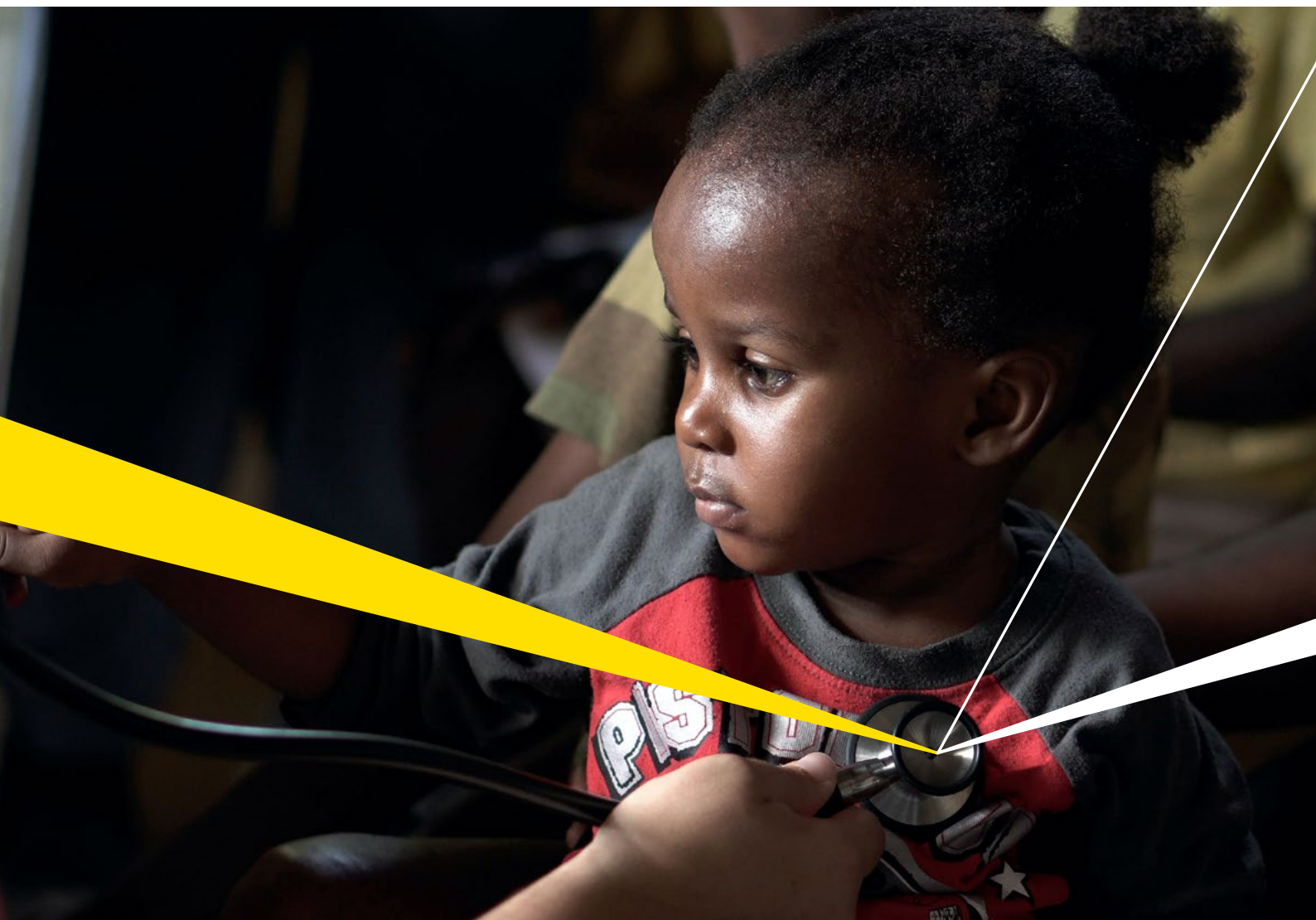


MEDICAL EQUIPMENT & CLINIC ELECTRIFICATION

Research Report

MARCH 2021 EFFICIENCY FOR ACCESS COALITION

VOLUME 1



This report was authored by CLASP as part of the [Low Energy Inclusive Appliances](#) initiative, a flagship programme of the [Efficiency for Access Coalition \(EforA\)](#). EforA is a global coalition working to promote high performing appliances that enable access to clean energy for the world's poorest people. It is a catalyst for change, accelerating the growth of off-grid appliance markets to boost incomes, reduce carbon emissions, improve quality of life and support sustainable development.

The Efficiency for Access Coalition consists of 15 Donor Roundtable Members, 16 Programme Partners, and more than 30 Investor Network members. Current Efficiency for Access Coalition members have programmes and initiatives spanning 47 countries and 25 technologies.

EforA is jointly coordinated by CLASP, an international appliance, energy efficiency and market development not-for-profit organisation, and the United Kingdom's [Energy Saving Trust \(EST\)](#), which specialises in energy efficient product verification, research, advice, data and insight.

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DEFINITIONS

Off/Weak-Grid Clinics	Primary healthcare facilities that have no access to grid electricity, or have intermittent/unreliable grid connections
Healthcare Energy Solutions	Energy systems designed for healthcare facilities, which may include appliances and/or medical devices.
Clinic Electrification	The equipping of off/weak-grid clinics with healthcare energy solutions that require power, which may include appliances and/or medical devices.
Medical Devices	In this context used only for specialised products that consume electricity and provide a specific health service (e.g., x-ray machine, steriliser).
Medical Equipment	An inclusive term used here to include both medical devices and other electrical appliances commonly used in clinical settings (e.g., phone chargers, fans).
Solutions Providers	Organisations that sell and/or deploy healthcare energy solutions, including public health organisations, NGOs, solar product distributors.

Executive Summary

EXECUTIVE SUMMARY

Donors and development agencies increasingly recognise the importance of the health-energy nexus, and have funded a range of new clinic electrification initiatives over the past few years. Many of these initiatives face an underappreciated challenge: a lack of appropriately designed medical equipment.

