



Ending Clubfoot Disability: A Global Strategy





© Global Clubfoot Initiative 2017

Table of Contents

| From the Chair of Global Clubfoot Initiative | 3 |
|---|----|
| Executive Summary | |
| Introduction | |
| Problem | 5 |
| Solution | 5 |
| Results | 6 |
| Collective Global Progress | 6 |
| Global Clubfoot Initiative (GCI) | |
| Ending Clubfoot Disability: A Global Strategy Vision | |
| Goal | |
| Objectives (by 2030) | |
| Global Context | 9 |
| Implementation Model | 10 |
| Proven Model for a National Clubfoot Program | |
| Implementation Strategy | 14 |
| Introduction | 14 |
| Target Countries | |
| Implementation Approach | 15 |
| Timeline | 16 |
| Global Scaling | 17 |
| Scaling Globally | |
| Shared Tools, Innovation and Research | 18 |
| Advocacy | 21 |
| Budget | 22 |
| Governance | 24 |
| Oversight and governing values | 24 |
| Risk Assessment | 24 |
| References | 26 |
| Appendix 1: Clubfoot and the Ponseti method | 27 |
| Appendix 2: Global Clubfoot Initiative Overview | |
| Appendix 3: Monitoring and Evaluation | |
| Appendix 4: Identification of Target Countries | |
| Appendix 5: Global Strategy Budget | 32 |

From the Chair of Global Clubfoot Initiative



Around 174,000 children – 1 in every 800 - are born with clubfoot globally every year. Clubfoot is a congenital deformity in which one or both feet are turned in and downward; untreated it leads to life-long disability. Children born in high-income countries receive immediate corrective treatment and the vast majority live a life unaffected by having been born with clubfoot.

However, most children born with clubfoot in Lower and Middle-Income Countries (LMICs) face a different future. For those born today, less than 15% will access treatment. The rest will face a lifetime severely affected by their clubfoot – experiencing ongoing pain, limited mobility, and reduced

opportunities in education, employment and relationships.

This doesn't have to be the case. We do not know how to prevent clubfoot but we do know how to treat it – and it costs less than \$400 a child.

Through developing and supporting national clubfoot programs and strengthening health systems to build clubfoot treatment into mainstream provision, our Global Clubfoot Strategy sets out why and how we will end preventable disability as a result of clubfoot.

Perhaps it is best said by parents and people affected by clubfoot who we regularly hear from. Just a few months before launching this strategy a parent of a child with clubfoot in Indonesia wrote to say:

"Many more populated [countries] desperately need organizations or services providing clubfoot treatment. Patients with clubfoot [need] more information and clinics for clubfoot. This raises concerns for us as parents and communities that have the same case. I hope clubfoot initiative expands its global reach."

We invite others to join us in our vision of a world where every child with clubfoot can walk and run free from disability. By 2030 we want at least 70% of children born with clubfoot in LMICs to access the treatment they need to walk and run free for the rest of their lives.

hinlan

Professor Chris Lavy Chair, Global Clubfoot Initiative (GCI)

Professor of Orthopaedic and Tropical Surgery, University of Oxford and Consultant Orthopaedic Surgeon

Executive Summary

Over 90% of children with clubfoot are born in countries where they have no or limited access to treatment. More than one million children cannot walk properly as a result of untreated clubfoot. Clubfoot is one of the leading causes of physical disability in the world. The good news is that it can be effectively and inexpensively treated with the minimally invasive Ponseti method, the gold-standard treatment for clubfoot that is well suited to low resource environments. The problem of untreated clubfoot is one we can solve.



The Global Clubfoot Initiative (GCI), an umbrella group of Non-Governmental Organizations (NGOs) working on the issue of clubfoot in Low and Middle Income Countries (LMICs), has developed a comprehensive plan to tackle the issue of clubfoot on a global scale. Based on the evidence and learning from a decade of experience, this blueprint proposal involves working with local partners and Ministries of Health to develop and support national clubfoot programs in 105 LMICs over the next 14 years.

The primary objective is to increase coverage of clubfoot treatment from less than 15% to over 70% in target LMICs by 2030. Using a well-tested program model of public-private partnership and cost-sharing, our plan leverages tools and technology to facilitate scaling, and describes how treatment and program quality will be measured and monitored to ensure

continuous improvement in treatment delivery. This way, national programs are developed, program efficiency is maximized and children receive high quality comprehensive clubfoot care.

With a total investment of \$160M it will be possible to treat over 1.2M children, generating \$154B in additional lifetime earnings and creating the capacity for each country to manage clubfoot on an ongoing basis by 2030. By working together, we can create a world where every child born with clubfoot can walk and run free of disability.



Introduction

Problem

Clubfoot (or talipes equinovarus), a congenital birth defect, impacts one in every 800 children born worldwide (1) and causes the feet to turn inward and upward, making it difficult to walk. An estimated 174,000 children are born with clubfoot each year.



Disability from clubfoot has virtually been eradicated in high-income countries as a result of effective treatment. However, 90% of children born with clubfoot approximately 158,000 children per year - live in LMICs (2) where there is limited or no access to proper treatment. Based on survey data in 2015, Global Clubfoot Initiative (GCI) found that approximately 13% of children born with clubfoot in LMICs are currently accessing treatment (2).

As a result, we estimate that at least 80% of children born

each year are not receiving proper treatment. Over one million children currently live with disability caused by untreated, or improperly treated, clubfoot, making clubfoot one of the major causes of physical disability in the world.

For people living with uncorrected clubfoot walking can be painful and extremely difficult. People living with disability in lower income countries are at higher risk of discrimination, physical and sexual abuse, neglect, illiteracy and inequality in almost all aspects of society (3,4). Disability due to clubfoot also presents an economic burden on families and societies due to lost opportunities in education and employment (5).

But it does not have to be this way. Clubfoot is relatively easy and inexpensive to treat effectively. World-class athletes, Steven Gerrard, Mia Hamm, and Kristi Yamaguchi, all reported to have been born with clubfoot, went on to have extraordinary careers thanks to receiving effective treatment at a young age. The problem of untreated clubfoot is one with a clear solution.



Solution

Clubfoot can be treated using a minimally invasive approach: the Ponseti method (see <u>Appendix 1</u> for a full description), is accepted as the gold standard clubfoot treatment and is endorsed by medical associations such as the American Academy of Orthopaedic Surgeons (6,7). Treatment involves serial castings over 5-8-weeks, a minor outpatient surgical procedure (Achilles tendon tenotomy) and a foot abduction brace, worn while sleeping for 4-5 years to maintain the correction and reduce risk of relapse.

The Ponseti method is cost efficient and has been shown to be effective when done correctly in up to 98% of cases (8). Given the relatively simple process the treatment is well suited to low resource settings.

Current evidence demonstrates that treatment is most effective if started in infancy and ideally under the age of 2 years and there is growing evidence that manipulation and casting can also reduce deformity and limit the extent to which surgery is required in older children as well (9). The Ponseti method makes it possible and practical to address the problem of clubfoot cost-effectively on a global scale.



