Promoting the
QUALITY OF MEDICINES Plus

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

Bangladesh, Ethiopia, Ghana, Nepal, and Senegal

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About PQM+

The Promoting the Quality of Medicines Plus (PQM+) Program is a six-year cooperative agreement between USAID and USP to sustainably strengthen medical product quality assurance systems in low- and middle-income countries. The program works to improve medical product quality through cross-sectoral and systems strengthening approaches and the application of international quality assurance standards across the pharmaceutical system. By sharing scientific expertise and providing technical support and leadership, PQM+ helps create resilient and robust local health systems that address diseases such as HIV/AIDS, tuberculosis, malaria, and neglected tropical diseases, as well as improve maternal, newborn, and child health.

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Contents

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Acronyms

CE	European Conformity
CMSD	Central Medical Stores Depot (Bangladesh)
CPAP	continuous positive airway pressure
CPTU	Central Procurement Technical Unit (Bangladesh)
DDA	Department of Drug Administration (Nepal)
DGDA	Directorate General of Drug Administration (Bangladesh)
DGFP	Directorate General of Family Planning (Bangladesh)
DGHS	Directorate General of Health Services (Bangladesh)
EFDA	Ethiopian Food and Drug Authority
EPPA	Ethiopian Public Procurement Authority
EPSA	Ethiopian Pharmaceuticals Supply Agency
EPSS	Ethiopian Pharmaceuticals Supply Service
EUA	emergency use authorization
GFDA	Ghana Food and Drug Authority
ISO	International Organization for Standardization
IVD	in vitro diagnostic
LMIC	low- and middle-income country
MA	market authorization
MD	medical devices
MNCH	maternal, newborn, and child health
MOH	ministry of health
NCL	national control laboratory
NGO	non-governmental organization
NRA	national regulatory authority
PMS	post-marketing surveillance
PQM+	Promoting the Quality of Medicines Plus
QA	quality assurance
SRA	stringent regulatory authority
USAID	U.S. Agency for International Development
USP	U.S. Pharmacopeial Convention
UEMOA	*Union Economique et Monétaire Ouest Africaine* (West African Economic and Monetary Union)
USFDA	U.S. Food and Drug Administration
WHO	World Health Organization

Executive Summary

The Promoting the Quality of Medicines Plus (PQM+) program, a U.S. Agency for International Development (USAID)-funded cooperative agreement implemented by U.S. Pharmacopeial Convention (USP), seeks to sustainably strengthen medical product quality assurance (QA) systems in low- and middle-income countries (LMICs). One group of medical products, medical devices (MDs),[1] is essential for quality care of maternal, newborn, and child health (MNCH), yet information regarding regulation, QA, and supply of MDs is scarce—in particular, their sourcing, procurement, maintenance, and general availability. To bridge this gap, PQM+ conducted a landscape assessment in select LMICs to gather this information.[2] This report 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.

All five countries surveyed have an established national regulatory authority (NRA) responsible for regulating MDs, among other duties, and most of the countries have regulatory staff dedicated to MDs. All countries have at least one publicly available **guideline documenting the process and requirements** for registration and approval of MDs[3] (Ethiopia and Ghana have several). All countries surveyed, except for Nepal, have requirements that MD manufacturers and importers present evidence of conformity to essential principles of safety and performance for MDs; these requirements are established by each respective NRA.

All five countries self-reported that **foreign manufacturers are the only source of MNCH devices** for their country, whether through donation or procurement processes. All five countries surveyed stated that non-governmental organizations (NGOs) and donors engage in procurement and distribution of devices, although only Bangladesh and Ghana have a **documented donation process**. Except for Ghana, the LMICs surveyed do not have a cadence for communications among procurement agencies, the NRA, and relevant government departments. In the public sector, communication cadence between MD and pharmaceutical regulators and procurers is critical to ensure procurement practices align with regulatory guidelines. Nepal and Senegal currently do not have documented MD or IVD registration processes and do not have any priority MNCH devices, as defined by either the World Health Organization (WHO) or as set by the country, registered in their respective countries. In Bangladesh and Ethiopia, most of the priority MNCH MDs are registered and are available for use in most hospitals and health centers—less so in local clinics. The availability and demand for the priority MNCH MDs are not known for Ghana, Nepal, or Senegal.

[1] Defined as “any instrument, machine, contrivance, implant, in vitro reagent that's intended to treat, cure, prevent, mitigate, diagnose disease in man” https://www.fda.gov/training-and-continuing-education/cdrh-learn/overview-regulatory-requirements-medical-devices-transcript#:~:text=It%20can%20be%20found%20in,%2C%20diagnose%20disease%20in%20man%E2%80%9D.

[2] The priority devices identified for this assessment fall largely in hospital settings and the assessment focused on public sector facilities.

[3] Some countries have separate guidelines for MDs; others have it written into their medicines’ registration guidelines.

Table 1. 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[4]	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

For all five countries surveyed, PQM+ recommends that updates/creation of regulations be made of the following:

- Required evaluation and monitoring of regulatory processes throughout the country's NRA to ensure continuous improvement and compliance to standards, policies, and procedures
- Formally documented mutual reliance and recognition agreements with stringent regulatory authorities (SRAs) for registration approvals, quality testing, adverse event reporting, and clinical trial determinations
- Reliance and recognition of laboratory testing of MDs from accredited laboratories
- Contract-accredited laboratories for quality testing of devices for high-risk devices
- Provisions for establishing exclusive MD regulatory staff, their training and development, and necessary infrastructure

A more detailed breakdown of the findings and recommendations for each country can be found within this report.

The overall findings from this assessment have also led to more questions and a need for deeper understanding of the processes and regulations that the NRAs and end users of these products are using, if at all. The following is a list of proposed future assessment topics that require more intensive analysis to better understand the root causes of MNCH MD QA and usage limitations:

- The overall effectiveness (or ineffectiveness) and consistent (or inconsistent) implementation of regulatory procedures and their effect in support or hindrance of achieving the United Nations Sustainable Development Goals, particularly increased access to priority MDs or IVDs for health emergencies

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

- Implementation of the registration process requirements and consistent effectiveness in identifying and rejecting registration of poor-quality MD products
- Root cause(s) of unimplemented or inconsistently implemented regulatory procedures
- Inventory of MDs that are required or usable versus the MDs and IVDs that are procured or donated in order to understand procurement priorities and decision-making processes[5]
- Health facility awareness of and adherence to regulatory guidelines for procurement, use, maintenance, and disposal of MDs
- MD supply versus demand at public health facilities
- MD quality controls and monitoring within public health facilities
- Requirements for MNCH MD service contracts, field technical support, maintenance, spare parts, consumables, and health care worker training
- Alignment, crossover, and reference between NRA regulations and procurement agents

[5] For example, do procurement decisions consider equipment that requires less expensive consumable options and/or equipment that requires less maintenance and training? Does the inventory of equipment include excess quantities of devices not needed or in use?

