

Preventing lifelong impairment: Access to clubfoot treatment in low- and middle- income countries

**Cluster 3 Country
Implementation**
Drive Availability and
Affordability

Prepared by
The Clinton Health Access
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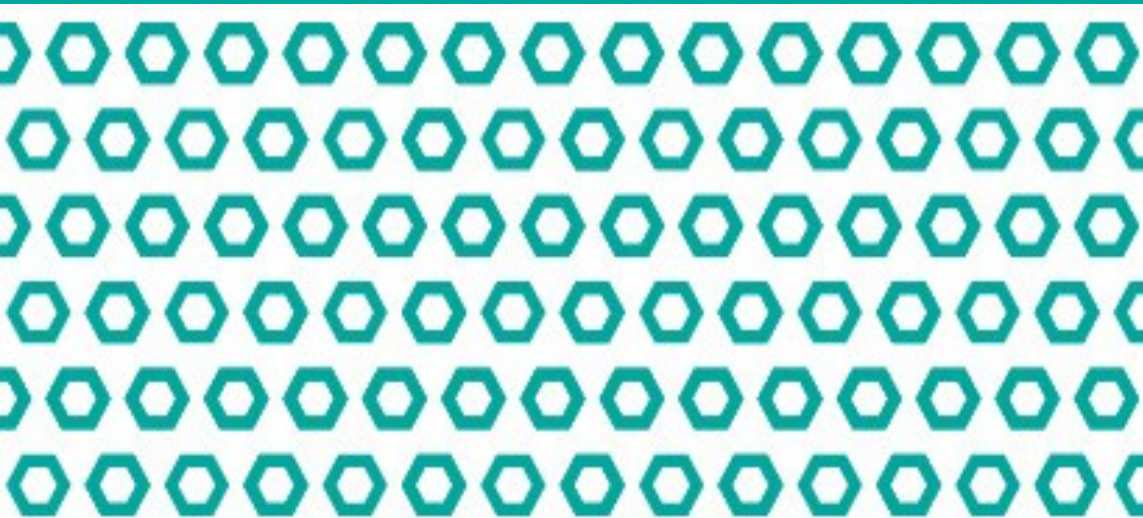
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Executive Summary

Congenital talipes equinovarus (CTEV), commonly known as clubfoot is one of the most common congenital conditions, affecting 1 in 800 births. Left untreated, it can lead to life-long impairment, impacting participation in society, education, and employment. Most children with clubfoot can be successfully treated with the Ponseti method, a low-cost, cost-effective, and minimally invasive treatment protocol. Despite progress, less than 1 in 5 children born with clubfoot in low- and middle-income countries (LMICs) currently receive treatment.

Low treatment rates are driven by low awareness about clubfoot, a lack of ownership and prioritization by governments and global donors, and a lack of systems needed to deliver an effective treatment. Clubfoot programs in LMICs are often implemented with the support of non-governmental organizations (NGOs;) in contrast to high-income settings where treatment is embedded in the primary and tertiary health services. While governments contribute and partner on these programs, overall ownership is limited. This is because clubfoot services require coordination and leadership between different departments within health ministries. Both are often missing. Global actors have also not yet prioritized congenital birth defects such as clubfoot under maternal, neonatal, and child health (MNCH). Now, there are no consensus or agreed treatment guidelines by the WHO that include the Ponseti method. This contributes to a lack of integration of clubfoot services within government-led systems for neonatal and child health care. For children born with clubfoot who have access to treatment in LMICs, a successful outcome is not always guaranteed. Success primarily depends on availability of quality treatment and adherence to a long-term treatment process. When this is not the case, relapse after initial or incomplete rehabilitation may still occur.

To increase access to clubfoot services in LMICs, further investment is needed to achieve the vision of a world where thousands of children each year can receive treatment for an impairment and therefore avoid a life-long impairment. The following actions are recommended:

- **Policy:** Advocate to global and national actors - ministries of health and donors - for the integration and mainstreaming of clubfoot treatment as an essential neonatal and child health service.
- **Provision:** Develop global guidance and standards on the delivery of clubfoot services and products.
- **Personnel:** Integrate clubfoot treatment into government-led MNCH policies, plans and training curricula for health workers at the country level.
- **Products:** Ensure an adequate supply of all treatment materials – plaster, padding and tenotomy supplies and affordable, quality Foot Abduction Braces in LMICs.
- **People:** Test, validate, adopt, and scale new solutions and technologies that promote patient-centred care to improve adherence in low resources settings.

Current and new stakeholders, such as implementing partners, suppliers, donors, country governments and end-user advocacy groups, should collaborate on strategies to achieve these objectives. Based on the learnings from initial actions, plans can be refined to inform a sector-wide strategy.

Clubfoot: Prevalence and Treatment

Clubfoot is one of the most common congenital birth conditions affecting one in 800 births globally.¹ Clubfoot is the common name used to refer to the congenital talipes equinovarus (CTEV) condition. Prevalence varies significantly across populations, with rates as much as seven times higher in the Western Pacific Region than the global average. Globally, 90% of the 180,000 new yearly clubfoot cases are found in LMICs,² and it is estimated that more than one million children and many more adults currently live with untreated clubfoot.

