Barriers to Access for MNCH Medical Devices

Landscape review of existing evidence
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### Abbreviations

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<th>Description</th>
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<tr>
<td>AMC</td>
<td>advance market commitment</td>
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<tr>
<td>ASPAK</td>
<td>Aplikasi Sarana, Prasarana &amp; Peralatan Kesehatan</td>
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<tr>
<td>bCPAP</td>
<td>bubble continuous positive airway pressure</td>
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<tr>
<td>CHW</td>
<td>community health worker</td>
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<tr>
<td>CPAP</td>
<td>continuous positive airway pressure</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>HBB</td>
<td>Helping Babies Breathe</td>
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<tr>
<td>IT</td>
<td>information technology</td>
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<tr>
<td>LMIC</td>
<td>low-to-middle-income country</td>
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<tr>
<td>MD4MD</td>
<td>Market Dynamics for MNCH Medical Devices</td>
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<tr>
<td>MNCH</td>
<td>maternal, neonatal, and child health</td>
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<tr>
<td>NEST360</td>
<td>Newborn Essential Solutions and Technologies 360</td>
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<tr>
<td>PHC</td>
<td>primary health care</td>
</tr>
<tr>
<td>PLAMAHS</td>
<td>Planning and Management of Assets in Health Services</td>
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<tr>
<td>POC</td>
<td>point-of-care</td>
</tr>
<tr>
<td>SARA</td>
<td>Service Availability and Readiness Assessment</td>
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<tr>
<td>SRA</td>
<td>strict regulatory authority</td>
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<tr>
<td>TPP</td>
<td>target product profile</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Introduction

Medical devices play an essential role in the prevention, diagnosis, and treatment of health conditions in mothers and newborns globally. Devices like ultrasound machines, blood pressure devices, and bubble continuous positive airway pressure (bCPAP) devices are critical to providing effective facility-based care for vulnerable populations, especially women and children.

However, medical devices have unique characteristics that make them difficult to manage effectively, particularly in low-resource settings. First, devices often serve multiple clinical uses across different health programs, complicating ownership and funding responsibilities. Many devices can also be difficult to own and manage, requiring extensive training, ongoing preventive maintenance, and a reliable supply of specialized parts and accessories. Finally, many devices are deeply interwoven with other health system capabilities. A diagnostic device, for example, is of little use unless paired with effective systems to treat the diagnosed condition.

The need to address these challenges is becoming increasingly critical. As countries make increasing progress towards achieving universal health coverage, and as more women choose to give birth in health facilities, demand is growing rapidly for device-intensive diagnostic and treatment services like ultrasound, anemia and preeclampsia screening, and newborn intensive care. There is also an expectation that this growing need for medical devices will be met with domestic rather than donor resources as countries move up in income status. Thus, strengthening access to medical devices is a critical area for long-term health system investment.

A great deal of knowledge already exists in the global health community regarding maternal, neonatal, and child health (MNCH) medical devices and the challenges/barriers they face. But this knowledge is currently scattered across a variety of donor, partner, country, and academic sources, and as a result, is not easily accessible to the broader community. As such, PATH—under the Market Dynamics for MNCH Medical Devices project (MD4MD) supported by the Bill & Melinda Gates Foundation—conducted a rapid desk research exercise focused on compiling information that was either publicly available or easily accessible, including: published literature, multilateral organization resources (such as policy briefs, technical reports, and guidelines); implementing partner projects (such as assessments, landscapes, and technical reports); donor investment documents (like the Gates Foundation and the United States Agency for International Development); and expert interviews with relevant project leads and medical device experts.

The goal of this report is to (1) summarize for policymakers and health system leaders the most important barriers that MNCH devices face, and (2) highlight potential interventions and key knowledge gaps to prioritize with future investments.

The focus of this evidence review is on eight specific devices: (1) manual blood pressure cuff (sphygmomanometer); (2) electric bCPAP device; (3) neonatal resuscitation device; (4) x-ray radiography machine; (5) point-of-care hemoglobin meter; (6) infusion device; (7) ultrasound (app-based “pocket” devices); and (8) ultrasound (traditional portable devices). By choosing a diverse and well-rounded

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1 Each of these devices is featured on at least two prominent MNCH or primary health care (PHC) priority lists—including (1) The Gates Foundation MNCH priority devices list, (2) 2016 Interagency RMNCH priority devices list, and (3) The Gates Foundation PHC priority interventions list—reflecting their critical importance to improving maternal and newborn health outcomes. They were selected in close consultation with stakeholders at the Gates Foundation in February 2021.
portfolio of devices, we can maximize the applicability of our learnings, with each focus device serving as an archetype for other key medical devices.

The evidence review is organized around a device’s journey from manufacturer to service delivery point, recognizing that potential barriers and interventions can occur along each step of this journey (Figure 1).

Figure 1: Five key categories of medical device barriers and interventions

For each device and each category, this review evaluates how well we can answer those key questions using existing evidence. By walking through this framework device by device and barrier by barrier, we can get a better sense of where the relative strengths, weaknesses, and gaps of our current body of knowledge and where to focus subsequent investments.

Because this evidence review is limited to a rapid desk research exercise, there are limitations to the depth of material included. For example, we were unable to capture detailed insights from ministries of health or country-based implementing partners unless they have been published in an academic journal or other publicly available sources. This evidence review is intended only to be a high-level overview of key knowledge gaps and potential interventions to inform future research and exploration.
Cross-cutting challenges and interventions

**Key MNCH device challenges are cross-cutting and interrelated.** This evidence review identified a wide range of articles, reports, and documents that collectively describe a complex, systemic, and often interrelated set of medical device access challenges. In this section, we summarize the most common, cross-cutting challenges, as well as their underlying causes, across the five categories in our evidence review framework.

**Key interventions are well-known but not well-tested on MNCH devices.** In addition to summarizing the challenges themselves, we also reviewed the medical device literature for evidence of solutions to address those challenges. Our findings, summarized in the tables below, highlight a wide discrepancy between theory and implementation. On the one hand, the medical device literature describes numerous potential tools, mechanisms, and interventions that can be applied to medical devices—often multiple solutions for the same type of issue. However, there is much less evidence (at least in publicly available literature) of when, where, and how to apply these solutions in a specific device or country context, or what broader lessons can be drawn from the implementations that do exist. Those examples we did find often lacked comparative analyses against other interventions or publicly available follow-up studies that would help clarify impact. This evidence gap limits our insights in a few key ways:

- Because there are relatively few examples of implementation, the examples we did identify are relatively isolated—they lack natural comparators within the same geography or device category that would allow us to draw out lessons learned.
- Many example interventions only tackle one specific barrier, even though the barriers themselves are often closely interrelated (as the previous section highlighted). It is possible that a well-designed intervention is not seeing an impact because other complementary interventions are also needed.
- The decisions that went into designing an intervention were often not well-explained, particularly how the implementers chose between multiple design options. This limits the ability to inform similar future interventions in a different context.

In summary, while high-level device barriers and potential solutions are both documented to some degree, device- and/or country-specific insights are lacking to effectively match these problems and solutions together in practice.

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**Supply & distribution**

Key supply and distribution barriers for MNCH medical devices include:

**Lack of devices designed for low-resource settings.** Many devices available in low-resource settings fall into one of two categories: (1) expensive devices originally designed for high-income country healthcare markets in the U.S., Europe, or elsewhere, or (2) devices that aim for the lowest possible initial purchase price, at the expense of long-term quality and maintenance costs. What is lacking is robust innovation into devices that balance low long-term cost with appropriate design for the end-user, such as reliability, simplicity, and robustness to varied environmental conditions. When prototype devices are developed, they are often not manufactured at a commercial scale. While country procurement and
regulatory practices (discussed in subsequent sections) contribute to this problem, some key supply-related drivers include:

- **Smaller and more diffuse low-to-middle-income country (LMIC) markets.** Healthcare spending is growing rapidly in LMIC markets, but still represents less than 25% of spending in markets like the U.S. and Europe.\(^6\) LMIC demand is also spread over many countries, each with its own unique characteristics and needs. Thus, manufacturers often have less financial incentive to develop devices specifically for low- and middle-income country markets because of this diffuse demand.

