distributed widely to professional staff. An official launch, training of users, and monitoring/evaluation are all necessary and are critical components of the distribution of the guidelines.[18]

- The STGs developed should be made specific to the level of service providers and health delivery outlets and with specific dosage and indication information to ensure rational use.

[18] Management Sciences for Health and World Health Organization. *Drug and Therapeutics Committee Training Course*. Arlington, VA: Management Sciences for Health; 2007.

ENSURE PRODUCT AVAILABILITY

Description

It is important to determine the source(s) of the new product during the planning phase to ensure its regular availability and because introduction of a new product will have a huge impact on budget planning. Planning should take into consideration the following factors: the product's use; intended levels of users; and the estimated demand for the product based on the geographic area(s) of intervention in the country. With this information, implementing agencies may determine what options are available to procure the required amounts of the product.

Key Considerations

- Is the product already available in the local market?
    - Is the product manufactured locally?
    - If not, what international manufacturers are marketing the product in the country?
    - Is local manufacturing a possibility?

Key Stakeholders

- Procurement and quantification unit in the MOH
- Manufactures
- Distributors
- Program managers
- Implementing partners

Summary of Source Options

Source	Pros	Cons
International manufacturers	• Product may be available more readily • Cost may be lower • Pre-qualified product may be available	• Import duties • Delay in shipments • Port clearance
Local manufacturer (already producing product)	• Government may have policy in place to support local manufacturers • Re-supply may be quicker	• Pre-qualified product may not be available • Increased demand may be difficult to fill
Local manufacturer (not yet producing product, but able to)	• Government may have policy in place to support local manufacturers • Re-supply may be quicker	• Possible delay in production of quality product due to set-up of new production line

Recommended Process

As described in the table above, there are two options to ensure product availability. The pros and cons of each option should be thoughtfully considered before a decision is made in favor of one or the other:

- Local production
- Importation

The easiest and quickest way to get a good quality product is to import from WHO pre-qualified manufacturers or other renowned regional/international manufacturers. This ensures product quality, and because of Current Good Manufacturing Practices (cGMP) certification, it is easier and faster to get a new product registered. At the same time, however, the country may look into the feasibility of local manufacturing. Local production is defined as production in low- and middle-income countries (LMIC) by locally owned companies or subsidiaries of multinational companies. The potential benefits of local production include an improvement in the reliability of supply, foreign import savings, development of innovation capacity, creation of enhanced export capacity, and development of human capital. Local production of high-quality medicines may also lead to cost savings and improvement in product quality, depending on the product to be produced and regular surveillance of an LMIC's quality control issues.[19] Furthermore, local production allows products to be more adapted to local cultural preferences. It is important to keep in mind that local production of a newly introduced product that has never before been manufactured in the country is very challenging and requires a lot of monitoring and quality assurance checks. Assistance from international organizations that support GMP certification may be one way of obtaining necessary help.

In instances where local capacity exists and there is enough demand in the country to cover the essential costs (manufacturing, advertising, distribution), countries may test the feasibility of local production. This may attract the interest of local pharmaceutical companies and may allow for savings on foreign import costs. In this case, interested companies who meet the cGMP guidelines and standards for quality assurance should apply to the country's DRA. Ideally, if a pharmaceutical manufacturer's association exists in the country, it could be approached and made part of the national working group. Alternatively, an expression of interest (EOI) should be published so that interested manufacturers may apply for registration.

In any case, since the product is completely new for a specific indication, and while the feasibility of local production and country capacity for local production are sorted out, importation is the first easy and quick option.

- When deciding to opt for local production, capacity in the country to start local production should be carefully reviewed to ensure that a good quality product is made available.

[19] Kaplan WA, Ritz LS, Vitello M. Local production of medical technologies and its effect on access in low and middle income countries: a systematic review of the literature. *Southern Med Review.* 2011;4(2):4–14.

PHASING OF THE INTRODUCTION

Description

The national working group should consider how to phase in the introduction of the new product. A country may opt to start small, in a reduced geographic area, before introducing the new product nationwide. A carefully thought out introduction plan will greatly increase the chances of success.

Key Considerations

- Availability of budget for procuring and distributing the product.
- Status of product registration in the country.
- Lead time between placing an order for the product and the time the product can be made available in the country.
- The capacity of the current medicine distribution system to take on the additional load.
- Training of service providers
- Demand generation

Key Stakeholders

- MOH/ RMNCH program managers
- Procurement, logistics team
- Central Medical Stores staff
- Donor agencies
- Implementing partners

Recommended Process

Step 1: Assess readiness of the health system

Bear in mind that the introduction of some new products may require a lot of interaction among different agencies (e.g., MOH, Ministry of Finance, donors, and implementing organizations). It is therefore important to assess: the readiness of the system; the extent of existing coordination among agencies to adapt to the changes involved; and then decide on options for the introduction of the new product (e.g., pilot introduction followed by national scale up versus nationwide introduction). For example, if the product will require training of service providers, revising the reporting and recording forms, and/or discussions with donors and Ministry of Finance to make the necessary funds available, it may be best to do a pilot and make necessary changes before implementing a national roll out.

Step 2: Expansion and sustainability

Sustainability is very important to consider from the start of the introduction process. Many new initiatives fail after the pilot phase, especially when long-term sustainability is not worked out during the pilot phase of introduction. Factors that should be considered to assess sustainability include the availability of funds, product availability, availability of human resources, and political commitment.

Donors, implementing partners, and the public sector should develop a long-term (five to ten-year) costed work plan while the pilot phase is being developed. This will help the country smoothly transition from the pilot phase to the expansion phase without interruption. Information on the target population(s), the geographic area(s) to be covered, and the time it will take to scale up to the national level should be included in the long-term plan. Another important element to consider is the inflation rate, which may impact the cost of implementation over time.

The assessment of the required human resources needed for expansion should be taken into consideration, including human resources required for program implementation (MOH staff required for making program changes), budgets, M&E, data on use, and staff who will be engaged in delivering the product to the target population(s).

Step 3: User preference research

If necessary, during the pilot introduction, user preference research may be conducted to access the reaction of end users to the new product. This information may serve as baseline data for any future studies on use as well as to inform necessary changes when transitioning from the pilot to the expansion phase.

- Plan the expansion and the pilot phase together to ensure the achievement of sustainability.

DELIVERY THROUGH THE HEALTH CARE SYSTEM

Description

Stakeholders from the national working group need to decide at which level of the health system and at which facilities the new product will be provided, which cadre of providers will be authorized to provide the product, and what the source of the product will be for facilities.

Key Considerations

Based on the registration requirements and regulations in the country for the introduction of a new product, the members of the national working group should discuss with relevant authorities and decide whether the product will be made available during the start-up phase through the:

- Public sector
- Private sector: for-profit, nonprofit, and social marketing companies
- Both sectors

Key Stakeholders

- MOH program managers
- Implementing partners' program managers
- Private medical practitioner associations
- Pharmacist association
- Manufacturers/importers/wholesalers

Recommended Process

Step 1: Availability through the public and private sectors

To ensure maximum accessibility and availability of the product, it is highly desirable that the product be made available through both the public and private sectors. In most developing countries, the private sector is the first point of contact made by patients seeking advice and referral. Therefore, the private sector should be on board when introducing a new product.