Clubfoot can lead to life-long impairment if left untreated. Clubfoot is idiopathic – i.e., an unknown cause or mechanism of apparent spontaneous origin – and affects the bones, muscles and tendons in the ankle and foot, causing one or both ankles to be positioned in equinus (pointing downward) and in varus (turned inward), with associated cavus and forefoot adduction. This position of the foot is rigid, and if left untreated will lead to life-long impairment, affecting an individual's ability to stand and walk (Figure 1). In high-income settings, impairment related to clubfoot is rare in younger patients due to almost universal access to treatment programs. Unfortunately, in LMICs access to safe and effective clubfoot treatment is rare.

With timely access to appropriate, safe, and effective treatment, clubfoot can be corrected. Multiple treatment protocols have been studied and the Ponseti method is now considered the gold standard treatment that is followed from birth to 4-5 years of age. The Ponseti method is minimally invasive and combines serial casting, orthotic treatment (bracing) and a minor surgical procedure (percutaneous tenotomy) to lengthen the Achilles tendon (see Figure 2). The Ponseti method has the best long-term outcomes compared to other clubfoot treatments.³ Developed in the 1950s by Dr. Ignacio Ponseti, the Ponseti method was popularized in the 1990s after finding that surgical interventions alone were often ineffective. Initiated in the first few weeks of life and followed compliantly, the Ponseti method is effective in resolving idiopathic clubfoot in more than 95% of cases in the corrective phase of treatment. Some patients

¹ Based on systematic meta-analysis, the Global Clubfoot Initiative uses a global incidence rate of 1.23 per 1,000 live births.

² Smythe, T. (2016) Birth Prevalence of congenital talipes equinovarus in low- and middle-income countries: a systematic review and meta- analysis. *Tropical Medicine & International Health*: 22-3.

³ Dobbs M, Gurnett C (2009) Update on clubfoot: etiology and treatment. *Clinical Orthopaedics and Related Research* 467: 1146-1153

experience relapse of deformity after the maintenance phase of treatment; this is commonly managed with further casting and Tibialis Anterior Tendon Transfer surgery if needed. Whilst early intervention has the best results, increasing evidence suggests that older children and adolescents can also benefit from the treatment; however, recognizing that treatment becomes more difficult with age, sometimes requiring more invasive surgery after serial casting to obtain a fully corrected foot and ankle position.⁴

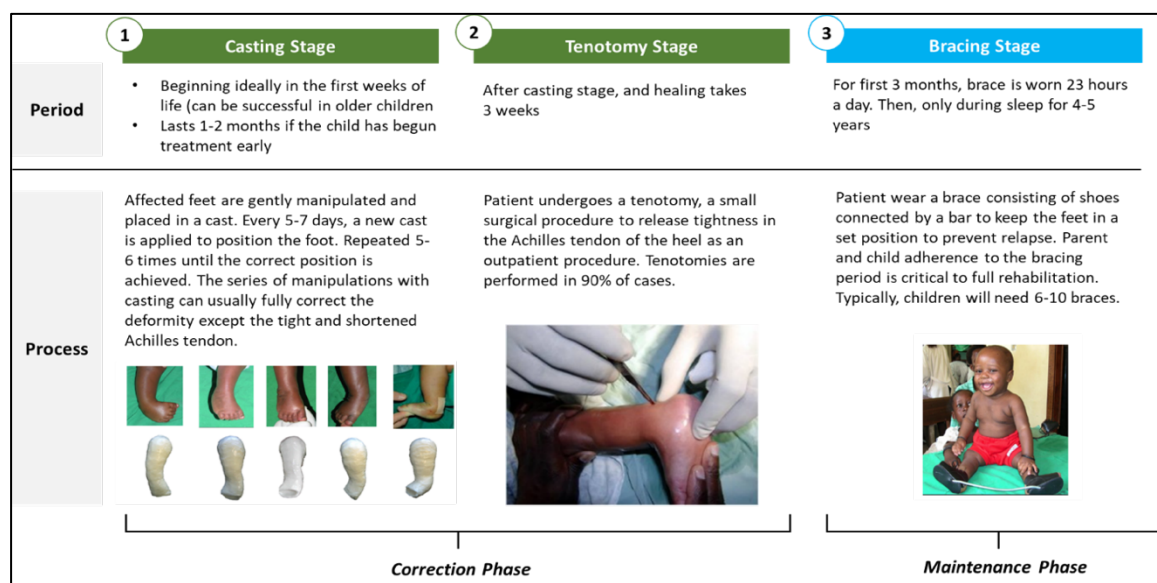
Figure 1: Untreated clubfoot in an adult (left) and child (right)

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⁴ <https://online.boneandjoint.org.uk/doi/full/10.1302/1863-2548.13.190079>

