

Creating a countrywide program model for implementation of a Ponseti method clubfoot treatment program in developing countries.

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Abstract

This year, up to 200,000 children will be born with clubfoot in the developing world. Clubfoot has been effectively eradicated as a permanent disability in the developed world. However, in countries where access to health care is severely restricted, a child born with this deformity is still faced with what will most likely be a crippling lifetime disability. It is estimated that in the next 10 years, there will be over 2 million adults living in developing countries who are disabled by this condition which could have been easily treated if addressed early in life.

After years of documented results, the Ponseti Method is now becoming recognized as the accepted standard for the medical treatment of clubfoot. The Ponseti Method is ideally suited for the developing world in that it is inexpensive, non-surgical and the casting component can be completed by trained paramedical personnel. If the Ponseti Method can be effectively utilized in sustainable countrywide programs in developing nations, the global eradication of clubfoot as a lifetime physical disability becomes a possibility.

The goal of countrywide clubfoot treatment programs in the developing world cannot be reached with the simple introduction of the technique to orthopedic surgeons in the country. This objective requires the construction of a well planned, strategic model which is broadly applicable, affordable and effective. Such a model must acknowledge and work within the limitations of a developing country.

One such model is the CURE Clubfoot Kenya (CCK) program, which successfully recruited 362 patients within the first twelve months. Of the 330 feet (208 patients) with idiopathic clubfoot who had fully completed treatment by the Ponseti Method, 90.3% of the feet were fully corrected. The CCK model was applied by CURE International to programs established in Ethiopia and Cambodia in early 2007 and will also be applied to programs currently under development in Haiti, Dominican Republic, Honduras, Niger and Zambia.

This paper discusses the lessons learned by CURE Clubfoot Worldwide as a strategic model was formulated, adapted and revised. It closes with a discussion of the critical issues that should be considered by those wishing to support and implement effective clubfoot treatment in developing nations.

Introduction

The Need for Clubfoot Treatment

Every year children are born in developing countries with the physical deformity, congenital talipes equinovarus, commonly known as clubfoot. Clubfoot is one of the most common three congenital defects (Kromberg & Jenkins, 1982; Mkandawire & Kaunda, 2002). In virtually 100% of cases in developed countries, clubfoot is identified and treated soon after birth. While available medical treatment in developed countries has essentially eradicated clubfoot as a permanent deformity, in the developing world, clubfoot is seldom treated and most often leads to lifelong disability.

The prevalence rate of clubfoot in the developed world has been established to be 1.1 per 1000 births (Barker, Chesney, Miedzynbrodzka & Mafulli, 2003). Research in Africa has estimated prevalence to be up to 2 per 1000 births. (Mkandawire & Kaunda, 2004) Medical research to date has not been able to categorically identify the underlying causes of the deformity, though investigations have been done in the fields of genetics, nutrition, viral causes and others (Wynne-Davies, 1972; Dietz, 2002; Honeini, Paulozzi & Moore, 2000; Loder et. al. 2006).

Over the last 15 - 20 years the generally accepted medical approach to the treatment of children with clubfoot has evolved from invasive surgical techniques to conservative, non-surgical methods such as the “French,” Kite and Ponseti methods. The most complete, long-term outcome research has been done at the University of Iowa under the direction of Dr. Ignacio Ponseti [Scher, 2006]. Over the last 10 years, North American and British physicians have been especially active in research and publishing, as well as training physicians throughout the world in the conservative, non-surgical Ponseti approach.

The Need for a Countrywide Clubfoot Treatment Approach

In the developing world there are, by conservative estimates, approximately 120,000 to 200,000 children born each year with clubfoot (Table 1).

Table 1
Clubfoot Births – All Developing Countries

	1:1000 Births	2:1000 Births
Africa	33,277	60,505
Asia		
- India	26,508	48,195
- China	19,151	34,820
- Others	27,793	50,533
Central/South America	7,506	13,647
Eastern Europe	1,229	2,234
Middle East	4,821	8,765
TOTAL	120,285	218,700

Source: WHO 2007

Of the 114 most impoverished developing nations, it is estimated that by 2006 only 21 countries have benefited from medical education and/or training on the conservative treatment of clubfoot (unpublished assessment conducted by CURE International). This training has ranged from a single medical seminar to the implementation of a countrywide clubfoot treatment effort. From this data it becomes clear that around three-quarters of children born with clubfoot in the developing world live in a country where no medical personnel have been trained in the conservative management of clubfoot.