Clear and evidence-based guidance on medical equipment should support the development and implementation of clinic electrification efforts, as well as the design and deployment of appropriately-sized energy systems that enable delivery of basic health services. Unfortunately, such guidance is often unavailable and commercial markets of off/weak-grid appropriate medical equipment are largely non-existent. Partially due to this mismatch, **WHO estimates that 70% of medical devices in the Global South do not function and remain unused.**¹

This report presents a preliminary assessment of technical and commercial barriers to large-scale deployment of medical equipment in off/weak-grid clinics, along with actionable recommendations to make progress against these barriers. In doing so, we hope to raise awareness among donors, policymakers, and industry stakeholders about the opportunity to improve the ultimate health service delivery impacts of clinic electrification through an increased focus on medical equipment.

Challenges

Medical equipment presents a unique set of technical and commercial challenges for stakeholders involved with clinic electrification. The report describes the following seven inter-related barriers:

- **Complexity:** A 2017 World Health Organization (WHO) report states that there are over 2 million different kinds of medical devices on the market, across more than 22,000 categories of devices.² Stakeholders must also navigate an immense amount of technological variation within individual product categories. Solution providers often make arbitrary choices or, at best, explore a limited set of equipment and supplier options.
- **Lack of Guidance:** Existing resources to guide equipment selection for off/weak-grid clinics are limited, inconsistent and often insufficient. Energy solution providers struggle to identify medical equipment that will enable clinicians to deliver the most impactful, appropriate and affordable suite of health services.
- **Inappropriate Design:** Medical equipment designers focus primarily on markets in Europe, North America or East Asia, where energy supply can accommodate virtually any load size. Voltage fluctuations and energy efficiency is often not a design consideration at all – in some cases, energy requirements are not even included in product specifications. In 2010, WHO estimated that up to 70% of medical devices in the Global South did not function, and one study found that nearly 33% of equipment failures were due to power supply problems.³
- **Immature Regulatory Frameworks:** Compared to the readily accessible and widely utilised energy and performance standards for common appliances such as refrigerators, standards for most medical devices are in their infancy. Existing standards focus almost exclusively on safety and reliability, and often include nothing related to energy requirements, efficiency or power supply.
- **Narrow Intervention Mandates:** Limited government health budgets and multiple competing priorities mean that donor organisations and philanthropies play a large role in health service delivery. The size of donors' responsibility requires prioritisation and compromise in the allocation of resources towards specific health system needs, which can lead to fragmented healthcare infrastructure.
- **Equipment Dumping:** Countries across the Global South struggle to prevent the selling or donating of old, low quality and inefficient medical equipment into their markets, also known as dumping. Donations account for up to 80% of all available medical equipment in some countries in the Global South, according to WHO estimates.⁴ This practice stunts the development of markets for appropriately designed medical equipment.

1. WHO (2010) Medical Devices: Managing the Mismatch. https://apps.who.int/iris/bitstream/handle/10665/44407/9789241564045_eng.pdf?sequence=1

2. WHO (2017) WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices. <https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1>

3. WHO (2010) Medical devices: managing the mismatch, https://apps.who.int/iris/bitstream/handle/10665/44407/9789241564045_eng.pdf?sequence=1

4. https://apps.who.int/iris/bitstream/handle/10665/44407/9789241564045_eng.pdf?sequence=1

EXECUTIVE SUMMARY

- **Sectoral Silos:** Existing efforts to convene the health and energy access communities are nascent and necessarily focus on a wide array of issues, with limited funding or capacity to engage deeply with medical equipment. Healthcare energy solution providers struggle to navigate medical equipment supply chains made up of large multinationals as well as small, highly specialised medical technology companies and start-ups. Medical equipment suppliers, in turn, are largely unaware of the unique needs of off/weak-grid clinics.
- **Prioritise Clinical Equipment Needs:** Health and energy access stakeholders should collectively develop preliminary guidance that provides explicit recommendations on equipment selection for energy solution design appropriate to community-level off/weak-grid health facilities.
- **Collect Medical Equipment Performance & Utilisation Data:** Data from medical equipment testing in both laboratory and field settings will improve procurement decisions, identify opportunities for design improvements and efficiency gains, and establish the performance baseline required to develop performance standards and ultimately a quality assurance framework for off/weak-grid medical equipment

Recommendations

Improved outcomes are possible with deepened coordination between the health and energy sectors, and a new approach to clinic electrification that incorporates a holistic focus on medical equipment alongside provision of energy systems. The following recommendations provide a starting point for this effort.

- **Convene Health & Energy Access Stakeholders around Medical Equipment:** A cross-sectoral convening space, aligned with existing efforts but focused explicitly on medical equipment, will allow the appropriate stakeholders to engage more deeply with technical, regulatory and market challenges specific to medical equipment, align on long-term goals, and set an agenda for technical innovation and market development.
- **Provide Targeted Support for Medical Equipment Innovation:** Dedicated funding, specifically for catalysing innovations and building markets in high-priority medical equipment categories, can help raise awareness about the importance of off/weak-grid medical equipment, accelerate existing R&D efforts and encourage new players to engage with the medical equipment space.
- **Improve Procurement Processes & Provide Policymaking Support:** Large-scale public health programmes can send important market signals by requiring that medical equipment suppliers address energy efficiency and design considerations relevant to off/weak-grid settings. General technical assistance to donors and policymakers should focus on the development of a supportive market ecosystem for medical equipment.



Introduction

As many as 59% of health care facilities in low- and middle-income countries lack reliable electricity.⁵ In sub-Saharan Africa, roughly 25 percent of all health care facilities have no energy access at all, while in rural India⁹ more than 39,000 village-level health centres serving 230 million people lack electricity.^{6,7}

Without energy, clinicians cannot utilise basic diagnostic tools, maintain inventories of critical medicines and vaccines, or access and share information relevant to patient care. As a result, patients suffer: mothers give birth in the dark, babies are born without neonatal warmers and preventative care for a wide range of treatable conditions is unavailable. The COVID-19 pandemic exacerbated this inequity in global access to modern health services, with hundreds of millions of people unable to access testing for the virus or receive potentially life-saving treatment if infected.