Introduction

The World Health Organization considers health care technology, of which MDs are one component, an essential building block of the health system. WHO estimates that there are 2 million kinds of MDs (categorized into more than 7,000 generic devices groups) on the world market (see WHO 2017 and WHO 2017). WHO (2016) defines an MD as "any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article" intended for a medical purpose. Its advisory document Interagency List of Medical Devices for Essential Interventions for Reproductive, Maternal, Newborn and Child Health lists thousands of devices specially designed for MNCH. While the availability of abundant MNCH devices is good news for the care of this vulnerable population, Kananura (2017) and Thairu (2013) point out that few of those devices are designed for low-resource settings, and the distribution across countries is fragmented.

Little is known about the effectiveness or efficiency of regulation or procurement or the availability or use of MNCH devices in LMICs. In fact, 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. Available documents, such as WHO and donor organizations' guidelines for regulation, procurement, and availability of MDs, present only general information (see WHO 2016). Substantive country-level evidence is largely missing. Of note, there is no standardized list of priority MNCH MDs across organizations. The WHO list mentioned above differs from that of PATH (see PATH, 2021).

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, have been found to be inadequate (i.e., missing important features) (AUDA-NEPAD 2018; and Briggs et al. 2021).[6] As a result, many rely on help from the European Medicines Agency or U.S. Food and Drug Administration (USFDA) (Rugera et al. 2014; Hubner et al. 2021). Achieving or maintaining safety standards can be expensive and difficult for non-profit organizations and local developers. Robust regulatory processes in high-income countries are high bars for African countries (Hubner et al. 2021).

Several studies (Perry 2011, Diaconu 2014, Compton 2018, Partnership for Supply Chain Management 2019, Houngbo 2017, and Marks 2019) highlight the insufficiency of funding for MDs, due mainly to a focus on other interventions and essential medicines. Rugera (2014), AUDA-NEPAD (2018), Hubner (2021), and Ayah (2020) point out that regulatory approval is not a sign of suitability in low-resource settings. In fact, MDs are designed for high-income countries, not local LMIC conditions (WHO 2010a).[7] Thus, almost 40–70 percent of devices in LMICs are partially or completely out of service due to factors such as inadequate infrastructure, absence of expertise and manuals in the local language, and inability to sustain long-term

[6] Briggs et al. examined registration of medical products by MRAs in nine countries, including three targeted for this report (i.e., Bangladesh, Nepal, and Senegal). The study found that products were registered in only one-third of the countries (Bangladesh, DRC, and Tanzania). Mali, Mozambique, and Senegal lack the legal provisions to mandate the registration of medical devices prior to entry onto the market. Nepal, Rwanda, and Uganda have legislation in place but do not yet register devices.

[7] NEST360 (in Kenya, Malawi, Nigeria, and Tanzania) uses an eight-step process to evaluate technology for newborn care in low-resource settings. Rigorous performance and usability testing is conducted on devices that are available for purchase and have regulatory approval. https://nest360.org/technology/

operations and costs of the device (Diaconu et al. 2014; Ayah et al. 2020; and Malkin and Keane 2010. MD procurement processes in LMICs are also not well documented (Diaconu et al. 2014). Public sector procurement of devices may be one-off, sporadic, or depend largely on donations. An estimated 70–80 percent of medical equipment in LMICs is either donated or funded by donors (Marks et al. 2019, WHO 2010b). While donated devices can address a need, poorly planned donations can burden organizations, facilities, and providers in already challenging situations. It is important to note that although donations are a frequently used strategy to address MD disparities, there is no reported experience with or evaluation of donated devices in LMICs (Marks et al. 2019).

Given the importance of MDs, including IVDs, to the quality of care of mothers, newborns, and children and the scarcity of information on the subject, particularly in LMICs, USAID requested the Promoting the Quality of Medicines Plus (PQM+) program implemented by USP to undertake a rapid assessment to gather information on this essential topic to inform USAID MNCH activities. Specifically, PQM+ gathered information on regulatory and QA systems governing MDs as well as the availability and use of certain MNCH devices in health facilities in five countries in Africa and Asia. The findings of this report will help USAID and other stakeholders, including donor communities and government agencies such as ministries of health (MOHs), NRAs, and other decision makers, to understand the issues countries face in trying to regulate MDs, identify information gaps for further study, and define priority areas for regulatory support/future MNCH activities.

Methodology

To determine what is known about MNCH MDs in LMICs, PQM+ conducted a desk review of available published literature and then designed a survey 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 (see Table 2.)[8] 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 2. Priority MNCH devices addressed in this report

Medical device	Function
1. Pulse oximeter	Measures oxygen saturation of blood
2. Continuous positive airway pressure (CPAP)	Delivers air pressure to keep airways open
3. Oxygen blender	Mixes medical air and oxygen
4. Oxygen concentrator	Supplies extra oxygen
5. Humidifier	When filled with water, adds moisture into the air
6. Flow splitter	Used with a concentrator to split flow of oxygen

[8] 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).

Medical device	Function
7. Suction pump	If airway is obstructed, suction of airways as part of delivery room resuscitation
8. Bilirubinometer	Determines the concentration of bilirubin in blood to assess the risk of jaundice
9. Phototherapy lights	Treats neonatal jaundice
10. Radiant warmer	Warming device that provides heat to help maintain body temperature of a baby
11. Fetal doppler	Solar powered device to detect and measure the fetal heart rate
12. Non-pneumatic anti-shock garment	Limits persistent post-partum hemorrhage (PPH) by managing hypovolemic shock
13. Blood pressure machine	Measures the systolic, diastolic, and mean arterial pressures
14. Glucometer	Measures the amount of sugar in a blood sample
15. Hemoglobinometer	Measures hemoglobin concentration in the blood
16. Syringe pump	Delivers fluids and medication through an intravenous line

In May 2023, PQM+ administered the survey 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 survey. Following data collection, PQM+ analyzed all quantitative data using Excel and performed content analysis of qualitative data.

Limitations of this appraisal

Given the wide gaps in information identified in the published literature, PQM+ undertook a somewhat narrow assessment of the state of essential MNCH MDs in LMICs. The survey tool did not attempt to gather important contextual data, such as whether: (1) there are *sufficient* regulatory resources (funds, staff, capacity, etc.) for overseeing MD controls; (2) regulatory procedures used for identifying and rejecting poor-quality MDs and whether these are *effective or are being implemented at all or correctly and consistently* and, if not, *why*; and (3) MDs (donated or otherwise) are able to be procured *effectively* in terms of circumstantial expedited registration approval and market authorizations (MAs), prioritization, quantity and types needed, and distribution in-country.