- **Product development disconnected from end-user needs.** Manufacturers sometimes struggle to incorporate end-user preferences from key target markets into product designs, either because that information is difficult/expensive to collect or because user needs are decoupled from those of higher-level decision-makers.\(^7\)\(^-\)\(^9\) This often results in a product that does not adequately meet the needs of the end-user, rendering it under-utilized despite strong potential.

- **Perceived inferiority of “appropriate technology”.** In other cases, users/procurers do not want products that are specifically designed for low-resource settings, viewing such devices as inferior and even patronizing. They would rightly prefer to address the underlying infrastructure, funding, and training barriers associated with brand-name devices.\(^10\) Such health systems strengthening or re-design efforts are highly complex and require a significant investment of time, political will, and other resources.

**Unnecessary layers of distribution.** Many medical device supply chains are highly fragmented with numerous distributors and sub-distributors operating in a given country.\(^11\) In addition to creating additional layers of price markups, this fragmentation also makes it more challenging and costly for manufacturers and procurement agencies to identify high-quality distributors and devices. While several factors contribute to this fragmentation, including country procurement and regulatory practices (discussed in subsequent sections), one major supply-related driver is a lack of visibility into true market demand:

- **Unclear market demand.** Manufacturers often have poor information about existing device availability and resulting demand in low-resource settings. Tracking demand and market opportunity across individual countries is costly, and manufacturers take on significant financial risk if they misjudge demand and over- or under-produce. Distributors mitigate this risk through a clear understanding of local demand, established customer relationships, and (depending on the device) a willingness to hold inventory, but the tradeoff is an additional layer of price markups, manufacturer/distributor-related transaction costs, and a more opaque and fragmented market.

<table>
<thead>
<tr>
<th>Solutions / Interventions to Address Supply &amp; Distribution</th>
<th>Type of Intervention</th>
<th>MNCH device examples</th>
<th>Intervention outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct grants or catalytic investments in product development or production scale-up</td>
<td>Neonatal Resuscitators; bCPAP, infusion devices, app-based ultrasound, POC hemoglobin</td>
<td>Many successful prototypes developed; very few scaled up to global commercial production; lack of evidence on the factors preventing scale-up</td>
<td></td>
</tr>
<tr>
<td>Establishing global initiatives that help consolidate and elevate key product development needs</td>
<td>Helping Babies Breathe (HBB; neonatal resuscitators); Saving Lives at Birth (bCPAP)</td>
<td>HBB seemingly successful at guiding product to market; less clear for Saving Lives at Birth; lack of comparative analysis to understand differences between initiatives</td>
<td></td>
</tr>
<tr>
<td>Developing target product profiles (TPP) and standardized specifications to provide clear signals to manufacturers</td>
<td>bCPAP, POC hemoglobin devices; developed by PATH and NEST360</td>
<td>Lack of evidence on how TPPs impacted product development; unclear if the TPPs were visible to key manufacturers or reflected a broad enough global consensus to influence decision making</td>
<td></td>
</tr>
</tbody>
</table>
**Solutions / Interventions to Address Supply & Distribution**

<table>
<thead>
<tr>
<th>Type of Intervention</th>
<th>MNCH device examples</th>
<th>Intervention outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creating demand certainty and visibility, e.g., through volume guarantees or advance market commitments</td>
<td>No evidence of application to MNCH priority devices; has been tried in pharmaceutical and vaccine markets, e.g., Sayana Press (volume guarantee), pneumococcal vaccine (AMC); lack of analysis on operationalizing in medical device context</td>
<td></td>
</tr>
</tbody>
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**Example of a knowledge gap: Why strategic procurement practices are infrequently used**

Strategic contract structures (e.g., framework contracts, lease agreements, bundled parts, and services) are common in many industries and could potentially improve device cost, availability, and uptime. However, they are infrequently used in many low-resource health system settings, with ministries of health typically utilizing one-off purchases instead. While existing literature clearly described this as a major barrier, we found relatively little analysis of the underlying root causes driving this lack of strategic procurement practices. For example, we could envision a variety of structural reasons that might prevent a government from taking advantage:

- **Broader government procurement restrictions.** The public procurement processes may be very rigidly defined since procurement can be a tightly regulated government function for anticorruption reasons.

- **Lack of future funding certainty.** Governments may not always be willing to commit to long-term funding obligations beyond the current annual budget cycle, especially if it is not included in a strategic plan or costed implementation plan.

- **Lack of future demand visibility.** If procurers do not have access to updated device inventories or needs assessments, or if conditions are changing rapidly (e.g., COVID-19), they may perceive higher risk in committing to long-term purchase volumes.

- **Suppliers or contractors unwilling to make a long-term deal.** If companies have had negative experiences in the past (e.g., difficulty in collecting timely payment from government entities), they may not have enough trust built up to enter a longer-term contract.

- **Problematic cost structure.** Certain procurement practices (e.g., extended warranties or value-based procurement) could result in a higher upfront cost, which might be unattractive to governments as they cannot always bear the costs. Others (e.g., external parts or maintenance contracts) may appear more expensive if they result in many diffuse facility-level costs being consolidated into one large central budget line item.

Further research to understand these root causes will better clarify what interventions are needed and build clearer links back to the broader literature on procurement reform. This is also an area where we would expect different types of devices to offer unique insights, as differences in characteristics like cost, maintenance, and useful life lead to different potential contract structures.

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**Procurement & financing**

Key procurement and financing barriers for MNCH medical devices include:

**Overall lack of funding for medical device capital and operating costs.** In low-resource settings, fiscal space constraints are a clear challenge across all areas of the health system. But medical devices face a few unique challenges that further contribute to a lack of funding:
• **Diffuse accountability/ownership.** Medical devices that have a broad range of use cases (e.g., infusion devices or blood pressure cuffs) or that are limited to a handful of health facilities (e.g., x-ray machines) often fall outside typical donor and government health program verticals, diluting responsibility for those devices’ funding and ongoing management.

• **Historical focus on other interventions.** Medical devices have not historically seen the kind of large-scale global campaigns and donor-driven agendas that have been successful with other medicines and human resource intervention areas (e.g., HIV/AIDS, vaccines, or essential medicines), and as a result, medical devices have been generally underinvested relative to other health system areas.2

• **Lack of data on device needs and costs.** Unlike with pharmaceuticals and vaccines, many health systems do not have formal information systems in place to track device availability. Thus, health managers often struggle to quantify device needs during the budgeting process. Additionally, funding requests often include only the device purchase price, not related costs like training, commissioning, maintenance, and spare parts.

• **Public-sector financing/budgeting constraints.** According to the World Health Organization (WHO), health ministries often fund medical device purchases out of emergency or ad hoc funding pools due to a lack of dedicated budget line items.2 Domestic funding levels are also often volatile year-over-year, which prevents health ministries from being able to commit to long-term contracts or multi-year leasing agreements or to plan for long-term device maintenance and operating costs. This dynamic forces procurers to realize the full device cost upfront rather than amortizing it over several years. For costly devices like ultrasounds and x-rays, finding room in any single year’s budget can be a major challenge.

**Fragmented and diffuse purchasing.** Most individual LMICs represent a small market in terms of overall medical device purchase volumes, and for countries where procurement is decentralized to subnational levels (e.g., Kenya), these volumes are fragmented even further. This overall procurement structure—with numerous small national and subnational procurement agents making independent purchasing decisions—leads to higher average prices and contributes to a proliferation of device models, which complicates training and device management.

**Low use of strategic purchasing practices.** Public-sector device procurements in low-resource settings are often structured as one-off tenders that are sporadic in their timing and purchase quantity and awarded to the lowest-cost qualified bidder.7,12 Medical device literature highlighted this practice as a key driver of other supply, distribution, and procurement challenges for several reasons:

• **Lack of demand aggregation and visibility.** Other contracting structures, such as long-term agreements and framework contracts, provide manufacturers with greater visibility and certainty into long-term demand, reducing their risk and allowing them to charge a lower margin. However, such contracts are not used frequently in public-sector medical device procurements, likely due in part to the long-term budgeting constraints mentioned previously.

• **Awards based heavily on initial cost.** Procurement contracts are often awarded based on upfront cost/price rather than a more holistic set of factors, including quality and long-term cost of ownership (such as a value-based procurement approach).13 Some procurers are legally required to select the lowest-cost bidder. This dynamic has ripple effects up and down the supply chain by increasing long-term device maintenance and operating costs and encouraging manufacturers to design products that compete only on initial cost.