Donors and development agencies increasingly recognise the importance of the health-energy nexus, and some included funding for clinic electrification as part of their pandemic relief efforts. Several publications from the last two years demonstrate the extent of recent progress in the field:

- Sustainable Energy for All (SEforALL) and the World Bank's Energy Sector Management Assistance Program (ESMAP) launched the first-ever catalog of commercial energy solutions for health service delivery,
- The Alliance for Rural Electrification showcased 16 in-depth case studies on the deployment of distributed renewable energy (DRE) systems in health care facilities,
- SEforALL published an overview of delivery models that can ensure the efficacy and long-term viability of solar energy systems for health centres and schools,

- The World Bank summarised findings from their country-level work on the potential for off-grid solar energy systems to catalyse a wide range of development benefits when incorporated into private sector-led clinic electrification efforts, and
- ESMAP supported the launch of the HOMER Powering Health Tool, which simplifies the process of sizing distributed generation systems to meet the needs of hospitals and clinics in developing countries where grid electricity is unavailable or unreliable.

In addition, pioneering efforts like SEforALL's Powering Healthcare initiative, IRENA's 2018 International Conference on Renewable Energy for Healthcare, Power for All's Renewable Energy and Health Campaign, and others have catalysed much-needed cross-sectoral dialogue focused on the health and energy nexus.⁸

Unfortunately, the scale of the challenge remains significant. Clinic electrification efforts are still nascent, and require large, long-term and holistic investment to achieve scale. Such investments now also must take place alongside the mobilisation of substantial resources focused specifically on COVID vaccine distribution. But clinic electrification also faces another less obvious but major challenge: a lack of appropriately designed medical equipment.⁹

5. Cronk and Bertram (2018) Environmental conditions in health care facilities in low- and middle-income countries: Coverage and inequalities, *International Journal of Hygiene and Environmental Health*, 221 issue 3, 40-422.

6. World Health Organization and the World Bank (2014). Access to Modern Energy Services for Health Facilities in Resource-Constrained Settings.

7. Power for All (2020) Indian Leaders Call for Improvement in Rural Healthcare via Solarization of Clinics. <https://www.powerforall.org/news-media/press-releases/indian-leaders-call-improvement-rural-healthcare-solarization-of-clinics>

8. UNICEF, GAVI, UNDP, CHAI, and the World Bank are just some of the other organizations that have new or emerging initiatives focused on the health-energy nexus.

9. For the purposes of this report, medical equipment refers to both the specialised medical devices used for diagnosis, treatment, or rehabilitation as well as the more general electrical appliances commonly used in clinical settings, such as fans.

INTRODUCTION

Current clinic electrification initiatives often focus on the energy system itself without equivalent consideration of the medical equipment required to deliver health services. In addition, few commercially available medical devices are designed to perform in harsh environments and with a limited energy supply.¹⁰ Medical device suppliers design most of their products for hospitals in Europe, North America or East Asia. Partially due to this mismatch, **WHO estimates that 70% of medical devices in the Global South do not function and remain unused.**^{11,12}

Furthermore, energy companies and organisations participating in clinic electrification efforts often struggle to understand which types of medical devices they should include in their healthcare energy solutions, and to find suppliers of appropriate and compatible versions of whatever products they try to include. This can lead to the deployment of energy solutions for facilities that lack basic medical equipment or unnecessarily expensive energy systems that power inefficient and inappropriately designed equipment.

In an attempt to raise awareness about the medical equipment component of the larger clinic electrification challenge, this report presents a preliminary assessment of technical and commercial barriers to large-scale deployment of well-designed medical equipment in off/weak-grid clinics. In doing so, we hope to raise awareness among donors, policymakers and industry stakeholders about the opportunity to improve the ultimate health service delivery impacts of clinic electrification through an increased focus on medical equipment. The report closes with a set of actionable recommendations for health and energy sector stakeholders to begin addressing these barriers.

Methodology & Scope

Little information exists about the current state and availability of medical equipment within the context of off-grid clinic electrification beyond vaccine cold chain equipment. To address this gap, the Efficiency for Access Coalition conducted a research and scoping exercise in late 2020 to better understand the broader medical equipment ecosystem, as well as the equipment-related challenges faced by stakeholders currently engaged in clinic electrification efforts.

The research process included 1) a set of interviews with stakeholders in both the energy access and health sectors actively engaged with clinic electrification efforts, and 2) extensive desk research, including analysis of policy documents and technical guidance from seven national governments and nine international organisations. The interviewees and resources are listed in Annexes 1 and 2.

Lastly, please note the following in regards to the overall scope of this report:

- We do not consider issues relevant to deployment of medical equipment beyond technical and commercial barriers, such as personnel training, capacity building and maintenance and operation costs. However, these are critical considerations from a broader health systems perspective and require additional research.
- We acknowledge the substantial progress made in developing and deploying off/weak-grid refrigeration and cold chain technology, a sector that has received substantial, long-term and targeted support mostly under the Global Alliance for Vaccination and Immunization (GAVI) along with other key institutions and will be central to COVID-19 vaccine distribution efforts across the Global South. The report references this success story where relevant to the challenges facing medical equipment innovation more generally, but does not include a full analysis of the evolution of the off/weak-grid cold chain sector.
- We believe there is a large market opportunity for off/weak-grid appropriate medical equipment, but, due to some of the unique complexities regarding current medical equipment supply chains, this report does not attempt to estimate the value of the opportunity. We understand that an estimate of market potential is an important tool in driving private sector engagement with emerging markets, and Efficiency for Access hope to facilitate such market research in follow up to this report.

10. We use clinic electrification efforts to encompass both off- and weak-grid environments, where conditions can be harsh and energy supply is limited and variable. Harsh environments refers to clinical settings in areas where equipment is exposed hot and/or humid climates (and/or highly variable climates), in remote areas with little to no transportation infrastructure or densely populated peri-urban areas with high volumes of patient throughput, and where there is a lack of trained technicians or other technical support staff.