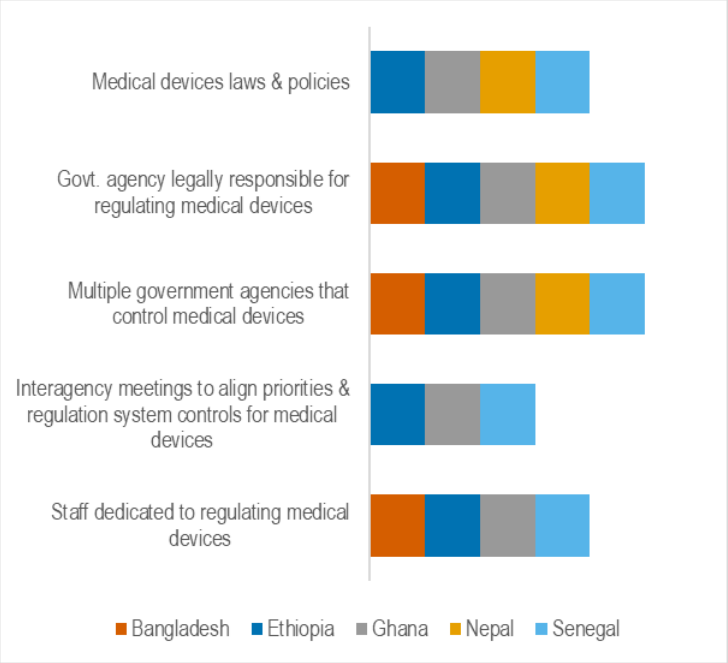
Furthermore, because PQM+ works at the national rather than sub-national level, other contextual factors, such as demand and supply of MDs at various public health facilities; usage, maintenance, and disposal within health facilities; and MD controls and monitoring within public health facilities, were largely excluded from data collection. Finally, the mechanisms for maintaining integrity of both NRA requirements and public health regulations are not fully understood. Information on the processes for how information on regulatory controls and alignment, crossover, and reference occur are still unknown.

Findings

Governance of medical devices: National laws and regulatory agencies

National regulation is more effective when supported by legal provisions. All countries except Bangladesh[9] have or are developing national legislation and/or policies to govern MDs (Figure 1). These include Ethiopia's Food and Medicine Administration Proclamation Number 1112/2019; and Ghana's National Health Policy. WHO's Global Atlas of Medical Devices 2022 indicates that Senegal has a national policy on health technology, although PQM+ could not access the document. Nepal is still developing its Health Care Technology Policy.

Figure 1. Governance of medical devices



In all five countries, multiple government agencies are responsible for various oversight of MDs, including procurement, although the **agency legally responsible for regulating MDs** is the NRA. NRAs include Bangladesh's Directorate General of Drug Administration (DGDA), Ethiopian Food and Drug Authority (EFDA), Ghana Food and Drug Authority (GFDA), Nepal's Department of Drug Administration (DDA), and Senegal's Agency for Pharmaceutical Regulation. All NRAs except DGDA are autonomous in their control of MDs; DGDA is semi-autonomous. Key informants in Ethiopia, Ghana, and Senegal affirmed that there are **interagency meetings** to align MD priorities and regulation system controls.[10] In Ethiopia, EFDA holds meetings with the inspection, licensing, and MDs directorates, as well as the central branch office that controls the country's ports of entry. In Ghana, the standards and revenue (customs) authorities are involved in interagency meetings. Senegal has a technical working group on MDs regulation. Interagency meetings occur quarterly in Ghana and as needed in the other countries.

[9] Bangladesh has a Health Act, but the MOH does not have legislation specifically supporting regulation of medical devices.
[10] Respondents did not specify how often in the last year meetings occurred.

Key informants in four of the five countries indicated that there are **regulatory staff** dedicated to overseeing MDs. **Ethiopia** has an MD team that registers MDs as well as experts in the inspection and licensing directorates and at ports of entry who control MDs. In **Ghana, the** GFDA has a MDs department charged with registering and regulating devices. Because there is no national mandate on MDs in **Bangladesh**, staff from the following agencies within the Ministry of Health and Family Welfare help regulate MDs in the country: Directorate General of Health Services (DGHS), which implements the different health programs; Central Medical Stores Depot (CMSD), which procures medical equipment for public hospitals; and the Ministry of Planning's Central Procurement Technical Unit (CPTU). Likewise, although there is no dedicated staff to regulate MDs in **Nepal**, DDA personnel from the registration division currently handle registration and MA for MDs. Staff from the Laboratory Directorate for IVD devices assist in **Senegal**.

Market authorization processes for medical devices

MA (registration and approval) processes for MDs are critical to assuring that only quality (safe and effective) devices reach the marketplace. All countries have at least one publicly available **guideline documenting the process and requirements** for registration and approval of MDs (Ethiopia and Ghana have several).[11] Senegal's Decision No. 3/2022/CM/UEMOA adopts the registration, importation, distribution, classification, safety and performance, and device listing guidelines of the West African Economic and Monetary Union (UEMOA).[12] Arema, a company that specializes in pharmaceutical and health regulatory affairs, maintains that this guide has been "well adopted and implemented" by Senegal, although very little information is available on what and how much has been implemented, and procedures for these processes have not been confirmed.[13] Table 3 outlines the requirements for registering MDs by country.

Table 3. Registration requirements by country

Registration Requirements	Bangladesh	Ethiopia	Ghana	Nepal	Senegal
Risk classification of devices	Y	Y	Y	N	Y
Process exceptions	Y	Y	Y	N	Y
Recognition/reliance	Y	Y	Y	N	Y
Donation approval process	Y	N	Y	N	N
Essential safety and performance principles	Y	Y	Y	Y	Y
Quality management system	Y	Y	Y	Y	Y

All countries except Nepal **classify MDs based on risk aligned with international best practice**. In Bangladesh, only devices that are classified[14] as medium- to high-risk are required to be registered. Ethiopia exempts low-risk devices from rigorous review but controls IVD devices. Ghana closely follows the Global Harmonization Task Force guidelines for MD

[11] See Bangladesh's Registration Guidelines for Medical Devices 2015; Ethiopia's Guideline for Registration Requirements of Medical Devices other than In Vitro Diagnostic Devices, Guideline for Registration of Medical Devices and Guidelines for Medical Device Donations; Ghana's Guideline for Registration of Medical Device as well as a host of guidelines pertaining to medical devices published on GFDA's website; and Nepal's Health Technology Product and Medical Device Directive 2074.