Step 2: Source of procurement

Those who will be implementing the product's introduction should be informed of the initial source for procurement and linking importers/manufacturers to this source.

Step 3: Cadre of health care providers

Depending on the product/service, a decision on the cadre of health provider(s) who will be involved in service provision should also be made:

- Specialist
- Physician
- Paramedics
- Community health workers

The STGs should be updated to include clear information for each cadre of health care provider, including the referral system in the event that any specific level of service provider will not be able to handle the condition or is not allowed to handle certain cases.

SUPPLY PLANNING

Description

A special focus is required on procurement processes, including addressing and promoting pharmaceutical good governance and regulatory components, and ensuring the smooth introduction of the new product into the health system, from receiving the product to its distribution to end users. These processes of are paramount importance when a product is new to the health system.

The relevant members of the national working group should discuss and carefully work out each component of the supply planning cycle: product specification, quantifying product requirements, selecting procurement methods, identifying procurement sources, managing tenders, establishing contract terms, assuring medicine quality, and ensuring adherence to contract terms. A few of these supply planning components have already been discussed in earlier sections. This section focuses specifically on quantification, procurement, demand forecast, storage, and distribution elements within the overall supply planning process.

Key Considerations

- The product is included in the quantification by the MOH.
- Capacity of the distribution system to absorb the change.

Key Stakeholders

- Quantification, procurement, and distribution staff in supply planning department of the MOH.
- MOH program managers
- Central and regional medical stores representatives
- DRA
- Donors
- Implementing partners

Recommended Process

The important aspects of the supply planning cycle to be considered are:

Quantification

Since the product is new, the working group may have to develop protocols for its quantification for all possible indications and its use for specific RMNCH conditions. Some of the important issues to consider are:

- In the absence of country-specific morbidity/mortality data, what assumptions can be safely used to avoid over or under procurement?

- What is the current mechanism used to determine order and tender quantities at each level of the health system?
- The country's formal qualification process should be assessed to evaluate criteria used to select suppliers.
- If protocols have not already been developed for the storage of RMNCH medicines, they should be prepared so that as soon as the product arrives in the country, it is stored as per the manufacturer's recommendations.
- Review quality standards specified for RMNCH medicines and make necessary edits.

The Global Supply Chain Technical Resource Team, under the UNCoLSC, has developed a forecasting guide for all 13 commodities. It can be accessed at http://siapsprogram.org/publication/rmnch-quantification/.

The algorithms in the forecasting guide are based on WHO recommendations and state-of-the-art technical information. Using the forecasting guide and the scale-up plan, the RMNCH department of the MOH, along with implementing partners, can quantify the need, with support from the department responsible for quantification and procurement. A plan should be made and tender requirements should be defined.

Demand Forecasting

Ideally, the logistics and supply planning departments should be consulted to develop a five-year rolling forecast based on initial and national scale-up plans. This forecast should be reviewed annually, with adjustments made, as appropriate. The adjustments should take into account factors that could increase demand, such as scale-up plans, a planned national-level awareness/product-specific behavior change communication (BCC) campaign, marketing campaigns, and/or training of service providers. Based on the forecast plan, the level of service delivery selected, and phasing of the new product's introduction, the national quantification team should determine the requirements for immediate use.

Procurement

Assess the current procurement mechanism in the country in both the public and private sectors:

- Procurement in the public sector
  - National and/or sub-national procurement system

- Procurement in the private sector
  - Wholesalers/distributors
  - Pharmaceutical companies
  - Importers

By now, the working group would have already identified the initial source for procurement. As noted above, in cases where a decision has been made in favor of local production, there may be a gap between the start-up phase and actual production. To avoid stock-outs or non-availability of the product in the interim period while local production and the registration process are in

process, the working group may reach out to the registration/regulation authorities for information on initial procurement procedures:

- Procurement using MOH funds
- Required availability of funds through international donors
- If the product is still in the registration phase, consider bringing the product into the country as a donation or have it procured by implementing partners for an initial training purpose and for the pilot phase.

Once the procurement mechanism is finalized, the quantities required for the initial phase need to be ordered. The procurement plan should include the schedule of requirements, along with the costs and source of funding, the processing time, and the estimated delivery date. The average time between product ordering and the receipt of the product will inform the time of ordering.

For countries with a central /national procurement mechanism, it is easier to procure and distribute. However, there are countries where sub-national procurement exists. For such countries, the department responsible for sub-national procurement should be sent complete information on the procurement source, revised STGs, EML, etc.

Distribution

The current mechanism for delivering products from warehouses to service delivery outlets and the community level should be evaluated and a determination made as to whether additional resources will be required for the specific product to be introduced. If special storage and transport conditions are not necessary for the new product, it is better to add the new product to the existing distribution system. In this way, there will not be extra costs as there would be if a parallel distribution system was designed for product distribution. However, if the new product requires special storage and distribution, budget must be allocated to ensure that appropriate mechanisms are put in place prior to product distribution. Moreover, additional resources will be required to make the product available at the community level for use by service providers, community health workers, and/or by end users. For example, a system to ensure that the product reaches community health workers, replenishment of stocks, ensuring proper storage at the community level, reporting on use, and necessary monitoring and evaluation. In this case, it will be necessary to formulate a system for the product to reach the intended users, resulting in a continuous uninterrupted resupply and reporting on use of the new product.

- Develop a forecast as close to real demand to ensure uninterrupted supply and to avoid stock-outs.

TRAINING OF SERVICE PROVIDERS

Description

Once the cadre of service providers authorized to provide the new product has been determined, appropriate training materials, including job aids, should be developed. The materials developed should first be field tested before they are finalized and endorsed by the MOH. A plan to train the trainers, followed by trickle down training, should be developed, finalized, and shared with all stakeholders. Pre-service and in-service curricula for doctors and paramedics (nurses, midwives, community health workers) should be reviewed and the new guidelines on the newly introduced product should be incorporated.

Key Considerations

- What training mechanisms or plans exist for relevant cadres of health workers?
- What training materials exist that need to be adapted?
- Who is responsible for training the cadres of providers?

Key Stakeholders

- MOH
- Curriculum development experts
- Implementing partners
- Representatives from pre-service and in-service curriculum development teams

Recommended Process

Step 1: Identify existing training materials from in-country and international sources.

Step 2: Adapt existing materials, tailoring them to the country's needs and to make them socially and culturally acceptable, or develop new materials.

Step 3: Develop training plan.

Step 4: Develop quality assurance plan for evaluating the effectiveness of the training sessions.

Step 5: Develop refresher training materials.

Step 6: Develop schedule for refresher training.

Step 7: Develop job aids; print, and distribute them.