11. WHO (2010) Medical Devices: Managing the Mismatch https://apps.who.int/iris/bitstream/handle/10665/44407/9789241564045_eng.pdf?sequence=1

12. We use the term "Global South" to identify low-income countries that are primarily, but not exclusively, in the Southern Hemisphere.

Technical & Commercial Barriers

TECHNICAL & COMMERCIAL BARRIERS

In some ways, it makes sense that clinic electrification efforts have not focused on the specialised equipment required in clinical settings. Medical equipment presents a unique set of technical and commercial challenges for governments, donors, solution providers and other stakeholders involved with clinic electrification – most of whom already face resource and capacity constraints in their current work.

The following sections attempt to explore and explain these challenges in seven inter-related areas:

- Technical Complexity and Variation
- Lack of Guidance
- Inappropriate Design
- Immature Regulatory
- Narrow Intervention Mandates
- Equipment Dumping
- Sectoral Silos

Technological Complexity and Variation: The term “medical device” encompasses an extremely wide range of technologies. A 2017 World Health Organization (WHO) report states that there are over 2 million different kinds of medical devices on the market, across more than 22,000 categories of devices.¹³ Even though the overwhelming majority of these are not relevant to off/weak-grid clinics, stakeholders must still navigate an immense amount of technological variation.

A wide range of medical devices can often deliver the same health service through different physical or chemical processes and with different underlying technology – and different energy requirements. For example, the Government of Bangladesh’s registry of medical devices includes eight categories of sterilisers, each of which use a different physical or chemical process to sterilise a given object. Even within the same category, differing core designs make direct comparison difficult: the Government of Ethiopia’s list of approved medical devices describes 12 different types of steam sterilisers, each with different designs and performance profiles.¹⁴

Faced with this level of complexity, solution providers often make arbitrary choices or, at best, explore a limited set of options regarding which type of device to procure and who to procure it from. Thomas Rieger, CEO of Solarkiosk, experienced this challenge when designing a solar-powered COVID-19 test lab: “We decided to focus on a single manufacturer for key pieces of equipment, because otherwise we would have spent way too much time comparing products that we barely understand made by manufacturers we had never heard of, and with no way to compare quality.”

Lack of Guidance: Healthcare energy solutions should reflect a clear and evidence-based understanding of which medical equipment is required to deliver basic health services. Unfortunately, resources to provide this guidance are limited, inconsistent and often insufficient.

Healthcare energy solution providers consistently flagged the challenges they faced in determining what equipment to include or prioritise, as well as their surprise at the lack of support available to help answer this question. Anshul Gaur, Director of Global Marketing and Grants at d.light, articulated this problem directly: “figuring out the most important medical equipment your system could power seems like a pretty simple question to answer, but there’s actually very little clear guidance on this.”

Our research did not identify a single example of guidance from national ministries of health on the selection of medical equipment explicitly intended to support electrification efforts. Instead, official guidance on medical equipment is generalised, can be hard to find and varies dramatically in terms of scale, focus and specificity.

Most countries provide general lists of recommended or allowable medical equipment, which tend to be extensive.¹⁵ Many also provide a more targeted list of equipment required for different tiers of health facilities, but the number of tiers and the names for those tiers varies, and the number of items on each type of list ranges widely from country to country.¹⁶ Table 1 summarises the variance across five countries.

13. WHO (2017) WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices. <https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1>

14. Ethiopian Food, Medicine and Healthcare Administration and Control Authority’s National Medical Instruments List.

15. National governments in the Global South often look to WHO to inform their guidance on essential or priority medical devices. Relevant WHO catalogs are compiled here: https://www.who.int/medical_devices/links/med-dev2017pub-cat.pdf?ua=1

Table 1: Comparison of National Medical Equipment Recommendations for Primary Health Facilities

COUNTRY	TOTAL ITEMS IN GENERAL GUIDANCE ON MEDICAL EQUIPMENT	ELECTRICAL APPLIANCES IN GENERAL GUIDANCE	SPECIFIC GUIDANCE FOR PRIMARY HEALTH FACILITIES	ITEMS ON LIST OF RECOMMENDED EQUIPMENT FOR PHCs	ELECTRICAL APPLIANCES IN PHC LIST
India	801	200	YES	47 (essential) + 8 (desirable)	13
Nigeria	381	11	YES	14	1
Rwanda	609	44	YES	114	10
Bangladesh	983	47	NO	-	-
Ethiopia	815	301	YES	45	1

These lists all include both electrical equipment and a variety of other non-electrical products and supplies, from furniture and bandages to chemical agents. The level of detail provided about each item also varies, from listing only the name of a given piece of equipment to providing a range of technical specifications. When specifications are provided for electrical appliances, the data and units of measurement can vary within a single equipment category.

Taken together, these inconsistencies make it hard for healthcare energy solution providers to identify a short list of medical equipment that should be included with an energy system and that will enable clinicians to deliver the most impactful, appropriate and affordable suite of health services. George Mike Luberega, an energy consultant at Solar Health Uganda, confirmed this: "We have tried to figure out where to go beyond lighting in terms of the equipment we provide for clinics, but we're not aware of any guidance about what suite of appliances is necessary and so we haven't been able to make much progress."

WHO has generated a variety of resources that provide a starting point to address this challenge, including:

- **Core Medical Equipment:** A list of 46 devices that includes information on the devices' basic functioning and importance in health service delivery.¹⁷

- **Compendium of Innovative Health Technologies for Low-Resource Settings:** A 2017 report describes innovative technologies with the potential to improve health service delivery in low-resource settings, the purpose of which was also "to raise awareness of the pressing need for appropriate and affordable solutions" across the Global South.²¹
- **Interagency List of Medical Devices for Essential Interventions for Reproductive, Maternal, Newborn and Child Health:** A list of devices required to support reproductive, maternal, newborn and child health interventions, broken out by each category and along the continuum of care.¹⁹

Each of these presents a wide range of information relevant to the design of off/weak-grid healthcare energy solutions, but taken together they do not readily enable prioritisation of equipment nor do they include the technical specifications required for energy system design.