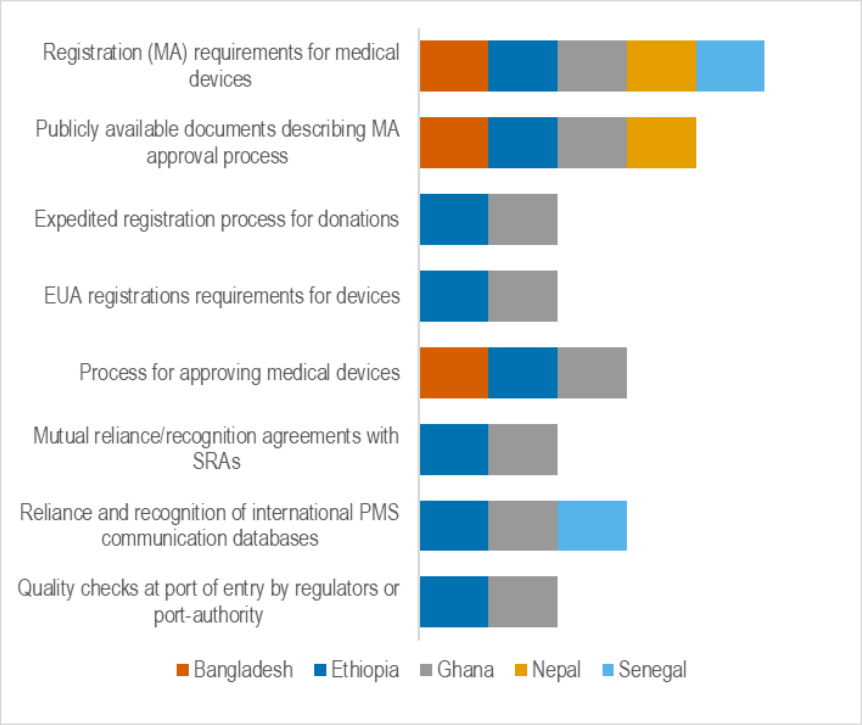
[12] The guidelines are on classification, marketing authorization, statement and communication of medical devices, and medical device safety and performance requirements.

[13] Medical Devices Regulation in Africa. https://www.arema-international.com/blog.php

[14] Every country classifies medical devices differently so there is no uniformity.

classifications, where all MDs are required to submit a registration application. Ghana has classification rules within their registration requirement document with several mentions of specific MDs, such as condoms, that have specific requirements. Finally, in line with UEMOA guidelines, only MD classes C (IIb) and D (III) are subject to MA in Senegal; classes A (I) and B (Iib) require approval for only the import declaration. Nepal's health technology directive lists some MNCH devices, but they are not evaluated based on risk (see https://healthnewsnepal.com/articles/medical-device-regulation-way-nepal/).

Figure 2. Registration of medical devices



Only Ethiopia and Ghana allow **expedited registration for donated devices** and **emergency use authorization** (EUA) for MDs (Figure 2). The GFDA monitors first-time donations; donated products must be registered after being donated a second time. Donated, used, and refurbished products have additional requirements before importation and use in Ghana. These include special requirements for proper use; availability of a local agent; adequate local arrangements for training, maintenance, spare parts, user and service manuals; and a list of quality and product documentation.[15] The EFDA recognizes the status of products in countries with SRAs and accepts their MA, registration, and free sale certificates in their donation process. While expedited and EUA mechanisms exist in Bangladesh, they are not used for MDs. In fact, Bangladesh documents provide no direction on how to handle donated MD/IVDs. Nepal's directive 2074 has no expedited registration procedure or EUA for donated products; all imported devices require import and marketing approvals. Senegal has no donation approval process.

Key informants in only Ethiopia and Ghana mentioned that their countries have mutual reliance or recognition agreements with SRAs. Currently, all five NRAs participate in WHO's collaborative registration procedure for medical products, which relies on assessments by

[15] See Bangladesh's Registration Guidelines for Medical Devices 2015

SRAs.[16] Yet, it is not clear whether or to what extent the NRAs use that reliance mechanism to facilitate registration of MDs. The EFDA does not mandate the registration of certain MDs (e.g., those for national health emergencies and for research and education). Nepal's guideline lacks a provision for process exceptions.

Table 4. International standards and norms consulted

Country	International standards
Bangladesh	ISO 13485, quality assurance certificate (USFDA, European Conformity (CE) marketing, RoHS* compliance) (Classes B–D); declaration of conformity (Class A)
Ethiopia	ISO 13485, CE marking, declaration of conformity, post-marketing surveillance (PMS) system
Ghana	ISO 13485, CE marking
Nepal and Senegal	ISO 13485; IMDRF^/IVD WG/N64 FINAL: 2021 (formerly GHTF</SG1/N045:2008); GHTF/SG1/N78:2012. In Nepal, products must meet national standards which are based on WHO/international norms.

*RoHS (Restriction of Hazardous Substances); ^MDRF (International Medical Device Regulators Forum); <GHTF (Global Harmonization Task Force)

All five countries require conformity assessments to determine the **safety and performance** of MDs. Regulatory staff routinely assess manufacturers' adherence to **international standards and norms**, particularly an International Organization for Standardization (ISO) 13485 quality management system and product QA certification from a recognized body (e.g., European Conformity (CE) marking indicating that they meet the health, safety, and environmental requirements of the European Union) (Table 4). Manufacturers and their MDs must be registered by EFDA in **Ethiopia** and comply with god manufacturing practices. A manufacturing license from DGDA is not required in **Bangladesh**.

In Bangladesh, neither the registration guidelines nor Drugs Act gives any direction on regulating licensing of MD manufacturing facilities. Although manufacturing facility inspections have been conducted for initial registration processing, there is no guidance document on conducting inspections. **Ghana's** registration process requires manufacturing site inspections for new manufacturer applications. **Nepal's** DDA has initiated registration of local manufacturers but not export manufacturers due to resource constraints.

Ethiopia and Ghana mandate **quality checks at ports of entry,** which involve inspection of registration approval documents and manufacturers' documents/QA certificates (Figure 2). **Bangladesh's** Drugs Act discusses the regulation of drugs (not specifically medical/diagnostic devices) at entry and exit ports. The key informant in Bangladesh stated that regulators or the port authority staff conduct quality checks at ports but that those inspections are inadequate. Resource constraints prevent quality checks at ports of entry in Nepal.

MDs are also subject to **quality testing**. Informants identified EFDA and Ghana Standards Authority and Food and Drugs Laboratory as capable of testing MDs. Only the informant in Ethiopia contended that the country's laboratories have the human resources to test MDs.[17] Ghana's laboratory tests only minor MDs. Bangladesh's MD testing laboratory has not yet been

[16] See full article: WHO collaborative registration procedure using stringent regulatory authorities' medicine evaluation: reliance in action? (tandfonline.com); Diapositive 1 (who.int). An SRA is a WHO-recognized regulatory authority that applies stringent quality, safety, and efficacy standards in its review of medicines for MA. Using SRAs' MA or free sale product certificates avoid duplication of effort and accelerates the review and approval process.