- Develop and field test the training curriculum.
- Integrate training under broader RMNCH/ FP trainings.

QUALITY ASSURANCE, MONITORING, AND EVALUATION

Description

To achieve the best results, it is essential that the MOH procurement department, the distribution unit, and the service provision unit work in close coordination. As with most essential medicines, essential RMNCH medicines and supplies are often generic products that can be made widely available in both the public and private sectors. However, ensuring access to quality products, rational use of these medicines and supplies, and quality service delivery require improving pharmaceutical policy, enforcing compliance with policies and procedures, and strict quality service delivery standards. Quality standards should be clearly laid out from the start for all components—quality standards for products and quality standards in service provision. In most programs, the quality of service delivery is accounted for, however, assuring product quality is often the missing component. This lack leads to the availability of counterfeit and low-quality medicines, especially in the private sector.

Key Considerations

- Have the supervisory reporting forms been revised to assure quality service delivery?
- Are the staff responsible for monitoring and supervision trained on the new reporting and recording forms?
- Who assures the quality of the new product?
- Is there a system to record adverse drug reactions?
- Is there a system to ensure the correct use of the product/commodity?
- Are the staff responsible for product quality aware of the specific requirements for the commodity? (special storage conditions, availability of enough quantities of a non-reusable item, source of procurement [whether they are WHO pre-qualified or assessed by an international organization responsible for quality assurance], on-site product quality checking).

Key Stakeholders

- Monitoring, evaluation, and supervision teams in the MOH and implementing partners
- NDRA

Recommended Process

Commodities

Ensuring product quality is as important as service delivery because good quality products are essential to safeguarding the health of women, newborns, and children. Reliable quality suppliers, appropriate pre- and post-shipment inspections, and surveillance throughout delivery, warehousing, and distribution processes should be ensured. Safety, cost (financing), availability, efficacy, response time, stability, storage requirements, adverse effects, contraindications, presentation, and requirements for administering the medicine should be taken into account**.** At

the same time, there should be a system to record any adverse drug reactions that may negatively influence the use of the newly introduced product.

Services

A monitoring framework and indicators for measuring the introduction of the new product, for both the product and product administration at facility and community levels, should be developed, finalized, and incorporated into the existing health management information system and national program for family planning/primary health care. As soon as implementation starts, the applicable monitoring and evaluation tools, with roles and responsibilities defined, should be ready and relevant staff should receive training on the tools. The health system should be ready to absorb this additional workload. A quality assurance mechanism, especially in the case of a new product to be made available at the community level, needs to be established through the national program and RMNCH program for all cadre of service providers, including community health workers and community midwives. During monitoring and supervision visits, responsible staff should check for the correct use of the new product.

- Develop quality assurance system for the product and product administration.

LOGISTICS MANAGEMENT INFORMATION SYSTEM (LMIS) INTEGRATION: REPORTING AND RECORDING

Description

Procurement data (national/sub-national), distribution data at all levels (central warehouse, regional warehouse, service delivery points), stock-on-hand, and consumption/use should be recorded. Therefore, existing reporting and recording forms should be updated to capture the additional information on the new product. This data should be used for informed decision making to improve access to and the availability of essential RMNCH medicines.

Key Considerations

- Can the existing forms be revised with minimal change to capture the needed data?
- Who should be trained?
- Is the system capable of accepting changes? For example, does the computer software allow for changes?
- How can the data be used for informed decision making?

Key Stakeholders

- Warehouse staff
- Representatives from the supply chain who are responsible for recording and maintaining the data
- Service providers

Recommended Process

The health system records information on products procured, distributed, used, and restocked. The availability of these data is vital for making evidence-based decisions. These data are also used as performance measures and to ensure that there is accountability at all level of the service delivery system.

Step 1: Integrate data on new product under the country's LMIS

The existing reporting and recording forms being used at all level of service provision should be reviewed to ensure any necessary revision of the forms to avoid duplication in recording information, and at the same time, to ensure that the additionally collected information is meaningful.

Step 2: Use data for decision making

The collected information may then be used for informed decision making.

Step 3: Explore the possibility of creating a web-based LMIS

Some countries still use a paper-based system for recording and transferring data to and from the central warehouse to service delivery points. To minimize errors that may occur with manual recording and manually transferring the data at different levels, the national working group may want to explore the feasibility of introducing computerized recording of data, at least at the central and regional warehouse levels.

Step 4: Assessing capacity of current LMIS

The support system (management information system) should also be geared to electronically record data fed into the system. If the country plans to use a mobile application for data recording and reporting on product supply and use, it should be field-tested first for the purpose of assuring efficiency and accuracy.

- Integrate the product into the existing LMIS to avoid creating parallel systems and duplication.

DEMAND GENERATION ACTIVITIES

Description

To increase access to and rational use of commodities, it is important that there is demand from prescribers and a positive health-seeking behavior from end users, thereby generating demand. Demand will foster a pull logistics system instead of the usual push system, which is very common in most countries. While most advocacy communication and social mobilization (ACSM) materials that are developed address both the prescriber and the end user, often one of the missing elements is advocacy for political commitment, which is essential for long-term planning and financial sustainability. The country should design specific campaigns to introduce the new product. The messages communicated should emphasize the benefits of the new product. The communication materials designed should articulate information in a culturally and socially acceptable way concerning the benefits of using the new product.

Key Considerations

- What is the end user's current health-seeking behavior regarding the specific disease/condition?
-
- Can the messages be incorporated under broader RMNCH messages?
-
- How can the language and materials be tailored to make them acceptable and effective within the local context?
-
- Are appropriate materials available internationally or from countries in same region or with the same demographics?
-
- Is there sufficient political commitment? Who is responsible for communication with political authorities?

Key Stakeholders

- MOH program managers
- Implementing partners working on behavior change communication (BCC) campaigns at both national and community levels
- Media partners

Recommended Process

Step 1: Review current BCC campaign and BCC materials

Since the introduction process involves new products that have new guidelines, BCC campaigns and related materials are required to effectively introduce them to the target audience(s).

Evaluate whether the message on the use of the new product can be part of an ongoing BCC campaign to reduce cost.

Step 2: Tailor BCC messages

Many times, BCC materials are available that have been developed by other countries/regions. The national working group should ensure that when this material is being used, the messages are tailored to the country's specific needs and address any barriers to end users adopting positive health-seeking behaviors. The ACSM activities should be specifically developed for the new product or generalized to RMNCH practices. However, the messages and materials should broadly cover all stages of behavior change, from pre-contemplation, to contemplation, to action, and maintenance.

Step 3: Involve stakeholders

Important stakeholders at all levels should be involved, especially representatives of those who have decision making authority in the home (husband, mother-in-law, community leaders, religious leaders, tribal chiefs). To create a positive supply and demand balance, advocacy efforts should target both prescribers and users. An inadequate demand from providers, users, or the health system, in general, may lead to inaccurate forecasting and a lot of wastage of unused products.

