क्लबफूटके सुधारके लीये पोन्सेटी चिकित्सा पध्धति

मातापिता एवं परिवारजनोंके लीये जानकारी:

क्लबफूट क्या है?

क्लबफूट नवजात शिशुओंमें पाई जाती हडीयों एवं जोडकी सबसे सामान्य विकृति है। करीबन एक हजार शिशुओंमें एक शिशुको यह होती है। क्लबफूट होनेकी सही वजह अभी तक ज्ञात नहीं हो पाई है लेकीन ज्यादातर किस्सोंमें यह पीढीगत विकारके कारण होती है। मातापिता द्वारा कुछ किये या न किये जाने पर यह नहीं होती है। इसलिये अगर अपने बच्चेको क्लबफूट हो तो मातापिताको अपराधभाव महसूस करनेकी जरुरत नहीं है। आपका दूसरा बच्चा भी क्लबफूटवाला हो ऐसी संभावना करीबन तीस बच्चोंमें से एक की है।

बच्चा चाहे क्लबफूटवाला हो लेकीन दूसरे सब तरीके से अगर सामान्य हो तो उसके मातापिताको आश्वासन दिया जा सकता है कि अगर बच्चेका इलाज इस क्षेत्रके विशेषज्ञ द्वारा करवाया जाय तो उसका पाँव दिखावेमें एवं कार्यमें सामान्य हो सकता है। क्लबफूटका इलाज ठीक तरह से किये जाने पर किसी प्रकारकी विकलांगता नहीं होती है एवं वह बच्चा संपूर्ण रुपसे बिल्कुल सामान्य क्रियाशील जीवन जी सकता है।



इलाजका प्रारंभ

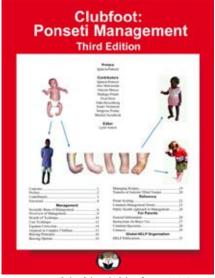
क्लबफूटकी विकृतिको ठीक करनेके लीये चार से सात सप्ताहकी अवधिमें चार से लेकर सात प्लास्टर पर्याप्त है। हरेक प्लास्टरसे पहले करीबन एक मिनट तक पाँवको नजाकतसे सीधा किया जाता है। ऐसा करने से पाँवके भीतरके, पीछेके एवं तलुअेके छोटे एवं तंग लीगामेन्ट्स और टेन्डन्स (कंडराएं) खींचते है । इसके बाद पंजे से लेकर जंघामूल तकका प्लास्टर लगाया जाता है। ठीक करनेके लीये सीधा किया गया पाँव प्लास्टरकी वजहसे यथावत् स्थितिमें रहता है। अगली बार जब पाँवको और सीधा किया जाय तब तक यह प्लास्टर लीगामेन्ट्स और टेन्डन्सको शिथिल करता है। इस तरहसे विस्थापित हुइ

हडीयां एवं जोड क्रिक रुपसे सही स्थान पर लाये जाते है। क्लबफूटके इलाजका प्रारंभ एक या दो सप्ताहकी उम्रसे ही कर देना चाहिये, ताकि इस उम्रमें उतकोंमें जो लचीलापन होता है उसका फायदा मिल सके।



प्लास्टरके बाद इतना ध्यान रखिये

- प्लास्टर लगानेके प्रारंभिक
 - छह घंटे तक प्रति घंटा और बादमें हर छह घंटे पाँवमें रक्तके संचरण पर नजर रिखये। पाँवकी उंगलीयोंको आहिस्ता दबाकर देखिये। दबाने पर उंगलीयां श्वेत हो जायेगी और दबाव छोड देने पर वे फिरसे त्वरित गुलाबी होने लगेगी जिसका मतलब है कि उंगलीयोंमें रक्तप्रवाह बराबर है। अगर उगलीयां गहरे रंगकी या ठंडी रहती है या दबाव छोड देने पर श्वेत से वापस गुलाबी नहीं होती हो तो प्लास्टर ज्यादा चुस्त हो सकता है। ऐसे हालातमें तुरंत ही अपने डॉक्टरका संपर्क किजीये या प्लास्टरको निकाल दिजीये।
- जंगलीयोंके अग्रभाग एवं प्लास्टरके अंतभाग पर नजर रखिये कि कहीं जंगलीयां प्लास्टरमें न चली गइ हो।
- सूखा एवं सख्त न हो जाय तब तक प्लास्टरको तिकये या नर्म गद्दी पर रखा जाना चाहिये। बच्चा जब भी सो रहा हो तब प्लास्टरके नीचे तिकया रखकर पाँवको उपर उठाये रिखये तािक एडी तिकये से बाहर रहे। ऐसा करने से एडी पर दबाव नहीं आता। यह दबाव अल्सरके लीये कारणभूत हो सकता है।
- प्लास्टरको स्वच्छ एवं सूखा रखिये। गीला होने पर वह ढीला हो जायेगा।
- बच्चेको प्लास्टर पर खडा न करें।



ज्यादा जानकारीके लीये अंग्रेजीमें पढिए Clubfoot :