WHO and World Bank also published a report in 2015 that included an indicative list of medical equipment for off/weak-grid clinics²⁰, and USAID's Powering Health initiative provides a thorough orientation to the technical aspects of healthcare energy system design including a list of recommended medical equipment. Similar to some of the issues described above regarding the country-level guidance, these two resources are inconsistent in their equipment recommendations and level of detail they provide.

16. Note that terminology used to refer to the lowest level of health centre differs across countries; this report refers to these facilities collectively as primary health centres.

17. WHO (2011) Core Medical Equipment, https://apps.who.int/iris/bitstream/handle/10665/95788/WHO_HSS_EHT_DIM_11.03_eng.pdf?sequence=1&isAllowed=y

18. WHO (2017) WHO compendium of innovative health technologies for low-resource settings: 2016-2017, https://www.who.int/medical_devices/publications/compendium_2016_2017/en/

19. WHO (2015) Interagency List of Medical Devices for Essential Interventions for Reproductive, Maternal, Newborn and Child Health, https://www.who.int/medical_devices/publications/interagency_med_dev_list/en/

TECHNICAL & COMMERCIAL BARRIERS

Sarah Baird, Executive Director of Let There Be Light International, sees such prior efforts as a critical foundation, but one that must be expanded upon: "prioritizing appliances is hard and can even become political, but given the limited resources of most organizations that do this work, and the complexity of the challenge, we need a clear, agreed-upon reference point to figure out what products to include."

Inappropriate Design: If solution providers are able to identify a specific type of desired equipment, commercially available versions are usually not designed for use in clinical settings with limited, unstable energy supplies and harsh operating environments.

Medical equipment designers focus primarily on safety and reliability of service provision, with the primary goal of selling products into clinical settings in Europe, North America or East Asia where large markets exist and energy supply can accommodate virtually any load size. Energy efficiency is often not a design consideration at all -- in some cases, energy requirements are not even included in product specifications. D.light's Gaur underscores the extent and implications of this challenge: "The bigger medical equipment players haven't shown any interest in the off-grid market and we haven't been able to find suppliers with products that reflect an understanding of our needs. As a result, we can't offer a more holistic healthcare solution."

Variation in the nature of energy supply in off/weak-grid clinical settings is one of the most important technical challenges. SELCO Foundation has an extensive track record of clinic electrification work in India, but they consistently struggle to find medical equipment that is compatible with DC electricity generated by distributed renewable energy (DRE) systems. Huda Jaffer, Director of SELCO Foundation, says that "aside from source incubators and start-ups, very few companies make products that work with solar. Almost all the products require an inverter." Power converters, however, represent an additional cost and reduce energy efficiency, thus necessitating the use of more electricity.²¹

Clinics with intermittent and fluctuating grid connections present further challenges.²² Equipment used in these settings must withstand extreme voltage fluctuations and surges, and potentially be compatible with both AC and DC power supply. The majority of equipment, however, lacks these design features and some ultimately ceases to function. In a survey of 147 Indian primary healthcare facilities, almost 22%

reported having suffered equipment damage due to voltage fluctuation.²³

Most medical devices cannot handle power supply volatility or otherwise function in harsh environments, which results in extremely high rates of device failure. In 2010, **WHO estimated that up to 70% of medical devices in the Global South did not function, and one study found that nearly 33% of equipment failures were due to power supply problems.**²⁴ Boston Nyer, COO of Equalize Health, described the material impacts of this challenge at the individual facility level: "A clinic we work with in Rwanda had to build two barns to hold broken medical equipment, and the poor quality of the power supply is the number one factor driving those equipment failures." While nonfunctioning equipment strains healthcare facilities, which must replace or repair equipment, it also leads to delayed or decreased healthcare delivery services for patients.

Unfortunately, medical equipment suppliers have little incentive to design models that are more appropriate for energy-constrained settings. Mainstream medical equipment manufacturers make significant investments to design equipment that passes the rigorous safety standards that govern national markets in places like the US and Europe. Nyer says, "Most suppliers have two or three versions of something, and they try to sell it all over the world. They are not designing things to meet the specific needs of any individual place beyond ensuring compliance with Food and Drug Administration (FDA) regulations."

Even when large medical equipment suppliers understand the need for off/weak-grid products, investment in product design and innovation can be hard to sustain. Niels Buning, New Business Development Manager at Philips, oversaw the company's African Innovation Hub that developed highly innovative respiratory monitors and fetal heart monitors. According to Buning, "everyone gets very excited about these products and their potential impact, but they're extremely hard to scale. Our responsibility is to deliver a return for our investors, but the commercial fundamentals are very challenging and it's hard to find a line of business willing to take on that risk."

20. WHO and ESMAP (2015) Access to modern energy services for health facilities in resource-constrained settings, <https://www.who.int/publications/i/item/9789241507646>

21. Efficiency for Access (2020) Performance and Efficiency of Off-Grid Appliances with Power Converters: Phase 1, <https://efficiencyforaccess.org/publications/performance-and-efficiency-of-off-grid-appliances-with-power-converters-phase-1>

22. In addition to electricity supply issues, many rural, grid-connected health facilities also have inadequate electrical wiring, which increases the potential for equipment damage.

23. CEEW (2017) Powering Primary Healthcare through Solar in India, <https://www.ceew.in/publications/powering-primary-healthcare-through-solar-india>

24. WHO (2010) Medical devices: managing the mismatch, https://apps.who.int/iris/bitstream/handle/10665/44407/9789241564045_eng.pdf?sequence=1

TECHNICAL & COMMERCIAL BARRIERS

In 2010, WHO estimated that up to 70% of medical devices in the Global South did not function, and one study found that nearly 33% of equipment failures were due to power supply problems.²⁸

Immature Regulatory Frameworks: Quality assurance based on internationally recognised performance standards and testing protocols is critical for the development of healthy and competitive markets. The consumer protection provided by quality assurance is even more important for products used in underserved communities.