The ACSM activities fall under the following two broad categories for designing BCC programs:

- Above-the-line activities
  - Mass media: print, radio/TV advertisements

- Below-the-line activities:
  - Community mobilization: community-specific mobilization and messages/ materials
  - Interpersonal communication activities: one-on-one sessions with users, political leaders, service providers

- Assess the possibility of integrating a demand generation campaign for the newly introduced product into an ongoing BCC campaign.
- Tailor messages to suit the country's specific needs.

PHASE-OUT PLAN FOR EXISTING RECOMMENDATION OR COMMODITY

Description

In cases where a new product replaces an existing product/recommendation, the situation becomes complex because changes need to be made at both the policy level and the implementation level. In such cases, all activities should be thought through diligently, with the minutest activities defined.

Key Considerations

- Is the new recommendation completely replacing the old one?
- Does the new recommendation complement the existing recommendation?
- Is there a need to reprogram activities (training, BCC, product procurement, revising the STGs) to incorporate the new recommendation?
- Are the finances worked out?

Key Stakeholders

- MOH
- Ministry of Finance
- Public sector representatives
- Private sector representatives
- Implementing partners

Recommended Process

Replacing the existing policy with a new one occurs in three phases:

- Policy review and change process: the processes and procedures leading up to the selection of the new treatment policy, including finance discussions.
- The transition phase: the period when the decision on the new treatment policy has been made but the policy has not yet been implemented.
- The full implementation of the new policy: national roll-out of the new policy.[20]

In the event a product/treatment guideline for any specific condition already exists, and the new recommendation/revision replaces the existing product/treatment guideline, there are usually old products available in the pipeline and warehouse for distribution and consumption. The country should design a mechanism to ensure the least wastage by using existing stocks while implementing processes to introduce the new product.

[20] Rational Pharmaceutical Management Plus Program. *Changing Malaria Treatment Policy to Artemisinin-Based Combinations: An Implementation Guide*. Arlington, VA: Management Sciences for Health; 2005. http://projects.msh.org/projects/rpmplus/Documents/upload/Malaria_Treatment_Policy_En.pdf

For example, in country A, the current STG for managing post-partum hemorrhage is the use of oxytocin as the first-line treatment, and ergometrine as the second-line treatment. The country decides to revise the recommendation as follows: use oxytocin as the first-line medicine and misoprostol as the second-line. In such cases, there would be stocks of ergometrine available. Until the training of service providers is completed on the use of misoprostol, the medicine is registered in the country, and it is decided that the country will move ahead with local production or import of misoprostol, providers can continue to use ergometrine. As soon as the system is ready for the new product and the existing stocks have been used, the country can move ahead with large-scale implementation of the new recommendation to use misoprostol.

- Develop a plan to ensure minimum wastage and smooth transition from the current to the new policy on product recommendation, procurement, and use.

PART B:
FINANCE MANAGEMENT

Description

As countries plan to introduce a new product, it is critical that the necessary activities are budgeted and that the required financing is available for the new product's smooth introduction. A well-developed budget has a catalytic effect on initial activities and the scale-up of high impact interventions and health systems strengthening initiatives.

Key Considerations

While the budget is being developed, the country should think through the following:

- Is there existing funding available that may be reprogrammed to cover activities for the new recommendation?
- What will be the source of funds, e.g., government budgets, bilateral or multilateral funds from formal and informal donors?
- What part of the costs may be covered by implementing partners?

Key Stakeholders

- MOH
- Ministry of Finance
- Donors
- Implementing partners

Recommended Process

Budget Components

All activities described in the program planning section above should have an allocated budget, along with the source for funding and a tentative timeline by which the funds will be made available to start implementation. The final budget should include the following:

- Cost of the product
    - Procurement
    - Storage
    - Distribution

- Training materials
    - Development
    - Printing
    - Training of trainers
    - Training sessions for service providers and community partners

- Stakeholder's meetings/workshops
    - Consultative group meetings
    - Change to policy document and dissemination of the newly developed policy

  - Update EML and STGs
  - Disseminate results of any pilot phase

- Printing and dissemination of materials

- Information, education, and communication materials
  - Development
  - Printing
  - Distribution

- BCC campaigns
  - Designing the campaign
  - Conducting BCC sessions
  - Cost of airing advertisements, publishing in journals, newspapers

- Operations research
- Ongoing monitoring and evaluation
- Review and revision of reporting and recording forms, including cost for printing and dissemination
- Cost associated with phasing out of the old product
- Follow-up meetings

Identify Source of Funding

The involvement of implementing partners and donor agencies is very critical to budget development so that the MOH can leverage any multilateral or bilateral funding mechanisms to support the new interventions. The MOH and the Ministry of Finance can assess the feasibility of reprogramming the public sector budget, which has likely already allocated budget for the now outdated recommendation. The next step is mapping the potential resources at the national level and through international funding. As mentioned earlier, the working group may initially advocate for mobilizing any available funds from within the MOH and determining the total cost for implementation to identify funding gap. This will facilitate the development of a funding strategy and will serve as a guiding resource when reaching out to donors. At the same time, there should be an accountability mechanism set up for use of funds.

Meeting of Stakeholders: MOH, Donors, Implementing Partners, Private Sector Organizations

To avoid duplication of resources, the program manager at the MOH should share information with partners on the funding that can be earmarked in their individual budgets for the new recommendation and for which component(s) of its introduction. For example, can one of the donors and/or implementing partners pick up the cost for product procurement and the development and printing of training/ BCC materials?

Establishing Accountability

Individual departments should be held accountable for the activities and budget for which they are responsible.

- Ensure that every activity in the pilot phase and the expansion plan is budgeted.
- Create an accountability mechanism.

ANNEX A. QUICK REFERENCE GUIDE*

Areas to address	Key activities	Key stakeholders	Time line	Comments
Country policy development	Establish mechanisms to engage with and contribute to the global policy adoption and development process for the new product. Participate in global, regional, and in-country meetings.			
	Inform policy makers and key stakeholders of ongoing discussions at the global level and progress made in other countries with similar demographic and health indicators.			
	Engage decision makers and facilitate discussions at the national level on the inadequacies of the existing recommendation and potential strategies for change.			
	Identify key partners and stakeholders. Formalize a working group that engages in the policy development process.			
	Review national regulations and policies to identify potential barriers to implementation.			
	Analyze the capacity of the health care system to appropriately manage and use the product. Key considerations may include capacity to: • procure and distribute the product • perform essential quality monitoring • provide the appropriate quality of medical care • train service providers • generate demand at the community level • involve community health workers in the distribution of the new product • implement demand generation activities to increase awareness in the community and among caregivers to adopt the new product • store the product appropriately • minimize losses and theft			
	Review information and study results on the use of the newly introduced product.			
	Develop and endorse the new policy.			

*adapted from the New Technologies for Tuberculosis control; A framework for their adoption, introduction and implementation.