• **Narrow focus on upfront device capital expenditure.** Budgeting constraints and lack of long-term funding certainty often force governments to purchase devices outright (i.e., spending money as soon as it is allocated and available) rather than pursue alternative ownership models (e.g., lease
agreements) that would spread out a device’s capital cost over time. Other contracting structures like after-sales service agreements and parts bundles, which help reduce the complexity of device management, are also less common, likely due to the intense focus on minimizing upfront cost.

**Reliance on donated devices.** An estimated 70-80% of medical equipment in low-resource settings is either directly donated or funded by donations. These donated devices, while critical to meeting demand for health services, create an additional layer of challenges for health systems:

- National-level decision-makers often lack visibility into the incoming flow of donated devices and therefore are unable to regulate them or direct them to facilities with the greatest need.
- Many device donors do not include funding for long-term device operating expenses, and even when they do, those needs can be challenging to quantify—for example, defining the incremental increase in biomedical engineering labor needed to maintain a specific set of donated equipment.

Underlying these challenges is often a fundamental power imbalance between the device donor and the recipient. Health policymakers may find it politically difficult to turn down donated devices because of the short-term health benefit those devices provide. Because the devices are “free”, they lack the leverage to push for other critical inputs like training, parts, maintenance, or decision-making over device placement.

<table>
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<tr>
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<th>MNCH device examples</th>
<th>Intervention outcomes</th>
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<tbody>
<tr>
<td><strong>Type of Intervention</strong></td>
<td><strong>Advocating for greater funding for medical devices through better awareness or increased prioritization</strong></td>
<td>Proposed for numerous MNCH priority devices; very little evidence summarizing actual medical device advocacy campaigns—especially at the country level—and analyzing what worked and did not work</td>
</tr>
<tr>
<td></td>
<td><strong>Advocating for dedicated government budget line items for medical device-related needs</strong></td>
<td>Proposed by HBB for neonatal resuscitation; no information on specific initiatives or their outcomes</td>
</tr>
<tr>
<td></td>
<td><strong>Strategic contracting practices to increase overall purchase volumes e.g., pooled procurement, long-term agreements</strong></td>
<td>Proposed for government procurement agencies in general; lack of evidence of application to MNCH priority devices at a country level</td>
</tr>
<tr>
<td></td>
<td><strong>Bundling parts and/or services with procurement to simplify device management</strong></td>
<td>Managed Equipment Services initiative in Kenya (x-ray)</td>
</tr>
<tr>
<td></td>
<td><strong>Increasing competition for procurement tenders by improving bid advertisement and/or selection process</strong></td>
<td>Proposed for government procurement agencies in general; lack of evidence of application to MNCH priority devices at a country level</td>
</tr>
<tr>
<td></td>
<td><strong>Pre-qualifying manufacturers and/or distributors, to improve procurer ability to identify high-quality devices</strong></td>
<td>Procurement guides/lists for bCPAP, POC hemoglobin, ultrasound (by PATH/NEST360)</td>
</tr>
<tr>
<td></td>
<td><strong>Value-based procurement practices—awarding contracts based on a holistic of criteria than just initial device cost</strong></td>
<td>Various organizations including PATH have published practices for general medical devices</td>
</tr>
<tr>
<td></td>
<td><strong>Modifying procurement to limit the number of device models in circulation (i.e., minimize device/parts proliferation)</strong></td>
<td>Proposed for several MNCH priority devices; no evidence of application at country level</td>
</tr>
</tbody>
</table>
Example of a knowledge gap: Diagnosing funding gaps for medical devices and related activities

As we summarized earlier in the report, existing medical device literature describes several high-level drivers of funding shortages. In addition to these factors, we can also imagine additional tactical causes driven by local politics and organizational dynamics. Thus, for any given country, organization, or device, we could potentially trace a lack of funding back to several practical underlying reasons, including:

- **A lack of data to inform “fundable” budget requests.** Decision-makers may intuitively understand the need for device-related funding, but if they do not have the data to quantify the gap/need, they may not be able to justify a particular request.
- **A lack of connections to the right gatekeepers and decision-makers.** Even if a need is justified and data-driven, it may not be considered unless it makes it into the hands of the right people. This introduces an interpersonal and intra-organizational dynamic into the process, which may differentiate otherwise similar health programs, regions, etc.
- **Fragmented ownership or jurisdiction over device funding.** Furthermore, if multiple health programs benefit from a medical device’s services, their leaders may disagree on how to divide up the capital and operating costs, and none may be willing to fund the full cost alone.
- **Other investments prioritized over medical devices.** Even if the right decision-makers are aware of the need, they may still choose to prioritize other areas, sometimes for political reasons; perhaps a different project was pitched more clearly, offered higher visibility, or was more politically expedient.
- **Overall shortage of fiscal space.** Even if the need is clear and medical devices are properly prioritized, there may still be an overall lack of funding available across the health system or government.

Once this deeper level of detail is reached, precise solutions become easier to identify, e.g., specific data system improvements or targeted advocacy initiatives. However, literature that discusses challenges at that level of detail is presently lacking for many countries and devices.

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**Policy & regulatory**

Key policy and regulatory barriers for MNCH medical devices include:

**Regulatory approval not indicative of suitability for low-resource settings.** Device manufacturers seek certification from strict regulatory authorities (SRAs) like the U.S. Food and Drug Administration (FDA) as a gold standard benchmark of quality. However, SRA approval does not factor in several criteria that are important for low-resource healthcare settings, such as tolerance to heat, humidity, fluctuations in electrical power, and other environmental conditions. For example, a prior PATH analysis of nearly 90 FDA-approved oxygen concentrators found that less than half met an additional set of temperature and humidity operating requirements. As a result, (1) manufacturers have less clarity on what characteristics to pursue in product development, since there are no standard criteria for suitability in this context, and (2) procurers face an additional challenge identifying quality equipment since they must now dig beyond existing quality certification standards.

**Lack of harmonized registration and regulatory processes.** While progress has been made to harmonize regulatory requirements for pharmaceuticals, this has yet to be extended to medical devices. Device registration processes and regulatory guidelines vary from country to country, creating an additional challenge and cost for manufacturers trying to market their products broadly across LMICs.
While prior PATH research indicates that this barrier is not a critical roadblock, it does have two important market impacts: (1) it pushes the market towards greater use of local distributors, who are more familiar with local regulations, and (2) the extra costs are proportionally greater for smaller manufacturers and newer entrants, creating an additional barrier to entry.

### Solutions / Interventions to Address Policy & Regulatory

<table>
<thead>
<tr>
<th>Type of Intervention</th>
<th>MNCH device examples</th>
<th>Intervention outcomes</th>
</tr>
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<tbody>
<tr>
<td>Ensuring that devices are included on appropriate essential health products lists</td>
<td>Proposed in academic literature for POC hemoglobin and handheld ultrasound, but no evidence of application at a country level</td>
<td></td>
</tr>
<tr>
<td>Ensuring that device regulatory classifications are appropriate and logical</td>
<td>Proposed in academic literature for POC hemoglobin and handheld ultrasound, but no evidence of application at a country level</td>
<td></td>
</tr>
<tr>
<td>Harmonizing country registration and regulatory approvals processes</td>
<td>International organizations like Asia/Pan-African Harmonization Working Party</td>
<td>Some succeed at aligning regulatory policies, but manufacturers still must register in each country, which limits the scope of impact</td>
</tr>
<tr>
<td>Negotiating lower tariffs on medical devices to reduce the end cost to buyers</td>
<td>Proposed for medical devices in general; lack of evidence of application to MNCH priority devices at a country level</td>
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</tbody>
</table>

### Service delivery

Key service delivery barriers for MNCH medical devices include:

**Lack of supporting ecosystem of infrastructure and equipment.** To function correctly, many devices require steady electricity and a temperature-, humidity- and dust-controlled environment, which are often lacking in low-resource healthcare settings. This leads to devices functioning improperly and breaking down more frequently, which limits their health impact and adds to facilities’ maintenance burden. Similarly, many devices rely on a broader ecosystem of other equipment and health services to realize their impact. For example, having a functional CPAP device on hand is not particularly useful unless there is also a functional oxygen source available. This effectively compounds the number of failure points that can prevent a device from serving patient needs.