Ponseti Management

 डीस्पोजेबल (उपयोग करनेके बाद फेंकने योग्य) डाइपरका उपयोग करें और प्लास्टर मैला न हो इसलीये डाइपर बारबार बदलते रिहये। प्लास्टरका उपरी छोर डाइपरके बाहर रिखये ताकि मलमूत्र प्लास्टरके अंदर न जाये। इलास्टीकयुक्त डाइपर ऐसी स्थितिमें अच्छा रहता है।

निम्नलिखितमेंसे कोइभी लक्षण आपको देखने मिले तो फौरन अपने डॉक्टरका संपर्क किजीये

- प्लास्टरके अंदर से बहकर कुछ बाहर निकल रहा हो या किसी प्रकारकी दुर्गन्ध आ रही हो
- प्लास्टरकी कोरके नजदीककी त्वचा लाल हो गइ हो, उसमें सूजन हो
- उंगलीयोंमें रक्तका संचरण ठीक तरहसे न हो रहा हो
- उंगलीयां प्लास्टरमें चली गइ हो
- शर्वी या वाइरल बुखार जैसे सुस्पष्ट कारणोंके बिना भी बच्चेको ३८.५ से. (१०१ फे.) से ज्यादा बुखार हो

प्रत्येक पांचवे से सातवें दिनमें नया प्लास्टर लगाया जायेगा।

प्लास्टरको निकालना

नया प्लास्टर लगानेके दो-तीन घंटे पहले ही प्लास्टरको निकाला जाता है। अस्पतालमें खास तरहकी कैंचीसे प्लास्टर निकाला जायेगा। प्लास्टरको भीगा करके भी निकाला जा सकता है। इसके लीये प्लास्टरको पानी से भरे टबमें रखिये। पंद्रह-बीस मिनट तक गर्म पानीको प्लास्टरके अंदर जाने दिजीये। प्लास्टरके छोरको ढूंढकर प्लास्टरको खोल दिजीये। बादमें रुइको भी निकाल दिजीये। बच्चेको अच्छी तरह नहलाइये।

सक्रिय इलाजकी अवधि

क्लबफूटकी विकृतिको ठीक करनेके लीये चार से सात सप्ताहकी अवधिमें चार से लेकर सात प्लास्टर पर्याप्त है। हरेक प्लास्टर पाँवकी उंगली से लेकर जंधाके उपरी हिस्से तक लगाया जाता है। प्लास्टर घूटनेको ९०°में रखकर लगाया जाता है। बहोत ठोस और कनकने पाँवको ठीक करनेके लीये आठ-नौ प्लास्टरकी जरुरत रहती है। हडीयोंकी स्थित एवं सुधारका अंदाजा डॉक्टर खुद ही लगा सकते है। इसके लीये पाँवके एक्सरेकी जरुरत नहीं है। ज्यादा जटिल हो ऐसे किस्सोंमें एक्सरेकी जरुरत रहती है।

सक्रिय इलाजकी समाप्ति

ज्यादातर किस्सोंमें सुधारको सम्पूर्ण करनेके लीये छोटीसी सर्जरीकी जरुरत होती है। एडीके पृष्ठ भागको इन्जेक्शन या क्रीमके जिरये सुन्न कर दिया जाता है। इसके पश्चात् एकीलीस नस लम्बी की जाती है और अंतिम प्लास्टर लगाया जाता है। अंतिम प्लास्टर तीन सप्ताह रखा जाता है। तीन सप्ताहके पश्चात् जब प्लास्टरको निकाला जाये तब तक एकीलीस नस उचित लम्बाइ और ताकत पुनः प्राप्त कर लेती है। इलाजके अंतमें पाँवमें अतिसुधार किया गया हो ऐसा लगना चाहिये। कुछ ही महिनोंमें वह अपनी सामान्य स्थित प्राप्त कर लेगा।

सुधारको कायम रखनाके लीये स्प्लीन्ट (ब्रेस)

सम्पूर्ण सुधार किये जानेके पश्चात् भी क्लबफूटकी विकृति पुनः होनेकी प्रकृति रखती है। इसे पुनः होने से रोकनेके लीये अंतिम प्लास्टरको दूर कर देनेके बाद स्प्लीन्टको पहनाना अनिवार्य है। एकीलीस नस लम्बी की गइ है या नहीं, इस बातका स्प्लीन्टको पहनानासे कोइ संबंध नहीं है। स्प्लीन्टमें दो बूट डंडे से जुडे होते है। उंगलीयोंवाला हिस्सा खुला हो ऐसे बूट स्प्लीन्टमें उपयोगमें लीये जाते है। पाँवको बूटक अंदर जमाये रखनेके लीये डोरी (लेस)का उपयोग किया जाता है। क्लबफूटवाले पाँव पर पहनाया जानेवाला बूट ६०° से ७०° बाहरकी और घूमाया जाता है और यदि बच्चे का एक ही