Areas to address	Key activities	Key stakeholders	Time line	Comments
Registration	Determine the registration status of the product.			
	Understand the registration requirements for the new product.			
	Discuss with the DRA the possibility of registering the new product using a fast-track mechanism, if available.			
	Where exemptions are given for the initial procurement, ensure that an application to register the product is submitted in good time to allow follow-on procurement to proceed promptly to avoid stock-outs.			
	Work with manufacturers and/or importers to secure registration of the product.			
Revise EML	Identify an existing committee or establish a new committee to manage the transition.			
	Develop a terms of reference and mechanisms for coordination and communication with key bodies/partners.			
	Determine the cost of and responsibilities for updating the EML.			
	Add the new product to the national EML; publish the revised EML.			
Update STGs/ service delivery protocols	Determine which program guidelines and tools are implicated, whether a new guideline needs to be developed or whether an addendum can be issued to support the new guideline, and which other associated materials need to be updated. In sum, decide whether amendments will be incorporated into the existing guidelines and materials or published as an addendum.			
	Determine the costs and responsibilities for updating the guidelines and associated tools.			
	Update and disseminate the guidelines and associated materials. Coordinate the process with training and implementation of ACSM strategies. Make key decisions about: • the level of the health care system and/or sector (e.g., public and private) where the new product will be available. • method of introduction for the new product: phasing in or introduction through a full national roll-out. • criteria for a facility to start using the new product. Determine the cadre of health care providers who will be allowed to provide the new product.			

Areas to address	Key activities	Key stakeholders	Time line	Comments
Product availability	Determine feasibility options for local production versus importation.			
	Determine source of product for any pilot phase.			
Phasing of introduction	Determine the first possible arrival date for the product. Develop phase-in or roll-out plan.			
	Make a schedule to review implementation progress and to adjust plans, as needed. Identify standards to determine whether introduction at a site is successful.			
Delivery through the health care system	Based on regulations in the country regarding any specific commodity, decide whether the product will be made available through: • Public sector • Private sector, including faith-based organizations, social marketing companies • Both			
	Will the product be made available through: • Tertiary level - specialists • Secondary level - physicians • Primary level - health centers, health posts			
Supply planning	Define geographic area for which forecasting is being done and level of coverage expected.			
	Determine which method of quantification will be used based on available data: Consumption and/or morbidity data.			
	Conduct quantification, which should include requirements for: • Phased or nationwide implementation • Buffer stocks for the different levels • Quantification for public sector, private sector, or both • Keep track of time to receive stocks			
	Refine forecasts based on experience from forecasting and set schedule for quantifying ongoing needs.			
	Determine mechanisms available for the procurement. Review donor and/or government requirements and restrictions for the procurement.			
	Monitor the procurement process and supplier performance. Communicate information on potential delays to the committee/working group managing the introduction.			
	Develop a distribution strategy.			
	Integrate the distribution of the new product into the overall distribution plan.			

Areas to address	Key activities	Key stakeholders	Time line	Comments
	Verify clearing/importation requirements and arrange timely exemptions.			
	Implement distribution plan.			
	Monitor the distribution process and communicate information on potential delays to the committee/working group managing the transition.			
Training of service providers	Develop training strategy, budget, and plan.			
	Develop and field-test training materials. Adapt tools for supportive supervision to incorporate the new recommendations.			
	Train core team of trainers.			
	Implement training plan.			
	Revise pre-service and in-service training curricula to incorporate the new recommendations into ongoing training.			
Quality assurance, monitoring, and evaluation	Monitor the quality of training.			
	Identify resources and develop a plan for strengthening health care systems to meet criteria for a site to start using the new product. Considerations may include capacity building to: • properly store the product • provide appropriate quality of care • manage the supply of products to avoid stock-outs or wastage • promote the rational use of medicines • adhere to registration requirements to assure safety, efficacy, and quality of the product • • set quality assurance standards and verification methods for procurement. Identify and secure funding to implement product testing.			
	Synchronize timing of capacity-building activities with the phased or nationwide implementation plan to ensure that sites meet the criteria for start-up.			
LMIS integration	Review and revise reporting and recording forms.			
	Ensure that staff who are responsible for completing the forms are trained on the revised formats.			
	Produce reliable, valid, and timely data on uptake, consumption, and outcomes, and track the product through the system.			

Areas to address	Key activities	Key stakeholders	Time line	Comments
Demand generation activities	Budget for and develop BCC and ACSM strategies, including above-the-line and below-the-line activities.			
	Develop and implement ongoing BCC and ACSM strategies to support rational use of the new product.			
	Reach out to appropriate agencies for them to include information on the new product in their materials.			
Phase out plan	Plan for replacing existing policy/product.			
	Arrange to liquidate existing product while the new product arrives in country. This should be done only if the existing product is not considered harmful.			
	Update all related materials and reorganize the warehouse to accommodate the new product.			
	Ensure minimum wastage.			
	Plan to move stocks from a location with higher stock levels to a place with no stock to ensure that the pipeline of the old product is used.			

ANNEX B. CASE STUDY

Ministry of Public Health
Deputy Minister Office for Health Care Services Provision
Reproductive Health Directorate

Guideline for Introduction of 7.1% Chlorhexidine Digluconate for Umbilical Cord Care

Kabul, Afghanistan

November 2015

CONTENTS

ACRONYMS AND ABBREVIATIONS

AMS	Afghanistan Mortality Survey
BCC	behavior change communication
BPHS	Basic Package of Health Services
CHW	Community health workers
EML	Essential medicines list
ENAP	Every Newborn Action Plan
EPHS	Essential Package for Hospital Services
IEC	information, education, and communication
LML	Licensed medicine list
MOPH	Ministry of Public Health
RH	Reproductive Health
TBA	Traditional birth attendant
UNICEF	United Nations Children's Fund
WHO	World Health Organization

ACKNOWLEDGMENTS

The Ministry of Public Health of the Islamic Republic of Afghanistan is committed to accelerating the reduction of maternal and neonatal deaths and improving the quality of maternal and neonatal health at both facility and community levels.

The Reproductive Health Directorate plans to introduce the use of chlorhexidine 7.1% for newborn cord care at birth and has initiated the development of a guideline for this initiative in Afghanistan with the support of Dr. Maheen Malik from the Systems for Improved Access to Pharmaceuticals and Services Program, implemented by Management Sciences for Health under the terms of cooperative agreement number AID-OAA-A-11-00021, and the Chlorhexidine Working Group, which is an international collaboration of organizations committed to advancing the use of 7.1% chlorhexidine digluconate (delivering 4% chlorhexidine) for umbilical cord care through advocacy and technical assistance. When effectively operationalized, these guidelines will further strengthen the system to provide this evidence-based intervention for improving of neonatal health and will contribute to the reduction of newborn mortality in Afghanistan.

I would like to thank the Reproductive Health Directorate (RHD) for taking the lead in this initiative and the members of the consultative workshop (M&E Directorate, CAH Department, UNICEF, USAID, Management Sciences for Health, AKDN, Save The Children-Himayat Project, and all other stakeholders) for their contribution in developing this guideline, and I am confident that the RHD and its many partners as mentioned above will coordinate their efforts in implementing this new high-impact intervention and will succeed in developing a strong partnership for improving the quality of health care services and improving the neonatal health in Afghanistan.