[17] Bangladesh's testing is presently limited to personal protective equipment (PPE). In the future, other devices will be added. Ethiopia's medical/in vitro devices laboratory has an established ISO 17025 quality management system framework and sufficient human resources to test devices but has not tested any MNCH devices.

established, and the capacity to test such devices is currently being developed.[18] Although the key informant in Nepal identified the National Bureau of Standards and Metrology and national medicine and public health laboratories as responsible for testing MDs, there are no national standards or testing methods for MDs and, to date, no devices have been tested in Nepal. Despite insufficient capacity, only Ghana uses a **contract laboratory** to fill testing gaps; there are no contract laboratories in Nepal to exercise this option. Bangladesh's regulations use reliance mechanisms to recognize other NRAs' testing and MA decisions, but there are no agreements with national control laboratories (NCLs) for other than the purpose of registrations.

Finally, **post-marketing surveillance** (PMS) is a necessary part of controlling the quality of MDs in circulation. **Bangladesh and Ethiopia's** guidance requires manufacturers to maintain a system for PMS. Neither the registration guidelines nor Drugs Act establishes any clear regulations on product sampling from the MD supply chain or national vigilance, nor are there provisions for recognizing the vigilance decisions of other countries or international bodies in Bangladesh. DGDA also does not have a department for MD/IVDs or vigilance-related activities to use or contribute to cooperative **international PMS databases**. The EFDA's inspection, licensing, and product safety directorates are responsible for PMS of MDs, although the quality of that surveillance does not meet international standards.[19]

Ethiopia is part of a *developing* PMS network among seven Intergovernmental Authority on Development members. However, there is little information about the PMS network's activity, and PQM+ could not confirm the existence of such a database. In **Ghana,** the GFDA's market surveillance department within the MD department monitors the safety and quality of devices post approval (the MD department also maintains an MD register), and the authority has a maturity level 4 safety monitoring department to monitor the safety of medicines, vaccines, and other health products. Nepal is not equipped to surveil MDs. Although PMS falls under the DDA, clear provisions for PMS and adverse reporting are missing from national legislation. Resource constraints also prevent DDA from carrying out oversight of imported MDs. **Senegal** has no specific guidelines for PMS of MDs that are publicly available. Instead, its harmonized registration process mandates regulatory requirements to ensure appropriate PMS activity.

Sources of MNCH medical devices

There are **no manufacturers** of any registered MNCH devices in any of the five countries surveyed. All countries are **heavily dependent on foreign sources** for their medical (including MNCH) devices. Ghana, Nepal, and Senegal import all such products from abroad (Nepal, mostly from India). Ethiopia imports more than 80 percent of its MDs (their survey responses indicating less than 20 percent are locally manufactured), while Bangladesh's domestic demand for medical equipment/devices is mostly met by imports.[20]

Another critical source of MDs is **international organizations**. USAID is the primary organization supporting access to MNCH MDs in **Bangladesh**, **Ethiopia, and Ghana**, and all three countries receive international donations. For instance, foreign companies such as Medtronic, GE Healthcare, Siemens Healthcare, Philips Healthcare, and DELFT Imaging

[18] The device lab space exists, and Bangladesh is developing methods to test devices. So far, only masks and condom testing are being developed.

[19] EFDA has announced the construction of a food, medicine, and medical device quality control center with funding from the World Bank. This is to implement the health goal of the Ethiopian government, that is, to update the safety and quality control system across all sectors to an international standard.

[20] See Bangladesh Investment Development Authority (BIDA). Medical Equipment and Devices Industry in Bangladesh. Dhaka: BIDA, March 2022, p. 14.

Systems have donated MDs to **Bangladesh** for research and development. Donors bring MDs into **Nepal** for use in their country programs and train local health care personnel to use those devices. The government does not import or allow refurbished devices as donations, however. U.S. charities and development organizations donate many devices and equipment, refurbished or otherwise, to Senegalese hospitals and medical practices (refer to the U.S. International Trade Administration website). PQM+ could not determine whether donated devices are monitored or tracked in most of the countries. Only Ethiopia and Ghana have specific requirements for donated devices; Ethiopia's requirements mention reporting defects and other problems and returning the device.

Procurement of medical devices

The survey sought to uncover how MDs are procured, since little is known about the process in LMICs. All countries have a national procurement policy; in Senegal, it is based mostly on UEMOA rules. Generally, public procurements are led by government agencies, although other non-governmental entities also may play key roles (see Table 5). There is some variance in the public procurement process in the five countries. MDs are procured every quarter in Ethiopia and annually and/or as needed in the other countries.

Table 5. Entities involved in public procurement of medical devices

Involvement	Bangladesh	Ethiopia	Ghana	Nepal	Senegal
Government agencies responsible	DGHS, CMSD, CPTU, DGFP	EPSA/S, EPPA	MOH, Ghana Health Services, Ghana AIDS Commission	Public Procurement Monitoring Office (under Prime Minister)	Public Procurement Regulatory Agency, Central Directorate for Public Tenders
Non-government entities involved		Private MD importers	Local NGOs	Public hospitals, medical and other institutions	

Note: Please refer to Acronyms list.

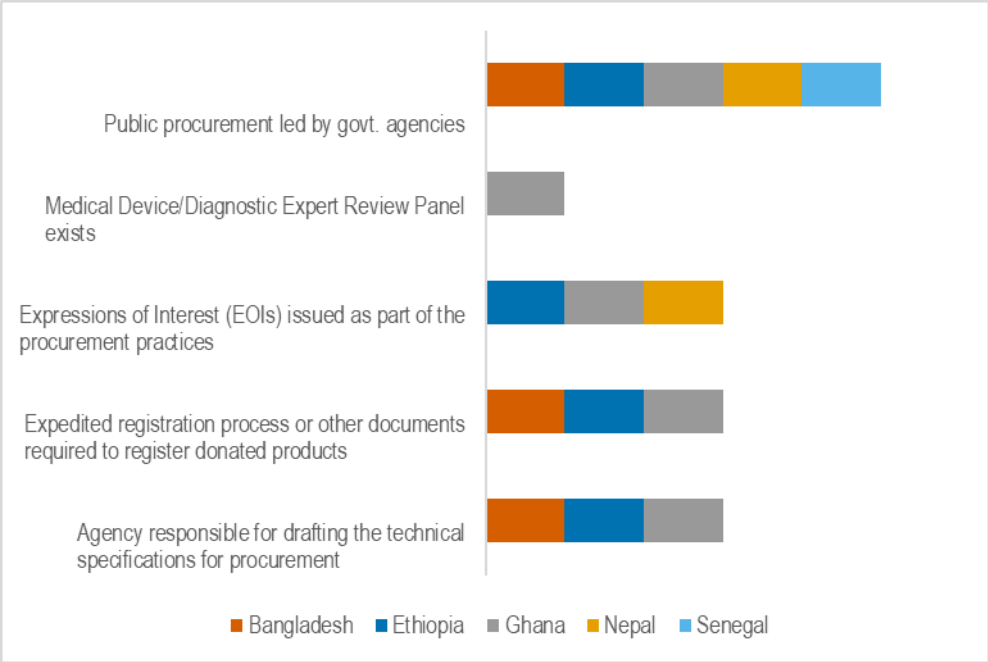
In **Ethiopia**, the Ethiopian Pharmaceutical Supply Service (EPSS) has a Procurement Strategic Plan 2020–2025 and Technical Specification for Selected Capital Medical Device. Together, they define the standards for MDs to be acquired and the procurement process for acquiring those devices. The MNCH devices, X-ray mammography, infant radiant warmer, bilevel positive airway pressure, continuous positive airway pressure (CPAP), newborn Incubator, fetal monitor, and OB/GYN ultrasound are included in the list of equipment. EPSS creates a three-year procurement plan based on the needs of health (including MNCH) programs and public health facilities. The plan is updated yearly as needed.

