

A conversation with MiracleFeet, February 8, 2019

Participants

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Note: These notes were compiled by GiveWell and give an overview of the major points made by Ms. Chesca Colloredo-Mansfeld, Ms. Andrea Norris, Ms. Christie Pettitt-Schieber, and Ms. Karyn Miller.

Summary

GiveWell spoke with by Ms. Colloredo-Mansfeld, Ms. Norris, Ms. Pettitt-Schieber, and Ms. Miller of MiracleFeet as part of its investigation into clubfoot treatment programs. Conversation topics included an overview of clubfoot and the Ponseti treatment method, MiracleFeet's program model, and room for more funding for clubfoot treatment programs.

Clubfoot overview

Clubfoot is a birth defect affecting 1 in 800 children, with approximately equal incidence rates around the world. The feet of individuals with clubfoot are turned upwards and inwards, which makes it very difficult and painful to walk properly unless the condition is treated. The condition may affect one or both feet.

In developed countries, 100% of clubfoot cases are treated at birth, so there is not much academic interest in the developed world medical community in the question of whether the condition should be treated or not.

The Ponseti Method for treating clubfoot

The Ponseti Method involves, in order:

- Serial casting
- Tenotomy to release the Achilles tendon
- Four to five years of bracing (brace only worn at night and for naps)

For children who start Ponseti before they are 12 months old, the corrective phase of treatment (casting and tenotomy) usually only takes two to three months. During the bracing phase, once a good bracing routine is established, children only need to visit healthcare facilities approximately every three to six months to check the feet and to see if they have outgrown their old brace.

Effectiveness

There is evidence that when done properly, the Ponseti Method effectively treats 95% of cases. Within this 95%, there is a 15-20% relapse rate. Relapse means that

even if children are properly casted, their feet might start to turn back in; this usually happens between the ages of two and five, and is usually associated with poor brace compliance.

Relapses can usually be corrected with one to three weeks of additional casting, but in ~15% of cases a very minor surgery such as a tibia transfer is required. This surgery restores full functionality of the feet, and is usually done when the child is five or six years old.

Comparison to surgery

In the past, clubfoot was routinely treated with surgery. The long-term results for the Ponseti Method are much better than for surgery because surgery to the feet causes scarring and stiffness. Over the past few years, the world has moved rapidly to endorse Ponseti as the gold standard for clubfoot treatment, so there is no longer much research being done on the difference between surgery and Ponseti.

The importance of bracing

Bracing is an integral part of the Ponseti Method because it greatly reduces rates of recurrence. Unfortunately, various studies have found that the primary challenge in adherence to the Ponseti Method is in the bracing stage. This is partially because it is more difficult for parents to see direct effects of bracing, compared to the casting phase, so it can be difficult to convince them that their child needs to wear the brace. It is also the case that braces are often not available, or are prohibitively expensive.

Evidence from the medical literature

A Cochrane Review on clubfoot treatment was released in 2014, but the review is now outdated, so MiracleFeet believes that it is more useful to look at more recent evidence. Recent studies, including the randomized trial Švehlík et al. 2017 (<https://www.ncbi.nlm.nih.gov/pubmed/28866453>), have shown that the Ponseti Method is now the gold standard of care to such an extent that it is no longer considered ethical to do surgery on children born with clubfoot under the age of two.

Ponseti for older children

While Ponseti has already been established as the gold standard for children up to the age of two, recent research has focused on the impact of using the Ponseti Method on much older children. There is substantial evidence, including Shah et al. 2019 (<https://www.ncbi.nlm.nih.gov/pubmed/30312250>), that the Ponseti Method works well for treating clubfoot in children up to the age of 10 or 12.