Dr. Najia Tariq
Deputy Minister for Health
Care Services Provision
Ministry of Public Health

VISION AND GOALS

The purpose of this document is to provide guidance to program managers and all providers of maternal and newborn health services from the Ministry of Public Health (MOPH) at the national level as well as other organizations on the actions and factors to consider in expanding access to 7.1% chlorhexidine digluconate for umbilical cord care. The document aims to create a positive environment by harmonizing and aligning activities with the current health system in Afghanistan to attain smooth and effective operationalization to effectively introduce the new product in a systematic way.

Strategic Goals

- Goal 1: Increase awareness and use of 7.1% chlorhexidine digluconate for umbilical cord care as part of essential newborn care by policy makers, birth attendants, and families
- Goal 2: Establish a sustainable supply-side strategy to support the demand for 7.1% chlorhexidine digluconate
- Goal 3: Generate increased demand at the country level to accelerate national scale-up
- Goal 4: Advocate for inclusion of chlorhexidine for umbilical cord care in country policies

BACKGROUND

Decreasing maternal, newborn, and child health mortality is still a major concern for most countries, and efforts are under way to achieve the desired goals through both global and in-country efforts. However, many countries are still lagging far behind. Global initiatives, such as Acting on the Call, Call to Action, the Every Newborn Action Plan, and Helping Babies Breathe, are all designed and have a common goal of improving maternal, neonatal, and child health outcomes. These global leadership and advocacy initiatives aim at making the essential maternal, newborn, and child health interventions and lifesaving, but often underused, commodities and services accessible to those who most need it across the continuum of care. Alarmingly, a large proportion of maternal newborn deaths could have been avoided if women, newborns, and children had access to adequate health services and products. The UN Commission on Life-Saving Commodities for Women and Children has selected 13 priority medicines: oxytocin, magnesium sulfate, misoprostol, 7.1% chlorhexidine digluconate, newborn resuscitation devices, injectable antibiotics, antenatal corticosteroids, amoxicillin, oral rehydration salts, zinc, female condoms, contraceptive implants, and emergency contraceptive pills.

A large proportion of maternal and neonatal deaths in Afghanistan occur during the 24 hours following delivery. In addition, the first two days following delivery are critical for monitoring complications arising from the delivery. According to the Afghanistan Mortality Survey(AMS 2010), the leading causes of death in children under five years of age are acute respiratory infections and other severe infections, each of which accounts for about 20 percent of under-five deaths in Afghanistan; 26.4% of neonatal deaths are caused by infection. Despite strong advances in decreasing child mortality in Afghanistan, about 44% of deaths in children under five years of age occur during the newborn period, the first 28 days of life.[1] The leading causes of newborn death include acute respiratory infections and other infections (38%), perinatal related disorders (16%), and preterm/low birthweight (12%).

In the recent Call to Action (May 2015), the MOPH has emphasized the need to refocus efforts on reducing newborn mortality, as noted in the "Kabul Declaration for Maternal and Child Health: Renewing Commitment to Reducing Preventable Deaths among Women and Children." Specifically, the MOPH commits to—

> *Increase **essential and emergency care of sick newborns to at least 50%** by 2020 (with special focus on case management of severe neonatal infection, kangaroo mother care, neonatal resuscitation, full supportive care for prematurity, use of chlorhexidine and postnatal care)*

Nearly one in three births (32%) takes place in a health facility: 27 percent are delivered in a public sector health facility (hospitals and health centers), and 5 percent are delivered in a private facility. More than two of three births (67 percent) take place at home. In the five years preceding the AMS, only 28 percent of women received postnatal care following their last birth.

[1] UNICEF Data & Analytics, Division of Policy and Strategy, 2013 Statistical Snapshot Child Mortality, http://www.childinfo.org/files/Child_Mortality_Stat_Snapshot_e-version_Sep_17.pdf.

Nearly one in five women received postnatal care within four hours of delivery, more than one in five (22 percent) received care within the first 24 hours, and 2 percent of women were seen two days following delivery.

It is widely known that hygienic conditions for home births are a challenge. There are also data demonstrating that hygienic conditions in hospitals are equally challenging, including hospital nursery outbreaks of highly resistant gram-negative bacteria.[2] Chlorhexidine has a *significant* residual antiseptic effect that inhibits bacterial growth for 24 to 48 hours after application. Whether the birth occurs at home or in a facility, chlorhexidine application at the time of birth provides continued protection during the critical first two days, when risk is greatest for acquiring sepsis caused by bacterial exposure through the cord stump.

[2]Zaidi AKM, Huskins WC, Thaver D, et al. Hospital-acquired neonatal infections in developing countries. *Lancet* 2005;365(9465):1175–88.

CORD CARE PRACTICES IN AFGHANISTAN

For many years, newborn cord care in health facilities was based on World Health Organization (WHO) guidance (2002) to keep the cord stump clean and dry and to not apply anything to the cord. This advice is noted in all newborn care training materials and clinical guidelines; however, no data or information is known on actual practice in the facilities. Save the Children conducted a qualitative research study on household newborn care in rural Afghanistan in 2008. The report indicates following practices for cord care.

The traditional birth attendant (TBA) commonly ties the umbilical cord once, about four finger-widths from the umbilicus, with a clean white thread and then cuts with a new razor blade (in some cases, the blade is not necessarily new or clean), though household scissors may also be used. Sometimes, the mother herself or grandmother is expected to cut the cord because this procedure confers heavy spiritual responsibilities on the cord-cutter. In both Faryab and Sar-iPul, many women cut the cord on a rubber shoe; in Shamali, the cord is sometimes cut on something made of silver, such as a coin or necklace.

Among both ethnic groups in Shamali, the norm is to put nothing on the umbilical stump, but even there, a few women say that a substance (powder) is applied to the stump. In Bamiyan, a little soot from a cooking pot is mixed with oil and placed on the stump to stop bleeding, but if there is no bleeding, nothing is applied. In all other locations, applying a drying or cosmetic substance is the norm. Some Pashtun TBAs put "black oil" they have purchased in the bazaar on the umbilical stump. Commonly, black powder (kohl) is put on the umbilical stump of a male infant so that his lips will be black in later life, while rouge or *surkhi* (lipstick) is put on a girl's stump so she will have red lips. Some Turkmen grandmothers said ashes from burned cotton should be applied to the stump in the case of bleeding. In some cases, drying substances such as talcum powder or local herbs (*sorkhat*) are applied. In one focus group discussion, grandmothers said that if a drying substance were not applied, then the stump would become soft and develop a noxious odor.[3]

The survey provides evidence that an intervention to avoid newborn-care sepsis as a result of cord infection at home birth is required.