**Staffing shortages and turnover.** Numerous articles cited instances where overburdened healthcare workers are spread too thin, across too many patients, to effectively operate and maintain many medical devices. This challenge is particularly acute for devices that are used in lengthy and labor-intensive clinical procedures (e.g., bCPAP devices used for delivering ventilation in neonatal intensive care units). Public sector health systems frequently also face challenges with staff retention and other labor issues like frequent health care worker strikes, which increase the complexity of managing and training the health workforce to operate and maintain medical devices.

**Insufficient training and clinical guidance.** Even when clinical staff members are present, they often lack sufficient training to properly use the medical devices they have on hand. This barrier generally does not stem from a lack of training materials but from difficulties in delivering the training, as well as a lack of mechanisms for long-term follow-up, clinical mentorship, supportive supervision, and on-the-job performance management. For example, many devices (e.g., neonatal resuscitators, ultrasound devices, even simple blood pressure cuffs) require frequent practice, ongoing supervision, and long-term skill-building to master. This cannot be addressed through workshops and school courses; it requires effective
long-term training and an ongoing management system. Staffing shortages and turnover, and device model proliferation (discussed below), amplify this training challenge.

<table>
<thead>
<tr>
<th>Solutions / Interventions to Address Service Delivery</th>
<th>MNCH device examples</th>
<th>Intervention outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving training via formal degree programs, workshops, short courses, etc.</td>
<td>Numerous examples across all our focus devices</td>
<td>Many successful examples of designing and delivering training in a variety of formats/contexts; fewer examples of incorporating ongoing supervision/mentorship into health ministries’ management systems</td>
</tr>
<tr>
<td>Clinical decision support guides to standardize decision-making for facility staff</td>
<td>Proposed in academic literature for bCPAP</td>
<td>Seemingly helpful where they have been implemented; limited by overall capacity for distributing to and orienting staff</td>
</tr>
<tr>
<td>Remote diagnostic support to reduce training and human resource barriers</td>
<td>A significant area of focus/innovation for imaging devices like x-ray and ultrasound</td>
<td>Very successful operational and business models for tele-ultrasound and teleradiology; does not solve root cause if staff shortages are driven by lack of funding; also, does not work without device and internet availability</td>
</tr>
<tr>
<td>Diagnostic support technology, e.g., computer-aided diagnosis or artificial intelligence to standardize decision-making and increase diagnostic accuracy</td>
<td>A significant area of focus/innovation for imaging devices like x-ray and ultrasound</td>
<td>Generally successful at their intended function, but because support exists only for specific diagnoses, it does not reduce the need for trained/qualified staff</td>
</tr>
</tbody>
</table>

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**Maintenance & repair**

Studies have estimated that anywhere between 30% and 70% of all medical devices in low-resource settings are currently non-functional.\textsuperscript{14,15} These studies highlight several barriers to effectively maintaining and repairing MNCH medical devices:

**Difficulty obtaining consumables, tools, and spare parts.** Replacement parts are frequently not standardized; a typical hospital could have hundreds of unique part types across all its medical devices. This creates a challenging supply chain management problem, since many of those parts are too expensive or low volume to stock preemptively on-site, but if they are only ordered when a breakdown occurs, the result is expensive emergency procurements and long delivery lead times. This problem is further compounded by a few underlying issues (in addition to the public-sector budgeting challenges mentioned previously):

- **Proliferation of device models.** Because of a lack of standardization across most device types, each time a new make or model is introduced (donated or procured), it comes with a unique ecosystem of parts, consumables, and operating procedures that must be incorporated into existing training, maintenance, and inventory management systems. Device donations and fragmented procurement are two key drivers of model proliferation.

- **Lack of inventory management system for device parts/consumables.** While most countries/facilities have systems in place to manage medicines and vaccines supply (e.g., logistics management information systems), these systems often do not include consumables and parts for medical devices, leaving facilities to manage these products on their own. This causes two downstream effects: (1) increased stockouts of these parts and consumables, and (2) a lack of data on parts consumption and true maintenance costs to inform central level budgeting and supply planning.
Shortage of trained biomedical technicians and engineers. Numerous studies across public-sector health systems in sub-Saharan Africa, Latin America, and Asia point to a shortage of biomedical engineers and technicians who are trained to repair and maintain medical equipment. In many health systems, entire districts or regions are served by a small central engineering team, leaving much of the day-to-day inspection and maintenance to facility handymen or clinical staff.

- **Broader public sector human resource shortages.** The lack of engineers/technicians is partly an extension of broader human resources challenges in public sector health systems (e.g., shortages of doctors and nurses), as well as competition from medical device distributors and after-sales service providers. Biomedical engineering is also a relatively recent professional classification and has historically been overshadowed by more classical medical professions like medicine and nursing.

- **Manufacturer exclusivity agreements influence the pool of trained engineers.** To preserve brand recognition and maintain a strong relationship with their distribution partners, many device manufacturers provide exclusive training and authorization to technicians from that distributor. As a result, public-sector biomedical technicians/engineers are not always trained and authorized to service all the equipment in their health facilities. While this dynamic has some benefits in allowing technicians to specialize on a smaller set of devices, it also can worsen existing staff shortages by limiting the pool of available engineers.

### Solutions / Interventions to Address Maintenance & Repair

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Example of a knowledge gap: Selecting strategies for maintenance and repair of devices

In previous examples, we highlighted gaps in our understanding of key barriers and their root causes. It is also possible to conduct a similar breakdown for potential solution areas. Numerous sources pointed to the importance of effective maintenance and repair in ensuring device uptime, and collectively, those sources described a variety of solutions. However, the solutions are often complex and overlapping, and we found a lack of holistic guidance on how to navigate the different options or when to deploy one solution over another. For example:

- *Additional training for staff/engineers.* A straightforward solution but assumes that training is the key barrier. At what point does it make sense to switch to a different solution, e.g., streamlining device models or implementing an assistive technology? Or shifting the type of training, e.g., remote/virtual training as opposed to in person?

- *Implementing an asset management software system.* The viability of this approach depends on existing IT infrastructure and underlying maintenance processes, and stakeholders must navigate decisions like: What levels of facilities should be included? Which devices should be included? Which features/functions are most critical?

- *Outsource maintenance to a third-party vendor.* The viability of this approach depends greatly on the strength and cost of the vendor market, as well as the government’s ability to manage the performance of external contractors. When should decision-makers consider this option instead of something like asset management software?

- *Change procurement practices.* Is it more cost-effective to buy cheaper devices that are replaced instead of repaired or buy more expensive devices that last longer and break down less frequently? Is it economical to purchase an extended warranty or handle repairs with in-house resources?

Most of these decisions are complex and multifaceted, and the ideal solution may vary greatly across devices and countries. What is missing in current evidence are frameworks, analyses, or example approaches for confronting and navigating that complexity.
Blood pressure cuff (manual)

Blood pressure measuring devices encompass a range of manual and digital varieties, intended for both home use and clinical settings. This evidence review focused specifically on manual blood pressure cuffs (also known as a sphygmomanometer) because they represent one of the simplest, least expensive, and most ubiquitous medical devices within the MNCH priority device portfolio.

The main sources of information reviewed on blood pressure cuffs were (1) WHO resources that focus on supply, procurement, and regulatory considerations and (2) published academic literature focused on the service delivery level, covering issues like device availability, quality, funding, and training. In addition to MNCH-specific use cases like detecting pre-eclampsia, this academic literature also focuses on non-communicable diseases and therefore emphasizes conditions like diabetes and cardiovascular disease. At least one study evaluated the cost-effectiveness of different blood pressure measuring devices in low-resource settings, and another explicitly assessed device suitability and working conditions.

KEY ISSUES

Procurement & Financing

- **Lack of funding at lower-level facilities.** While the devices themselves are typically cheap (US$7 on UNICEF Supply Catalogue), the lack of funding available at lower levels of the health facility is also correspondingly lower; hence cost can still be a barrier. Funding is also likely an underlying challenge for the calibration, parts, and training barriers described previously.

Service Delivery

- **Parts/accessories availability.** Manual blood pressure cuffs typically also require a stethoscope to listen for changes in blood flow when taking a measurement, although stethoscopes, like blood pressure cuffs, appear to be almost ubiquitous in health facilities, even in low-resource settings. More problematic is a lack of sufficient variety in cuff size. One study in South Africa found that many facilities had cuffs that were an inappropriate size for the patient’s arm (typically a facility would have multiple cuffs of varying sizes), which can lead to inaccurate measurement.