Government agencies in **Bangladesh** procure MDs based on material requests made by public health departments, quoted tender requests, budget restrictions, and prioritized national health care needs. Foreign companies investing in hospitals and medical education in Bangladesh must submit a project proposal, which is reviewed by the Bangladesh Investment Authority, to obtain a license from DGHS.[21] Foreign MD companies are also assessed by the Ministry of Health and Family Welfare and licensed by DGDA. In **Ghana**, annual and emergency procurement is processed through public tenders; non-governmental entities also submit procurement applications to the Central Tender Procurement Committee. Unregistered devices

[21] Refer to U.S. International Trade Administration website, https://www.trade.gov/country-commercial-guides/bangladesh-healthcare-and-pharmaceuticals.

are procured as well, thereby demonstrating a lack of cohesion among health authorities. **Senegal** also issues public tenders. In **Nepal**, health care facilities and municipalities issue open bids to procure products they need without governance or regulatory system controls. There are no specific procedures or processes for emergency procurement.

Figure 3. Procurement of medical devices



Three of the five countries have an MD diagnostic division within the NRA. In **Ethiopia**, the division oversees registration, listing, and market control and surveillance. Furthermore, it inspects manufacturers, importers, and wholesalers. The **Ghana** division ensures that the MDs imported, manufactured, and offered for sale and distribution are registered in line with the country's Public Health Act 2012. The MD/IVD division within **Bangladesh's** DGDA, however, is being developed, and DGDA's medical product regulators oversee registration, listing, and market surveillance and control for all medical products.

In **Ghana,** donated, used, and refurbished products undergo additional requirements to be allowed for import and use in the country. The additional requirements include communicating special conditions for proper use; availability of a local agent; adequate local arrangements for training, maintenance, spare parts, users' and service manuals; and a list of quality and product documentation (see "Guideline for Donation of Medical Devices"). **Emergency procurements** may occur on an *ad hoc* basis in Bangladesh and through public tender in Ghana. Ethiopia's EPSS provides essential medicines and MDs during emergencies. EPSS procures products through established procurement procedures. The Ethiopian government will also give priority to non-governmental entities to get hard currency. In **Nepal**, there are no specific procedures or processes for emergency procurement.

Some respondents identified some of the biggest **challenges** encountered during the procurement process. These are scarce hard currency in Ethiopia; pricing and differences in quotations and unapproved/unregistered MNCH MDs in Ghana; and bureaucracy, bias, lengthy delays, inadequate technical specification, managerial non-professionalism, and inadequate location and logistics supports in Bangladesh. The respondent in Nepal had no knowledge of any emergency procurement process in that country.

Priority levels are decided by government agencies based on public health demands in Bangladesh and Ethiopia. The respondent in Bangladesh suggested, however, that devices for only the very basic needs were being procured by the government. In Ghana, an application may be expedited if the product is for public health programs (HIV, malaria, tuberculosis, etc.) or any other condition determined by GFDA and MOH products for tender.

Expressions of Interest are issued annually as part of the procurement practice in Ethiopia, Ghana, and Nepal. The Ethiopian Pharmaceuticals Supply Agency (EPSA) implements an open and restricted tender in Ethiopia. The process is conducted at the Central Tender Procurement Committee in Ghana and Open Bid in Nepal.

A Medical Device/Diagnostic Expert Review Panel exists in Ghana. The GFDA has a technical advisory committee of industry, academia, and research experts for MDs that offer technical advice in relation to the safety of MDs. The Ethiopia respondent stated no, while the respondent in Nepal had no knowledge. No information was obtained as to whether any MNCH MDs had been reviewed previously or whether the expert review panel is consulted routinely.

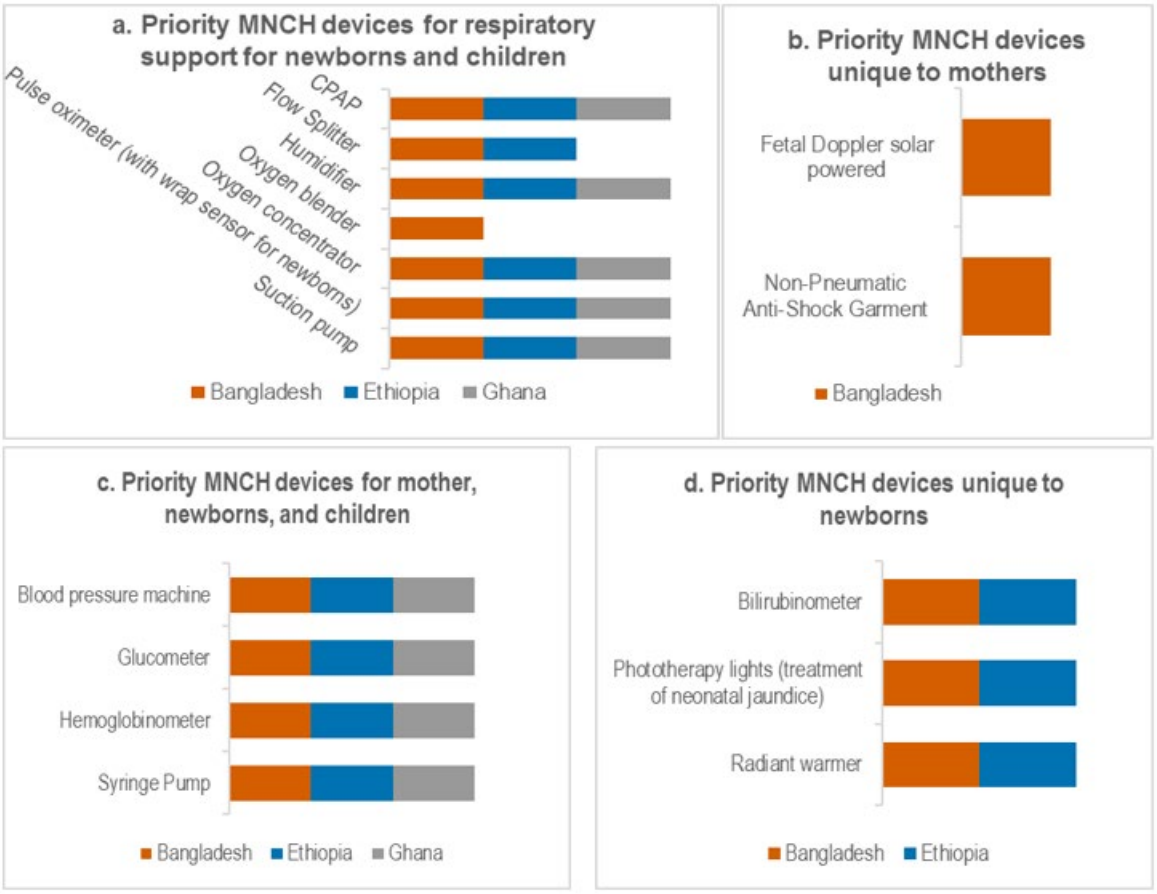
T**echnical specifications for procurement** in Ethiopia are prepared and announced by EPSS, internationally and domestically, when the tender is open and closed. The procurement committee for the respective health institutions develop and submit their specifications for the procurement process in Ghana. In Bangladesh, **forecasting** for MDs is performed when different levels of medical services facilities request procurements. In the past, and depending on funding, the Bangladesh government relied on the tender process. However, national emergencies have forced an *ad hoc* approach.[22] Key informants in the other countries gave no information on technical specifications.