Results

Corrected feet have the same movement, function and appearance as unaffected feet and are pain free. Treatment transforms the life of a child born with clubfoot forever, giving them the opportunity to participate fully in their families and communities, go to school and ultimately secure meaningful employment. In addition to transforming quality of life, we estimate that treatment unleashes \$120,000 in regained earnings over the life of the child (or put another way results in a net present value of \$13K per child treated) - extraordinary return on investment given the global average treatment cost is currently \$331 per child (10, 11).

Collective Global Progress

In the last decade, significant progress has been made in developing national programs to deliver effective Ponseti treatment in LMICs. NGOs, working closely with Ministries of Health, have been increasing access to treatment through partnerships with local healthcare providers to build capacity within existing health structures in LMICs. These programs use public health principles to maximize accessibility and uptake of treatment, laying the groundwork for global scaling. In 2009, these organizations came together to form the Global Clubfoot Initiative.

Global Clubfoot Initiative (GCI)

GCI is a consortium of organizations (<u>Appendix 2</u>) with technical and organizational expertise in clubfoot management using the Ponseti method, and experience in establishing national clubfoot programs in LMICs. GCI aims to be an inclusive platform that:

- provides training, clubfoot management resources and best practices
- creates links and encourages collaboration between organizations to coordinate activities and facilitate scaling
- collects and shares information on clubfoot management.

With the support and encouragement of the governing members, GCI has made the development of a collaborative and coordinated effort to end the disability caused by untreated clubfoot its primary strategic focus going forward.

Surveys conducted by GCI indicate that in 2015 13% of children in LMICs were accessing treatment, up from less than 1% in 2005. In 2015 over 24,000 new children were enrolled for treatment across 54 LMICs and GCI members have now supported the treatment of over 120,000 children since 2005. (Appendix 3).

Cereage Map 9 578 9 57577 9 5757 9 5757 9 5757 9 5757 9 5757 9 5757 9

Map: Coverage in Target Countries as of 2015

Some countries (notably China, Egypt, Nigeria, Pakistan, Thailand) reported that there was additional activity in the country not measured by this survey.

This map, based on self-reported program data, shows coverage in all target countries in 2015. More than 80% of children projected to be born with clubfoot in LMICs were in the 54 countries shown as having a reported coverage level.

With recently developed training curriculum designed specifically for use in low resource environments, availability of low cost brace options, and custom-built mobile-tools for the collection and analysis of patient treatment information to facilitate monitoring and evaluation of treatment and program quality,

there is widespread agreement that with this implementation model and strategy we can end the disability caused by clubfoot by 2030.

GCI is open to membership by any organization supporting the treatment of children with clubfoot and we welcome collaboration towards the objectives of this strategy.

Ending Clubfoot Disability: A Global Strategy

While great progress has been made over the last decade, it is time to scale this up globally. We believe a bold new initiative is needed to ensure that every child born with clubfoot has the opportunity to access effective treatment to prevent disability.



This Global Strategy aims not just to treat clubfoot but to put structures in place to ensure treatment in the future. This strategy will strengthen health systems and work in conjunction with and support other global health agendas. We strongly believe that in the future, the foundations built through this strategy will be used to address other childhood conditions causing disability.

This plan builds on a proven capacity-building model, public-private partnerships, extensive

analysis of data to drive decision making, collaboration across national and international NGOs and stakeholders and the use of technology to reduce cost and improve outcomes.

Vision

A world where every child born with clubfoot can walk and run free from disability

Goal

By 2030, all children born with clubfoot will be able to access high quality and effective treatment

Objectives (by 2030)

- 100% of target LMICs have a national clubfoot program delivering comprehensive clubfoot care
- At least 70% of children born with clubfoot access Ponseti treatment in target LMICs
- 100% of national clubfoot programs meet at least 70% of the global clubfoot quality metrics
- 100% of national clubfoot programs meet at least 70% of the global clubfoot *program sustainability* metrics

The graph below illustrates how the number of children starting treatment each year will need to increase in order for our objectives to be fulfilled by 2030. If progress continues at the current pace,



only 36,000 children under age 1 will be treated annually by 2030; with this global strategy, we aim to more than triple this number by 2030.

Global Context

This strategy to end disability from clubfoot aligns well with other global health priorities and goals, including:

- UN Convention on the Rights of Persons with Disabilities to 'enable maximum ability, independence and participation'
- UN Sustainable Development Goals numbers 1,3,4,8, 10, and 17
- World Health Organization Rehabilitation 2030 Call to Action seeking to 'strengthen health system delivery of rehabilitation services'
- The Lancet Commission on Global Surgery 2030 calling for *"universal access to safe, affordable surgical care"*



Implementation Model

Proven Model for a National Clubfoot Program

Our goal is that each LMIC should have a national clubfoot program. Among the experienced organizations working in this field, there is broad consensus around the critical components needed to deliver quality care as well as the best way to implement a national program. This model, detailed below, is what we aim to establish in each target LMIC as part of Ending Clubfoot Disability: A Global Strategy.

In order to deliver comprehensive clubfoot care and gain successful outcomes for children born with clubfoot, the national program needs to provide each of the following steps for every child:

| 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 |

In addition to providing quality comprehensive care at the clinic level, a strong national program incorporates the following:

Providing central coordination

A centrally coordinated approach puts planned and effective services in place including training, advocacy, sensitization, monitoring and evaluation, procurement, and distribution. A local Program Coordinator coordinates training, manages purchasing and inventory levels of supplies and braces, establishes identification and referral systems, uses clinic-level quantitative and qualitative data and reports to identify and trouble shoot areas of the program that are under-performing. The coordinator works to advocate for policy change and increased Ministry of Health or equivalent Ministry involvement (this will be abbreviated to MoH hereafter). Often a Medical Director, usually a leading orthopaedic surgeon, is appointed to provide clinical oversight and to lobby for policy change as needed. In especially large countries such as India these activities are organized on a regional and state level.

Achieving national coverage

Multiple concurrent strategies are utilized to build up coverage¹ within a country, including raising awareness of clubfoot, increasing knowledge of treatment availability and efficacy, establishing referral pathways and establishing a network of clinics to maximize accessibility.

A Program Coordinator develops and manages the program alongside the implementing partners (in most cases, a public private partnership). Building a network of clinics is typically done by initially establishing clubfoot clinics within the orthopedic or rehabilitation departments of public hospitals in the major cities. At the start, clinics often function one day a week which allows for efficiency and enables families to meet and support each other. As identification and referral processes are established and awareness that clubfoot is a treatable condition increases, treatment capacity is added by opening clinics in new locations to facilitate access and by adding clinic days in areas of high demand.

Planning of clinic distribution aims to balance the need for there to be sufficient cases so that clinicians maintain proficiency in delivering treatment at the same time as ensuring that travel time and costs for patients are optimized. It is highly recommended that each clinic enrolls a minimum of 2 new children each month (24 annually).

Scaling up coverage through a national programme: Bangladesh

Bangladesh, a low-income country with approximately 4000 expected cases of clubfoot per year, initiated a national programme for clubfoot with the support of Walk for Life in 2009. In 2009, the MoH had no budget allocation for treating clubfoot, and orthopaedic surgeons reported long waiting lists full of children with untreated clubfoot. Since then, 19,500 children have received Ponseti treatment and coverage has been scaled up to more than 70% of expected cases. 95% of children are enrolled in treatment under the age of 1 year and surgeons in the country report that cases of older children needing surgery for clubfoot are rare (14-16).