- **Community health worker use.** Manual blood pressure cuffs are cheap and small enough that they can be used at nearly every level of health facility, even by community health workers. However, they still require a great deal of training and practice to place, inflate, listen, and read the device correctly to obtain an accurate measurement. While formally trained healthcare workers typically receive this training in school, it is a barrier for community health workers and may limit their ability to screen effectively for pre-eclampsia and hypertension.

Maintenance & Repair

- **Device calibration.** Manual blood pressure cuffs must be re-calibrated by an accredited laboratory at regular intervals (e.g., annually), especially now that mercury-based devices have largely been phased out. Without this calibration, they can develop systematic measurement bias that results in over- or under-diagnosis of hypertension. This seems to be a challenge for healthcare providers globally, and low-resource settings are no exception. One study across eight LMICs found that most facilities using manual blood pressure cuffs do not calibrate them regularly. While this broadly classifies as a “maintenance” challenge, it presents a rare combination of (1) devices that are cheap and widespread across the health system, and (2) maintenance that must be performed off-site at a specialized facility.
KEY KNOWLEDGE GAPS

Supply & Distribution
- Manufacturer lists. We were unable to find a landscape of blood pressure cuff models or manufacturers that are available in low-resource settings, making it difficult to assess whether device quality is a significant barrier worth investigating further.
- Quality assurance. Global-level guidance is generally lacking on quality-assured suppliers for manual blood pressure monitoring devices. Existing device validation mechanisms, such as the British and Irish Hypertension society, focus primarily on digital models marketed towards high-income healthcare markets.

Procurement & Financing
- Procurement channels. We also did not find any sort of mapping of the most common buyers of manual blood pressure cuffs in health systems across sub-Saharan Africa or Asia. Is procurement typically centralized through public central medical stores? Do health facilities frequently purchase themselves from local suppliers?
- Device quality and quality control. Because of all the knowledge gaps mentioned previously, we know very little about the actual quality of devices that are being purchased and supplied to health facilities in low-resource settings or what mechanisms are in place to ensure that low-quality devices are not produced or imported. We would suspect this to be a particular challenge if procurement is highly decentralized and locally driven.
Bubble CPAP device (electric)

Bubble continuous positive airway pressure (bCPAP) devices, when paired with an oxygen source, are a gentle way to deliver noninvasive ventilation to newborns with infant respiratory distress syndrome. Although some physical nonelectric devices have been developed, most commercially available models are electric and are thus the primary focus of this evidence review.

The main sources of information reviewed on bCPAP devices were supplier mappings and trend research in product development and supplier mapping from organizations such as NEST360\textsuperscript{22,23} and PATH\textsuperscript{24-26} as well as published academic literature. Some relevant studies included those using clinician surveys and literature reviews to highlight key barriers to access along the value chain\textsuperscript{27,28} those that sought to establish the cost-effectiveness of bCPAP against other oxygen delivery methods such as nasal oxygen and mechanical ventilators\textsuperscript{29,30} and those that discussed barriers to effective use at the service delivery level\textsuperscript{29-36}.

KEY ISSUES

Supply & Distribution
- High device cost / inadequate funding. Although bCPAP devices are generally cheaper than mechanical ventilator-based CPAP, the bCPAP models in PATH’s 2014 Device Selection Guide still ranged from US$800-$6,000, which is a huge expense for many health facilities. While the cost issue is not unique to bCPAP devices, it is one of the most cited barriers in the literature.
- Prevalence of improvised devices. bCPAP devices are one of the few medical devices that can plausibly be improvised from local materials. Given the high cost of commercial models, providers have a strong incentive to circumvent funding challenges and build a low-cost improvised device, despite those devices often being medically inferior (among other limitations, they typically do not heat or humidify the air being delivered). This creates a unique quality control challenge since the improvised devices are locally made and never pass through any centralized procurement or import process.

Procurement & Financing
- Donated devices. At least one study found that the vast majority of commercial bCPAP devices in use in Kenyan hospitals were donated\textsuperscript{37}. This high prevalence of donated devices led to concerns about long-term sustainability, training, and maintenance barriers, in line with the general medical device literature described previously.

Service Delivery
- Training and staffing. Procedures requiring bCPAPs generally require frequent attention/supervision from clinical staff, so understaffing of neonatal units is a particular problem for these devices (e.g., one study of a hospital in Malawi\textsuperscript{36} saw an average of 30 neonatal patients supported by at most two nurses, which greatly limits the capacity for care). Overall lack of training was also cited as a key barrier, exacerbated by high staffing turnover and device proliferation\textsuperscript{27}. One study also noted that bCPAP training needs were different between secondary and tertiary levels, with nursing staff at secondary levels being much more reliant on training aides and decision guides than at tertiary levels, where pediatric specialist staff were more common\textsuperscript{38}.
- Limited supporting infrastructure. bCPAP devices require an array of supporting infrastructure and equipment, including a steady electricity supply, a source of oxygen, and various consumables like nasal prongs. Numerous studies cited these supporting elements as barriers.\textsuperscript{27} Electricity is often unreliable or nonexistent in health facilities, especially in lower-level hospitals. While maintenance is not a huge problem with bCPAP devices themselves, it is a much bigger issue with supporting devices like oxygen concentrators.
KEY KNOWLEDGE GAPS

Supply & Distribution
- **Commercialization.** At least a few low-cost and/or non-electric bCPAP prototypes have been developed and tested, but none of them appears to be commercially available and the reasons why are not clear—none of the articles discuss any specific roadblocks or challenges to commercialization. Are there no manufacturers willing to take on production? Is country registration and/or regulatory approval a barrier? Are there certain capabilities the prototypes are missing (e.g., heated and humidified air) that clinicians are unwilling to compromise on? Further investigation is needed to help clarify these reasons.
- **Manufacturer lists.** Apart from PATH’s list of recommended manufacturers, we were unable to find a landscape of bCPAP models or manufacturers that are available in low-resource settings to understand whether access to high-quality devices is a barrier.

Procurement & Financing
- **Donated devices vs. donated funding.** We found little information in general about the procurement and distribution channels most common for bCPAP devices in low-resource settings. As an example, sources mentioned that a large portion of bCPAP devices in use was donated, but it is unclear whether those findings refer to actual device donations or donor funding support of normal procurement processes. Clarifying this distinction will be important for designing procurement-related interventions.

Service Delivery
- **Device availability.** While numerous sources discussed barriers at the service delivery level, we did not find any systematic reviews of actual device availability. Are devices available in sufficient quantity in all the facilities that are supposed to have them? It should be determined whether this is just a gap in the literature or an actual barrier to access.
Infusion device

Infusion devices are used to administer fluids into a patient's body in a controlled manner. Several types of infusion devices exist, differing in the volume of fluid delivered, intended clinical setting, and mechanism of fluid delivery. While some mechanical devices do exist, most traditional infusion pumps are electronic devices that are programmed by the user to deliver fluids at precise volumes, pressures, and/or time intervals, and are the focus of this evidence review.

The main sources of information reviewed on infusion devices were a WHO series of papers under the Priority Medical Devices project that use infusion pumps as a specific example to highlight broader challenges; PATH documentation on barriers with traditional infusion devices and development of an electricity-free, low-cost prototype infusion delivery system to help combat those barriers; Rice360 documentation of a similarly developed and tested low-cost infusion delivery system that can operate with only intermittent electricity; and academic literature on infusion devices which fall into one of two categories (1) facility readiness assessments that check for availability of devices and personnel and (2) feasibility studies for low-cost infusion device prototypes.

KEY ISSUES

Supply & Distribution

- **High cost / inadequate funding.** Most electronic infusion devices cost at least US$1,000 and can range to more than US$3,000. This price creates a major barrier for many governments and health facilities and makes them reliant on external donor funding to ensure that facilities are adequately equipped. While the high cost is not a unique issue to infusion devices, it is one of the most cited barriers and a key driver of product innovation.