WHO's Performance, Quality and Safety (PQS) standards described in Box 1 below demonstrate the potential for such an approach to transform supply chains for off/weak-grid

medical equipment, but the scope of that effort is limited to immunisation equipment. In the off-grid solar sector, programs like [VeraSol](#) offer a comprehensive suite of quality assurance services that address the unique performance characteristics of off-grid products.

The [International Medical Device Regulators Forum \(IMDRF\)](#), a voluntary group that consists of six national governments plus the EU and WHO, is the primary platform to coordinate development and harmonisation of global medical device standards. IMDRF launched in 2011 and published its initial guidance on medical device performance in 2018, which did not include energy performance.²⁵ Because this effort is so nascent, most medical equipment suppliers design products to meet FDA or European Commission regulations. These standards focus almost exclusively on safety and reliability, and often include nothing related to energy requirements, efficiency or power supply.



Unused and non-functional medical equipment at a district hospital in Kenya. Photo credit: Equalize Health

25. IMDRF (2018) [Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices](#)

Vaccine Refrigerators: A Roadmap to Innovation

WHO's Expanded Programme on Immunization (EPI) was established in 1974 to eradicate six vaccine-preventable diseases and, due to the number of deaths prevented, is considered one of the world's most successful public health programmes.²⁶ To ensure that costly vaccines were not lost due to inadequate cold chain technology, WHO established the Performance, Quality and Safety (PQS) system, which developed the first-ever performance specifications and test procedures for solar-powered medical equipment.²⁷

The need for PQS-compliant cold chain, refrigeration and other immunisation-related products in weak/off-grid contexts catalysed the development of a whole new class of refrigeration and rewarded companies with quality products with an opportunity for name recognition, ease of sales, marketing and after-sales service to a guaranteed market.

The PQS Catalogue is now central to global vaccine cold chain procurement, and demonstrates the potential impact of long-term investment in regulatory frameworks and quality assurance specifically focused on off/weak-grid appropriate medical equipment.

In addition, technological innovation initially catalysed by the PQS process has spilled over into the nascent but growing commercial market for off-grid refrigerators. Sure Chill and SunDanz were early leaders in the vaccine refrigerator space, and both went on to develop Global LEAP Awards-winning off-grid refrigerators for household and retail use.

26. WHO (2014) The immunization programme that saved millions of lives <https://www.who.int/bulletin/volumes/92/5/14-020514/en/#:~:text=Given%20the%20number%20of%20deaths,public%20health%20programmes%20to%20date>

27. WHO (2020). WHO PQS Devices Catalogue https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

TECHNICAL & COMMERCIAL BARRIERS

Narrow Intervention Mandates: Healthcare is often chronically underfunded in the Global South. Limited budgets and competing priorities often result in government dependency on donor organisations and philanthropies that attempt to fill the gap by funding a wide range of public health programmes, many of which include provision of medical equipment. In many places, such initiatives play a primary role in enabling basic health service provision and supporting core elements of the broader health system. This, in turn, can have unintended consequences for medical equipment supply chains.

The scale of donors' responsibility requires prioritisation and compromise in the allocation of resources towards specific health system needs, which can lead to fragmented healthcare infrastructure. Donor-funded public health investments often focus on a specific health outcome or demographic; for example, immunisations or maternal and child health. Programme implementers typically procure and distribute only the equipment required to achieve this targeted outcome, such as refrigerators or fetal heart monitors. While this makes sense given the mandate and goals of an individual programme, it often results in missed opportunities for public health organisations operating in remote areas to install equipment that would deliver a broader suite of health services. Dr. Paul Sonenthal, a physician who also consults with Partners in Health, confirmed these limitations: "the purpose of a given health centre is shaped by the donor's interest. There may be a general list of essential equipment for a community health centre in a given country, but what actually gets procured will reflect the individual donor's priorities."

This kind of procurement is also subject to country- and donor-specific regulations. "Donors have an outsized influence on the details of the procurement process – what type and brand of refrigerator gets purchased for an individual facility may reflect considerations in the donor country," said Emily Keyes at FHI 360. As a result, public health experts and programme implementers may not always have the mandate or flexibility to procure the most appropriately designed or energy efficient medical equipment.

Equipment Dumping: Countries across the Global South struggle to prevent the selling of old, low quality and inefficient models of various appliances and equipment into their markets, also known as dumping. This practice can stunt the development of markets for higher-quality appliance products, and is a major challenge for medical equipment supply chain development as well.

One reason that dumping has a particularly damaging impact on medical equipment markets is that, in addition to commercial sales of inappropriate products, large-scale donations of outdated equipment and excess inventory are also common. And while some donations are well-intentioned, others reflect commercial motivations. Sonenthal finds that to a large extent, "when an international company has overstock, they make a donation to clear it and get the tax write off." WHO provides donation guidelines, but even well-meaning donations may not match the recipient's needs.²⁸ Estimates indicate that as little as 10-30% of donated medical equipment ever serves its intended purpose, due to a variety of challenges including lack of required energy supply and infrastructure, an inability to service products in recipient countries, and damage during shipping or last-mile transportation.²⁹

Given the scale of the need and the limited funding made available to many countries in the Global South, national governments often have no other option than to accept even sub-optimal donations. **In most places, donations make up an overwhelming majority of all available medical equipment – up to 80% in some countries in the Global South, according to WHO estimates.**³⁰ However, donations at this scale greatly reduce the interest among commercial players in developing products that are specifically tailored to these markets. Nyer underscored this, saying that "medical equipment donations lower willingness to pay and flood the market, making it far less attractive for medical equipment suppliers to expand into a country with lots of donations."

28. WHO (2020) Donation of medical equipment https://www.who.int/medical_devices/management_use/manage_donations/en/

29. *ibid*

30. WHO (2010) Medical Devices: Managing the Mismatch: https://apps.who.int/iris/bitstream/handle/10665/44407/9789241564045_eng.pdf?sequence=1

Promoting High-Performing Weak/Off-Grid Cold Chain Equipment

In 2016, Gavi, the Vaccine Alliance established the [Cold Chain Equipment Optimisation Platform \(CCEOP\)](#) to support countries in improving their cold chains. Through the platform, Gavi committed US \$250 million between 2017-2021 to jointly invest with countries to purchase and install high-performing, durable equipment. This funding has already led to the installation of over 100,000 vaccine refrigerators.