The strategies that have contributed to these achievements include:

- Working in partnership with Ministry of Health from the programme's inauguration by the Minister for Health in 2009
- Providing clinic services within government hospitals with oversight from MoHemployed surgeons and support from Walk for Life for clinic staff, treatment supplies and brace manufacturing and distribution
- Awareness building through 13,000 community health clinics, media and parent advocates
- Overcoming barriers to access by locating clinics so that very few families have to travel more than 60 km for treatment

The success of the program has been recognized by the Bangladesh clubfoot program winning the "BMJ Healthcare Award South Asia 2016 - Excellence in Delivery of Primary Care" in 2016.

¹ Coverage is defined as 'the percentage of children projected to be born with clubfoot in any given year who start Ponseti treatment in the same year.' Rates are calculated using World Bank population data, a global clubfoot birth prevalence rate of 1.24/1000 births, and program data on the numbers of children starting treatment. (12,13)

Supporting quality clubfoot care

A national clubfoot program supports clinics to deliver quality care, through ensuring appropriate human resources are in place, supporting training and development, availability of supplies including clubfoot braces, patient adherence and follow up and monitoring and evaluation (M&E). The quality metrics for a clubfoot program are set out in <u>Appendix 3</u>.

Human resources: Each clinic should have a minimum of two trained Ponseti practitioners and the routine availability to one clinician who will perform the tenotomy. While it varies, in many countries rehabilitation professionals provide clubfoot treatment with oversight from an orthopaedic surgeon. The surgeon will also perform tenotomies and may provide surgery for the complex cases that cannot be completely corrected with Ponseti treatment. In addition, clinics should have parent educators or clinic assistants who can help educate the families and provide critical follow-up support throughout

treatment to help families adhere to treatment, especially during the more challenging bracing or maintenance phase of the Ponseti method when there is a higher risk of non-adherence. These educators / assistants may also provide support with administrative tasks or data entry.

Training: Clinic staff need access to training, development, and on-going mentoring with technical and management support. Training in administration, reporting, data collection and analysis, and financial accountability are also important facets of any national program. In the longer term, training in the

A typical clubfoot clinic

One clubfoot clinic is typically required to provide treatment to a catchment area of 1-2 million people. A single clinic, open 1 day per week, treats between 25-50 new patients each year and provides follow up care for children who are in bracing.

A typical clubfoot network

A clubfoot clinic network can grow to 10+ clinics to provide national coverage. The number of clinics needed is determined by the population size, birth rate, and ease of access to clinic locations.

manufacturing of suitable low cost braces such as the Steenbeek brace creates jobs locally and supports a sustainable method of treatment.

Availability of supplies (including braces): Over time, it is anticipated that capacity for procurement of sufficient supplies and maintaining supply chains will be embedded into national health planning; this will support economies of scale. Braces are a critical component of quality care to ensure the clubfoot



deformity does not recur following initial correction. There are now several affordable bracing options being utilized by GCI members in LMICs (<u>see Pg 20</u>).

Monitoring and Evaluation: Members of GCI have agreed upon a set of metrics to measure quality and sustainability at a clinic and national clubfoot program level (<u>Appendix 3</u>). Individual clinics must be able to record and analyse patient data to support service improvement and patient care. The national program aggregates clinic level data to review performance, enable quality assurance, and support continuous quality improvement. These include treatment quality measures (such as tenotomy rates, number of casts) as well as program indicators (such as % of children enrolled under 2 years old and % dropping out during treatment). In addition to these, work is underway to develop a Patient Reported Outcome Measure (PROM) for clubfoot to measure the impact of treatment on a child's quality of life; this is likely to cover areas such as % of children achieving plantigrade foot, ability to wear a normal shoe, parent satisfaction, and absence of pain.

GCI has collected data from clubfoot treatment providers in LMICs since 2007. Over time, the number and the quality of data submitted has improved, however data collection is still a significant challenge. National clubfoot programs should support the coordination of clubfoot data and the development of better tools for data collection and analysis.



Planning for Sustainability

National programs play a key role in ensuring that treatment for clubfoot is embedded within national health systems, and that structures are put in place to ensure sustainability of services in the future – this is a core objective of the Global Strategy.

Currently, national programs are commonly public-private partnerships between the MoH, local and international NGOs and implementation partners, as well as parent groups. Most programs have been created in public hospitals with the local government or MoH contributing healthcare providers' time, clinic space and occasional some of the treatment supplies (in many cases covering 50% of the cost burden of clubfoot care). The MoH and local and international NGOs often collaborate to provide support for components of the program that the government may not yet have capacity to provide, for example, this may include support for braces, coordination, administration, quality management, logistics, training of health workers, awareness raising, and patient and family support.

Support endorsed through the Global Strategy allows time and resource for the national clubfoot program to become embedded within national health and social care structures. As a program matures, partnerships with the MoH will be essential for the success of this strategy. The expectation is that the MoH will take on the core delivery of the clubfoot program; it is anticipated that as local government

capacity increases over time by strengthening the systems needed to provide each component of treatment and the national clubfoot program, the role of NGOs will decrease.

A public private partnership for clubfoot: India

Since its inception, the CURE International India Trust (CIIT) clubfoot programme's aim has been to reach the poorest of the poor with quality Ponseti treatment. They work primarily with government funded and managed institutions where the general public has free access to care. The table below shows the public and private roles and responsibilities working together towards the shared vision of India free from clubfoot disability. This illustrates how the government and an NGO share cost to reduce dependence on outside support and to increase the likelihood of full integration in to the public health system:

State Government

- Depute dedicated doctors for every clinic to provide quality Ponseti treatment
- Ensure availability of quality treatment materials (casting and tenotomy supplies)
- Provide clinic space for treatment, parent education, brace and record storage
- Integrate identification and referral of cases into existing community health awareness and screening team efforts

CURE India

- Appoint program managers and coordinators to work with the respective state government.
- Distribute foot abduction brace for every child free of cost
- Establish and maintain 24X7 state level clubfoot helplines
- Appoint counselors to educate parents, maintain medical records and ensure adherence and follow up.
- Maintain medical records for every child

The roll out of this partnership model has resulted in Memorandums of Understanding being signed between 28 of 29 state governments and CURE International India Trust, and more than 35,000 children enrolled in treatment to date (17).

More detailed information on how we will measure progress towards sustainability is included in <u>Appendix 3.</u> The indicators we have chosen to measure sustainability are those that reflect that the structures are being put in place to ensure sustainability of the national programme in the longer term.

Implementation Strategy

Introduction

The member organizations of GCI have together laid out an approach whereby national programs for clubfoot can be built and supported in the countries of highest need. This will require the collaboration of multiple stakeholders, including governments, disabled persons' organizations, local and international NGOs, professional bodies and parent groups. We estimate that this will require an investment of

\$159M (an average of \$11M/year over 14 years) of support in addition to what governments are currently contributing, plus an increase of \$36M in local government spending over 14 years.