पाँव क्लबफूटवाला है तो सामान्य पाँव कम बाहरकी और घूमाया जाता है (४०° से ५०°)। स्प्लीन्टके उंडेकी लंबाइ बच्चेके कंधोंकी चौडाई जितनी या थोडीसी ज्यादा होनी चाहिये। स्प्लीन्टको कम से कम तीन महिनों तक दिनके २३ घंटे पहनाया जाता है। इसके बाद समय कम किया जाता है। दो से चार साल तक सोनेके दौरान (रातको एवं दिनमें) पहनाया जाता है। जब स्प्लीन्ट पहनानेकी न हो ऐसे समयमें साधारण बूट पहनाये जा सकते है।

स्प्लीन्टको पहनानेके पहले दो दिन बच्चेको असुविधा हो सकती है क्युंकि वह बांधे हुए पाँवको अनूकूल होनेकी कोशिश करता है। यह बात बहुत महत्वपूर्ण है कि स्प्लीन्टको किसीभी स्थितिमें निकालना नहीं है, क्युंकि स्प्लीन्टको न पहनानेकी वजहसे क्लबफूटकी विकृति पुनः होना सुनिश्चित है। दो दिन बीत जानेके बाद बच्चा स्प्लीन्टसे अनुकूलन साध लेता है।

क्लबफूटको श्रेणीबध्ध प्लास्टर लगाके सम्पूर्णतया ठीक करनेके बाद ही स्प्लीन्टको पहनाया जाता है। बच्चा करीबन चार सालका होने तक क्लबफूटकी फिर से होनेकी संभावना रहती है, चाहे उसे बिलकुल ठीक क्युं न किया गया हो! उपर बताये गये तरीकोंके मुताबिक स्प्लीन्ट लगातार पहनाये जाय तो ९० प्रतिशत बच्चोंमें वह प्रभावक रहता है। क्लबफूटको पुन: होने से रोकनेके लीये सबसे सफल तरीका स्प्लीन्ट नियमित पहनाना ही है। स्प्लीन्टके उपयोगसे बच्चेके बैठने, रेंगने या चलनेके विकासमें किसी भी प्रकारकी बाधा नहीं आती है।

स्प्लीन्टको पहनानेकी सूचनायें

- स्प्लीन्टको पहनानेसे पहले बच्चेक पाँव पर हमेशा सूती मोजे पहनाये। प्लास्टरसे शायद बच्चेके पाँवकी त्वचा अति संवेदनशील हो जाय ऐसा हो सकता है। ऐसेमें केवल दो ही दिनके लीये मोजेकी दो जोडकी जरुरत पड सकती है। दूसरे दिनके पश्चात केवल एक ही जोड मोजेका इस्तमाल किजीये।
- बच्चा अगर आसानीसे स्प्लीन्टको पहन लेता है तो क्लबफूटवाले पाँवमें पहले और अच्छे पाँवमें उसे बादमें पहनाइये। अगर स्प्लीन्ट पहनाते वक्त बच्चा अपने पाँवको उछालता रहता है, तो पहले उसे अच्छे पाँवमें पहना दिजीये क्युंकि दूसरे पाँवमें



- स्प्लीन्ट पहनाते वक्त वह पाँव उछालता रहेगा।
- पाँवको स्प्लीन्टमें डालकर टखनोंके पडेको सबसे पहले बांधीये। यह पडा एडीको स्प्लीन्टमें सख्तीसे जकड रखनेमें सहायरुप होता है। पडे पर छेद मत किजीये क्युंकि उपयोग होनेके साथसाथ चमडे का पडा खींचता जायेगा और छेद करने का कोई मतलब नहीं रहेगा। यह बात याद रहे कि टखनोंका पडा बूटका सबसे महत्वपूर्ण हिस्सा है।
- यह देखते रहीये कि पाँवकी एडी स्प्लीन्टको छू रही हो। अगर बच्चेके पाँवकी उंगलीयां आगे-पीछे हिल सकती है तो इसका मतलब यह है कि एडी स्प्लीन्टको छू नहीं रही है और पट्टेको ज्यादा कसकर बांधनेकी जरुरत है। स्प्लीन्टके अंदर पाँवकी उंगलीयोंका अग्रभाग सूचित करनेवाली रेखा अंकित किजीये। अगर एडी योग्य स्थान पर है तो पाँवकी उंगलीयां इस रेखाके ठीक उपर या उससे आगे होगी।
- बूटको कसकर बांधीये। लेकिन रक्तका संचरण थम न जाय यह ध्यान रखना जरुरी है।
- यह बात सुनिश्चित कर लिजीये कि बच्चेकी उंगलीयां सीधी ही रहे और कोइ भी उंगली कहीं टेढी न हो जाय। जब तक यह सुनिश्चित न हो जाय तब तक आप चाहे तो मोजेके अगले हिस्सेको काटकर भी सभी उंगलीयोंको स्पष्ट रुपसे देख सकते है।