Program model

MiracleFeet's program is designed to increase access and adherence to the Ponseti Method, because it has been shown that strict adherence to the Ponseti Method improves clinical outcomes. MiracleFeet works to build capacity in the countries

where it works. Its goal is to provide everything necessary to ensure that any child born with clubfoot:

1. Gets identified and referred to a clinic
2. Gets excellent treatment at the clinic
3. Adheres to the treatment protocol

Partnerships

Sustainability

It is important to MiracleFeet to create programs that will last for a long time, even after MiracleFeet is no longer directly involved. For this reason, it focuses on integrating additional knowledge and training into the healthcare system at every level, with the hope that its local partners and the Ministry of Health will be able to build on MiracleFeet's work in the future.

Healthcare providers

MiracleFeet works with whatever local healthcare providers are involved in treating clubfoot, which may include:

- Surgeons
- Orthopedic surgeons
- Physiotherapists
- Physicians' assistants
- Casting technicians
- Local doctors
- Health workers
- Workers in public hospitals

The specific type of healthcare providers that MiracleFeet works with is very context-dependent. For example, in South America and Southeast Asia MiracleFeet largely works with orthopedic surgeons, since these tend to be fairly numerous in those areas. In Africa, on the other hand, there are very few orthopedic surgeons, so MiracleFeet is likely to work with other types of healthcare providers, especially physical therapists and casting technicians.

Policy work

MiracleFeet hopes to integrate every element of its program into the existing health infrastructure. For example, MiracleFeet works with whoever is in charge of medical education to integrate the Ponseti training curriculum into medical or physical therapy schools. It also always seeks to have a memorandum of understanding (MOU) with the Ministry of Health, and to have the Ministry of Health endorse its program.

MiracleFeet also engages in advocating for policy changes to make clubfoot programs more sustainable. For example, it might push for legislation to make sure that clubfoot is recognized as a disability that should be treated.

Phase 1 - Implementing the Ponseti Method

MiracleFeet generally begins its work in a country's largest city or capital city. It tries to work wherever children with clubfoot already go for treatment, which is often a large pediatric public hospital.

MiracleFeet's first goal is to ensure that any child who comes to the clinic receives excellent treatment. It does this by providing training, materials, and counseling services.

Training

MiracleFeet sends regional trainers to ensure that every healthcare provider who is involved in clubfoot treatment is properly trained in the Ponseti Method. Sometimes the providers have already received some basic training in the Ponseti Method, but often they haven't.

Materials

MiracleFeet provides hospitals with the supplies necessary for the Ponseti Method, including plaster of Paris for casting, a scalpel and anesthesia for tenotomies, and braces. If the hospital where MiracleFeet is working already has these materials, MiracleFeet does not provide them. It is common for hospitals to already have scalpels, anesthesia, and plaster of Paris, although they often run out of plaster of Paris, so MiracleFeet may keep a backup supply to ensure that every child who comes in can get a cast.

Braces, by contrast, are almost never available, so MiracleFeet provides high-quality braces for free in all the locations where it works. It either imports its own braces or uses locally produced braces, depending on the situation.

Family counseling

Parents who bring a child with clubfoot to a clinic are often worried about the child's future, and don't understand the treatment the child will receive. To address this, MiracleFeet hires "parent educators" (also called "clinic assistants" in some locations), who sit down with parents and talk to them about the treatment.

The parent educators act as the point person for the family, doing home visits and following up with families who fail to show up for appointments. They educate the family about the treatment process and reinforce this education at every one of the family's appointments. A particularly important piece is counseling the parents on bracing.

In addition to counseling the family, parent educators are often involved in collecting data. This includes the family's demographic information and contact information, and the child's diagnosis, among other things.

Phase 2 – Expanding coverage

Once MiracleFeet has ensured that children who go to a certain clinic will get high-quality treatment, the next step is to put in place processes to make sure that the family of every child born with clubfoot is informed about the condition and is referred to that clinic to seek treatment. In this phase, MiracleFeet also expands its coverage across the country by simultaneously creating a network of clinics, raising awareness, and fighting stigma.

Education at the clinic level

Rather than hiring people to actively seek out children born with clubfoot, MiracleFeet aims to educate the people who would see children born with clubfoot anyway. For this, it works with existing public health programs and other organizations, such as other local NGOs.