Target Countries

Over 90% of children with clubfoot are born in 105 upper-middle, lower-middle and low income countries, as defined by the World Bank. These 105 'target countries' are those where the need is greatest and where the most number of children can be reached, having more than 50 cases of clubfoot per year. For more details on the selection process and country list, see <u>Appendix 4</u>



Implementation Approach

The Global Strategy will deliver two different approaches to build strong national programs based on the World Bank's income classification: Approach 1 in upper middle income countries and Approach 2 for lower middle and low income countries (5).

| Upper middle income countries (37 Priority Countries, 26% of Cases) | Lower middle income & low income countries (68 Priority Countries, 64% of Cases) | |
|---|--|--|
| Goal: Establish national "pilots" that demonstrate effective clubfoot programs | Goal: Work with governments to establish initial collaborative funding of national programs | |
| Plan: Build programs that treat 15% of annual | Plan: Build programs that treat 70% of annual | |
| cases by Year 5 | cases by Year 5 | |
| Exit: After 5 years, MoH takes over 90% of | Exit: After 7 years, MoH gradually takes on | |
| program costs and increases coverage to 70% | some costs; NGO support will decrease but | |
| of annual cases | will not completely end. | |

Countries with higher levels of wealth have the capacity to support their own clubfoot program. The Global Strategy proposes developing and supporting a pilot program to demonstrate proof of concept over 5-years. The 5-year period will allow time to develop a cadre of trained Ponseti providers, build an

evidence base that can be used to demonstrate impact and make the case for policy change, and advocate for MoH adoption (see table above).

Countries with lower levels of wealth need longer periods of assistance in funding clubfoot programs. In these countries, we propose building capacity across the country to reach 70% of expected cases after 5 years. As the program becomes embedded in the public health system, the MoH (or in some cases, beneficiaries, where it is affordable for them to pay for some



treatment supplies) will gradually adopt more of the costs to the point where it will be possible to maintain the program with minimal external support (approx. \$3M/year globally). In countries with weaker health systems, ongoing external support beyond the lifetime of the Global Strategy may be required.

(These two approaches were developed with input from public health experts, orthopedic surgeons, health economists and epidimiologists, to estimate the total cost to solve the global problem of untreated clubfoot. While they provide a useful way to understand the issue at a macro level, a detailed plan will need to be developed for each country by local stakeholders to determine specifically what external support is needed and by whom, and what timeframe is realistic to build a full national program).

Timeline

To reach the goal of 70% treatment coverage in LMICs by 2030, program capacity must be increased until approximately 109,000 children are treated each year (5). In the first 5 years, the focus will be on increasing the number of implementing countries (approximately 10 each year), until all 'target countries' are reached. The final nine years focus on increasing coverage within all 105 countries. This plan increases global coverage until 90%+ children have access to proper treatment.



Global Scaling

Scaling Globally

In order to effectively and sustainably reach global coverage, the 105 target countries will be prioritized using the following criteria:

- Number of children with clubfoot not accessing treatment (with priority to greater numbers)
- Income level of the country (with lower income given higher priority)
- Level of engagement from regional health stakeholders
- Presence of a strong local partner
- Political stability of that country
- Availability of funding for that country



This process will be adaptive and iterative to ensure that objectives are met and progress is evaluated continuously. The list of target countries and progress towards global scale up will be reviewed annually by GCI.

The process of roll out within countries will vary depending on current levels of coverage and whether there is already a national programme in place. Some countries currently do not have any clubfoot treatment services in place, or very low levels of coverage or engagement. Others have the framework of a national programme well established, but need to make progress towards increasing coverage, quality or sustainability.

Global scale up generally consists of the following steps occurring in each country:

- Funding secured
- Active interest or engagement from national stakeholders
- An 'implementing partner' (typically a NGO with a national or regional footprint with experience in delivering health, rehabilitation or disability services) identified and available
- If needed, a period of 'country priming' to identify potential program partners and to build relationships with local government, local partners and an implementing partner; country priming may include initiating a small pilot Ponseti clinic in a major treatment center
- Joint planning and action by the country partners for national program implementation
- Advocacy, awareness raising and improved identification and referral increase demand for Ponseti treatment services
- As demand increases, an increase in provision of Ponseti treatment services coordinated and established via the national program coordinator, including developing brace manufacturing or reliable supply chains for external provision of braces
- Provision for sustainability and quality built in to national planning from the outset

'Ground up' national programme building: Benin

In 2012, a group of health professionals in Cotonou, Benin, approached CURE Clubfoot requesting to be trained in the Ponseti method. Training was facilitated in neighbouring Togo, and a clinic initiated. Over time, small amounts of support via the Togo Clubfoot Programme were added for training, logistics, procurement, sensitisation and parent counselling.

In 2017, it became obvious that the clinic was running very well and there was a solid foundation from which to consider expansion. The lead clinic physiotherapist became a change champion and led on engagement with the Ministry of Health and other potential partners, successfully advocating for both the Ponseti method and a national program by demonstrating the impact of the first clinic. Scale up, with collaboration from the MOH and other stakeholders is now underway.

Key success factors:

- Organic development driven from within the country with external support provided as need identified and support requested
- Starting with a single clinic to: establish the credibility and effectiveness of the Ponseti method; build into a centre of excellence to use as an example to the MOH and for future training; assess the specific areas of need for support
- A local change champion to advocate with MoH and others has helped to: convince other stakeholders of the benefit and need; provide real, local examples of the disability and treatment and identify key stakeholders to involve in the next stage
- Involving a neighbouring country in the early stages for support, problem solving and mentoring.

In 2016, Mercy Ships added additional support through mentoring clinical staff at the clinic, sensitisation, and working to raise the profile of the clinic's work with clubfoot.

Shared Tools, Innovation and Research

Even where Ponseti treatment is available, barriers to scaling include availability of trained providers and quality braces, treatment compliance, data collection and analysis, support for identification and referral of cases from rural areas and communication with families. GCI and its members have invested in innovative tools to address some of these systemic hurdles thanks to support of several generous donors including DFID, Google.org, Oak Foundation, USAID and Vitol Foundation.

Training and Education

To enhance capacity and training opportunities, the Africa Clubfoot Training (ACT) curriculum is a standardized curriculum for basic and advanced clubfoot treatment training with modules designed specifically for low resource settings. Developed by CURE Clubfoot, Global Clubfoot Initiative and the University of Oxford with support from DFID, ACT also includes a Train the Trainers component designed to build capacity for countries to meet their own training needs. These modules have incorporated the

latest findings in interactive training concepts, coupling the theory behind the Ponseti method with practical experience using rubber foot models and children affected with clubfoot. ACT has been piloted extensively in Africa and the material is now being adapted and translated for rollout to other regions.

Phase two will involve development of mobile-based versions enabling trainees to master more of the theory prior to the course, freeing more time for hands on experience, and providing them with a referral tool once they return to their clinics. This material will also be adapted to train community health workers and paramedical professionals to identify and refer children with clubfoot, as well as to provide support to parents and caregivers.