स्प्लीन्टके उपयोगसंबंधी मददकर्ता जानकारी

• स्प्लीन्ट पहननेके दो-तीन दिन तक बच्चा उसका प्रतिरोध करेगा। स्प्लीन्टके पीडादायी होनेकी वजह से नहीं किन्तु उसे कुछ नया एवं अलग-सा महसूस होनेकी वजहसे वह ऐसा करता है।



- स्प्लीन्ट पहने हुए आपके बच्चेक साथ आप खेला किरये। दोनो पाँव अलग अलग न हिला सकनेकी वजहसे बच्चा अक्सर चीड जाता है। ऐसी हालतमें उसे कुछ अच्छा महसूस करानेकी यह चाबी है। अपने बच्चेको यह बात अवश्य सीखानी चाहिये कि स्प्लीन्ट पहने हुए भी वह दोनों पाँव एक साथ उछाल सकता है या घूमा सकता है। स्प्लीन्टके डंडेको आप हल्के से हिला कर यह सीखा सकते है।
- स्प्लीन्ट पहनानेको नित्यक्रम ही बना दिजीये। दो सालका हो जानेके बाद बच्चेके सोनेकी जगह पर ही स्प्लीन्टको रखें। इससे बच्चेको यह पता चल जायेगा कि सोनेके वक्त स्प्लीन्टको पहनना जरुरी है। स्प्लीन्टके पहननेको नित्यक्रम बना देने से बच्चा उसका प्रतिरोध करे ऐसी संभावना बहोत कम है।
- स्प्लीन्टके डंडेको किसी चीजसे लपेटे रखिये। ऐसा करने से बच्चा जब भी उसे पहने तब खुदको, आपको एवं फर्निचरको डंडे से टकराने से बचा सकते है।
- त्वचा पर कहीं भी लाल धब्बा दिखने पर लोशन मत लगाइये। लोशन लगानेसे समस्या बदतर हो सकती है। स्प्लीन्टके उपयोगसे थोडा-सा लाल होना सामान्य बात है। अगर कोइ लाल धब्बे या छाले नजर आये तो अपने डॉक्टरका संपर्क किजीये। विशेषतः एडीके पृष्ठ भागमें चटकीले लाल रंगके धब्बे या छाले पडना यह निर्देश करता है कि स्प्लीन्टको कसके पहनाया नहीं गया है। यह बात सुनिश्चित कर लीजीये कि पाँवकी एडी स्प्लीन्टको छू रही हे।
- अगर आपका बच्चा स्प्लीन्ट पहनने से कतरा रहा हो और उसकी एडी स्प्लीन्टको ठीक से छू न रही हो तो निम्नलिखित बातें आजमायें।
 - ~ एक और छेद करके टखनोंके पट्टेको ज्यादा कसकर बांधीये।
 - बूटकी डोरीको कसकर बांधीये।
 - बूटकी जीभको निकाल दिजिये। जीभ निकालकर स्प्लीन्ट पहनने से बच्चेको कोइ ईजा नहीं पहुंचेगी।
 - बूटकी डोरीको उपर से शुरु करके नीचे तक बांधते जाइये, तािक फुँदना उंगलीयोंकी ओर रहे।

लम्बी अवधि तक किया जानेवाला निरीक्षण

क्लबफूट सम्पूर्णतया ठीक हो जानेके पश्चात् दो साल तक प्रति तीन-चार महिने आपके डॉक्टरको दिखाते रहिये। दो सालके बाद यह अवधि कम की जा सकती है। क्लबफूटकी तीव्रता एवं पुन: होनेके झुकावको घ्यान में रखकर आपके डॉक्टर स्प्लीन्ट पहनानेकी अवधि तय करेंगे। इलाजको जल्दी से खत्म मत कर दिजीये। लम्बी अबधिके बाद इसके पुन: होनेकी संभावनाको रोकनेके लीये करीबन ८ से १० साल तक डॉकटरको सालमें एक बार दिखाना चाहिये।

पुनः होना

प्रथम दो-तीन सालके दौरान अगर यह विकृति फिर से हो तो पाँवको सीधा करनेके लीये प्लास्टर लगाया जाता है। कभीकभार एकीलीस नसको फिरसे लम्बी करनेकी जरुरत भी पडती है। स्प्लीन्ट ठीक तरहके हो तब भी कुछ किस्सोंमें छोटे से ओपरेशनकी जरुरत रहती है। बच्चा तीन सालका हो जानेके बाद यह ओपरेशन किया जाता है। इस ओपरेशनमें पांवकी अंदरुनी किनारमें से नसको लेकर पाँवके केन्द्रस्थानमें स्थानान्तरित किया जाता है।

उग्र क्लबफूट

उग्र क्लबफूटमें भी पोन्सेटी चिकित्साके जिरये बेहतर परिणाम पाये गये है। फिर भी उग्र क्लबफूटके साथ जन्मे ५ से १० प्रतिशत बच्चोंके पाँवके लीगामेन्ट्स इतने कनकने होते है कि उन्हें पोन्सेटी चिकित्सासे ठीक नहीं किये जा सकते है। जब यह बात स्पष्ट हो जाय कि श्रेणीबध्ध फ्लास्टर बनाने पर भी विकृतिको ठीक करनेके प्रयासमें विफलता प्राप्त हुइ है तब शल्यक्रिया (सर्जरी) करनी आवश्यक हो जाती है।

