Promoting the **Quality** of **Medicines** Plus

A Rapid Assessment of Regulation and Supply of Priority MNCH Medical Devices in Africa and Asia

Bangladesh, Ethiopia, Ghana, Nepal, and Senegal

Background

Medical devices (MDs) are essential for quality care of maternal, newborn, and child health (MNCH), yet information regarding regulation, quality assurance (QA), and supply of MDs is scarce in low- and middle-income countries (LMICs)—in particular, their sourcing, procurement, maintenance, and general availability. This brief provides a concise summary of the regulatory frameworks and controls for MDs and in vitro diagnostics (IVDs) required for MNCH in **Bangladesh, Ethiopia, Ghana, Nepal, and Senegal,** identifying strengths and weaknesses in regulatory controls and priority areas that need to be addressed. The criteria for the selection of countries to survey was based on a combination of USAID priority countries as well as the availability of local resources to support data collection in those countries.

Little is known about the effectiveness or efficiency of regulation or procurement or the availability or use of MNCH devices in LMICs. A search of published English-language literature on the subject yields only a few resources. Many donor and implementing partner materials on the subject are unavailable to the broader community. Although scant, accessible resources do reveal the tremendous hurdles LMICs face in acquiring essential MNCH devices. The most challenging issues relate to regulatory systems, financing, procurement, supply, service delivery, and maintenance and repair of devices. Generally, regulatory systems in LMICs, particularly regulatory capacity for overseeing MDs, are inadequate.

Objective

Given the importance of MDs, including IVDs, to the quality of care of mothers, newborns, and children and the scarcity of information regarding regulation, QA, and supply particularly in LMICs, USAID requested the Promoting the Quality of Medicines Plus (PQM+) program implemented by the U.S. Pharmacopeial Convention (USP) to undertake a rapid assessment to gather information on this essential topic to inform USAID's MNCH activities. Specifically, PQM+

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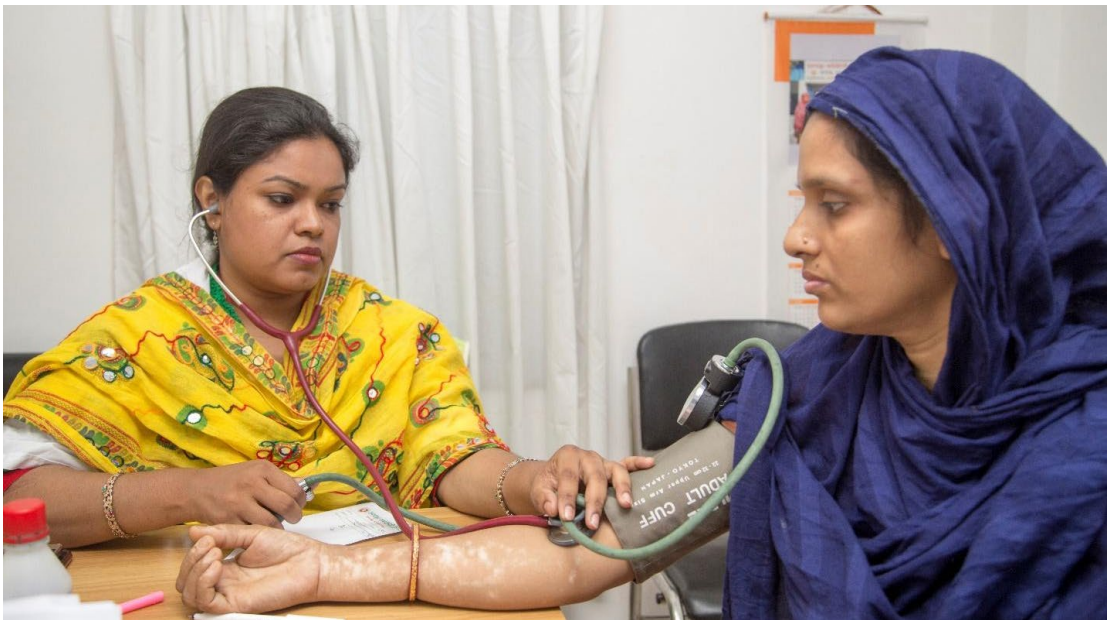
gathered information on regulatory and QA systems governing MDs as well as the availability and use of certain MNCH MDs in health facilities in five countries in Africa and Asia.

To determine what is known about MNCH MDs in LMICs, PQM+ conducted a desk review of available published literature and then designed a questionnaire around the regulatory systems in place to govern MDs, relevant stakeholders, sourcing and procurement processes, and availability and QA of registered MNCH devices. Initial piloting of the questionnaire in Bangladesh and Ghana allowed PQM+ to expand the instrument and validate a list of 16 essential MNCH MDs on which to focus. These 16 devices relate to respiratory support for newborns, devices unique to newborns and mothers, and cross-cutting diagnostic devices for mothers, newborns, and children.[1] The criteria for the selection of countries to survey was based on a combination of identified USAID priority countries as well as the availability of local resources to support data collection in those countries.

