Medical devices are critical for detecting and treating many serious health conditions facing mothers and newborns, including anemia, pre-eclampsia, and neonatal respiratory distress. However, medical devices face unique challenges that make them difficult to manage effectively, particularly in low-resource settings, leaving many populations without sufficient access. PATH, with funding from the Bill & Melinda Gates Foundation, is leading the Market Dynamics for MNCH Medical Devices (MD4MD) project to diagnose key accessibility barriers for maternal, newborn, and child health (MNCH) devices in five focus countries and to identify, prioritize, and pilot interventions to address those barriers.

As a first step towards achieving this objective, PATH conducted an initial literature review of more than 200 academic and institutional sources, consolidating existing knowledge of MNCH device barriers and identifying key evidence gaps. The review is organized around a device’s journey from manufacturer to service delivery point (summarized in the Figure on the next page), recognizing that potential barriers and interventions can occur along each step of this journey. The purpose of this brief is to provide policymakers with a high-level summary of the most important barriers, interventions, and conclusions detailed in the full evidence review.

* The MD4MD grant focuses on eight priority MNCH medical devices: manual blood pressure cuff (sphygmomanometer); bubble CPAP device; neonatal resuscitation device; x-ray radiography machine; point-of-care hemoglobin meter; infusion device; ultrasound (app-based "pocket" devices); and ultrasound (traditional portable devices). The five focus countries include Burkina Faso, Indonesia, Kenya, Malawi, and Senegal.
Figure. Key steps and potential barriers along a device’s journey from manufacturer to delivery point.

**Identified barriers**

This body of literature describes a complex and interrelated set of barriers across the device value chain that impede broader access to MNCH medical devices. However, the literature is often high-level and lacking in country-specific root causes. Key barriers include:

**Supply & Distribution**
- Demand is scattered across small, individual country and sub-national markets.
- Manufacturers lack visibility into market size and customer needs in each country.
- As a result, fewer products are designed specifically for these markets.
- Costly layers of distribution are needed to reach the end customer.

**Procurement & Financing**
- Funding for medical devices is limited by factors like diffuse accountability and a lack of data on device cost and need.
- Fragmented and one-off procurement cycles drive higher prices and lower quality.
- Public sector budgeting mechanisms lack the long-term financial certainty needed to fund device operating costs.

**Policy & Regulatory**
- Regulatory standards from the U.S. and Europe omit criteria that are important for low-resource settings, such as tolerance of varied environmental conditions.
- Fragmented device registration and regulatory processes increase the cost of commercializing a product.

**Service Delivery**
- Health facilities often lack reliable electricity and the supporting infrastructure needed for device operation.
- Facility staffing shortages combined with complex training and supervision needs further limit the effectiveness of available devices.
Maintenance & Repair

- Fragmented procurement leads to a proliferation of device models, complicating maintenance training and spare parts management.
- Spare-part shortages and a lack of trained biomedical engineers to service equipment lead to broken devices sitting unrepaired.

Identified interventions

Similarly, this body of literature also describes numerous potential mechanisms and interventions that could address the barriers mentioned above. However, relatively few examples have been applied to MNCH devices specifically, leaving little insight into best practices and the overall quality of proposed solutions. Key proposed interventions include:

Supply & Distribution

- Providing direct, catalytic investments in product development.
- Improving manufacturer clarity into demand and customer needs, through mechanisms like target product profiles or advance market commitments.

Procurement & Financing

- Strengthening data infrastructure to support procurement, budgeting, and advocacy efforts.
- Addressing obstacles to leasing models and after-sales service agreements that simplify financial management.
- Addressing obstacles to strategic procurement practices that aggregate demand and improve device selection.

Policy & Regulatory

- Harmonizing country registration and regulatory processes.
- Updating clinical guidelines and essential device lists.

Service Delivery

- Improving education and ongoing mentorship/supervision programs.
- Developing clinical decision guides, remote support, and diagnostic technology to assist clinical staff in medical device use.

Maintenance & Repair

- Utilizing asset management systems and tools to organize maintenance activities.
- Developing training and task-shifting programs to support biomedical engineers.
- Expanding programs for training and recruiting biomedical engineers/technicians.

Conclusion

In summary, while high-level device barriers and potential solutions are both documented to some degree, device- and country-specific insights are lacking to effectively match these problems and solutions together in practice. This knowledge gap includes several elements:

- Many sources did not discuss the underlying root causes of the barriers they identified. These root causes are likely systemic, interrelated, and specific to a particular country context.
- The decisions that go into designing an intervention are often not well-explained. In many cases, a single barrier could potentially be addressed through multiple different interventions, but few sources discussed the conditions in which one solution should be favored over others.
• Many interventions are isolated and lack natural comparator interventions within the same geography or device category. This lack of comparators makes it difficult to assess how device- and country-specific nuances might affect outcomes.

• Existing literature does not provide a substitute for critical data infrastructure like device inventories and supplier/distributor mappings, which appear to be lacking in many low-resource settings.

These identified knowledge gaps point to several potential areas for investment and future research, including:

• **Developing approaches to make data collection more sustainable and efficient**, such as investing in asset management software systems or designing digital innovations to automate routine device inventory data collection. A lack of data underlies or exacerbates many of the key challenges and improving visibility into basic device inventory data (e.g., device numbers, manufacturer and model names, functionality) is critical for identifying gaps in availability, budgeting, allocating, organizing maintenance, and other important management activities.

• **Addressing barriers to implementing strategic procurement and financing approaches.**
  
  Budgeting and procurement sit at the heart of the public-sector device value chain, directly affecting both upstream supply and downstream service delivery and maintenance. Many proposed reforms, such as leasing models, after-sales service agreements, pooled procurement, and Value for Money, are well-understood and have a strong track record of success in other contexts/industries. However, there appear to be strong institutional structures and incentives that make such mechanisms difficult to enact in a public health context. Devoting more effort to understanding and adjusting these underlying structures/incentives would have broad impact throughout the rest of the system.

• **Focusing on multiple complementary investments within a single geography.** As mentioned above, medical device challenges are complex and interrelated; and as a general rule, it is likely more effective to target several interventions within a single health system rather than spread those interventions out across several unrelated geographies.

• Finally, additional research and knowledge generation is needed to (1) map out specific supply pathways for each priority device and highlighting their differences, (2) detail root causes and complex interactions between different barriers, and (3) inform the specific tradeoffs that managers must balance when deciding on an intervention.

Capturing these detailed insights can go a long way in developing a translatable set of lessons that can inform more effective and efficient future investments, improving access to critical MNCH medical devices, and ultimately improving health outcomes for populations in low-resource settings.

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