अनुभवी डॉक्टरको ढूंढीये

मध्यम कक्षाके क्लबफूटका इलाज करनेमें मर्यादित अनुभववाले डॉक्टरको सफलता प्राप्त हो सकती है। मगर उग्र किस्सोंमें सफलता प्राप्त करनेके लीये अनुभवी हाथोंकी जरुरत है। ठीक तरह से सीधे न किये जाने से एवं बुरी तरह लगाये गये प्लास्टरकी वजहसे योग्य इलाजमें विलंब होगा और सही इलाज करना मुश्किल या असंभव हो जायेगा। क्लबफूटके इलाजके लीये ओपरेशनके बारेमें सोचने से पहले, बिना ओपरेशनकी पोन्सेटी चिकित्सा पध्धतिमें निपुण हो ऐसे पिडियाट्रिक ओर्थोपेडिक सर्जनकी सलाह लेनी चाहिये।

सामान्य सवाल

क्लबफूटवाले बच्चेका भविष्य

पोन्सेटी चिकित्सा द्वारा किये गये क्लबफूटके इलाजसे बच्चेका पाँव करीब करीब सामान्य हो जानेकी संभावना है। कुछ बच्चोंके पाँवमें छोटीसी भिन्नता पाइ जा सकती है। इलाज किया गया पाँव दूसरे सामान्य पाँव से थोडा-सा छोटा रहता है। आकृतिमें बताया गया है इस तरह पिंडीके स्नायु पतले रहते है। यह असमानता क्लबफूटकी उग्रता पर आधारित है। पेरकी लंबाइ कम रहना कभीकभार पाया जाता है। इससे कोई मुश्किल पैदा नहीं होती और अक्सर किशोरावस्थामें पहुंचने तक बच्चा उस पर ध्यान भी नहीं देता है। एक या दो सालमें बच्चा यह असमानता साधारणतया भूल जाता है या उसकी उपेक्षा करता है।

खेलकूद

पोन्सेटी चिकित्सासे इलाज किये गये कई मरीजों पर अभ्यास किया गया है। ऐसे अभ्यासमें देखा गया है कि क्लबफूटको ठीक किया गया हो ऐसे बच्चे एवं बडे खेलकूदमें अन्य किसी भी सामान्य व्यक्तिकी तरह हिस्सा ले सकते है। क्लबफूटको ठीक किया गया हो ऐसे कई उत्कृष्ट खिलाडीयोंसे हम परिचित है।



डॉ. विन्सेन्ट मोस्का, चिल्ड्रन होस्पिटल, सीएटल, यु.एस.ए



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The Ponseti Method for Clubfoot Correction Information for Parents

A companion flyer to the book: Clubfoot: Ponseti Management

What is clubfoot?

Clubfoot is the most common deformity of the bones and joints in newborns. It occurs in about 1 in 1,000 babies. The cause of clubfoot is not exactly known, but it is most likely a genetic disorder and not caused by anything the parents did or did not do.



Therefore, there is no reason for parents to feel guilty about having a child with clubfoot. The chances of having a second child with a clubfoot are approximately 1 in 30.

Parents of an otherwise normal infant who is born with clubfoot can be reassured that their baby, when treated by an expert in this field, will have a normal looking foot with essentially normal function. The well-treated clubfoot, causes no handicap and the individual is fully able to live a normal active life. Starting treatment

The foot is gently manipulated for about 1 minute every week to stretch the short and tight ligaments and tendons on the inside, back, and bottom of the foot. A cast that extends from the toes to the groin is then applied. The cast maintains the correction obtained by the manipulation and relaxes the tissues for the next manipulation. In this manner, the displaced bones and joints are gradually brought into correct alignment. Treatment should begin during the first week or two of life to take advantage of the favorable elasticity of the tissues at that age.

Cast care at home

- 1. Check the circulation in the foot every hour for the first 6 hours after application and then four times a day. Gently press the toes and watch the return of blood flow. The toes will turn white and then quickly return to pink if the blood flow to the foot is good. This is called "blanching". If the toes are dark and cold and do not blanch (white to pink), the cast may be too tight. If this occurs, go to your doctor's office or local emergency department and ask them to check the cast. If your child has a soft roll fiberglass cast, remove it.
- 2. Note the relationship between the tips of the toes and the end of the cast. If the toes seem to be shrinking back inside the cast, the cast has slipped down and correct pressures on the foot are not being maintained. This might create skin pressure sores. Call the orthopedic clinic immediately, and tell the doctor that this has occurred. The cast needs to be changed.
- 3. Keep the cast clean and dry. The cast may be wiped with a slightly dampened cloth if it becomes soiled.
- 4. The cast should be placed on a pillow or soft

pad until dry and hard. Whenever your child is on his/ her back, place a pillow under the cast to elevate the leg so that the heel extends just beyond the pillow. This prevents pressure on the heel that could cause a sore.