Within the 25% of developing nations where the Ponseti has been taught to varying degrees, most clubfoot affected children encounter problems accessing the treatment at the most basic level. More frequently than not, there are only a handful of trained surgeons in each country which limits access. Beyond the limitations of few surgeons, if even a very small fee is charged for this treatment, it effectively puts treatment out of the financial reach of most families. In reality, less than five countries have structured,

countrywide clubfoot treatment programs, and therefore, conservatively 90% of all children born with clubfoot in the developing world will not receive treatment of the deformity, whether due to cost and/or accessibility issues

A simple extrapolation of the birth statistics indicates that if left untreated, cumulatively over a 10 year period there will be 2,000,000 physically disabled people in developing countries with a deformity that could have been simply and inexpensively corrected.

The burden of an untreated clubfoot is significant. The lifelong impact extends beyond just the affected child. In many developing countries, general educational levels are low and superstition regarding disability is common. A qualitative investigation on the impact of disability in Kenya revealed that approximately 75% of mothers in Kenya have experienced rejection by their husband and/or family members after giving birth to a child with a disability (Kinyanjui, 2006).

For a child growing up with untreated clubfoot, opportunities are limited. When family resources are scarce, able-bodied children are educated in preference to the disabled child. USAID estimates that no more than 5-10% of disabled children are enrolled in school (USAID, 2007). Unemployment levels are very high among the physically disabled because physical impairments can significantly reduce participation in a manual labor economy. In addition, the social stigma attached to physical deformities can often limit marital prospects and contributes to isolation and marginalization (USAID, 2007). With these things in mind, it comes as no surprise that the disabled in the developing world are among the most impoverished.

The affordability and simplicity of the Ponseti method makes it ideally suited for use in the developing world. Acknowledgement of this fact has spawned numerous efforts to train groups of physicians in various developing nations. Unfortunately, orthopedic surgeons, often the first people in a developing country to receive training in Ponseti have limited additional capacity to treat clubfoot patients given that the surgeons are already in very high demand. One example is the country of Malawi, where there are four qualified

orthopedic surgeons to serve a population of around 12 million people (unpublished assessment, CURE International, Malawi, 2007,). It would appear that while orthopedic surgeons are professionally suited to perform Ponseti given their qualifications, they may be poorly equipped to be high volume Ponseti practitioners in vastly over-stretched health systems. Anecdotal data suggests that where paramedical health professionals are trained in the technique, availability to patients is improved, though most government healthcare facilities are still pressured by demanding caseloads, inadequate support and sometimes low motivation.

Table 2
2006 Physician and Health Expenditure Statistics
Selected Countries

Country	Physicians per 1000 Population	Annual Health Expenditures per Population
Afghanistan	0.19	\$14.00
Brazil	1.15	\$290.00
Cambodia	0.16	\$24.00
Colombia	1.35	\$168.00
Dominican Republic	1.88	\$148.00
Egypt	0.54	\$66.00
Ethiopia	0.03	\$6.00
Haiti	0.25	\$33.00
Honduras	0.57	\$77.00
Kenya	0.14	\$20.00
Malawi	0.02	\$19.00
Malaysia	0.70	\$180.00
Mali	0.08	\$24.00
Nepal	0.21	\$14.00
Niger	0.02	\$9.00
Nigeria	0.28	\$23.00
Uganda	0.08	\$19.00
Zambia	0.12	\$54.70
Zimbabwe	0.16	\$46.10
United Arab Emirates	2.02	\$711.00
United Kingdom	2.30	\$2,900.00
United States of America	2.56	\$6,096.00

Source: WHO 2007

Given the factors of cost and accessibility to the patient, it is proposed that to have the best chance of effectively eliminating clubfoot in the developing world, a fully strategic

approach is required (Garrett, L., 2007). It is the position of CURE Clubfoot Worldwide (CCW) that the approach must go further than the training of surgeons. It must work to eliminate the barriers to care for patients, leverage the existing in-country health care and rehabilitation resources and provide the financial support and incentives to deliver successful patient treatment.

