Access to medical devices is critical to effective health care delivery

Medical devices are a critical but often overlooked component for effective facility-based care, especially for women and children. Medical devices have unique characteristics that make them difficult to manage effectively, particularly in low-resource settings. For instance, devices can serve multiple clinical uses across different health programs—complicating ownership and funding responsibilities. They also often require extensive training, ongoing preventive maintenance, and a reliable supply of specialized parts and accessories.

Recent PATH studies under the Market Dynamics for Medical Devices (MD4MD) project highlighted the extent of current gaps in medical device access. In an inventory of over 800 health facilities across four countries, PATH found that critical devices like x-rays, ultrasounds, and infusion devices were available in less than half of eligible facilities, with even fewer (less than 20 percent) having sufficient quantities to meet anticipated patient needs. Almost a quarter of observed devices were also nonfunctional. Lastly, supply was often fragmented across 20+ manufacturers per device in each country—complicating training, maintenance, and procurement efforts. These barriers echo those identified for broader healthcare equipment, such as cold chain equipment (CCE) and laboratory diagnostic devices.

Scaling Access to Lifesaving Equipment (SCALE) project

PATH, with funding from the Bill & Melinda Gates Foundation, is leading the Scaling Access to Lifesaving Equipment (SCALE) project—which builds on previous research and initiatives under MD4MD. With a vision that patients should have reliable access to device-related health services, this project seeks to ensure medical devices are available and functional in sufficient quantities across health facilities. SCALE is unique in its crosscutting focus on medical devices and equipment that span a range of health programs, such as HIV/AIDS, immunization, primary health care, and maternal, newborn, and child health. Through the SCALE project, PATH will identify and test promising new business and operating models, while strengthening the underlying systems for managing all durable medical devices and equipment.

Project snapshot

**Goal:** To accelerate best practices in medical device management and improve access to the health care services they support.

**Key focus areas:**
1. Strengthening the enabling environment that supports effective medical device management, by:
   a. Supporting the development or revision of key policies and regulations that govern device management.
   b. Clarifying data standards and systems to inform evidence-based decision-making for devices.
2. Piloting new, innovative models that improve effectiveness and efficiency of device management, by:
   a. Testing procurement models that provide good value for money and are responsive to user needs.
   b. Testing maintenance models that efficiently use scarce biomedical engineering resources.

**Focus countries:** Kenya and Malawi.

**Duration:** December 2022 through December 2025.
**Key activities and focus areas**

**Strengthening the enabling environment for medical device management**

PATH will focus on engaging and strengthening both public- and private-sector organizations that play critical roles in the medical device ecosystem to ensure a sustainable market and ultimately improve access to health services.

**Establishing a strategic policy framework**

Medical devices are often financed, purchased, and maintained in an ad hoc fashion. Developing a comprehensive strategic framework is critical to ensuring consistent and effective medical device management. To achieve this, key project activities include:

- Developing practical guidance for identifying optimal purchasing and maintenance models for the main device archetypes within a health system, based on attributes like cost, complexity, and reliability.
- Supporting ministries of health in developing and implementing high-priority national medical device policies or guidelines.
- Engaging global and regional stakeholders to advance a strategic agenda for medical device access, including supporting performance, quality, and safety (PQS) guidelines for CCE, and other global-level standards.

**Improving data for decision-making**

For many public health systems, expensive, one-off inventories are the primary means of collecting data on device availability and performance. Thus, data visibility is lacking throughout the system, which impacts informed decision-making for policymakers and health facilities alike.

A key project activity to address this challenge is to support ministries of health in developing and implementing high-priority data standards or data use strategies, such as developing performance indicators for medical devices or incorporating device management data into the national health information system. PATH will complement these national data standards and policy efforts by engaging with existing global-level efforts, particularly the PQS Electronic Monitoring System (EMS) efforts for CCE.

**Testing new models for device management**

Inefficiencies in existing procurement and maintenance models greatly impact overall access to medical devices. This project will identify and pilot new systems and models that address those inefficiencies, building a business and advocacy case for broader scale-up of such models and complementing efforts to strengthen the enabling environment for medical device management.

**Piloting strategic, cost-effective procurement models**

Procurement of medical devices is often focused on one-off purchases at a low initial price—disregarding a device’s total cost of ownership, alternative procurement models like leasing, and the undue burden of device maintenance. PATH will support buyers of medical devices in adopting, adapting, and managing ideal procurement models for key device archetypes. Key project activities include:

- Providing targeted guidance for ministries of health to identify, prioritize, and effectively advocate for new procurement pilot opportunities.
- Piloting one to two new procurement models for a specific subset of devices, as proofs of concept to demonstrate potential for improving outcomes like availability and functionality of devices in health facilities.

**Piloting efficient, effective maintenance models**

Inadequate maintenance is a major driver of suboptimal device performance. PATH will help buyers and managers of medical devices adopt optimal maintenance models for key device archetypes—focusing resources on areas that best drive efficiency and effectiveness. Similar to activities for improving procurement models, these project activities will focus on providing targeted technical and/or advocacy guidance to ministries of health and then piloting one to two new maintenance models for a specific subset of devices.

**Toward a future of increased device access**

Through this project, PATH aims to validate promising procurement and maintenance models while strengthening underlying systems for device management. Achieving these outcomes will lay a critical foundation for improved and equitable access to medical devices and the health services they support.

PATH’s Market Dynamics program:
https://www.path.org/programs/market-dynamics/