5. Prevent cast soiling by frequent diaper

t 1 Cast 4 or 5

changes. Keep the upper end of the cast out of the diaper to prevent urine/stool from getting inside the cast. Disposable diapers and diapers with elasticized legs are ideal if available.

Notify your doctor or the clinic nurse if you notice any of the following:

- Any foul smelling odor or drainage coming from inside the cast.
- Red, sore, or irritated skin at the edges of the cast.
- Poor circulation in the toes (see #1 above).
- Cast slipping off (see #2 above).
- Child running a fever of 38.5°C/101.3°F or higher without an explainable reason, such as a cold or virus.

A new cast will be applied every 5 to 7 days

Soft roll fiberglass casts: Within 2-3 hours of the next appointment, find the end of the last roll that was applied and unravel all of the fiberglass material. Then remove the cotton padding. Bathe the child.

Plaster casts: The nurse will remove the cast with a special plaster knife; therefore, the cast must be softened the day you are coming to the clinic. To do this, put your child in a tub or sink, making sure that warm water is getting inside the cast (about 15–20 minutes). After the bath, wrap a soaking wet hand towel around the cast and cover with a plastic bag. A bread sack works well for this.

Duration of active treatment

Four to eight casts (each extending from the toes to the upper thigh, with the knee at a right angle), over a period of four to eight weeks, should be sufficient to correct the clubfoot deformity. Even very stiff feet require no more than nine or ten casts to obtain maximum correction. X-rays of the foot are not necessary, except in complex cases, because the surgeon can feel the position of the bones and the degree of correction with his/her fingers.

Completion of active treatment

A minor office procedure is required to complete the correction in most feet. The back of the ankle is made numb, either with a numbing cream or an injection, after which the Achilles tendon is completely divided with a narrow scalpel. A final cast is applied. The tendon regenerates at the proper length and strength by the time the cast is removed 3 weeks later. At the end of the treatment, the foot should appear slightly overcorrected, assuming a flatfoot shape. It will return to normal in a few years.

Maintaining correction – the foot abduction brace

Clubfoot deformity tends to relapse after correction. To prevent relapses after removal of the last cast, a foot abduction brace must be worn, regardless of whether or not the Achilles tendon was cut. The foot abduction brace consists of straight-bordered, high-top, open-toed shoes that are attached to the ends of an



adjustable aluminum bar. The distance between the heels of the shoes equals the width of the baby's shoulders. Modifications to the shoes are made to prevent them from slipping off. The shoe on the clubfoot is outwardly rotated 70 degrees and on the normal foot (if the child has only one clubfoot), 45 degrees. The brace is worn 23 hours a day for at least 3 months and, thereafter, at night and during naps for 4 to 5 years.

During the first and second nights of wearing the brace, the baby may be uncomfortable as he/she adjusts to the legs being tethered together. It is very important that the brace not be removed, because recurrence of the clubfoot deformity will almost invariably occur if the splint is not worn as prescribed. After the second night, the baby will have adapted to the splint. When not required to wear the brace, ordinary shoes can be worn.

The foot abduction brace is used only after the clubfoot has been completely corrected by manipulation, serial casting and, possibly, Achilles tendon release. Even when well corrected, the clubfoot has a tendency to relapse until the child is approximately 4 years old. The foot abduction brace, which is the only successful method of preventing a relapse, is effective in 95% of the patients when used consistently as described above. Use of the brace will not delay the child's development with regard to sitting, crawling, or walking.

Wearing instructions for the foot abduction brace

- **1. Always use cotton socks** that cover the foot everywhere the shoe touches the baby's foot and leg. Your baby's skin may be sensitive after the last casting, so you may want to use two pairs of socks for the first 2 days only. After the second day, use only one pair of socks.
- 2. If your child does not fuss when you put the brace on, you



may want to focus on **getting the worst foot in first** and the better one in second. However, if your baby tends to kick a lot when putting on the brace, focus on the better foot first, because the baby will tend to kick into the second shoe.

3. Hold the foot into the shoe and tighten the ankle strap

first. The strap helps keep the heel firmly down into the shoe. Do not mark the hole on the strap that you use because, with use, the leather strap will stretch and your mark will become meaningless.



4. Check that the child's heel is down in

the shoe by pulling up and down on the lower leg. If the toes move backward and forward, the heel is not down, so you must retighten the strap. A line should be marked on the top of the insole of the shoe indicating the location of the tips of the child's toes; the toes will be at or beyond this line if the heel is in proper position.

- 5. Lace the shoes tightly, but do not cut off circulation. Remember: the strap is the most important part. The laces are used to help hold the foot in the shoe.
- 6. Be sure that all of the baby's toes are out straight and that none of them are bent under. Until you are certain of this, you may want to cut the toe portion out of a pair of socks so you can clearly see all the toes.