Registration status and reported availability and use of MNCH MDs in country health systems

As **Figure 4** shows, not all 16 priority MNCH MDs are available in the five countries surveyed for this report. Only in Bangladesh are all 16 devices registered; 13 are registered in Ethiopia and 9 in Ghana. The priority devices unique to mothers as well as the oxygen blender are not registered in Ethiopia or Ghana. Ghana has also not registered the flow splitter (a respiratory support device) or devices unique to newborns. The key informant in Nepal indicated that DDA has not registered any of the 16 MNCH devices. The survey yielded no information on the registration status of the devices in Senegal.

[22] The government has established specialized hospitals for burn victims, patients having eye problems, for gastroenterology and hepatobiliary patients, patients with cardiovascular disease, and neuro-disordered patients.

Figure 4. Registered MNCH devices by country



The GFDA has given registration and market approvals for more than half the MNCH MDs surveyed under the actions and requirements laid out in the Registration of Medical Devices document implemented by GFDA. The availability of these MNCH devices in different health facilities in Ghana was not able to be determined at this time. Further collaboration and discussion with other MOH authorities is required to understand the availability at health facilities.

The survey was able to obtain information on the use of the 16 priority MNCH devices at several levels of the health care system only for Bangladesh and Ethiopia. Although more than half the targeted MNCH devices are registered in Ghana, PQM+ interviews could not determine at this time their availability and use in different health facilities in Ghana. The informant in **Ethiopia** reported use of 15 priority devices (syringe pump excluded) in national referral hospitals, regional health centers, and local health facilities. In **Bangladesh**, all respiratory support devices for children and newborns; devices for mothers, newborns, and children; and devices unique to newborns (listed in **Figures 4a, 4c, and 4d**) are said to be used in both national referral hospitals and regional health centers. The two priority devices unique to mothers (**Figure 4b**) are not used in those facilities, although powered fetal dopplers are used. The respondent further identified other MNCH MDs used at those levels of the health care system in Bangladesh (see **Box 1**). In local health facilities, clinics, and/or health posts in Bangladesh, nearly half the priority MNCH devices across all four categories of devices assessed are not used. These include the devices unique to mothers, the bilirubinometer for newborns, nearly

half the respiratory support devices for newborns and children (CPAP, flow splitter, and oxygen blender), and syringe pumps.

When asked who is responsible for monitoring the use of MNCH devices in facilities at the various levels of the health system, the respondent in **Bangladesh** indicated that monitoring is centralized—DGDA monitors the quality of all health facilities, while DGHS monitors the supply chain for all facilities in the country. In **Ghana**, established contact persons at the various health facilities across the country submit FDA adverse report forms to the Ghana FDA for safety reviews by the Technical Advisory Committee for Safety.[23] **Nepal** is moving toward a decentralized health system; consequently, there is still no provision for monitoring bodies at the local and regional levels. DDA is the authorized body at the national level. No information was obtained for Ethiopia and Senegal.

[23] The Technical Advisory Committee for Safety was formed to act as a forum to advise the FDA on matters relating to the post-approval safety, quality, efficacy, and effectiveness of products granted MA by the Authority. The mandate of the Technical Advisory Committee is to provide the FDA with ongoing and timely medical and scientific advice on current and emerging issues related to post-approval product surveillance based on spontaneous reports received from health care professionals and decisions taken by NRAs worldwide.

Discussion

The 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.

In terms of regulation of devices, **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.

For example, despite recognized weaknesses in their MA processes, four of the five countries do not use reliance as a mechanism for registering MDs. By leveraging a reliance mechanism, countries can accelerate the review and approval process of safe, quality products. A reliance mechanism would help mitigate limited staff capacity to review dossiers for MDs. Although some surveyed countries have reliance mechanisms written approval processes, they are not implemented effectively. For example, for some MDs, they may be using reliance mechanisms while they may not be using them for others.

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. Having experienced MD regulatory staff to ensure that devices meet requirements is critical; in the absence of such experts, consultants can be brought in to help understand requirements and teach MD regulators.

Another challenge related to MA is that **although MD donations are accepted by the five countries, regulatory processes in place to control** the quality or suitability of those donations are **inadequate.** Donated, refurbished, and sophisticated MDs require training, installation, initial calibration, typical preventative maintenance, and other registration requirements such as shelf-life, safety, and performance standards.

Finally, 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**. In all countries surveyed, point-of-entry inspection was sporadic if inspected at all. PMS of MDs is a necessary part of the MD regulatory framework to maintain QA of devices used for health care. Regulatory requirements should be developed to ensure appropriate PMS activity is implemented.

For successful PMS of MDs, capacity to test MDs is critical. Findings in this assessment indicate that **the NCLs in all five countries are not (adequately) equipped to test MDs.** However, while vital, ensuring that imported devices meet essential safety and performance standards through QA testing is impractical for the five countries' NCLs to conduct on their own. Establishing relationships with other qualified QA testing laboratories and using reliance and recognition of testing conducted by SRAs and ISO-accredited laboratories is an established strategy for countries that fall short in this regard. Currently, however, there is no reliance or recognition of contract-accredited laboratories as part of the regulatory systems to fill the NCLs' testing gap in Bangladesh and Ethiopia. Nepal also does not contract out quality testing of MDs. Reliance and recognition require updated regulations to allow for this type of approval and regulatory expertise to understand the testing documentation required as part of the technical documentation for registration and market approvals.