Many health workers do not even know that clubfoot is treatable, so MiracleFeet goes to maternity hospitals to educate health workers on the condition and tells them where to send children born with clubfoot. MiracleFeet also trains midwives to recognize clubfoot and send children for appropriate treatment. It can be difficult to identify children with clubfoot because stigma against the condition causes many mothers to hide the fact that their infant has clubfoot.

Geographic expansion

In addition to making sure there are early identification and referral processes in place, MiracleFeet expands its network of clinics across the country. It starts by replicating its program in other large cities. This step is important because the distance to a clinic is a huge impediment for seeking treatment.

In countries where MiracleFeet has more than one clinic, it hires a country coordinator, who is then responsible for strategy in the entire country. Country coordinators are local, and usually have a background in program management and experience working in public health and/or with people with disabilities.

Data collection

MiracleFeet collects large quantities of data to ascertain that:

1. Children are getting high-quality treatment in the clinic
2. Children have good outcomes once they've departed treatment

MiracleFeet then uses this information at every level of the organization, making decisions about how best to support its partners.

Platform

MiracleFeet keeps comprehensive electronic medical records for all of the patients in its programs using the customized clubfoot app built on Dimagi's CommCare platform. The CommCare platform has been tested in low-resource settings, and is

so widely used that 1 in 200 babies worldwide are registered on a CommCare device.

Treatment quality and adherence

MiracleFeet uses this mobile application to collect data on the quality of treatment. It determines whether doctors are adhering to the Ponseti Method by measuring:

- The average number of casts that children get in the corrective phase
- How many children get a tenotomy
- How many children drop out in the casting or bracing phase

It also measures how successfully its partners are referring newborns to the clinic by measuring the proportion of patients who are at their first visit before their first birthday.

Dropout

MiracleFeet records how many children drop out at any phase of the Ponseti treatment. Its goal is for only 10% of patients to drop out in the casting phase and only 20% in the bracing phase. It holds all of its clinics to these goals, measuring dropout rates and giving the clinics feedback throughout the year.

MiracleFeet also holds its clinics accountable to ensure that every child completes at least two years of bracing. Ideally children would complete four years of bracing, but MiracleFeet focuses its measurements on the two-year mark because there are diminishing marginal returns to additional bracing, with most of the benefit seen in the first year.

Impact evaluations

Patient satisfaction

MiracleFeet is currently engaging in an impact evaluation with the Acumen Fund's Lean Data team. It is surveying a sample of its patients in Tanzania, the Philippines, and Mumbai who enrolled four or more years ago, and so should have completed the majority of their treatment.

Lean Data has interviewed the families of 200+ patients in each of the locations, using a survey that MiracleFeet and Lean Data co-designed to obtain information on patient satisfaction. The survey includes questions such as:

- Can the child run/walk/play?
- Is the child bullied?
- If the child is of school age, are they in school?
- How satisfied are the parents with the feet?
- Can the child wear shoes of their choice (with or without modifications)?

Healthcare providers

MiracleFeet and Lean Data have also partnered to evaluate MiracleFeet's impact at the healthcare level. They are conducting a comprehensive survey of MiracleFeet's providers to assess MiracleFeet's impact on the providers' ability to deliver quality comprehensive clubfoot care with the Ponseti Method.

Internal evaluations

MiracleFeet is conducting internal evaluations of its Liberia and Nicaragua programs, two older programs with a smaller number of children, to try to draw conclusions about MiracleFeet's impact. This smaller-scale study is following up with patients who enrolled four to five years ago, and is measuring outcomes using questions similar to those from the Lean Data survey.

Dropout

MiracleFeet is particularly interested in investigating reasons for dropout. In addition to the studies already referenced which will provide insight into outcomes after four years for those who did not complete bracing, MiracleFeet is also currently conducting a single-clinic qualitative study in Mumbai to understand why patients dropped out of treatment. It also recently worked with its partner organization in Bangladesh on a similar project.