Helpful Tips for the foot abduction brace

- **1. Expect your child** to fuss in the brace for the first 2 days. This is not because the brace is painful but because it is something new and different.
- 2. Play with your child in the brace. This is key to getting over the irritability that is often due to the inability of the child to move his/her legs independently of each other. You must teach your child that he/she can kick and swing the legs simultaneously with the brace on. You can gently push and pull on the bar of the brace to teach your child to flex and extend his/her knees simultaneously.
- 3. Make it routine. Children do better if you make this treatment a routine in your life. During the 4 years of night and naptime wear, put the brace on any time your child goes to the "sleeping spot." The child will know that when it is that time of day, the brace needs to be worn. Your child is less likely to fuss if you make the use of this brace a part of the daily routine.
- **4. Pad the bar.** Bicycle handlebar tape works well for this. By padding the bar, you will protect your child, yourself, and your furniture from being hit by the bar when the child is wearing it.
- **5. Never use lotion on any red spots** on the skin. Lotion makes the problem worse. Some redness is normal with use. Bright red spots or blisters, especially on the back of the heel, usually indicate that the shoe was not worn tightly enough. Make sure that the heel stays down in the shoe. If you notice any bright red spots or blistering, contact your physician.
- 6. If your child continues to escape from the brace, and the

heel is not down in the shoe, try the following.

- a. Tighten the strap by one more hole.
- b. Tighten the laces.
- c. Remove the tongue of the shoe (use of the brace without the tongue will not harm your child).
- d. Try lacing the shoes from top to bottom, so that the bow is by the toes.
- 7. Periodically tighten the screws on the bar.

Long term monitoring

Following full correction of the clubfoot, clinic visits will be scheduled every 3-4 months for 2 years, and then less frequently. Your physician will decide on the duration of bracing depending upon the severity of the clubfoot and the tendency for the deformity to relapse. Do not end treatment early. Yearly visits will be scheduled for 8 to 10 years to check for possible long-term relapses.

Relapses

If the deformity relapses during the first 2-3 years, weekly manipulations and casts are reinstituted. Occasionally, a second Achilles tendon release is needed. In some cases, despite proper bracing, a minor operation is needed when the child is older than 3 years to prevent further relapses. The operation consists of transferring a tendon (the tibialis anterior) from the inside border of the foot to the center of the foot.

Severe clubfoot

Although the results are better if extensive bone and joint surgery can be avoided altogether, 5-10% of infants born with clubfoot have very severe, short, plump feet with stiff ligaments that are unyielding to the stretching and casting. These babies need surgical correction after it is clear that attempts have failed to improve the deformity with a series of casts.

Find experienced doctors

A surgeon with limited experience in the treatment of clubfoot may succeed in correcting a mild clubfoot, but most cases require experienced hands for success. Poorly performed manipulations and casts will delay proper treatment and will make appropriate treatment difficult or impossible. Referral to a pediatric orthopedic surgeon with expertise in this non-surgical (Ponseti) correction of clubfoot should be sought, certainly before considering surgery.

Common Questions

What is the future of children with clubfoot?

The child with a clubfoot, corrected by the Ponseti method described in this brochure, can be expected to have a nearly normal foot. Some minor differences may be noticed. The treated clubfoot is slightly smaller than the normal foot and there is a slight reduction in the size of the lower leg muscles. The amount of difference depends on the original severity of the clubfoot. A small, but insignificant, degree of shortening of the leg may be seen. These differences do not cause problems and often go unnoticed by the child until he/she reaches adolescence.



when body image becomes a concern. The differences are usually forgotten or ignored in a year or two.

Sports

Outcome studies of patients treated by Ponseti management show that children and adults with corrected clubfoot may participate in athletics like anyone else. We know many excellent athletes who have corrected clubfoot.



Vincent S. Mosca, M.D. Seattle Children's Hospital





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Ending Clubfoot Disability:A Global Strategy



















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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.

Professor Chris Lavy

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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).

Coverage Map

| 375 | 300 788 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300 285 | 300

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

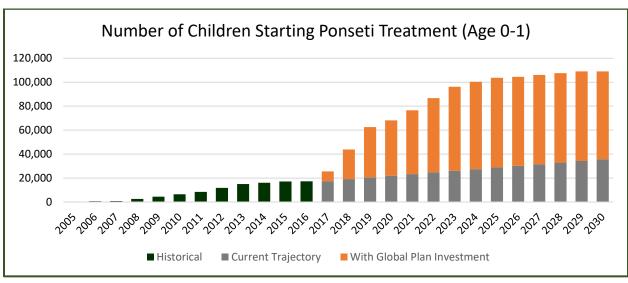
By 2030, all children born with clubfoot will be able to access high quality and effective treatment

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	A child is born with clubfoot and identified correctly as such and referred
Referral	for treatment, ideally within the first few months of life
Clubfoot Clinic and	The haby and family are able to access a dedicated clubfoot clinic
Access	The baby and family are able to access a dedicated clubfoot clinic
Capacity, training and	The child receives proper treatment by clinicians trained in the Ponseti
resources	method and treatment supplies are available
Casting	The child's feet are manipulated and casted according to Ponseti protocols
Casting	for 4-8 weeks
Tenotomy	A tenotomy of the Achilles tendon is performed by a trained provider
Foot Abduction Brace	A FAB is fitted and used consistently as the child grows
(FAB)	A FAB is fitted and used consistently as the child glows
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 Appendix 3.