In addition to ACT, individual NGOs have a range of resources to train other healthcare practitioners and other Community Health Workers and Community Based Rehabilitation workers.

Plans and funding are in place to support mentorship of medical practitioners via low bandwidth video conferencing and for front line health workers to automatically log new cases of clubfoot for follow up.

Building capacity and rolling out training: Tanzania

In Tanzania, GCI member Miraclefeet in partnership with Tanzania Clubfoot Care Organisation (TCCO) will scale the ACT training model to produce an adequate number of quality trainers over the next two years. One to two experienced clinicians from each of the five coordination zones in the country will complete the 'Train the Trainers' ACT course, enabling them to provide new clinicians with basic and advanced clubfoot treatment training.

TCCO will also integrate ACT methodology in their 2-week fellowship (immersion) at zone training centers, providing fellows with opportunity for practical training under supervision. These zone trainers will be responsible for support supervision of clinics in their zones and for mentoring providers.

Through cooperation with the physiotherapist school in Moshi and Zanzibar, physiotherapy students will receive 2 days training in the Ponseti method using the ACT methodology to further ensure sustainability.

This illustrates how aspects of the program, in this case training, become embedded in local institutions, reducing the overall cost of delivering high quality care. The local government incur minimal costs when adding material to an existing physiotherapy training course.

Data Collection and Reporting



A mobile-phone based data collection tool, CAST, has been created by Dimagi, a leading m-health developer, designed for use in low bandwidth environments to support data collection and live tracking at a patient and clinic level, and facilitate national data aggregation. This is currently being piloted in two countries and will be made available through GCI to any program to support streamlined and standardized data collection at the clinic level. It provides an electronic medical record as well as real time reports, saving clinics considerable time and providing critical data to allow clinics to actively manage patients and clinic quality.

Communication with Families

An SMS system has been developed to deliver text messages to parents' cell phones, including appointment reminders. This system is being integrated into CAST, the new data collection tool, to enable low-cost and personalized communication with family members based on phase of treatment. Eventually parent-to-parent communication is envisioned with the goal of creating the kinds of support groups that have facilitated adherence in high income countries.

Low Cost Braces and Sensor Technology

There are now more low-cost braces available costing less than \$20 thanks to several human-centered design projects, providing functionality that mirrors the expensive braces (retail at \$360-1,000) used in high income countries. Testing is underway to determine whether the addition of sensor technology, potentially integrated into CAST, would further support brace adherence.

Training programs have been developed for local staff to build quality Steenbeek Foot Abduction Braces; these have been run in Uganda, Rwanda and India. There are a number of brace options currently utilized by GCI members:

- Steenbeek brace locally produced, developed by those involved with Uganda Sustainable Clubfoot Program
- MiracleFeet brace developed by MiracleFeet, Stanford, Clarks Shoes, and Suncast
- Iowa brace developed by the University of Iowa



Tools under development or planned for the future

A number of additional tools and resources are needed to support implementation of the Global Strategy. These include: guidance to support national clubfoot programs in their procurement of supplies and braces; additions to the ACT curriculum (as well as translations and adapting to non-African contexts) such as an Advanced Surgical Clubfoot Treatment Provider Course; a Counsellor training package; Clinic selection tools; Quality Standards; an M&E Framework and support to embed clubfoot in the WHO country-level Rehabilitation Services mapping tool.

Ongoing Research

In order to ensure the national programs are continuing to incorporate the latest developments in clubfoot treatment, technology, and management, GCI will continue to collate and disseminate best practice based on the latest research. In order to inform the Global Strategy, further research is needed to continuously improve treatment outcomes and program delivery. The following topics are of particular interest:

- Clubfoot in the older child and adapting techniques to patient age
- Short, medium and long term patient reported outcomes
- Barriers and enablers to adherence with treatment, cost-benefit analysis of solutions to improve adherence

Advocacy

International and national advocacy is needed to increase political, financial, and technical commitments towards establishing and developing national clubfoot programs.

At a national level, GCI partners will work in collaboration with local stakeholders, parent organizations, health professionals and disabled persons' organizations to promote MoH engagement and support for national clubfoot programs. This will support the sustainability, so that in the long-term clubfoot treatment is embedded within national health provision and resourced accordingly and clubfoot training is incorporated in national medical training curricula.

Internationally, GCI partners will work in collaboration with others to advocate for clubfoot, the Ponseti treatment and clubfoot program management to be embedded in relevant global guidance, tools and resources, including on any relevant web pages. Clubfoot should be a part of any global public health initiative; it may straddle a number of thematic areas including disability, rehabilitation, global surgery,



birth defects and/or child health.

GCI partners will work to promote awareness of clubfoot and the Ponseti treatment, getting it on the agenda at relevant international conferences and included in global plans – for example, in the WHO Rehabilitation 2030 strategies or the Lancet Global Surgery plans.

National and international stakeholders are encouraged to sign up to support the Global Clubfoot Strategy and pledge their support to national and global implementation.

Budget

In order to estimate the cost of reaching 70% of children born with clubfoot, a costing model was developed using real-world data from 7 NGOs currently supporting clubfoot treatment in 14 countries.

Cost data were analyzed to determine global average 'fixed' and 'variable' costs. Fixed costs include costs associated with training and mentoring, outreach and awareness, patient education and follow-up, program coordination, and monitoring and evaluation. (See <u>Appendix 5</u> for full breakdown and an explanation for how fixed costs are adjusted for larger national programs).

Variable costs include casting and tenotomy supplies, foot abduction braces, transport subsidies and/or home visits. An additional 30% is added to account for the cost of managing the program management by the supporting NGOs, such as programme management staff, travel and M&E costs.

Based on this model, we estimate the cost (external to current Ministry of Health provision) of delivering the Global Strategy to be \$193 million over the next 14 years. \$159M will be provided through supporting NGOS. \$34M is assumed to be covered by local governments as they actively absorb cost over time (see <u>Appendix 5</u> for more information). See the text box on page 14 with details of the national clubfoot program in India for an example of where the government is taking on provision of various elements of program and treatment provision. Currently, the split between government and NGO provision varies widely between countries – typically, as a minimum the Ministry of Health provides clinic space and staffing, and in many cases treatment supplies and support for other program elements.



The cost per child will steadily decrease over time from an

average of \$317 in 2017 to \$82/child in 2030 as costs decline as many elements of the program become integrated into the public health system. For example, training costs decline as Ponseti training is delivered by medical and physical therapy programs, identification and referral systems become embedded in government-run birth defect screening and newborn and maternal health programs, and the government ensures basic casting supplies are readily available. Funding reaches its peak in 2022 with annual needs of approximately \$16M from outside sources. It declines to \$3M/year by 2030.

The average annual investment to achieve this plan is \$11M, a relatively small investment to solve a major public health problem. \$3M/year would be required to maintain these programs on an ongoing basis globally. This covers the cost of a local administrator in each country to coordinate and monitor services provided by the government as part of their public health system.