CURE Clubfoot Worldwide

The CURE Clubfoot Kenya (CCK) project began in October 2005 as a means of using the Ponseti method to effectively treat the estimated 1200 - 2000 children born in Kenya annually with clubfoot. The project is directed by CURE International Orthopedic surgeon, Dr. Joseph Theuri, and was made possible with funding from Johanniter International.

Currently, the CCK project consists of 15 Clubfoot Treatment Clinics located strategically around the country. These are staffed almost exclusively by physiotherapists, occupational therapists, orthopedic technologists and plaster technicians and are housed in clinics operated by the Ministry of Health, Association for the Disabled of Kenya and other NGO organizations. Surgeons participate at every location to perform percutaneous tendo Achilles tenotomies when required. Clinic sites were identified and asked to sign participation agreements. After agreeing to become an approved CCK clinic, participating clinical personnel are trained in the Ponseti technique over the course of a two day theory and practical workshop, and closely monitored at their clinic locations.

Treatment information (including Pirani Severity scoring (Pirani, 2003) at every visit) is collected by health professionals and entered into a standardized Clubfoot Treatment Record Form. The data is used by the CCK Program Coordinator to monitor treatment progress and the amount of treatment materials utilized. Data from each patient record is entered into a centralized database.

In less than two years since its establishment (November 2005 – August 2007), CCK has treated 682 children (232 currently in active treatment) for a total of 1084 feet utilizing

the Ponseti Method. The goal of treatment at CCK clinics is to reduce or eliminate the clubfoot deformity using the Ponseti method so that the patient has a functional, pain-free, plantigrade foot with good mobility and no need for modified shoes (Pirani, 1996; Pirani 1992). In this aim the CCK clinics have attained a 90.3% success rate, with the remaining 9.7% requiring surgical intervention on resistant deformities.

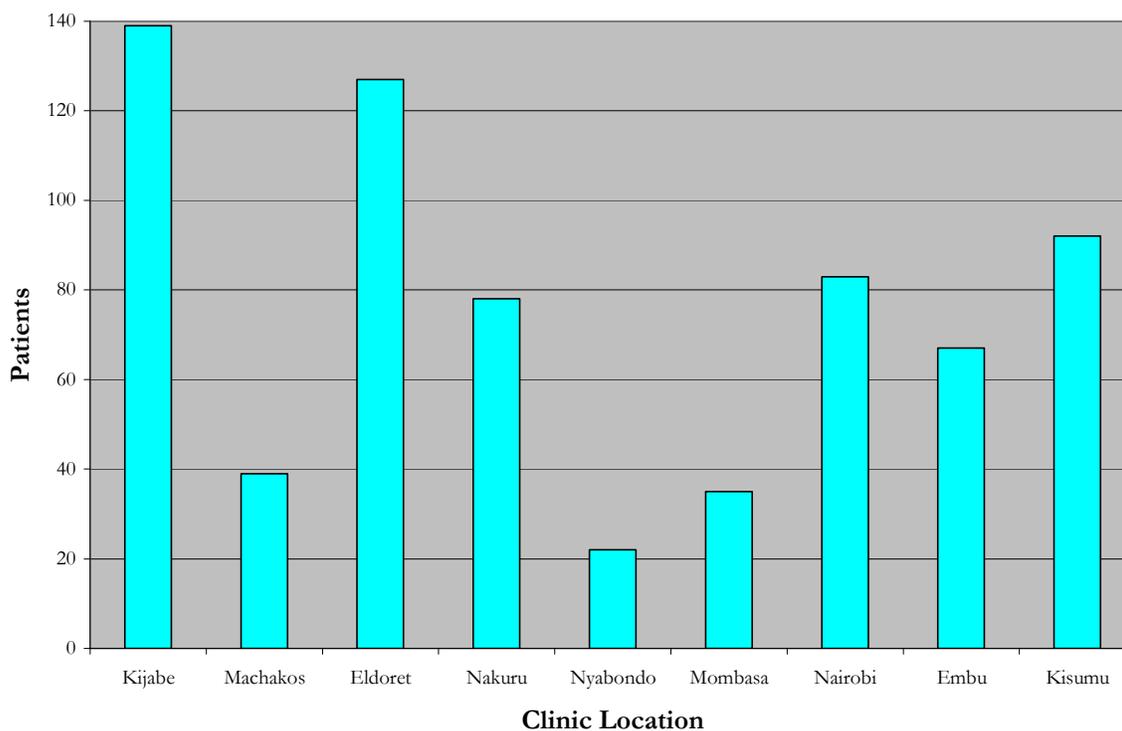
Table 3
CCK Outcomes of Treatment using Ponseti Method
 October 2005 - January 2007