In terms of assuring the quality of MDs during procurement, countries surveyed lacked complete guidance on procurement of MDs. In most cases, procurement was based on existing guidelines for other types of medical products, especially pharmaceuticals. Guidance on procurement of MDs is based on their risk category, which ensures that the related maintenance and associated consumables is critical.

Finally, in none of the countries do governing agencies responsible for public health communicate or collaborate effectively with one another.[24] Instituting regular interagency meetings (and with any other essential agency) to gather information on the most appropriate actions to ensure quality health services, align procurement priorities, and share challenges, concerns, and priorities would help enhance efficiencies in procurement. For example, in Ethiopia, the Maternal, Child, and Adolescent Health Service Lead Executive Office, which works closely with other executive offices within the MOH and regional health bureaus, does not engage directly with EFDA even though it provides technical support to regions and health facilities. MOH agencies also do not collaborate to monitor and control MDs in public and/or private health facilities. Regular interagency meetings or mandated fora between or among government agencies would help strengthen the regulatory and procurement processes in Bangladesh and Ghana.

This lack of coordination in Bangladesh has been observed between two organizations under the health ministry. One is the DGHS, and the other is CMSD. The interdepartmental communication between these organizations is lacking, and administrative measures including mandated fora among government agencies should be considered for improvement of the procurement process in Bangladesh .

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. Although the survey obtained information on the distribution of the 16 focus devices, questions remain as to the appropriateness and proper use of the devices. In some places, the data showed that the 16 devices were found to be **unevenly distributed** in national/regional and local health facilities. That is, most devices are used in primary facilities, but only half are used in secondary or tertiary facilities. Further work is needed to ascertain whether there are processes in place to monitor MDs in public health facilities and how those processes work.

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 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.

[24] See Rozina Islam, "Procurement of medical equipment lacks coordination." prothomalo.com, 20 April 2021 for a discussion of the problem in Bangladesh.

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 regulatory and quality of MDs are required to pinpoint critical limitations and develop appropriate solutions to address them.

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Annex: Background on Medical Devices

MNCH devices encompass a wide range of equipment, instruments, tools, and technologies (**Table A1**). They are designed to assist in the prevention, diagnosis, treatment, and monitoring of the health conditions of pregnant women, newborn infants, and children. They can improve health outcomes by enabling early detection and treatment of complications (see **Table A2**). The availability and proper utilization of these devices are therefore essential to a comprehensive health care system (WHO 2003, 2010a, 2016, and 2020).

Table A1. Types of MNCH medical devices

Types of devices	Examples and use
Obstetric	Fetal monitors, ultrasound machines, labor monitoring equipment, vacuum extractors, and forceps used during pregnancy, labor, and childbirth
Neonatal care	Incubators, radiant warmers, neonatal ventilators, phototherapy units for jaundice treatment, neonatal monitors, and feeding pumps commonly found in neonatal intensive care units
Pediatric care	Various diagnostic tools, monitoring equipment, respiratory support devices, infusion pumps, and nebulizers used in pediatric wards and clinics to address the medical needs of infants, children, and adolescents
Diagnostic	Ultrasound machines, blood pressure monitors, blood glucose meters, thermometers, and other diagnostic tools to ensure accurate and timely identification of health conditions
Nutritional	Breast pumps, feeding bottles, specialized nipples, enteral feeding pumps, and oral rehydration devices to assist in the nutritional support and feeding of infants and children

Sources: NEST360° Qualified Technologies 2020, WHO 2016

Table A2. Health outcomes of MNCH medical devices

Health area	Outcomes
Maternal health	Monitor, diagnose, and treat pregnancy-related conditions. For example, fetal heart rate monitors help assess the well-being of the fetus during labor, enabling timely interventions if needed. Other devices, such as birthing beds, facilitate a safe and comfortable environment for labor and delivery.
Newborn health	Infant incubators provide a controlled environment for premature babies and those with low birth weight, ensuring their body temperature remains stable and reducing the risk of complications. Neonatal resuscitation devices assist with breathing or clearing the airway during emergencies.
Child health	Facilitates early diagnosis, treatment, and monitoring of various conditions. For example, pediatric monitors measure vital signs such as heart rate, oxygen saturation, and blood pressure, allowing for early detection of abnormalities. Devices such as nebulizers deliver medication directly to a child's respiratory system, providing quick relief from conditions such as asthma.
Prevention and management of complications	Complications during pregnancy, childbirth, and early childhood can be dealt with by MNCH medical devices. Vacuum extractors or forceps assist in safe and controlled deliveries, reducing the risk of birth injuries to both mother and baby. Devices are also available for managing such conditions as jaundice, hypothermia, or respiratory distress in newborns.
Access to health care in low-resource settings	MNCH medical devices play a crucial role in improving access to health care in low-resource settings, where the availability of skilled health care providers may be limited. Portable and cost-effective devices designed for resource-constrained environments enable essential interventions and care to be delivered even in remote areas.

There is no country-specific literature available on the MNCH device supply chain. However, based on information provided by implementing partners in LMICs, **Box A1** presents a stylized supply chain for medical devices in those countries. As shown, various actors—regulatory

authorities and their designated departments or divisions, manufacturers, importers, procurement agencies, NGOs, distributors, health care facilities, and international aid and donor organizations—play important production, distribution, regulatory, and user roles.

Box A1. Overview of typical supply chain for MNCH medical devices and typical actors responsible for supply

Manufacturers (from large multinational companies to small-scale local producers): Produce MNCH medical devices. Design, produce, and package devices according to quality standards and regulatory requirements.

Importers/Distributors: Source MNCH medical devices from manufacturers and import or procure devices into LMICs. Importers often have established networks and partnerships with local health care providers and government agencies to ensure efficient distribution.

Regulatory authorities: Oversee registration, QA, and safety of medical devices. Establish regulations and standards that manufacturers and importers must adhere to. Review and approve product registrations, conduct inspections, and monitor PMS to ensure compliance.

Procurement agencies: Responsible for centralized procurement of medical devices. Often work closely with government and health care facilities to determine need, specifications, and quantities of medical devices required. Coordinate procurement process and manage tendering and bidding processes.

Health care facilities (hospitals, clinics, community health centers, etc.): End-users of MNCH medical devices. Acquire devices from procurement agencies or local distributors. Maintain adequate supply of devices; ensure their appropriate use and maintenance.

NGOs and donor organizations: Play important role, especially in LMICs. Collaborate with governments, manufacturers, and other stakeholders to improve access to MNCH medical devices. May engage in procurement, distribution, capacity building, and advocacy to support effective use of devices.

Sources: Partnership for Supply Chain Management 2019, USAID GHSC-PSM 2020, and USAID MTaPS 2022