Figure 2: Ponseti Treatment Protocol



Treating clubfoot is highly cost-effective, yet coverage in LMICs is low. The cost of supporting treatment for one child outside of the costs typically supported by the health system (clinic space, staff, etc) is estimated to be US\$500.^{5,6} In comparison, the estimated gain in earnings during the child's life due to increased productivity is US\$120,000. Clubfoot treatment is reported to be highly cost-effective when measured in disability-adjusted life year (DALY) gained compared to other global health interventions.⁷

There has been significant progress in increasing access to treatment since the Ponseti method was popularized: in 2017, 58 LMICs reported having a clubfoot treatment program, up from less than 10 in 2007. Yet, 85% of children born with clubfoot in LMICs still did not access treatment in 2017.^{8,9} Examples of countries with a coverage over 50% include Bangladesh, Rwanda, Paraguay, Nicaragua, Malawi,

⁵ <http://globalclubfoot.com/wp-content/uploads/2017/06/Global-Clubfoot-Strategy-final-copy.pdf>

⁶ In a global survey in 2017, GCI found that 70% of program countries contributed clinic space and healthcare worker staff to clubfoot clinics.

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5321308/>

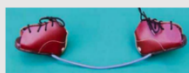

⁸ Global Clubfoot Initiative (2019) Global Clubfoot Data 2017 Survey results. <https://globalclubfoot.com/wp-content/uploads/2019/07/Global-Clubfoot-Data-2017.pdf>

⁹ <https://gh.bmj.com/content/3/4/e000852>

and El Salvador. There is limited data on the estimated number of adults living with untreated clubfoot.

Foot Abduction Orthoses or Braces (FABs) are the primary assistive product needed to complete treatment. The braces are composed of two boots connected with a fixed bar. The boots are attached to the bar at the desired angle of external rotation (70 degrees for an affected foot, and 45 degrees for a non-affected foot), the bar length is set to ensure the feet remain at shoulder width apart and prevent the feet pointing downward. Braces used in LMICs are either locally produced, such as the Steenbeek FAB (SFAB) or imported and adjusted to the user (Figure 3). Prices for standard Ponseti braces range from US\$10 for a locally made brace to US\$250 for high-end products. For the full treatment process, six to ten braces are needed over 4-5 years. In LMICs braces are at times reused across patients.

Figure 3: Select Foot Abduction Braces deployed in LMICs¹⁰

Type	Production	Cost	Description
 Steenbeek Foot Abduction Brace (SFAB)	Locally-made	\$8-\$20	Developed by Michiel Steenbeek in Uganda in 1997. Open-source pattern / design with instructions for orthopedic technicians and shoe cobblers to make a clubfoot brace out of basic, locally-available materials (plywood, leather, metal bar). Bar is not adjustable. Steenbeek brace is widely used and accepted across LMICs.
 MiracleFeet Brace	Pre-fabricated	\$20 to produce	MiracleFeet partnered with Stanford University, Suncast and Clarks Shoes to create a low-cost brace that has all the easy-to-use features of high-priced alternatives (e.g. clip-on shoes). Parents report that the child-friendly color and design reduces stigma. This brace is currently used in 32 countries.
 Iowa Brace	Pre-fabricated	Launched at \$50-\$100, primarily serving higher-end market segments	Developed by University of Iowa since 2012, Iowa brace was designed to be low-cost, and with a focus on comfort and reducing skin irritations and ease of use. The shoe is composed of lightweight breathable mesh, and the bar made of fiber-reinforced nylon and has a level of flexibility built-in. The brace is known to be durable.

Several WHO publications and tools include clubfoot, but global treatment guidelines are yet to be developed. Multiple WHO departments have developed resources that reference clubfoot diagnosis and treatment. These include the guidelines for the screening of newborns for congenital anomalies. Through application of these guidelines, health workers at primary healthcare facilities should be able to identify clubfoot and appropriately refer for treatment. The guidelines include training

¹⁰ Not all braces are represented. Mitchell Brace and Denis Browne Brace are previous designs that are still used in some contexts, but have largely been replaced in LMICs by SFAB. Both are pre-fabricated and very costly.

materials for primary healthcare setting, but more training is needed at the community level, where many babies are born and diagnosed. Surveillance tools that include clubfoot are being piloted by WHO Department of Maternal, Neonatal, Child, and Adolescent Health, to increase efficacy of monitoring newborn health and birth defects. To support appropriate treatment of clubfoot, WHO's Global Initiative for Emergency and Essential Surgical Care has promoted rapid implementation of cost-effective interventions for congenital anomalies like clubfoot. The Global Cooperation on Assistive Technology (GATE) developed a Priority Assistive Products List, which includes the clubfoot braces. GATE has also published Assistive Product Specifications to support the procurement of clubfoot braces.¹¹ To complement existing resources, evidence-based global treatment guidelines could be developed. The WHO guideline development process would ensure identification of, and alignment with gold standards of treatment.