Platform-eligible cold chain equipment satisfies a higher standard of performance criteria beyond minimum WHO PQS requirements. At the global level, CCEOP work includes a market-shaping component that improves the availability and installation of platform-eligible cold chain equipment (CCE). In 2020, Gavi released a Cold Chain Equipment Optimisation Platform Technology Guide that advises health facilities on CEE purchasing decisions. The guide also includes guidance for off-grid health facilities and CEOP-compliant off-grid devices.

This funding has already led to the installation of over 100,000 vaccine refrigerators.

TECHNICAL & COMMERCIAL BARRIERS

Sectoral Silos: While silos between health and energy sector stakeholders remain a significant challenge for clinic electrification efforts generally, the challenge is even greater when it comes to medical equipment. These silos reinforce all the challenges described above, but in some ways they exist because of these challenges in the first place.

Existing efforts to convene the health and energy access communities are themselves nascent and, as a result, must focus on a wide array of issues without the funding or capacity needed to engage deeply with medical equipment providers. SEforALL's Powering Healthcare initiative created some of the first opportunities for health and energy sector stakeholders to share information and collaborate. In doing so, it helped generate broad buy-in to the relationship between energy access and health service delivery, and it continues to facilitate discussions that inform the broader clinic electrification agenda. The Health and Energy Platform of Action, led by WHO, UNDP, UNDESA and the World Bank, demonstrates another important evolution in the push for high-level coordination between the health and energy sectors. However, dialogue facilitated by platforms like these necessarily focuses on strategic challenges, without the resources or mandate to engage deeply with the technical aspects of medical equipment design or the development of commercial markets for that equipment.

Healthcare solution providers in particular struggle to navigate medical equipment supply chains made up of large multinationals as well as small, highly specialised medical technology companies and start-ups. SolarKiosk's Rieger describes it as "the most difficult sector we have ever encountered, where the suppliers often don't perceive any incentive in engaging with a solar company like ours." Medical equipment suppliers, in turn, are largely unaware of the need for medical devices that are compatible with DRE systems and designed to function in harsh environments, partly due to the commercial dynamics surrounding equipment donations and dumping described above.

SELCO Foundation Director Huda Jaffer explained that, "We need to build a convergence between health and energy experts, especially when it comes to appliances. We need each of these groups to demystify what they do for the other."



Recommendations

RECOMMENDATIONS

Some of the barriers described above represent structural challenges that will require sustained effort over many years by national governments and international organisations to address. But near-term progress in several key areas is possible with deepened coordination between the health and energy sectors, and a new approach to clinic electrification that incorporates a holistic focus on medical equipment alongside provision of basic energy systems.

Such collective effort has the potential to catalyse the development of a new generation of medical equipment that enables holistic health service delivery in resource-

constrained clinics, while also creating the technical and market infrastructure to enable rapid deployment of innovative healthcare energy solutions, which can in turn benefit their counterparts in developed countries.

The following recommendations, listed in the table below and mapped against the challenge(s) they can help address, provide a starting point for this effort.

Table 2: Mapping Clinic Electrification Challenges to Proposed Recommendations

		RECOMMENDATIONS				
		CONVENE HEALTH & ENERGY ACCESS STAKEHOLDERS AROUND MEDICAL EQUIPMENT	PRIORITISE CLINICAL EQUIPMENT NEEDS	COLLECT MEDICAL EQUIPMENT PERFORMANCE & UTILISATION DATA	PROVIDE TARGETED SUPPORT FOR MEDICAL EQUIPMENT INNOVATION	IMPROVE PROCUREMENT PROCESSES & PROVIDE POLICYMAKER SUPPORT
BARRIERS	Technological Complexity & Variation	X	X	X	X	
	Lack of Guidance	X	X			X
	Inappropriate Design	X		X	X	X
	Immature Regulatory Frameworks	X		X		X
	Donor Priorities	X	X		X	X
	Equipment Dumping			X		X
	Sectoral Silos	X		X		

RECOMMENDATIONS

1. Convene Health and Energy Access Stakeholders around Medical Equipment

A cross-sectoral convening space similar to and aligned with existing efforts like SEforALL's Powering Healthcare and Power for All's [country-specific campaigns](#) but focused explicitly on medical equipment will allow the appropriate stakeholders to engage more deeply with technical, regulatory and market challenges specific to medical equipment.

Such a convening space will elevate the issue of off/weak-grid medical equipment and ultimately help clinicians, public health experts, governments, donors, established players in the medical equipment market, early-stage innovators and solution providers to align on long-term goals and set an agenda for technical innovation and market development. Efficiency for Access sees such a convening space as a necessary starting point for progress on the other recommendations listed below.

2. Prioritise Clinical Equipment Needs

To aid in the development of formal recommendations by ministries of health or international public health institutions, health and energy access stakeholders should collectively develop preliminary guidance that provides explicit medical equipment recommendations for community-level primary health facilities that take the guesswork out of solution design.

Such guidance should build on existing resources to the extent possible, but should also reflect consensus input from a representative group of stakeholders achieved through an open, transparent and inclusive process of stakeholder engagement. Such guidance would ideally be in a 'living' platform that allows for periodic updates that reflect technology and market evolution.

This could provide a foundation for development of official guidance at the national level and inform related efforts by international organisations such as WHO and GAVI Health, the Vaccine Alliance. It would also substantially reduce the time that companies spend determining what equipment to include in a given solution and gathering technical data about the equipment to inform solution design, while ensuring that commercial offerings provide a standardised level of care.

3. Collect Medical Equipment Performance and Utilisation Data

Clinic electrification investments should include support for medical equipment testing in both laboratory and field settings.