The projected budget assumes that over this period of time the national programs treat 1.2M children at an average cost of \$161 over the time period. Annual capacity reaches 109,000 new children enrolled

each year by 2030 representing 70% of all cases in LMICs. We assume that 20% of the cases in each country are treated within the private system and 100% of cases in very high income countries (US, Europe, Japan etc.) are treated, which brings global coverage to 91% by 2030.

| Year | Cases Treated | Percent Coverage in Target LMICs by NGOs/Government | NGO Costs (USD) | Government Costs (USD) | Total Funds Required (USD) | Cost Per Child |
|-------|------------------|---|--------------------|---------------------------|----------------------------------|-------------------|
| 2017 | 26 K | 16% | \$8.2 M | \$0 | \$8.2 M | \$319 |
| 2018 | 44 K | 28% | \$12.3 M | \$0 | \$12.3 M | \$280 |
| 2019 | 63 K | 40% | \$16.4 M | \$0 | \$16.4 M | \$261 |
| 2020 | 68 K | 43% | \$18.1 M | \$0 | \$18.1 M | \$266 |
| 2021 | 77 K | 49% | \$16.8 M | \$1.4 M | \$18.2 M | \$238 |
| 2022 | 87 K | 55% | \$16.1 M | \$2.6 M | \$18.7 M | \$216 |
| 2023 | 96 K | 62% | \$13.9 M | \$3.5 M | \$17.4 M | \$181 |
| 2024 | 100 K | 64% | \$12.1 M | \$3.6 M | \$15.7 M | \$156 |
| 2025 | 104 K | 67% | \$10.6 M | \$3.2 M | \$13.8 M | \$133 |
| 2026 | 105 K | 67% | \$9.7 M | \$3.2 M | \$12.8 M | \$123 |
| 2027 | 106 K | 68% | \$8.0 M | \$3.7 M | \$11.7 M | \$110 |
| 2028 | 108 K | 69% | \$7.0 M | \$3.8 M | \$10.8 M | \$100 |
| 2029 | 109 K | 70% | \$6.4 M | \$3.8 M | \$10.2 M | \$94 |
| 2030 | 109 K | 70% | \$3.1 M | \$5.8 M | \$8.9 M | \$82 |
| Total | 1.2 M | | \$159 M | \$34 M | \$193 M | \$161 avg. |

The following table summarizes the funds required to deliver the strategy 2017-2030:



Governance

Oversight and governing values

GCI will be accountable and responsible for governing the Global Clubfoot Strategy and will coordinate an independent board to govern its strategic direction, provide strategic oversight of delivery and, as appropriate, be accountable for the management of any significant Global Strategy collective funds.

GCI is committed to ensuring that comprehensive clubfoot care is available in LMICs through supporting sustainable national clubfoot programs. The design and approach of the Global Clubfoot Strategy will work towards a sustainable model through ensuring the following values are upheld by all implementing partners:

- Involvement of local representatives in decision making and design of local programs;
- Support, buy-in and endorsement is secured from local community and stakeholders;
- A commitment to measuring program and patient outcomes, and continuous quality improvement based on these;
- Economic and financial viability are key factors in decision-making;
- Investment in developing local skills necessary to implement and expand services;
- Robust plans are made for maintaining the clubfoot program in the long term, including ensuring clubfoot treatment becomes a priority for local and/or national public health decision-makers.

To measure the impact of the Global Clubfoot Strategy as a whole over time, and be transparent and fully accountable for stewarding funders' resources appropriately, the indicators below will be measured to review strategy effectiveness. This is in addition to the national clubfoot program quality and sustainability indicators (<u>Appendix 3</u>) GCI members have agreed to monitor and evaluate national activity, and include:

- Number of new or expanded geographic areas where GCI partners work (yearly)
- Number of beneficiaries served by Global Clubfoot Strategy projects
- Number of national programs funded, and numbers of potential beneficiaries within these in five, ten and fifteen years.
- Number of global or national advisory or decision-making bodies that make policy or technical recommendations (strategies, guidelines, resources) that improve widespread access to comprehensive clubfoot care
- Number and type of projects rigorously measuring changes in clubfoot health impact, use, and coverage.

Risk Assessment

Coordinating a global strategy among multiple global stakeholders is a significant challenge that GCI is prepared to address. In addition, there are a host of other risks in launching such a bold strategy. Below are some of the identified risks and proposed solutions:

Governmental adoption – Program success is contingent upon adoption of programming by in-country governmental entities. Lack of resources, competing priorities, and political unrest can impact progress in the countries.

- Experience with previous governmental partnerships and large networks will allow us to navigate these barriers.
- A priority will be establishing WHO support, building on established government relationships, and developing relationships brokered through international champions.
- The Global Strategy Governing Board will annually review progress against the strategy and revise as necessary.

Resistance to the Ponseti method – Some providers are skeptical of the Ponseti method, some continue to use surgery as the primary method for correction and some lack experience in Ponseti method.

- Integration of the Ponseti method in medical secondary education and having experienced Ponseti providers conduct training(s) with their peers to improve awareness.
- Influential bodies (e.g. WHO, professional bodies) endorse the Ponseti technique.
- Training, communication and tools dissemination of ACT, development of mACT, and providing free education to those in cost prohibitive environments.

Limited data collection – It may be difficult to accurately monitor progress against the Global Strategy if data collection processes are not well developed.

- Tools and technology have been developed (e.g. CAST) to support improvements in data collection.
- Resources to support national clubfoot programs will include data collection and staff training will emphasize its importance.

Low bandwidth and computer literacy – Some regions may have trouble with making use of useful technology due to lower bandwidth and technological literacy.

- All of our tools can be utilized offline.
- Piloted, user-friendly tools, coupled with training, will increase capacity for providers.