Delivery of Clubfoot Services in LMICs

Non-governmental organizations (NGOs) collaborate with governments to deliver clubfoot services. Clubfoot treatment programs in most LMICs are implemented by NGOs. Some implementation partners such as the *International Committee of the Red Cross (ICRC)*, *CBM International* and *Hope and Healing International* operate in rehabilitation more broadly. Others such as *MiracleFeet*, *Hope Walks*, and *Walk for Life* focus on clubfoot only (see Annex). These NGOs collaborate with ministries of health on the planning of clubfoot treatment programs. They also typically provide technical support, funding, products (including braces), monitoring and evaluation tools, management support and support for awareness raising and training initiatives. Governments on their end allocate clinic space, staff time and, on occasion, supplies and treatment materials.

Implementing partners coordinate and are broadly aligned about key program pillars. The existing implementation partners have historically coordinated their work to limit duplication, as evidenced by a presence in different geographic regions. The *Global Clubfoot Initiative (GCI)* – a sector umbrella organization, founded in 2009 between *CURE International* (now *Hope Walks*), and *CBM International* – promotes

¹¹ https://www.who.int/phi/implementation/assistive_technology/APS3-Clubfoot_braces_oc_use.pdf?ua=1

collaboration, coordination, and training amongst clubfoot implementation partners that work in LMICs. GCI also centralizes and disseminates data for its members, conducts sector research and champions new tools and technologies (see Case Study 1). GCI operates on a small annual budget that is in part funded by membership fees, with the remainder coming from sub-grants on collaborating projects with member organizations and fees from trainings on the Ponseti method conducted in the UK. Specific interventions to deliver clubfoot services differ between implementing partners, but there is consensus on what a national clubfoot program for LMICs should entail (Figure 4).¹² The existing partners deploy similar training and treatment programs.

Figure 4: Pillars of a national program for comprehensive clubfoot care ¹³

Awareness	A child is born with clubfoot and there is awareness that clubfoot is a treatable condition
Identification and Referral	A child is born with clubfoot and identified correctly as such and referred for treatment, ideally within the first few months of life
Clubfoot Clinic and Access	The baby and family are able to access a dedicated clubfoot clinic
Capacity, training and resources	The child receives proper treatment by clinicians trained in the Ponseti method and treatment supplies are available
Casting	The child’s feet are manipulated and casted according to Ponseti protocols for 4-8 weeks
Tenotomy	A tenotomy of the Achilles tendon is performed by a trained provider
Foot Abduction Brace (FAB)	A FAB is fitted and used consistently as the child grows
Adherence	The child adheres to bracing and follow up for 4-5 years

RunFree 2030 lays out a roadmap to increase access to treatment by 2030. GCI launched a joint global strategy in 2017 to end clubfoot, called *RunFree 2030*. This strategy lays out a roadmap to reach 70% of children born with clubfoot by 2030. According to GCI, a total investment of US\$160 million will enable the treatment of over 1.2 million children, generating US\$154 billion in additional lifetime earnings.

¹² <http://globalclubfoot.com/wp-content/uploads/2017/06/Global-Clubfoot-Strategy-final-copy.pdf>

¹³ RunFree2030 Global Clubfoot Initiative (2017) RunFree2030 - Ending Clubfoot Disability: A Global Strategy. Online at <http://globalclubfoot.com/wp-content/uploads/2017/06/Global-Clubfoot-Strategy-final-copy.pdf>



Case Study 1: GCI's Africa Clubfoot Training (ACT) curriculum

GCI, along with CURE International, CURE Ethiopia and led by Oxford University, was instrumental in piloting and developing the ACT curriculum with funding from the UK's Foreign, Commonwealth & Development Office (FCDO) via the Tropical Health Education Trust (THET). ACT includes several modules for implementing the Ponseti method: Level I Basic, Level II Advanced and Train the Trainer modules.

A key outcome of the ACT programme has been the upskilling of trainers who can then go on to build clinical capacity within their own countries, reducing reliance on external training faculty. ACT is now in use in over 30 countries and considered the global gold standard for training health workers in clubfoot treatment in LMICs. A version of ACT is accredited by the UK Royal College of Surgeons for use in the UK. A module for surgical training to upskill local surgeons is being developed by Oxford University through a follow-on grant from FCDO via THET. MiracleFeet has worked with GCI and OPENPediatrics, a division of Boston Children's Hospital, to develop ACTonline, an on-line version of ACT to support virtual and blended learning.

Barriers to Accessing Clubfoot Treatment

Only few clubfoot treatment programs in LMICs are government-led, limiting full integration. While governments contribute to and partner on clubfoot programs, evidenced by 70% of countries reporting that their government provided clinical space and staff according to the GCI to manage clubfoot, these programs are often led by the implementing NGO partner. Examples exist where the Ministry of Health has taken full ownership, such as the clubfoot project in the Democratic Republic of the Congo, but this is uncommon. Barriers to governments taking charge of clubfoot services may include:

- A lack awareness about clubfoot and its treatment;
- Confusion within the ministry of health about which department should lead, given that clubfoot treatment involves multiple disciplines; and
- A perception that clubfoot treatment is an NGO-led intervention.