Laboratory-based performance testing will generate foundational data on medical equipment energy requirements, durability and service delivery. The resulting data will improve procurement decisions, identify opportunities for design improvements and efficiency gains, and establish the performance baseline required to develop performance standards and, ultimately, a quality assurance framework for off-/weak-grid medical equipment similar to WHO's PQS test protocols.

Field research on the use of medical equipment in clinical settings would complement laboratory-based performance testing. Such research will enable the development of an "ideal" clinic energy profile that can serve as a model for solution design, while also generating data on energy consumption in real-world settings to compare against laboratory performance. In addition, field research can document the utilisation patterns of medical equipment mapped against the procedures that require clinicians to use that equipment. Remote data collection post-installation can complement field research and further inform and improve product design. This will create an integrated perspective on the energy and equipment requirements for delivering specific health services.

4. Provide Targeted Support for Medical Equipment Innovation

Donors, governments and development finance institutions should make funding available that is specifically dedicated to catalysing innovations and building markets in high-priority medical equipment categories. Such funding can help break down the silos described above by raising awareness about the importance of off/weak-grid medical equipment, accelerate existing R&D efforts and encourage new players, especially those in the local market, to engage with the medical equipment space.

This support should include dedicated R&D funding as well as competitions and innovation prizes that identify early-stage market leaders and innovators as well as provide signals to the broader market regarding product quality. Funding should also target the development and bolstering of local supply chains.

RECOMMENDATIONS

5. Improve Procurement Processes and Provide Policymaker Support

WHO's PQS Catalogue is the only example of a performance standard and regulatory framework for off/weak-grid medical equipment that guides funding and procurement decisions, while CCEOP's complimentary framework accelerates demand for high performing, appropriately designed equipment. The PQS and CCEOP approach should serve as a reference point for efforts to improve procurement of a broader quite of medical equipment.

As a first step, large-scale public health programmes that include procurement of medical equipment for use in off/weak-grid clinical settings should require that medical equipment suppliers address energy efficiency and design considerations relevant to those settings. Such procurement actions have the potential to provide important market signals about the need to adapt medical equipment for off/weak-grid clinics.

UNDP's Sustainable Health in Procurement Project (SHiPP) is a new initiative that has the potential to demonstrate the potential impacts of procurement-focused interventions. In addition, the energy performance components of the existing PQS certification process should be updated to further incentivise manufacturers to prioritise energy efficiency improvements, cost reduction and use of low GWP refrigerants. This would enable solutions providers to develop cost-effective and holistic healthcare energy systems anchored by highly efficient refrigeration technology.

Lastly, technical assistance to donor organisations and relevant government institutions in target countries should focus on the enabling environment required to support long-term market building efforts that stimulate and streamline demand for off/weak-grid medical equipment. Such interventions can play an important role in increasing the commercial attractiveness of emerging markets for key private sector players.



CONCLUSION

Energy access and health sector stakeholders have made significant progress in raising awareness of the need for investment in clinic electrification, and many donors prioritised this in their response to the COVID-19 crisis. To date, however, most of these efforts focus primarily on provision of energy itself and do not address the specialised medical equipment required by off/weak-grid clinics.

This report explored some of the most important technical and commercial barriers that contribute to the exclusion of medical equipment from most discussions of, and investments in, clinic electrification. A lack of guidance and undeveloped regulatory frameworks, coupled with vast technological variation and complexity, make it difficult for solution providers to understand what equipment to include with healthcare energy solutions while also precluding the development of appropriately designed products. Sectoral silos, donor influence and widespread equipment dumping further exacerbate these challenges.

The recommendations described in this report can help address these challenges. Convening spaces can help stakeholders from both the energy and health sectors align on long-term goals and set an agenda for technical innovation and market development. Developing baselines

for medical equipment performance can provide much needed data, which will help inform procurement decisions, design improvements and a quality assurance framework. Establishing preliminary guidance with explicit medical equipment recommendations for community-level primary health facilities would provide crucial knowledge for companies and provide a baseline for the creation of official guidance at the national level. Dedicated funding for research and development, competitions and innovation prizes will help identify early-stage market leaders and scale the market. And lastly, introducing efficiency and design considerations into existing procurement actions along with technical assistance for donors and ministries of health can provide initial market signals that, in turn, have the potential to catalyse early-stage market development and stimulate demand for off/weak-grid medical equipment.

Some organisations have already begun to address the challenges and develop blueprints relevant to the recommendations described here. Greater support is needed to scale these existing initiatives, attract new entrants to the market and more broadly increase awareness of the opportunity for a new generation of off/weak-grid medical equipment to transform health outcomes in some of the world's most under-resourced communities.



Annex 1: Interviews

- Sarah Baird, Let There Be Light International
- Niels Buning, Philips
- Binagwaho Gakunju and Anshul Gaur, d.light
- Huda Jaffer and Shingle Sebastian, SELCO Foundation
- Gil Karie, Ignite
- Josh Karliner, Healthcare Without Harm
- John Keane, SolarAid
- Emily Keyes, FHI 360
- George Mike Luberenga, Solar Health Uganda
- Ian Milimo and Nevra Gomdeniz, United Nations Development Programme: Sustainable Health in Procurement Project (SHiPP)
- Boston Nyer, Equalize Health
- John Parapatt and Saira Zaikdi, CHAI
- Richard Parry, Lauren Thomas, Gad Cohen and Jacob Bowman, eleQtra
- Thomas Rieger, Solarkiosk
- Luc Severi, Sustainable Energy for All
- Paul Sonenthal, Partners in Health

Annex 2: References

Intergovernmental or Organisational Guidance

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Governmental Guidance:

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- [GHS Standard Hospitals: Standard modular design concept \(Ghana\); 2016](#)
- [National Medical Instruments list with minimum specification \(Ethiopia\); 2013](#)
- [Primary Clinic -- Requirements \(Ethiopia\); 2012](#)
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- [Classification of Medical devices & IVDs \(South Africa\); 2019](#)
- [Registration Guidelines for Medical Devices Bangladesh; 2015](#)



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