Counterfactuals

Funding for clubfoot programs

In most cases MiracleFeet is the sole funder of the clubfoot programs it supports. This strongly suggests that in most of the countries where MiracleFeet works, there would be no clubfoot program without MiracleFeet's involvement.

The situation prior to MiracleFeet's work

MiracleFeet has not systematically collected rigorous baseline data on what was happening in any given country before it began working there, but its work on the ground has provided it with a fair amount of anecdotal evidence.

Generally, in the best case, one or two public hospitals would have a provider who was trying to do the Ponseti Method. Unfortunately, MiracleFeet found that very few of these providers were adequately trained. In addition, there were no braces, so even if the doctor was doing the Ponseti Method correctly, the feet would relapse after the casting and tenotomy.

Example: Tanzania

When MiracleFeet began working in Tanzania about five years ago, there were very few places in the country where anyone was treating with Ponseti. There was also an inadequate supply of braces. MiracleFeet started out supporting five clinics, and there are now 28 clinics across the country administering proper Ponseti, complete with bracing.

Stories from families

Parents often share stories about what it was like to seek treatment for their child's clubfoot prior to MiracleFeet's work. They often say that their child received below-knee casts, meaning that the child was not properly treated since the Ponseti Method requires that casts go up to the thigh. Parents also often say that they sought treatment at a healthcare facility but were told that the condition was not treatable.

Potential work to investigate counterfactuals

Before launching its next program, MiracleFeet could potentially conduct a small evaluation of the country to get a better understanding of what is being done to treat clubfoot in the absence of a MiracleFeet program. Lean Data's provider evaluation should also give some insight into how well providers were able to deliver Ponseti care prior to MiracleFeet's involvement.

Room for more funding

With additional funding, MiracleFeet would aim to increase coverage rates to ~70% in the countries where it works, and begin programs in countries that currently have no clubfoot treatment program.

Current clubfoot treatment coverage rates

MiracleFeet is an active member of the Global Clubfoot Initiative (GCI), which is an umbrella organization for all the organizations that work on clubfoot. The GCI has surveyed every organization and every doctor that it knows of in the world who is working on clubfoot, and its current estimate is that only ~15% of children born with clubfoot in low- and middle-income countries (LMICs) are being reached.

There is a very small set of countries where MiracleFeet has worked for several years where coverage is nearing ~70%, including Nicaragua, Paraguay, and Liberia. Unfortunately, coverage is much lower than this in most of the countries where MiracleFeet works, particularly in the larger countries.

Tanzania

MiracleFeet currently has 28 clinics in Tanzania, and its goal for 2019 is to enroll 1494 new children in treatment. There are ~3000 children born with clubfoot in Tanzania every year, and MiracleFeet's goal is to reach ~70% of these, or ~2100 children per year.

Nigeria

MiracleFeet's Nigeria program is very new. It has just started to work with an orthopedic surgeon, and is developing clinics in two public hospitals. Nigeria has a population of ~200 million, and it is estimated that 9,300 children are born with clubfoot in Nigeria every year. MiracleFeet expects it will only reach ~75 children in Nigeria this year, so there is enormous potential to increase coverage.

Countries with no program

MiracleFeet has a list of countries that have no clubfoot treatment programs.

Costs of expanding coverage to 70%

Together, MiracleFeet and GCI member organizations have developed a model to estimate the costs of reaching 70% of children expected to be born with clubfoot in every LMIC. Their current estimate is that investing ~\$160 million in clubfoot programs over 15 years– for their development, implementation, maintenance, and hand-off to the government – would be enough to reach 70% of clubfoot patients in every LMIC where more than 50 children are born with clubfoot each year. Under this model, 1.2 million additional children would be treated over 15 years, as well as building the capacity to treat future generations.

*All GiveWell conversations are available at
<http://www.givewell.org/research/conversations>*