A lack of government ownership and coordination likely limits resource allocation from government budgets to establish referral networks and expand service capacity. Lack of awareness about clubfoot and its treatment likely occurs not only in government but at all levels of the health system.

A lack of personnel skilled in providing clubfoot management poses a barrier to increasing treatment coverage. Implementation of the Ponseti method demands a multidisciplinary team, often comprised of an orthopaedic surgeon or medical doctor to carry out the tenotomy, allied health professionals (such as physiotherapists,

orthotists) to provide serial casting and bracing and to implement rigorous follow up programs. A systematic process of increasing the number of health workers skilled in the management of clubfoot is needed.

Clubfoot – along with other congenital birth conditions – is not integrated and mainstreamed by large bilateral donors. There has been very little support from bilateral global health donors for clubfoot. USAID and FCDO have contributed ~US\$5 million under different grants over the past 10 years. The progress has therefore been funded through a patchwork of grants from several family and corporate foundations, including Oak Foundation, Glencoe Foundation, Vitol Foundation, Google.org as well as high net worth individuals, Rotary clubs, and faith-based donors. These amount to current investments in clubfoot that are estimated at US\$10-12 million per year. Most donors in this sector are not traditional global child health donors, which contributes to the isolation of clubfoot programs from health system investments.

When children receive treatment, bracing adherence can be a challenge. Long-term adherence to treatment protocol is critical to avoid relapses. More research is needed to determine more precisely the risks of stopping treatment at different ages. Current best practice is that the FAB is worn until the age of 4-5 years. Research from Bangladesh on children who had dropped out of treatment at the ages of 2-4 found that 20% had signs of relapse 4-6 years later.¹⁴ Walk For Life (WFL) – a project that was established to scale access to clubfoot treatment in Bangladesh through a network of clubfoot clinics assessed that difficulty with using the foot abduction brace is the main reason for adherence issues (42%), followed by family challenges (31%), and financial and transportation issues (15%). Employing clinical assistants to encourage adherence can improve outcomes. Patient management tools, such as the Clubfoot Administration SysTem (CAST) developed by MiracleFeet with support from Google.org, can also help facilitate this process (see Case Study 2). Some partners help subsidize patient travel.

Case Study 2: Clubfoot Administration SysTem (CAST) Mobile Application

¹⁴ Angela E, Ma-mun C, Leila K, Abdur R, Shams U, Obaidul H. Factors Affecting Parents to 'Drop-Out' from Ponseti Method and Children's Club-foot Relapse. Ortho Res Online J. 6(3). OPROJ.000638.2020. DOI: 10.31031/OPROJ.2020.06.000638

CAST is an offline-capable and mobile-optimized solution that allows to keep electronic medical records, improve clinic management, and monitor and evaluate the quality of treatment and patient outcomes around the world. MiracleFeet has successfully implemented CAST in its own clinics, but the cost of the software license, cost for integration and training, and difficulty in set up are reported challenges to wider adoption. There is opportunity for GCI to centrally host CAST database so each organization can download the application and upload and access the data.

MiracleFeet is developing sensor technology in partnership with the Indian Institute of Technology, Bombay and others to remotely collect adherence data. Sensors were placed in braces to determine whether braces were being worn correctly. The sensors will then transmit data back to the CAST app to inform clinic administrators when to intervene or when to request a follow-up visit. Early testing is underway.

Access to affordable, quality braces can be a challenge in LMICs; however, several good options exist. The quality of locally-made braces can be difficult to control and standardize. A range of prefabricated brace designs are made at large-scale manufacturing sites with standardized quality control systems. These products offer a greater comfort, are more attractive in terms of design and have more functional features but can be more expensive and require more extensive inventory management to accommodate supply chains. In addition, inefficient supply chains in LMICs can restrict import. A hybrid approach of using locally available materials in a central fabrication site shows promise. Quality can be improved by leveraging local plastics and shoe manufacturing capacity, upskilling orthopaedic technicians or shoe cobblers, implementing quality controls, and setting up feedback loops from users. One such example is the central fabrication of SFAB in Bangladesh (see Case Study 3).

Case Study 3: Walk For Life’s manufacturing model for SFAB

Walk For Life (WFL) aims to increase access to clubfoot treatment in Bangladesh through a network of clubfoot clinics. WFL operates a centralized model to produce low-cost, quality controlled SFAB from common materials in Bangladesh. Trained, specialized manufacturing staff include:

- **Specialized cobblers:** dedicated shoe cobblers who are trained by WFL to fabricate the SFAB; each cobbler is focused on a specialized step of the process.
- **Factory supervisor:** day-to-day supervisor of the cobblers and supports the staff in the brace centre with both technical and managerial functions.