[3] Save the Children US, Household care of the newborn: A qualitative research initiative in rural Afghanistan Unpublished report submitted to Afghanistan Ministry of Public Health; August 5, 2008.

POLICY DEVELOPMENT

In January 2014, the WHO provided the following recommendation on umbilical cord care:

Daily chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) application to the umbilical cord stump during the first week of life is recommended for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1,000 live births). Clean, dry cord care is recommended for newborns born in health facilities and at home in low neonatal mortality settings. Use of chlorhexidine in these situations may be considered only to replace application of a harmful traditional substance, such as cow dung, to the cord stump.[4]

Recently, the MOPH conducted a landscape analysis of the existing intervention in the Essential Package for Hospital Services (EPHS) and Basic Package of Health Services (BPHS). The subcommittee also reviewed interventions that are not being used for feasibility, cost, impact, and social acceptability and scalability and accordingly recommended them for inclusion in the EPHS and BPHS.

In reviewing feasibility, acceptability, and scalability of the new intervention, most respondents were of the opinion that chlorhexidine is a very cost-effective intervention (65% respondents) requiring low human resources investment (67% respondents). The survey further strengthens the view that introduction of 7.1% chlorhexidine digluconate is among the key interventions that should be implemented to bring about a significant decrease in the neonatal mortality rate.

The Afghanistan Every Newborn Action Plan (ENAP) also includes 7.1% chlorhexidine digluconate as an intervention for providing newborn care.

Stakeholders' Group Meeting

Under MOPH leadership, a meeting of stakeholders was organized on May 17, 2015. About 40 participants attended the meeting, which had representation of staff from MOPH, donor agencies, implementing partners, and neonatal care specialists. The group divided in four subgroups and worked on the following four components—

- Programmatic guidance
- Development of training materials
- Development of information, education, communication (IEC) and behavior change communication (BCC) materials
- Monitoring and evaluation

After extensive deliberations among the participants, the groups collectively agreed on including chlorhexidine for umbilical cord care, and the decisions have guided the finalization of the introduction guideline.

[4] World Health Organization. *WHO Recommendations on Postnatal Care of the Mother and Newborn*. 2013. http://apps.who.int/iris/bitstream/10665/97603/1/9789241506649_eng.pdf

PROGRAMMATIC GUIDANCE

These programmatic guidelines support of the following goals and objectives:

Goal 1: Increase awareness and use of 7.1% chlorhexidine digluconate for umbilical cord care as part of essential newborn care by health care providers, birth attendants, and families

Objective: Create an enabling policy and regulatory environment to increase introduction and uptake of a quality 7.1% chlorhexidine digluconate product for umbilical cord care at country level

- Prioritize interventions to provinces where 7.1% chlorhexidine digluconate might show greatest health impact
- Develop procurement guidance for government tenders and create a brief to describe differences among dosage forms
- Provide guidance around appropriate product packaging

Goal 2: Establish sustainable supply-side strategy to support the demand for 7.1% chlorhexidine digluconate

Objective: Establish local or regional production capacity for an affordable and quality product to increase the availability of and access to 7.1% chlorhexidine digluconate

- Generate a realistic dialogue within the country about the benefits and risks of local production
- Improve in-country technical and regulatory capacity to produce and market quality 7.1% chlorhexidine digluconate
- Support country-led initiatives to manufacture 7.1% chlorhexidine digluconate for umbilical cord care where local production is determined to be feasible

Goal 3: Generate increased demand at the country level to accelerate national scale-up

Objective: Shape local markets to increase use of 7.1% chlorhexidine digluconate for umbilical cord care

- Monitor and plan for coordinated introduction and rollout effort across key geographies
- Coordinate technical meetings and undertake cost analysis in multiple scenarios to assist with decision making on type of product (single container vs. bulk container, one-day vs. seven-day application, and home vs. facility births)
- Integrate 7.1% chlorhexidine digluconate for umbilical cord care into programmatic guidance and/or kits related to newborns in emergency/crisis settings

- Accelerate replication of successful implementation models to other provinces
- Support country-led initiatives to pilot and scale up 7.1% chlorhexidine digluconate for umbilical cord care
- Create a set of measurable outcomes for cord care intervention
- Identify and set numerical target goals for Country Working Group to monitor the progress of chlorhexidine implementation

Goal 4: Advocate for inclusion of chlorhexidine for umbilical cord care in country policy actions

Objective: Advocate for an enabling policy environment for use of chlorhexidine for umbilical cord care programming countrywide

- Raise awareness and action to integrate chlorhexidine in the program interventions
- Bolster credibility of Country Working Group by demonstrating range and breadth of organizational support and involvement
- Expand supportive network to key country stakeholders

Product formulation: Gel vs. Liquid. The consensus is to use the gel formulation considering local preferences and contextual issues. However, since the United Nations Children's Fund (UNICEF) has already procured liquid chlorhexidine for the pilot in two provinces, stakeholders have agreed that for now both liquid and gel will be used.

Number of days of application: (Standard regimen, one day vs. seven days) At the stakeholders' meeting, the group highlighted the need to keep the cord aseptic through application of 7.1% chlorhexidine digluconate and at the same time address the current cultural practices related to application of traditional substances (black oil and kohl, rouge, lipstick, coal dust) until the cord separates. Seven-day application of 7.1% chlorhexidine digluconate or until cord separates has been recommended.

PRODUCT REGISTRATION

The MOPH Reproductive Health (RH) Department will take the lead and work with the General Directorate of Pharmaceutical affairs to facilitate the inclusion of 7.1% chlorhexidine digluconate for umbilical cord care in the essential and licensed drug lists. .

Update National Essential Drug List and National Licensed Drug List

The RH Department within the MOPH will advocate inclusion of 7.1% chlorhexidine digluconate in both the national essential drug list and the national licensed drug list with specific indication for umbilical cord care. The two lists are required to ensure availability product through the public sector as well as private sector outlets, including retail pharmacies.

Update Standard Treatment Guidelines

The newborn care section of the MOPH RH department will update the standard treatment guidelines to ensure the revised guideline includes use of 7.1% chlorhexidine digluconate for umbilical cord care. The department will work to facilitate inclusion of chlorhexidine within the health system (BPHS/EPHS) and in collaboration with Grant & Contract Management Unit, private sector, and other related stakeholders ensure the guideline has been updated as part of the ENAP 2015–2020. The new STGs will be distributed as part of the comprehensive ENAP.

Delivery through Health System

According to the 2010 AMS, 60% of women receive prenatal care and 34% of births are attended by a skilled birth attendant; however, the remaining 64% of births are attended by a family member, neighbor, or TBA. Based on the findings from the survey, it has been decided that 7.1% chlorhexidine digluconate will be recommended for use in all births—home and facility based and through both the public and private sectors.

Phasing of Introduction

Phased introduction has been recommended. Early implementation in UNICEF focus provinces will provide a good start-up opportunity for this new intervention, following which the new intervention will be expanded gradually to other provinces. Expansion to the entire country has been recommended based on findings and lessons of the operationalization's early implementation phase.