- 1. Smythe, T, Kuper, H, Macleod, D, Foster, A and Lavy, C (2017) Birth prevalence of congenital talipes equinovarus in low- and middle-income countries: a systematic review and meta-analysis. Trop Med Int Health, 22: 269–285. Doi:10.1111/tmi.12833
- 2. Global Clubfoot Initiative (2009, 2011, 2013, 2015(unpublished)) Global Data Survey, accessed online at: http://globalclubfoot.com/global-information/ May 2017
- 3. UNICEF (May 2013) Children & Young People with Disabilities Fact Sheet, accessed online at: https://www.unicef.org/disabilities/files/Factsheet A5 Web NEW.pdf May 2017
- Save the Children (2011) Out from the Shadows, accessed online at: <u>http://www.savethechildren.org.uk/resources/online-library/out-shadows-sexual-violence-against-children-disabilities May 2017</u>
- International Centre for Evidence in Disability (2013) The Economic Costs of Exclusion and Gains of Inclusion of People with Disabilities, accessed online at: <u>http://disabilitycentre.lshtm.ac.uk/new-report-economic-costs-exclusion-gains-inclusionpeople-disabilities/</u> May 2017
- Church C, Coplan J, Poljak D, Thabet A, Kowtharapu D, Lennon N, Marchesi S, Henley J, Starr R, Mason D, Belthur M, Herzenberg J, Miller F (2012) A comprehensive outcome comparison of surgical and Ponseti clubfoot treatments with reference to pediatric norms. Journal of Children's Orthopaedics 6: 51-59
- Lykissas M, Crawford A, Eismann E, Tamai J (2013) Ponseti method compared with soft-tissue release for the management of clubfoot: A meta-analysis study. World Journal of Orthopedics 4 (3): 144-53
- 8. Morcuende J, Dolan L, Dietz F and Ponseti I (2004) Radical reduction in the rate of extensive corrective surgery for clubfoot using the Ponseti method. Pediatrics 113: 376-380
- Ayana B, Klungsoyr P (2014) Good results after Ponseti treatment for neglected congenital clubfoot in Ethiopia: A prospective study of 22 children (32 feet) from 2 to 10 years of age. Acta Orthopaedica 85 (6): 641-645
- 10. Miraclefeet (2017) MiracleFeet Clubfoot Cost Model (unpublished)
- 11. Miraclefeet (2017) MiracleFeet Net Present Value Model (unpublished)
- 12. World Bank (2016): Population and Birth Rate projections through 2030, accessed online at http://data.worldbank.org/data-catalog/population-projection-tables September 2016
- 13. World Bank (2017) Country classifications, accessed online at: <u>https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups</u> March 2017
- 14. Evans A, Chowdhury M, Kabir M, Rahman F (2016) Walk for life the National Clubfoot Project of Bangladesh: the four-year outcomes of 150 congenital clubfoot cases following Ponseti method. Journal of Foot and Ankle Research 9:42
- 15. Ford-Powell V, Barker S, Khan M, Evans A, Dietz F (2013) The Bangladesh clubfoot project: the first 5000 feet. Journal of Pediatric Orthopaedics 33:e40–4.
- 16. Evans A, Perveen R, Ford-Powell V, Barker S (2014) The Bangla clubfoot tool: a repeatability study. Journal of Foot Ankle Research 7:27
- 17. George, S (2016) Clubfoot Simplified. Dispelling Myths and Misunderstanding Around Clubfoot and its Treatment. Notion Press

Appendix 1: Clubfoot and the Ponseti method



The goal of clubfoot treatment is to provide long term correction of the deformity resulting in a foot that is fully functional and pain-free.

The Ponseti method is a low cost, effective treatment consisting of casting and bracing. The simplicity of this method has made it possible to treat clubfoot in the lowest resource settings. Initially developed in the 1940's by Dr. Ignacio Ponseti, a 30-year evaluation has shown long-term positive patient outcomes. The Ponseti method has grown in popularity and is now accepted as the "gold standard" for clubfoot treatment.

Prior to the development of the Ponseti method, clubfoot treatment generally consisted of strapping, casting and invasive surgical procedures. Outcomes of these techniques were poor and involved long treatment times. Incomplete corrections of the clubfoot

deformity were common, and long-term results showed high levels of continued pain and disability.

The Ponseti method of treatment consists of 5-8 weeks of serial manipulations of the feet and immobilization in plaster casts, an Achilles tendon tenotomy (which is commonly performed as an outpatient procedure under local anaesthetic) and sleep-time bracing of the feet until 5 years of age. Scientific studies have shown the Ponseti method to be effective in up to 98% of cases, resulting in a 'normal-looking' foot not requiring adaptive footwear and with comparable function to unaffected individuals.

The Ponseti method is completed in two phases, both of which are essential to achieving correction of the foot:

- Treatment phase: Achieve correction of deformity (manipulation, casting, tenotomy).
- Maintenance phase: Maintain correction (using Foot Abduction Braces)



Overview of GCI

Global Clubfoot Initiative (GCI) is an umbrella organization for organizations working with children with clubfoot in LMICs. Through advocacy, education and collaboration GCI works towards the goal it shares with its partners: that every child born with clubfoot should receive the treatment they need to live a life free from disability.

GCI partners with all of the major organizations providing services for children with clubfoot in LMICs who between them enroll more than 23,000 children for Ponseti treatment each year. Collectively these organizations have a vast wealth of knowledge and experience in setting up and running national clubfoot programs in some of the most challenging environments in Africa, Asia and Latin America.

<u>Governing Partners</u>: CBM International; CURE; Feetfirst Worldwide; International Committee of the Red Cross (ICRC); Miraclefeet; Mobility Outreach International; STEPS UK and Walk for Life.

<u>Associate Partners:</u> ALTSO; The International Centre for Evidence in Disability, London School of Hygiene & Tropical Medicine; Aide Medicale et Developpement; Anthrologica; Beit Cure Hospital Malawi; Cameroon Clubfoot Care Project; Clubfoot Correction Awareness Initiative; Farrukh Foundation; Handicap International; IMPACT Foundation; Italian Group for the Protection and Promotion of the Ponseti Method; Mercy Ships; On His Path; SIGN; STEPS South Africa; Suresteps Africa; Talipes Together; World Orthopaedic Concern; Zero Clubfoot and Zimbabwe Sustainable Clubfoot Program.

GCI's board of trustees and medical advisory board includes many of the world's leading experts in the Ponseti technique and its application in low-income countries. Many of these individuals have dedicated significant portions of their careers to pioneering and promoting the Ponseti method and have experience in working with Ministries of Health to establish national clubfoot programs, treating clubfoot clinically, training health workers in clubfoot management and advocacy for children with clubfoot. A full list of GCI medical advisors can be found on the <u>GCI website</u>.

Experience and history of clubfoot treatment by GCI members

Over the past 15 years the importance of addressing clubfoot in LMICs has been increasingly recognized and coordinated programs that provide services on a national level for children with clubfoot have been established in many countries.

In 1999, the Uganda Sustainable Clubfoot Care Project was started as a partnership between MoH, academic institutions and national and international NGOs – the first of its kind. In 2007 three NGOs collaborated on a ten-country project, to support clubfoot treatment by establishing and strengthening national clubfoot programs and training of health workers in the Ponseti technique. This successful project saw over 7000 children enrolled for treatment over 2 years.

In 2009, following the ten-country project, a collaboration of partner organizations formed the Global Clubfoot Initiative. Since then, Global Clubfoot Initiative has been an inclusive platform for organizations of all types and sizes to collaborate on behalf of children with clubfoot.

Appendix 3: Monitoring and Evaluation

Measuring progress against the Global Strategy Objectives

The following indicators have been agreed upon to measure program progress towards the quality and sustainability of national clubfoot programs:

| Objectives, by 2030 | Measure | Method |
|--|--|--|
| 100% of target LMICs have a national clubfoot program | Evidence of national clubfoot programs Country-level data on numbers of children treated | Biennial global data collection WHO Rehabilitation survey data Biennial global data collection |
| estimated children born with clubfoot in target LMICs | | |
| 100% of national clubfoot programs meet 70% of the global clubfoot quality metrics | For all children enrolled in treatment, by 2030: 85% of all children will receive ≤ 8 casts per foot prior to first brace 80% of all children will receive a tenotomy prior to first brace 90% children complete the corrective phase of treatment and receive a first FAB 80% of children receiving a FAB remain in FAB 2 years after starting treatment PROM completed for 100% of children in treatment at 2 years, with good outcome in >70% (once development of a PROM completed) 75% of children start treatment under age 1 year 90% of children start treatment under age 2 years | Biennial global data collection Aggregated CAST data where available Sample surveys |
| 100% of national clubfoot programs meet 70% of the global clubfoot program sustainability metrics | By 2030: An increase from 2017 baseline of MoH providing treatment support (e.g. clinic space, clinic staff, training, braces) MoH capacity for national program coordination (incl. contribution of staff, clinic space and treatment materials) MOU in place between MoH and partner organizations National clubfoot trainer assigned and financially supported by the MoH available to the national clubfoot program with an active clubfoot training plan in place Early detection and referral systems for clubfoot integrated into existing health services Sustainable supply chain for good quality braces Contribution of beneficiaries Ponseti method included in medical curricula Active national change champion Clubfoot recognised and embedded in national disability sector | Biennial global data collection Aggregated CAST data where available Sample surveys |

Appendix 4: Identification of Target Countries

To identify our target countries, we have used the World Bank country income group classifications (high, upper middle, lower middle and low) and estimated the number of children with clubfoot in each country based on World Bank population data, birth rate and a global clubfoot birth incidence rate of 1.24 in 1000.