- **Quality controller:** ensures final quality of all products and timely final distribution.
- **Technical expert:** responsible for ensuring technical and clinical considerations of the braces are correct in each product. The technical expert regularly communicates with international advisors and the clinical providers to create the final product.

WFL braces that are made in Bangladesh are sold at US\$ 9.5. While production was initiated for the local market, braces currently are exported to 9 countries, including Myanmar, Thailand, Brazil, and Mexico. By combining both low-cost, locally available materials with trained staff and manufacturing quality controls, WFL has been able to produce affordable braces that are widely regarded to be of high quality, while also providing local employment. There is potential to expand this model to other countries.

Market Challenges

To make appropriate, affordable, quality clubfoot services and braces available to LMICs in a sustainable manner, several criteria need to be met and therefore investigated. The demand and supply dynamics that have challenged the development of a market are summarised below.

Demand

Awareness	Low awareness exists on the part of policy makers, parents, and healthcare providers on the fact that clubfoot can be treated, on the benefits of treatment, and service delivery.
Political Will and Ownership	Clubfoot is not yet fully integrated into health systems. Governments contribute significant resources to clubfoot treatment programs, but these programs are often led by implementing NGO partners. While there is a desire for governments to assume more ownership, this is inhibited by a lack of clarity about which department should lead and limited coordination.
Financing	Current investments in clubfoot services are estimated at US\$10-12 million per year. Additional investment by governments and traditional MNCH donors would support integration and sustainability of services.
Adherence	While challenges exist, which may prevent children from adhering to the full course of treatment, there is evidence that the Ponseti Method is well suited to LMICs and excellent outcomes are possible.

Supply

Quality	Locally produced braces exist, but the lack of quality control mechanisms leads to inconsistent quality.
Supply chain	Imported braces often incur high costs and delays with import and distribution. NGO partners usually purchase in bulk, but face challenges with ensuring local availability of the right combination of sizes for children.

Enablers

Provision	A lack of personnel skilled in providing clubfoot management poses a barrier to increasing treatment coverage. A systematic process of increasing the number of health workers skilled in the management of clubfoot is needed.
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Policy	Evidence-based global treatment guidelines could be developed to improve quality, consistency, and broader adoption of services.
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Approach to Increasing Access

Increasing access to clubfoot treatment in LMICs will require a multi-faceted approach that combines interventions that address global barriers to access, encourage government and donor prioritisation, and accelerate the scale-up of models and tools that increase capacity and improve adherence.

For a world where thousands of children can receive treatment for an impairment and therefore avoid a life-long impairment, the following is recommended:

Policy	Advocate to global and national actors - ministries of health and donors - for the integration and mainstreaming of clubfoot treatment as an essential neonatal and child health service.
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- *Rationale:* Despite evidence for the cost-effectiveness and success of existing service model, donors and policy makers do not consider clubfoot treatment as part of essential package of MNCH services. Clubfoot is not yet integrated with government-led services.
- *Proposed activities:* To increase awareness and commitments for clubfoot treatment by MNCH donors, advocacy activities - bilateral meetings, panels - with MNCH actors should be supported. The investment case for inclusion of clubfoot treatment in the portfolio of MNCH services should be presented to MNCH donors.
- *Long-term outcome:* Sustainable and sufficient financing to support the integration of clubfoot treatment with MNCH services at the global and country-level.

Provision	Develop global guidance and standards on the delivery of clubfoot services and products.
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- *Rationale:* No WHO guidelines exist for clubfoot treatment that include the Ponseti method, which would accelerate government buy-in and country implementation.
- *Proposed activities:* Support WHO to develop treatment guidelines and facilitate the dissemination of these guidelines through bilateral meetings, high-level engagements, etc. to encourage adoption.
- *Long-term outcome:* Growing number of countries with clubfoot treatment programs, increasing global coverage of children that initiate and complete treatment.

Personnel

Integrate clubfoot treatment into government-led MNCH policies, plans and training curricula for health workers at the country level.

- *Rationale:* Limited referral pathways; low number of clinics that provide quality treatment and a limited number of physiotherapists, orthopaedic surgeons, and other trained staff.
- *Proposed activities:* Support LMIC governments to develop and implement national clubfoot plans that are integrated into MNCH policy, coordinate funding from across different sources (public, private, NGO) and integrate quality robust Ponseti training into the curriculum of midlevel providers in a country.
- *Long-term outcome:* Capacity and policy to support a high percentage of children with clubfoot receiving treatment in LMICs.

Product

Ensure an adequate supply of all treatment materials – plaster, padding and tenotomy supplies and affordable, quality Foot Abduction Braces in LMICs.

Market visibility of existing products

- *Rationale:* Imported low-cost braces face challenges with inefficient supply chains and import processes and are largely purchased through donor funding.
- *Proposed activities:* Work with global procurers and distributors to include braces in catalogues that will improve market visibility.