Table 1. Priority MNCH devices addressed in this report

Medical device	Function
Pulse oximeter	Measures oxygen saturation of blood)
Continuous positive airway pressure (CPAP)	Delivers air pressure to keep airways open
Oxygen blender	Mixes medical air and oxygen
Oxygen concentrator	Supplies extra oxygen
Humidifier	When filled with water, adds moisture into the air
Flow splitter	Used with a concentrator to split flow of oxygen
Suction pump	If airway is obstructed, suction of airways as part of delivery room resuscitation.
Bilirubinometer	Determines the concentration of bilirubin in blood to assess the risk of jaundice
Phototherapy lights	Treats neonatal jaundice
Radiant warmer	Warming device that provides heat to help maintain body temperature of a baby
Fetal doppler	Solar powered device to detect and measure the fetal heart rate
Non-pneumatic anti-shock garment	Limits persistent PPH by managing hypovolemic shock
Blood pressure machine	Measures the systolic, diastolic, and mean arterial pressures
Glucometer	Measures the amount of sugar in a blood sample
Hemoglobinometer	Measures hemoglobin concentration in the blood
Syringe pump	Delivers fluids and medication through an intravenous line

[1] Priority devices were identified from World Health Organization (WHO), *Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health*. Geneva, Switzerland: WHO, 2016, 9789241565028_eng.pdf (who.int); and NEST360, "Qualified Technologies for Newborn Care in Low-Resource Settings," 2020, 0b77a5_55cbeb589f834d9e976a48605f64707c.pdf (filesusr.com).



A health facility staff member in Bangladesh uses a blood pressure cuff during a medical visit.

In May 2023, PQM+ administered the questionnaire to key informants from the NRAs in Bangladesh, Ethiopia, Ghana, Nepal, and Senegal. In some cases, PQM+ spoke to regulatory authority staff or other relevant stakeholders to validate responses. PQM+ also interviewed PQM+ staff and assessed relevant regulatory and policy documents from the five countries to triangulate findings from the questionnaire. Following data collection, PQM+ analyzed all quantitative data using Excel and performed content analysis of qualitative data.

Key Findings and Recommendations

Findings

The key findings of this rapid assessment raise several concerns about the regulation and use of MDs in the five countries studied and highlight the need for further in-depth analysis of specific issues (see Table 2 for assessment results).

- Although a regulatory framework (laws, regulations, and processes) exists in all five countries, those frameworks have not established many of the necessary regulatory systems controls and requirements needed to oversee MDs, including MNCH devices.
- Despite recognized weaknesses in their market authorization (MA) processes, four of the five countries do not use reliance as a mechanism for registering MDs.
- Although four of the countries (excluding Nepal) have dedicated staff for regulating MDs, the capacity of that staff in effectively meeting the regulatory needs is not known.
- Although MD donations are accepted by the five countries, regulatory processes in place to control the quality or suitability [2]of those donations are inadequate.

[2] Donated devices that require expensive consumables or regular and costly preventative maintenance are not able to be used in countries that cannot afford these extra costs associated with the use of the instrument.

- Once MDs are in circulation in the country, whether donated or procured by the government with or without registration or authorization, market control and surveillance of these devices is limited.
- Findings in this assessment indicate that the national control laboratories (NCLs) in all five countries are not adequately equipped to test MDs.
- None of the countries' governing agencies responsible for public health communicate or collaborate effectively with one another.
- Major gaps in information persist on the reported use of priority MNCH devices at several levels of the health care system in the five countries.

Table 2. Assessment Results

Data Point	Bangladesh	Ethiopia	Ghana	Nepal	Senegal
Regulatory authority responsible for MD regulation	Yes	Yes	Yes	Yes	Yes
Regulatory staff for MDs	Yes	Yes	Yes	No	Yes
Documented registration approval process	Yes	Yes	Yes	No	No
Manufacturers required to classify MD risk[3]	Yes	Yes	Yes	No	Yes
Local manufacturers of MNCH MDs	No	No	No	No	No
NGOs/donors involved in MD procurement and distribution	Yes	Yes	Yes	Yes	Yes
Documented donation process	Yes	No	Yes	No	No
Regular communication between NRA and procurement agencies	No	No	Yes	No	No
Number of registered MNCH MD products	16	13	9	0	0

Recommendations

1. Regulatory agencies need to develop a comprehensive regulatory framework for priority MDs that includes considerations for each regulatory function, adopting a risk-based approach that optimizes scant financial and human resources. This would include formal documentation of mutual reliance and recognition agreements with stringent regulatory authorities (SRAs) for registration approvals, quality testing, adverse event reporting, clinical trial determinations, and potentially contracting accredited laboratories for quality testing of high-risk devices. PQM+ can create a sample/draft regulatory framework for use by countries in developing their own regulatory framework.
2. Once this framework is developed, regulatory agencies should monitor and evaluate regulatory processes throughout the country to ensure continuous improvement and compliance with standards, policies, and procedures.
3. Further capacity-building efforts are required to establish a dedicated cadre of trained MD regulatory staff.
4. Finally, further in-depth analyses of the challenges with regulation and quality assurance of MDs are required to pinpoint critical limitations and develop appropriate solutions to address them.

[3] The NRA sets guidelines on classification, but manufacturers should use the guidelines and let the NRA know how they classify a device based on those guidelines.