Service Delivery

- **Lack of supporting infrastructure.** Traditional infusion pumps require a reliable supply of electricity and are particularly susceptible to electrical fluctuations and failures, due to the precise volumes they need to deliver and their reliance on software and pre-programmed settings to control fluid delivery. Additionally, infusion pumps are often used in combination with other devices, such as ventilators, patient monitors, and operating theater equipment. This can create an additional barrier if those devices must also be available and functional.
- **Low device availability.** While data on the availability of infusion pumps is limited to a couple of studies, those data points indicate that availability is a major challenge. In a sample of hospitals in Rwanda, only 15% of district hospitals and 65% of referral hospitals had sufficient infusion devices available. In Uganda, only 3 of 10 sampled hospitals had access to an infusion device.
- **Cost and availability of consumables.** Infusion devices require a variety of consumables like pump lines, connectors, intravenous sets, and syringes. These consumables can sometimes be manufacturer- or device-specific, which can make sourcing them difficult, especially if it was considered during the procurement process. These consumables also represent a significant operating expense for health facilities, creating problems if those costs are not tracked and budgeted.
- **Complex user interfaces.** Traditional infusion pumps often have a complicated interface that is designed for maximum versatility but increases the knowledge burden on staff. They are a well-known cause of user error and adverse events even in U.S. healthcare settings; in fact, in the U.S., FDA at one point launched an improvement initiative specifically aimed at infusion pumps. In low-resource settings where hospitals are often understaffed and clinicians undertrained, this risk of error is even more severe.
KEY KNOWLEDGE GAPS

Supply & Distribution
- **Commercialization.** PATH, Rice360, and various other organizations have developed low-cost and/or electricity-free infusion pump prototypes, but they do not appear to be commercialized or sold at scale despite literature establishing their viability. Why is this? Is the market too small for manufacturers and distributors to take an interest in? Are there clinical tradeoffs with the low-cost devices that providers are unwilling to make? Is the real bottleneck a shortage of trained staff? Investigating the reasons behind this lack of scale-up could yield important insights into the underlying root cause barriers.
- **Manufacturer and distributor lists.** As with other devices, it is not clear which manufacturers are marketing products in any of the focus countries, and whether products sold by the main medical equipment distributors are of sufficient quality.

Procurement & Financing
- **Procurement channels.** Because of the lack of literature focused on infusion device procurement, it is unclear how the devices make their way down to the service delivery point. Are most infusion devices donated by outside organizations or procured through typical government channels?
- **Procurement process.** If devices are procured through the government, is the funding coming from general revenues or earmarked donor support? How are they making product selections and structuring purchases? These are all important questions for understanding why device access is a barrier.

Policy & Regulatory
- Are there specific clinical guidelines or regulatory barriers to commercializing some of the low-cost prototypes that are available?

Maintenance & Repair
- We found very little information about the maintenance of infusion pumps in low-resource settings. Does this reflect a gap in the literature or is it an indication that maintenance is not a significant barrier?
Neonatal resuscitation equipment is required to provide ventilation for newborns who have difficulty establishing breathing at the time of birth. Manual bag-valve masks are the most common device used for this purpose (tube and mask devices are no longer recommended as the standard of care), and they can be found in both reusable and disposable varieties. Both types of bag-valve masks are covered in this evidence review.

The main sources of information reviewed on neonatal resuscitators were Helping Babies Breathe (HBB) resources (including a supplier landscape, market analysis, procurement guidelines for governments, a toolkit for navigating procurement regulations, and training materials for clinicians; PATH resources (including an assessment of procurement and logistics issues related to HBB rollout and a survey of clinician preferences); WHO/UNICEF technical specifications for neonatal resuscitation and global market and supply updates; WHO Service Availability and Readiness Assessment (SARA) surveys; the MNCH Asset Tracker; and published academic literature, including on (1) establishing the feasibility, efficacy, and cost-effectiveness of neonatal resuscitation in low-resource settings, (2) analyzing the impact and effectiveness of broad global-level interventions like HBB, (3) facility-level assessments that track the availability of neonatal resuscitation services, and (4) surveys of key barriers to providing basic newborn care and resuscitation.

**KEY ISSUES**

**Procurement & Financing**
- **Low funding for neonatal services and resuscitation equipment.** Numerous sources identified funding as a key barrier, stemming from a variety of related factors: a lack of prioritization relative to other health needs; a lack of permanent government budget line items for equipment and/or neonatal health services; a reliance on funding from donors and nonprofits; and insufficient financial guidelines at subnational levels. Unique to neonatal resuscitation is the fact that funding needed for training is much higher than for the devices themselves.

**Service Delivery**
- **Training and staffing.** Because neonatal resuscitation is a time-sensitive, life-saving procedure, there is very little margin for error in technique. And while the bag-valve masks themselves are relatively simple devices, the resuscitation procedure itself requires a great deal of clinical skills training. Two key barriers to neonatal resuscitation training in low-resource settings are falloff of skills after initial training and difficulty putting classroom learnings into clinical practice. This translates to a need for ongoing mentoring, follow-up training, and quality routine supervision, all of which are lacking in many health systems. High staff turnover further increases the erosion of training effectiveness. As a result, rates of fully trained healthcare workers remain relatively low, ranging from around 44% to 75% even in countries with training programs in place. The HBB alliance—and numerous other interventions—have helped direct attention and resources towards training and have innovated new training materials and approaches, but training remains a sizable training barrier.
- **Availability of devices.** While referral hospitals and larger facilities generally seem to have a consistent supply of resuscitation equipment, this does not extend to other levels of the health system in many countries. In one survey, lack of supplies/equipment and general procurement/supply chain challenges were identified in 9 of 12 countries. HBB found in its end line study that resuscitators were available in 53% to 88% of health facilities across several countries. Here again, HBB helped, but there are still gaps.
**Maintenance & Repair**

- *Reprocessing and sterilization.* Reusable bag-valve masks have particularly strict disinfection requirements between uses due to their frequent contamination with maternal and neonatal bodily fluids. This creates another significant barrier at the service delivery level. High-level disinfection and/or sterilization requires a dedicated process (e.g., boiling, steaming, immersing in chlorine solution), often with its own dedicated workflow, equipment, and space within a clinic.  
  Multiple studies have found poor compliance with these required processes, with facility staff often only rinsing with soap and water between use. This process also leads to devices being out of service for some time, which can complicate demand planning and quantification.

**KEY KNOWLEDGE GAPS**

The overall body of knowledge for neonatal resuscitators is relatively strong, owing to large historical investments in initiatives like HBB and the ongoing MNCH Asset Tracker work. These initiatives have focused particular attention on understanding challenges with global and national policies, training, service delivery, and maintenance of reusable devices. A couple of areas where further evidence would be useful include:

**Financing & Procurement**

- *Procurement channels.* Based on available literature, it is not clear who the main buyers, manufacturers, and distributors are in each country, how purchase contracts are typically structured, and how product selections are made (e.g., cost, quality).
- *Financing/budgeting guidelines.* Unclear funding guidelines were mentioned as a barrier as well as an overall lack of prioritization and funding. However, it is not clear from the literature exactly how those funding decisions are made, where the process is breaking down, and whether it is unique to neonatal resuscitation equipment (e.g., because of the high cost of training relative to the device itself).
Point-of-care hemoglobin analyzer

Anemia is one of the world’s leading causes of disability and analyzing the blood concentration of hemoglobin is a critical diagnostic criterion. Point-of-care (POC) hemoglobin testing technologies are a high priority due to the lack of access to laboratory diagnostics in many low-resource settings. Most POC hemoglobin analyzers are minimally invasive (i.e., require a sample of capillary blood drawn from a fingerprick), though some noninvasive models are under development. Both types are included in this evidence review.

The main sources of information for point-of-care hemoglobin analyzers were NEST360 target product profiles with the identification of several available models for low-resource settings, PATH target product profiles and landscape of existing devices, both invasive and noninvasive, and published academic literature heavily focused on establishing the accuracy of various devices and methods currently under development, usually comparing them against a laboratory hematology analyzer or a HemoCue POC device. Other published literature discusses key service delivery issues, such as training, sample collection techniques, pricing of services, and availability of testing supplies.