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 (see Pg 20).

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 Appendix 3. 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

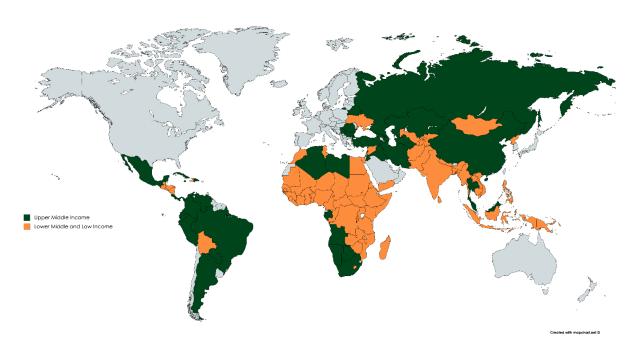
Introduction

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 Appendix 4



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

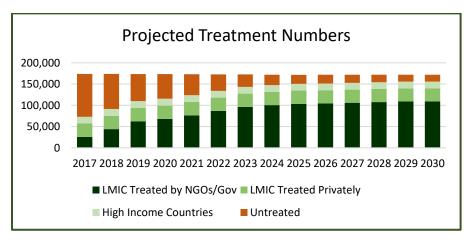


treatment supplies) will gradually adopt more of the costs to the point where it will be possible to maintain the program with minimal external support (approx. \$3M/year globally). In countries with weaker health systems, ongoing external support beyond the lifetime of the Global Strategy may be required.

(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.



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 Appendix 5 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.

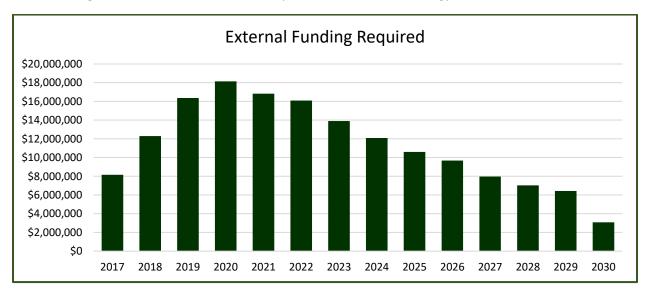
The average annual investment to achieve this plan is \$11M, a relatively small investment to solve a major public health problem. \$3M/year would be required to maintain these programs on an ongoing basis globally. This covers the cost of a local administrator in each country to coordinate and monitor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

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 (Appendix 3) 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.

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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)



Appendix 2: Global Clubfoot Initiative Overview

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 GCI website.

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	 Biennial global data collection WHO Rehabilitation survey data
Increase coverage of Ponseti treatment to 70% of estimated children born with clubfoot in target LMICs	Country-level data on numbers of children treated	Biennial global data collection
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 is included in a national plan (health / rehabilitation / other) 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.

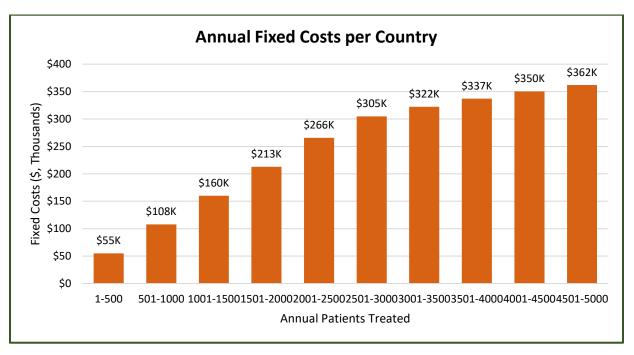
Priority Upper Middle Income	Cases	Priority Lower Middle Income	Cases	Priority Low Income	Cases
China	19,729	India	31,906	Congo, Dem. Rep.	4,145
Brazil	3,688	Nigeria	9,084	Ethiopia	4,001
Mexico	2,879	Pakistan	6,781	Tanzania	2,656
Russian Federation	2,211	Indonesia	6,157	Uganda	2,149
Iraq	1,600	Bangladesh	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	Togo	325
Libya	152	Tajikistan	318	Haiti	325
Cuba	139	Bolivia	316	Sierra Leone	287
Turkmenistan	137	Papua New Guinea	271	Eritrea 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	Guillea-bissau	65
Costa Rica	85	West Bank and Gaza	183		
	83	Mauritania	171		
Bulgaria 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%
Fixed Costs	Training	17%
	Outreach and Awareness	9%
	Parent Education	5%
	National Coordination and Administration	37%
	Monitoring and Evaluation	21%
	Other	11%