Strengthen the production of quality, locally-made braces

- *Rationale:* The lack of control mechanisms leads to inconsistent quality of locally-made braces.
- *Proposed activities:* Document and disseminate best practices from quality FAB manufacturers. Invest in local fabrication by supporting establishment of centres of excellence.
- *Long-term outcome:* Sufficient supply of an assortment of clubfoot braces to meet the needs of all patients.

People

Test, validate, adopt, and scale new solutions and technologies that promote patient-centred care to improve adherence in low resources settings.

- *Rationale:* Long-term adherence to clubfoot treatment protocol is critical to achieve successful outcomes, but adherence is a major barrier. Some solutions and technologies (i.e., patient management systems, brace sensors) have the potential to improve adherence.
- *Proposed activities:* Promote adoption and integration of technologies for patient data collection to track patient adherence (for example: MiracleFeet's CAST application). Test and validate innovative solutions addressing adherence to identify most effective options and include in clubfoot guidelines and training to accelerate adoption.
- *Long-term outcome:* Increased percentage of children who complete full treatment protocol and do not experience relapse.

Annex

Profiles of major clubfoot implementing organizations (alphabetical order)

	Christian Blind Mission (CBM) International	CURE International India Trust (CIIT)	Hope and Healing International (HHI)	Hope Walks	International Committee of the Red Cross (ICRC)	MiracleFeet	Walk for Life (WFL)
	www.cbm.org	www.clubfootindia.in	www.hopeandhealing.org	www.hopewalks.org	www.icrc.org	www.miraclefeet.org	www.walkforlife.org
About	Christian international NGO, committed to improving the quality of life of people with disabilities in the poorest communities of the world irrespective of race, gender or religious belief.	CURE International India Trust (CIIT) is a 12-year-old National Charity Organization striving to ensure compulsory and complete treatment for children born with clubfoot.	Hope and Healing International (HHI) spun off from CBM and continues as a separate international Christian aid charity that works to help people with disabilities in LMICs.	Largest Christian program for the treatment of clubfoot. Formerly part of CURE International, Hope Walks works with the national health system to ensure quality clubfoot for all.	Neutral, impartial, and independent organization focused on humanitarian protection and assistance for victims of armed conflict and situations of violence. ICRC supports 189 rehab clinics around the world, several which include clubfoot clinics.	US-based NGO that provides treatment to children born with clubfoot. MiracleFeet provides organizational, technical, and financial support to clinics to scale the Ponseti method.	Project that was established with support from The Glencoe Foundation focused on scaling access to clubfoot treatment in Bangladesh through a network of clubfoot clinics.
Regional Coverage	CBM works with more than 300 partner organisations in 51 countries in Africa, Asia, and Latin America.	Established 324 designated weekly clubfoot clinics in government medical colleges and hospitals across 240 districts in India.	In 2019, HHI supported programs in 18 countries in Africa, South & Southeast Asia, and Latin America.	Supporting 136+ clinics in 17 countries in Africa and Latin America.	Projects in; Gaza, Afghanistan, Sudan, Pakistan, Tajikistan, Yemen, Tindouf, Iraq, Myanmar, India, Cambodia, Guinea Bissau, Somalia	Supporting 301 sites in 29 countries across Africa, Latin America and South and Southeast Asia.	Bangladesh (33 clinics) and Myanmar (8 clinics)
Service Delivery	Through a disability-inclusive development approach, CBM aims	CIIT in partnership with the state and the national government has incorporated	HHI works to support local partners to provide access to health and	Hope Walks collaborates with national governments to implement a	Physical Rehabilitation Programme supports physical rehabilitation of patients by	MiracleFeet has developed a comprehensive system to support	WFL helped government adopt clubfoot treatment in national guidelines

Preventing Lifelong Impairment: Access to Clubfoot Treatment in Low- and Middle-Income Countries