The 'target countries' for the Global Strategy are the 105 LMICs with more than 50 cases of clubfoot per year; these countries account for 90% of the children born with clubfoot globally.

The remaining 34 LMICs each have less than 50 new cases of clubfoot per year - 0.3% of the global total. These countries will therefore not be direct targets for the strategy but the Global Strategy Working Group will be open to dialogue and engagement where individual countries express interest.

The 78 high-income countries account for 9.2% of all cases of clubfoot and Ponseti treatment is routinely offered and managed through public and private health systems. These countries are therefore not a focus for the Global Clubfoot Strategy.

| Category | Number of Countries | Annual Clubfoot Cases | Percentage of Global Clubfoot Cases |
|--------------------------------|------------------------|--------------------------|--|
| Target Countries: | | | |
| Upper Middle Income | 37 | 45,500 | 26.1% |
| Lower Middle Income | 38 | 82,600 | 47.5% |
| Low Income | 30 | 29,300 | 16.8% |
| Total Target Countries | 105 | 157,400 | 90.4% |
| Non-Target Countries: | | | |
| High Income | 78 | 16,000 | 9.2% |
| Small LMICs (<50 annual cases) | 34 | 600 | 0.3% |
| Total Non-Target countries | 112 | 16,600 | 9.5% |
| Total | 217 | 174,000 | |

Priority countries and cases - Clubfoot cases are calculated using 2017 Population and Birth Rate data from the World Bank DataBank, and an incidence of 1.24 per 1000.

| Priority Upper | Cases | Priority Lower | Cases | Priority Low Income | Cases |
|--------------------|--------|----------------------|--------|---------------------------|-------|
| Middle Income | | Middle Income | 1 | | |
| China | 19,729 | India | 31,906 | Congo, Dem. Rep. | 4,145 |
| Brazil | 3,688 | Nigeria | 9,084 | Ethiopia | 4,001 |
| Mexico | 2,879 | Pakistan | 6,781 | Tanzania | 2,656 |
| Russian Federation | 2,211 | Indonesia | 6,157 | Uganda | 2,149 |
| Iraq | 1,600 | Bangladesh | 3,836 | Mozambique | 1,393 |
| Turkey | 1,589 | Egypt, Arab Rep. | 3,047 | Afghanistan | 1,350 |
| Iran, Islamic Rep. | 1,588 | Philippines | 2,937 | Niger | 1,301 |
| Angola | 1,457 | Kenya | 1,987 | Madagascar | 1,070 |
| South Africa | 1,390 | Vietnam | 1,892 | Mali | 969 |
| Algeria | 1,126 | Sudan | 1,668 | Burkina Faso | 919 |
| Argentina | 932 | Myanmar | 1,166 | Malawi | 856 |
| Colombia | 909 | Ghana | 1,106 | Chad | 814 |
| Thailand | 853 | Yemen, Rep. | 1,073 | Senegal | 721 |
| Peru | 755 | Cote d'Ivoire | 1,073 | Nepal | 716 |
| Venezuela, RB | 740 | Cameroon | 1,072 | Zimbabwe | 667 |
| Malaysia | 641 | Morocco | 850 | Burundi | 625 |
| Kazakhstan | 453 | Uzbekistan | 843 | Somalia | 606 |
| Ecuador | 410 | Zambia | 833 | Guinea | 585 |
| Dominican Republic | 265 | Ukraine | 590 | South Sudan | 579 |
| Jordan | 248 | Guatemala | 549 | Benin | 494 |
| Azerbaijan | 225 | Syrian Arab Republic | 512 | Rwanda | 451 |
| Romania | 219 | Cambodia | 457 | Korea, Dem. People's Rep. | 448 |
| Paraguay | 175 | Sri Lanka | 395 | Тодо | 325 |
| Libya | 152 | Tajikistan | 318 | Haiti | 325 |
| Cuba | 139 | Bolivia | 316 | Sierra Leone | 287 |
| Turkmenistan | 137 | Papua New Guinea | 271 | Eritrea | 218 |
| Belarus | 136 | Tunisia | 242 | Central African Republic | 206 |
| Lebanon | 115 | Lao PDR | 221 | Liberia | 199 |
| Panama | 93 | Congo, Rep. | 212 | Gambia, The | 107 |
| Namibia | 91 | Honduras | 210 | Guinea-Bissau | 85 |
| Serbia | 89 | Kyrgyz Republic | 187 | | |
| Costa Rica | 85 | West Bank and Gaza | 183 | | |
| Bulgaria | 83 | Mauritania | 171 | | |
| Botswana | 68 | Nicaragua | 147 | | |
| Gabon | 64 | El Salvador | 129 | | |
| Georgia | 59 | Mongolia | 83 | | |
| Jamaica | 57 | Lesotho | 75 | | |
| | | Timor-Leste | 58 | | |

Countries marked in bold have or are progressing towards a national program for clubfoot (based on a GCI survey in 2016 of clinicians and program coordinators)

Appendix 5: Global Strategy Budget

The current costs detail NGO provision external to the elements that Ministries of Health support, based on 2016 budget data from 7 NGOs working in 14 countries.

| Continent | Weighting Based on Global Cases | Variable Cost (Per Child) | Fixed Cost (For 1-500 Children) | Total Cost/child (Including 30% programme management cost) |
|---------------------|---------------------------------------|------------------------------|---------------------------------------|--|
| Latin America | 8% | \$137 | \$46k | \$506 |
| Africa | 32% | \$113 | \$67k | \$443 |
| Asia | 60% | \$72 | \$50k | \$247 |
| Weighted Average | | \$90 | \$55k | \$331 |



| | Category | Percentage |
|----------------|--|------------|
| | Casting Supplies | 40% |
| | Tenotomy Supplies | 7% |
| Variable Costs | Foot Abduction Braces | 36% |
| | Transport Subsidies and Home Visits | 5% |
| | Other | 12% |
| | | |
| | Training | 17% |
| | Outreach and Awareness | 9% |
| Fixed Costs | Parent Education | 5% |
| Fixed Costs | National Coordination and Administration | 37% |
| | Monitoring and Evaluation | 21% |
| | Other | 11% |