KEY ISSUES

Supply

- Maintaining accuracy/reliability in new product development. The core development challenge facing POC hemoglobin analyzers is that reducing the cost, size, and invasiveness of the devices tends to also reduce the reliability of their results, often to an unacceptable level. Numerous invasive POC hemoglobin analyzers exist in various stages of commercial development, and while they may be relatively accurate in lab settings, results are much more variable when the devices are used in the field. Tests are highly sensitive to variations in collection technique, environmental conditions, etc., so changing variables like the operator, location, or device model can lead to differences in accuracy. A variety of noninvasive devices have also been developed (using light passing through the bloodstream to estimate hemoglobin concentration instead of an actual blood sample). A few, such as the Masimo Pronto, are commercially available, but many are still in the validation phase and generally lack sufficient evidence of accuracy and reliability over a wide range of conditions. As a result, only one set of devices—made by HemoCue AB—is currently recommended by WHO.

Service Delivery

- Training and staffing. For HemoCue systems—as with many POC diagnostics—training is a particular challenge given the tests’ sensitivity to collection technique described previously; healthcare workers must be trained to achieve a high degree of standardization to ensure accuracy and/or sample collection efficiency. Understaffing is also a barrier and can lead to staff forgetting to request/conduct a hemoglobin test or frustration at the time it takes for POC results to come back.

- Cost and availability and POC devices and tests. Lack of availability of HemoCue devices was a near-universally recognized barrier, both for POC devices and the accompanying cuvettes. Of these, the same sources pointed to the cost of the device (US$400+) and cuvettes (US$0.75 - $0.99 per test) as the underlying reason, although there could be some related underlying dynamics:
  - Funding for POC hemoglobin testing could fall under laboratory services in some ministries of health, which has historically been underfunded relative to other programs.
  - Healthcare workers may not perceive a strong need for tests due to other qualitative methods for diagnosing anemia and low-cost treatments available in the form of iron supplements (despite these methods not always being effective).
The recurring cost per test is unique and may be problematic for facilities to maintain in their budgets without a dedicated funding line item.

Compared to other devices on our priority list, the HemoCue is not exorbitantly expensive, but it also has the potential to be used at lower levels of the health system (e.g., district hospitals and health centers), where that expense may be more significant.

### KEY KNOWLEDGE GAPS

The previous sources provide extensive information on the supply and service delivery sides of our framework, discussing current product development and validation challenges in detail, as well as key difficulties in using POC devices in a field setting. Where the current literature lacks detail is in the space between those two points on the framework, namely barriers in distribution, procurement, funding, and global/country policy:

**Supply & Distribution**
- Who are the main distributors of devices and especially test strips/cuvettes in our focus countries? Are these distributors accessible to lower-level health centers or are they limited to traditional laboratory equipment/commodity supply channels?

**Procurement & Financing**
- What are the main funding sources for HemoCue and other POC diagnostics? Within the ministry, are devices funded/managed by laboratory departments or do other departments like MNCH also contribute? If they do, how do they coordinate activities like purchasing and quantification?

**Policy & Regulatory**
- Given the large number of devices being developed (or that show significant promise) compared with the small number recommended by WHO, we expected to find more clinical policy discussion around the right threshold for accuracy and precision of a POC tool. Are there settings, e.g., clinic or community screenings, where a less accurate device could still offer significant health benefits?

**Service Delivery**
- While numerous studies cited device availability as a challenge, almost all were qualitative judgments rather than an actual quantified gap, e.g., facilities that have hemoglobin testing capability as a percentage of those that should have the capability. The same is true for training gaps. This challenge is mentioned very frequently in the literature, but not systematically quantified and broken down into root cause issues (e.g., most often as a side note in the Discussion section of an article about device accuracy).

**Maintenance & Repair**
- Manufacturers like HemoCue indicate their devices are intended for long-term use without breaking down or requiring preventive maintenance, but is this the case in reality? We did not find studies on device failure rates in low-resource settings. Does this reflect a lack of a serious barrier or a gap in available literature?
Ultrasound device (app-based and portable)

Ultrasound devices come in a wide range of sizes and configurations, but can be broadly separated into three categories: (1) large “bedside” ultrasounds that are intended to be used in a stationary hospital context, (2) “portable” ultrasounds that are small, self-contained laptop units or carts (e.g., <15 lbs.) that can be easily transported from one room or clinic to another, and (3) “hand-held” or “app-based” units, which typically consist only of a small probe/transducer and connect to a user’s smartphone or tablet for a screen and user interface. This evidence review focuses on the latter two variants, and particularly the interactions between them in a given setting since they are both competing in the “point-of-care ultrasound” market.

The main sources of information for app-based and portable ultrasound devices were WHO technical specifications for portable laptop/cart-based ultrasound in the context of COVID-19 response, PATH device selection guide for portable and older handheld ultrasound devices well-suited to low-resource settings, Gates Foundation ongoing investments in a newer type of smartphone app-driven handheld model, and published academic literature focusing on ideal specifications for portable ultrasound in low-resource settings; availability of devices in health facilities; innovations in clinical application; development of technologies to support diagnosis and training, as well as barriers in service delivery, training, and maintenance.

KEY ISSUES

Supply

- Device cost and overall funding. Surveys of physicians across many countries in Asia, Latin America, and Africa show that the cost of ultrasound devices is one of the main barriers to their wider availability in health facilities. For example, only 40-60% of Kenya family medicine physicians said they had access to a point-of-care ultrasound device, even at tertiary care facilities. Prohibitive device cost is inextricably linked with inadequate funding for ultrasound procurement and use. One set of survey respondents felt that political will (and therefore funding) for broader ultrasound use was low due to competing financial and professional interests from other specialty areas within the radiology community.

Service Delivery

- Training and staffing. Along with cost, a lack of healthcare worker capacity to use ultrasound was one of the most common barriers identified. This problem breaks down into two related issues: (1) a lack of specialized training on ultrasound use as part of formal medical education, often because devices are not available in medical schools or because curricula have not been updated to reflect broader clinical applications, and (2) an increasing desire to task shift ultrasound use from traditional practitioners (e.g., sonographers, radiologists) to nurses and health technicians. Both issues are even more acute with app-based handheld devices, given that their lower cost and increased portability make them ideally suited for use in lower-level health facilities. Existing literature describes a variety of approaches to address these two related issues:
  - Specialized training courses (short-term). Numerous studies describe training programs for health workers of all education levels. General success criteria include planning for practical hands-on sessions; planning around workers’ existing schedules; including device and image management as topics in addition to ultrasound use; incorporating follow-up supervision into planning, and sensitizing workers to legal and ethical implications of ultrasound use (e.g., with sex determination).
  - Training institutions and associations (long-term). A more sustainable approach than specialized short-term courses is the establishment of radiology associations and formal educational institutes dedicated to training local sonographers. Over the last decade, several such institutes have begun to emerge across Africa.
• Tele-ultrasound and mobile ultrasound teams. Both approaches serve to make a scarce resource (trained sonographers/radiologists) more accessible to a broader group of patients, and both have been in use for decades.\textsuperscript{84,89} Traditional barriers to these solutions include a lack of cellular network, electrical infrastructure, and poor battery life on older portable ultrasound devices. These barriers are all receding, however, as infrastructure and battery technology improve. The latest generation of app-based handheld devices represents another significant enabler of both approaches.

• Assistive technology. Artificial intelligence-supported ultrasound is becoming common in the latest portable and handheld ultrasound devices (including those in which the Gates Foundation has invested\textsuperscript{90}) and increasingly ready for clinical application.\textsuperscript{91} These technologies have the potential to supplement ultrasound training approaches by assisting the provider in diagnosing specific conditions they are programmed to detect.

• Patient data privacy. As the use of smartphone/tablet/laptop-based ultrasound devices and assistive technologies become more common, so too do issues of patient privacy and data security. Many countries have defined eHealth and mobile health strategies and generally have patient data privacy regulations in place, but reviews of these policies and regulations show that they are frequently not comprehensive, up-to-date, and/or specific enough to prevent privacy and data security issues.\textsuperscript{92}

Maintenance

• Lack of parts and maintenance capability. Device malfunction and lack of maintenance capabilities appear to be a significant barrier, according to both clinician surveys and articles that reported having to replace malfunctioning devices within the study period.\textsuperscript{77,83} However, there is some evidence that maintenance may be more of an issue with older, larger portable ultrasound units, and decreasingly a problem for newer generations that have fewer parts and lower power requirements.\textsuperscript{93} Availability of a key consumable—ultrasound gel—is another related challenge due to its relatively high cost. At least one study mentioned that availability of specialized probes/transducers was limited in many countries, due to their cost and related lack of demand.\textsuperscript{83,94}

KEY KNOWLEDGE GAPS

Overall, the body of available literature for point-of-care ultrasound is fairly robust, touching on most of the main categories in our framework. However, a few key knowledge gaps remain, especially country-level details needed to pinpoint specific root cause issues, including:

Procurement & Financing

• Who are the main suppliers and buyers in each focus country, and how are the buyers funded (e.g., through donations or internal sources)? How are procurement contracts structured, and how frequently are servicing and training included? Are ultrasound devices funded and managed by radiology departments, MNCH departments, or both/neither? If both, how do they coordinate procurement, training, and management of devices?