During the early implementation phase, the reporting and recording forms will be revised to incorporate information on distribution, use, and ensuring quality standards in use of 7.1% chlorhexidine digluconate. Feasibility of conducting on-the-job training for community health

workers will be tested using the curriculum developed for each cadre of service provider. The findings from the initial phase will guide the expansion strategy, and the lessons learned will guide any changes to the national introduction guideline.

SUPPLY PLANNING: QUANTIFICATION, PROCUREMENT, AND DISTRIBUTION

In the new intervention, 7.1% chlorhexidine digluconate will be used for both facility-based and home births. Data from the AMS indicates that 60% of women receive prenatal care, which will offer an opportunity to distribute the product during those visits. However, not all women deliver at a facility or with a skilled birth attendant. Hence, in the initial phase of the project, the working group agreed that chlorhexidine will be provided at the time of delivery and will be distributed through both skilled care providers and community health workers (CHWs).

Feasibility of adding 7.1% chlorhexidine digluconate to the clean delivery kits will be tested because these are widely distributed and used by CHWs. This offers an opportunity to women to purchase and keep 7.1% chlorhexidine digluconate with them to be used at the time of delivery. However, this plan needs more work, and the RH department of MOPH will be discussing this issue with General Directorate of Pharmaceutical affairs (GDPA) and partners involved in clean delivery procurement and distribution.

For the first year, the plan is to implement chlorhexidine for cord care in UNICEF target provinces with a gradual expansion to other provinces.

Quantification will be done using the algorithms developed for the 13 UN Commission commodities.[5] The product is currently available through UNICEF, Lomus Pharmaceuticals Pvt. Ltd. (Nepal), and Drugfield Pharmarmaceutical Ltd. (Nigeria). Universal Corporation Ltd. (Kenya) is in the process of registering the product and expects the product to be available for domestic sales and export by September 2015.

[5] JSI and SIAPS. *Quantification of Health Commodities: RMNCH Supplement.* Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health. Submitted to the United Nations Children's Fund by JSI. Arlington, VA: JSI Research & Training Institute, Inc.; 2014. http://siapsprogram.org/publication/rmnch-quantification/

TRAINING OF SERVICE PROVIDERS

An orientation package will be developed for CHWs, nurses, midwives, and doctors. Depending on the cadre of health care provider, the contents of the manual will vary to address their specific training needs.

Public Sector

The guideline on use of 7.1% chlorhexidine digluconate will be included in the Essential Newborn Care learning resource package, the Community-Based Health Services guideline, and the BPHS package guidelines, which are being revised and coordinated with Kabul Medical University (Midwifery department) and Ghazanfar Institute of Health Sciences or inclusion in preservice trainings.

The training manual for CHWs, nurses, and midwives curriculum will include the following components and will be part of the comprehensive newborn care training manual. Currently, CHWs have a refresher training scheduled twice a year, and information on use of chlorhexidine will be made part of this refresher manual.

- Background
  - Newborn care statistics
  - Information on 7.1 % chlorhexidine digluconate
- Hand washing
- Technique for application of 7.1 % chlorhexidine digluconate
- Counseling to mother on importance of applying nothing to the cord other than chlorhexidine
- Introduction of the reporting record forms with revisions to include information on chlorhexidine
- Orientation on available job aids and other developed IEC material

Private Sector

The RH Department at MOPH will communicate through the MOPH officer of the Private Sector Coordination Directorate to orient private sector providers on the issue.

QUALITY ASSURANCE, MONITORING AND EVALUATION, LOGISTICS MANAGEMENT INFORMATION SYSTEM INTEGRATION

The reporting and recording forms will be revised to include information on use of chlorhexidine this includes- the supervisory forms used by the staff of the RH Department at both facility level and community level. The information will be entered in the health management information system for both levels. In the initial phase, reporting will be done on the following indicators:

- Number of CHWs and doctors trained on use of chlorhexidine
- Number of community awareness session
- Total number of births reported in the intervention area
- Number of births where chlorhexidine was used by CHW or mother
- Number of births followed by the supervisor to verify use of chlorhexidine
- Stock status (any reports of stock-outs for more than a month)
- Availability of IEC material at health centers

BCC CAMPAIGN AND IEC MATERIAL DEVELOPMENT AND CAMPAIGN

Overview of Strategic Approaches for Demand Generation

Advocacy: Operates at the political, social, and individual levels and works to mobilize resources and political and social commitment for social change and/or policy change for chlorhexidine. It aims to create an enabling environment at any level, including the community level, to ask for greater resources, encourage allocating resources equitably, and remove barriers to policy implementation of scaling up chlorhexidine for cord care of newborns. It provides advocacy resources for using the Commission platform to raise awareness and engage stakeholders in addressing chlorhexidine-related gaps in policy.

BCC campaigns and IEC material will be designed with messages on use of chlorhexidine focusing on community: family members who are involved in caregiving on importance of applying chlorhexidine only

Community-Based Media: Community-based media reach communities through locally established outlets. Such outlets include local radio stations and community newsletters or newspapers as well as activities such as public meetings and sporting events.

Community Mobilization: Through community individuals, groups, or organizations, plan, carry out, and evaluate activities on a participatory and sustained basis to improve newborn lives, either on their own initiative or stimulated by others. A successful community mobilization effort not only works to solve problems but also aims to increase the capacity of a community to successfully identify and address newborn needs.

Counseling: One-to-one communication with a trusted and influential communicator, such as a counselor or health provider. Counseling tools or job aids will be produced to help clients and counselors improve their interactions, with service providers trained to use the tools and aids.

- Service providers:
  - Use of chlorhexidine for umbilical cord care
  - Importance of hand washing prior to applying chlorhexidine

Communication channel used: The messages will be broadcast using mass media, print media, and display of IEC material at health facilities. Chlorhexidine-specific posters, brochures, and flip charts will be developed to aid the communication.

The messages will also be delivered through following activities:

- Community health leaders
- Awareness sessions for the mothers through neighborhood meetings and one-on-one meetings with family members responsible for taking care of the newborn

PRODUCT AVAILABILITY[6]

Supplier / Manufacturer	Format	Size	Price	Contact
Drugfield Pharmaceutical Ltd. (Nigeria)	Gel	3 g tube	USD 0.38	Mr. Olakunle Ekundayo, Managing Director http://www.drugfieldpharma.com
		10 g tube	USD 0.47	
		25 g tube	USD 0.58	
Lomus Pharmaceuticals Pvt. Ltd. (Nepal)	Gel	3 g tube	USD 0.27	Mr. Prajwal Pandey, Marketing Director prajwalpandey@lomus.com.np http://www.lomus.com.np
		10 g tube	USD 0.41	
UNICEF Supply Catalogue	Liquid	10 ml dropper bottle	USD 0.36	https://supply.unicef.org Product number S1531515

[6] This information is from: Chlorhexidine for umbilical cord care. http://www.healthynewbornnetwork.org/topic/chlorhexidine-umbilical-cord-care