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	<p>to ensure the full participation of people with disabilities as empowered self-advocates in all development and emergency response processes.</p> <p>CBM is supporting comprehensive health care systems and services in eye health, ear and hearing care, physical rehabilitation, inclusive education and livelihood.</p> <p>CBM implements inclusive emergency response and disaster risk reduction actions where needed.</p> <p>CBM supports the setting up and/or running of several National clubfoot programmes in LMICs. In many countries, clubfoot management (identification, referral, Ponseti treatment and training) is also supported through general physical</p>	<p>clubfoot treatment in the public health system in India.</p> <p>The government in this partnership provides 1. Healthcare professionals to be available at the designated clubfoot clinic, 2. Clinic space including storage for braces and medical records, 3. Treatment materials for weekly casting and tenotomy and its system to identify and refer children born with clubfoot to the nearest CURE Clubfoot clinic.</p> <p>CIIT in this partnership ensure 1. Ponseti training workshop, 2. Offline and online documentation, 3. Foot abduction brace, 4. 24/7 clubfoot helpline at the national, state and district level, 5. Program managers including counsellors who work with parents to complete both the hospitals based treatment and</p>	<p>rehabilitation services and assistive technology for people with disabilities.</p> <p>HHI sponsors clubfoot treatment and braces and leverages its strengths in other programs (i.e., training orthopaedic surgeons, establishing rehabilitation services) to deploy clubfoot treatment.</p>	<p>holistic clubfoot program model that includes the training and mentoring of national clinical providers, raising public awareness of clubfoot and its treatment, providing parent education and support and monitoring, evaluation and learning so all children with clubfoot can access appropriate quality care and walk free from impairment.</p> <p>In addition to the Africa Clubfoot Training (ACT), Hope Walks has developed an Early Detection and Referral (EDR) program for CHW and a clubfoot clinic Parent Advisors training program. Hope Walks is launching the pilot of a digital solution to support the treatment and follow-up of children with clubfoot for clinicians and clubfoot clinic Parent Advisors.</p>	<p>providing training and technical support to establish services.</p> <p>Clubfoot treatment is part of the portfolio of services offered in some countries. All products and services are offered free of charge and ICRC often provides stipends for travel and accommodations for caregiver and child during the initial treatment period. Because of ICRC's focus in conflict areas, compliance and adherence to treatment protocol can be particularly challenging because of conflict, migration, or displacement.</p> <p>ICRC also develops partnerships in countries with other clubfoot partner organizations to support their operations.</p>	<p>clubfoot patients and their parents in LMICs.</p> <p>Working in collaboration with Ministries of Health, and local NGOs, MiracleFeet trains healthcare workers to establish clubfoot clinics that identify cases, educate parents, and provide the Ponseti method. MiracleFeet supplies materials including the plaster casting materials and braces.</p> <p>A clinic administrator manages the treatment protocol, provides education to the family and promotes adherence. MiracleFeet has pioneered the CAST mobile application for patient management and data collection, which is now used in over 200 clinics around the world, launched the first 3D foot model, and introduced ACT Online - an online version of the ACT I Basic training course - in</p>	<p>and established cost-sharing arrangements for a network of clinics. The network ensures that parents only must travel to a maximum of 70 km to access a clinic.</p> <p>WFL did awareness-building, through training healthcare workers, particularly community- and hospital-based.</p> <p>WFL's model originated in partnership with government, but the relationship ended in 2020, and WFL is now working with private sector as this is where 60% of population access health services.</p> <p>WFL uses a household income assessment to deploy tiered pricing for services. ~70% of families are willing and able to contribute to their child's clubfoot treatment. Sustainability of the workshops is yet to be determined.</p>
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	rehabilitation programs	home/community based rehabilitation with bracing.				2020. Currently testing new solutions, including and sensors to track brace wear.	
Impact	In 2019 more than 32,900 clubfoot treatment sessions. Each year more children are enrolling for treatment. CBM continued to support the National (or State) clubfoot programs in DRC, Cameroon, Bangladesh, and India.	Enrolled over 75,000 children and every month add an average 1,000 new children. Over 5,600 healthcare professionals given hands on training on the Ponseti method. Established 324 designated clubfoot clinics across India.	In 2019, over 200,000 children were treated for clubfoot, cleft lip, other birth malformations and severe burns.	Enrolled 134,000 children in LMIC since 2006. In 2020, over 5,000 children started clubfoot treatment (89% under the age of 1).		Over 50,000 children have been enrolled in 200+ MiracleFeet-supported programs in LMICs. In FY 2019, 87% of children who start treatment completed bracing and 75% completed least two years of bracing.	Enrolled over 27,500 children in clubfoot clinics and delivered over 60,000 braces since inception.
Braces	In most CBM supported clubfoot programs, the SFAB is used as a first choice. Produced within country or in the region. Michiel Steenbeek is a physiotherapist working with CBM International and developed the SFAB (1998).	Steenbeek FAB are made by persons (both men and women) with disabilities. Different sizes are colour coded and children and their parents find the light weight braces very comfortable and compliant.	HHI primarily uses the SFAB, with supplemental imported braces, particularly donations from HICs.	Hope Walks generally uses the SFAB to ensure locally sustainable access. Hope Walks works to centralize the production of braces to ensure higher quality and lower cost. Braces in standard sizes are then shipped to the various clinics within the network.	Promotes local production of SFABs where possible. However, producing SFABs in conflict situations was rather difficult. Hence, developed its own FAB which was centrally produced in Switzerland. Because of a shift to new supplier, Alfaset, who is currently not yet able to produce clubfoot braces, ICRC has been evaluating alternate suppliers.	MiracleFeet has developed a low-cost prefabricated alternative to expensive braces found in HICs. The MiracleFeet brace was developed by Stanford University and made of synthetic materials. MiracleFeet provides MiracleFeet braces for free in some countries and provides locally made SFABs braces in others based on local partner preferences.	WFL has developed centralized, local production of SFAB. To improve consistency of fabrication quality, WFL has adopted quality improvement and control strategies in collaboration with Michiel Steenbeek and clinicians to give feedback. WFL's braces costs \$9.50. Products sell to 9 countries, including Myanmar, Thailand, Brazil, Mexico.