Policy & Regulatory

• Do country eHealth and mobile health policies adequately reflect the challenges specific to portable and handheld, smartphone-based ultrasound devices? Do device registration and essential equipment lists accurately reflect these devices and their capabilities?

Service Delivery

• How extensive is the proliferation of different ultrasound models, and what impact does that have on staff training? What is the gap in the availability of portable ultrasound devices (e.g., percent of facilities that do not have them, rather than percent of clinicians who say it is a barrier)?
Medical x-ray machines fall into a few different categories based on their underlying technology: (1) conventional film x-rays, (2) computed radiography systems that replace traditional film with a reusable, digitally scannable phosphor plate, and (3) fully digital systems where an electronic image is captured directly by a flat panel detector. This evidence review covers all three types of x-ray devices.

The main sources of information for medical x-ray machines were WHO guides to radiographic technique, RAD-AID conference proceedings and a series of detailed country reports focused on radiology workforce and training, infrastructure, and policy in about two dozen low- and middle-income countries, standardized educational and professional development resources from various international associations, and published academic literature focusing on the availability of devices and radiologists in specific countries, procurement and contracting practices, training, and other service delivery barriers, and technology innovation.

KEY ISSUES

Supply
- **High device cost.** The cost of a quality digital x-ray machine often exceeds US$100,000, so it is no surprise that funding to purchase such devices is often a barrier. The result is that device availability is much more consolidated and centralized in referral-level hospitals than is ideal for basic radiography devices that have broad primary care applications. As a result, two of the main areas of innovation for x-ray devices are (1) lowering the capital cost of equipment, particularly digital x-ray detectors, and (2) transporting radiography equipment safely and effectively as part of a mobile clinic.
- **Technology migration.** There is a broad shift globally from conventional film x-rays to computerized and digital technologies, but these technologies differ significantly in cost structure and supporting infrastructure requirements, and successfully migrating will require shifts in the way that organizations procure and budget for x-ray equipment. Conventional film x-rays require specialized infrastructure (dark rooms) and expensive, specialized consumables (film, processing chemicals) to develop images. Fully digital x-ray technologies have very low operating costs, are more reliable, and enable remote/computer-aided diagnosis, but they come with much higher initial capital costs. Thus, there is a risk that procurement departments focused heavily on initial costs will not fully account for the long-term cost savings that digital x-rays offer.

Service Delivery
- **Clinical and technical skills gap.** Numerous articles, reports, and surveys point to a lack of radiologists and radiographers as a critical barrier—and one that would limit access even if the above equipment gap were to be addressed. Unlike many of the other devices, interpreting x-ray images requires a high degree of clinical skill and is difficult to task shift. Therefore, efforts to address this barrier have typically fallen into a few categories:
  - **Teleradiology and volunteer radiology.** Digital x-ray images can be stored and shared anywhere in the world, making it possible to interpret images and make diagnoses remotely. This is a well-established business model in middle- and high-income countries (e.g., to serve remote/rural areas), and there is precedent for such businesses in low-resource settings as well. A similar model exists for volunteer radiologists to donate their time to interpreting images from low-resource healthcare settings, such as one implemented by Partners in Health in Haiti.
  - **Computer-aided diagnostics.** While algorithms and artificial intelligence cannot replace the need for advanced training, they can help improve diagnostic accuracy and standardize the overall diagnosis approach. This is another key area of current technological innovation.
Training institutions, associations, and partnerships. As with ultrasound devices, the long-term solution for radiology/radiography skills shortages is to invest in formal education and training institutions to increase the pipeline of available workers. There is some evidence that historical shortages are beginning to be addressed as new programs are opening at local universities and cohort sizes have generally increased in recent years.¹²⁻¹⁴

Procurement
- **Flawed decision-making processes and criteria.** One survey of radiologists across 52 LMICs⁹ provided helpful detail about specific procurement-related processes and challenges, including:
  - Only a third of radiologists surveyed said they had the final say in x-ray equipment purchasing decisions—more commonly, hospital administrators or government officials were the primary procurement decision-makers.
  - Those decision-makers tended to focus on initial device cost rather than quality or long-term cost of ownership.
  - Service contracts are underutilized; they are offered by 85% of vendors but only included in less than 40% of purchases.
  - Trainings are often insufficient or excluded from initial purchase contracts; they are likely getting squeezed out of the budget during the bidding process due to the heavy focus on initial cost.
- **Donated devices becoming less frequent.** One positive trend noted in this same survey⁹ is that device donations are becoming much less common, likely for a few reasons: (1) 95% of respondents felt the drawbacks (poor quality, no training, limited parts) outweighed the benefits, and (2) cost pressure in high-income country healthcare markets causing hospitals to keep their equipment past the point where donating would be feasible, and (3) modern equipment is becoming increasingly available in LMIC healthcare markets.

KEY KNOWLEDGE GAPS
As with ultrasound, the overall literature on x-ray barriers is relatively robust, especially at a general/global level. The knowledge gaps that remain are mostly focused on mapping a general problem to a specific country-level context to pinpoint root cause issues, including:

**Procurement & Financing**
- Identifying the underlying issues driving the procurement challenges described in the literature, e.g., is there a budgeting or cash flow problem driving procurers’ focus on initial costs? Are service and training contracts underutilized because governments or vendors are unwilling to enter into long-term agreements? Or because they prefer to utilize existing internal training/maintenance resources?

**Policy & Regulatory**
- Do country eHealth and mobile health policies adequately reflect the challenges specific to teleradiology? Are there significant barriers to registering, selling, and importing x-ray devices that will need to be considered as new technologies come onto the market?

**Service Delivery**
- For each focus country, given investments in radiology education programs, how large is the skills gap projected to be over the next 5 to 10 years? Will shortages of qualified staff continue to be a key bottleneck, or will that bottleneck increasingly shift to challenges like equipment availability and maintenance? Similarly, what lessons can we learn from specific companies or organizations that offer teleradiology services in each of our focus countries?
Conclusion

As an initial step in the MD4MD project, PATH identified and summarized more than 200 documents that discussed the barriers to access faced by eight priority MNCH devices. This evidence demonstrated that most important medical device barriers and proposed interventions are cross-cutting—challenges with funding, training, maintenance, and supporting infrastructure were nearly universal across the eight priority devices. However, we found few detailed sources capable of providing practical, device- and country-specific recommendations in a systematic way. Most sources did not discuss issues like identifying underlying root causes, prioritizing when multiple barriers are present, or deciding between multiple potential solutions. These identified knowledge gaps point to several potential areas for investment and future research, including:

- **Clarifying differences in supply pathways across MNCH devices.** This is an extremely useful gateway for investigating many barriers and solutions in a more specific way. Understanding who specific buyers, sellers, and distributors are, how they differ by device type, and what they see as the most important challenges can provide a great starting point for further investigation with other stakeholders. As well, by clarifying overall fragmentation in the market, or quantifying layers of distribution between manufacturer and facility, we can better explain issues with price markups, model proliferation, and/or supply/demand visibility.

- **Identifying ways to make medical device 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. Device inventory data represents a critical input for several key decisions and analyses, such as (1) measuring the overall gap in device access; (2) identifying geographies or health system levels where access is particularly poor; (3) quantifying device proliferation and its implications for training and spare parts management; and (4) assessing the quality of current device maintenance management practices.

- **Identifying structural barriers to implement proven solutions, such as 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-based procurement—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 previously, 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.

- **Developing frameworks and decision guides to help stakeholders navigate multiple competing solution options.** Multiple strategies and intervention options exist for addressing many medical device barriers, but existing literature is not always helpful in identifying which one is ideal for a given device and country situation or under what conditions one ideal solution gives way to another. Future research to analyze these inflection points and build them into decision-making frameworks can better enable health system leaders to identify and implement potential solutions.
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