Stage of Treatment	No. of patients	No. of Feet	Percentage
Treated	189	298	90.3%
Resistant	13	22	6.7%
Surgery	6	10	3.0%
Total	208	330	100

Table 4
CCK Age Distribution
 October 2005 - January 2007

Age at Presentation	Percentage
0 – 6 months	67%
7 – 12 months	23%
13 – 24 months	10%

Table 5
CURE Clubfoot Kenya - Total Patients by Clinic *
August 2007



* note: 6 new clinic sites have not yet been included

CCK is now moving into a new phase of partnership with the Kenyan Ministry of Health with the eventual aim of handing over the staff funding and supply of materials for the clinics while maintaining the training and quality control aspects of management. This partnership has been planned since the early stages of the program and hastened by the success of the program.

The CCK program model is currently in the process of being adapted to local conditions in additional developing countries around the world. Thus far, the model has been applied in Ethiopia and Cambodia, with both countries launching nationwide campaigns in the first half of 2007. Additional programs are currently in development in Honduras, Haiti, Dominican Republic, Zambia, Afghanistan, and Niger.

The CURE Clubfoot Ethiopia (CCE) program currently has 220 patients (336 feet) in eight clinic locations around the country. A number of surgeons and organizations have been involved in training efforts in Ethiopia since 2004. The CCE program, in partnership with Black Lion Hospital (Addis Ababa, Ethiopia), CURE Clubfoot Worldwide, and CBM are expanding those efforts to create a network of participating, approved clinics across the country. CCE has also been involved in training medical officer students at two regional hospitals in the Ponseti technique.

CURE Clubfoot Cambodia (CCC) was launched in May 2007 and as of this paper's completion date, is in the early stages of development. Cambodia currently has four CCC clinics treating a total of 21 patients (34 feet).

Critical Issues to be Addressed within a Structured Clubfoot Treatment Program

In designing and implementing a strategic countrywide clubfoot program, issues which have been identified by CURE Clubfoot Worldwide as critical to the success of the effort include:

- Access to medical professionals
- Affordability of treatment for families
- Establishing critical minimum volume
- Adequacy of training
- Physician Leadership
- Utilizing a multi-strategy approach for establishing a country program
- Quality of program management
- Availability of medical supplies and materials
- Parent awareness and education

1. Access to Medical Professionals

The number of physicians in developing countries is severely restricted, and to a lesser extent, so is the availability of other health care professionals such as nurses and physiotherapists. Additionally, many of those working in the public health sector are regularly transferred to different departments or regions. These issues pose a challenge

to the establishment of a reliable and effective clubfoot program and need to be addressed.

As identified earlier, CCW has found that simply training orthopedic surgeons in a developing country will not necessarily translate to patients being treated ‘on the ground’. The overwhelming load of routine urgent orthopedic patients as well as the lack of economic incentives limits the implementation of the Ponseti method on any wide scale basis. Creating a program that can utilize the participation of surgeons as well as other medical professionals was thus assessed to be key to creating a program that is capable of scale.

The approach adopted by the CCW model is to train a minimum team of three personnel from each institution selected as a clinic site. This team includes one physician and two paramedical staff (such as nurses, physiotherapists, occupational therapists or orthopedic technologists). Training qualified paramedical personnel to use the Ponseti method is believed to be a pragmatic alternative to the use of only orthopedic surgeons, as their increased availability ensures that patients who come for treatment can be seen in a timely manner. The training of a physician at an institution has the dual role of equipping someone to perform tenotomies as well as giving a clinic more credibility and a voice of support in the higher levels of hospital management.

Trained personnel are sent back to their clinic locations equipped to share their expertise in order to offer on-site training to other health professionals at that facility. New staff additions to an existing clubfoot clinic are trained at regularly repeated ‘refresher’ workshops, thus gradually increasing the number of people who can use the technique, which supplements those lost to transfers within the health system. The approved clinic sites are requested to allot one morning per week to run a clubfoot treatment clinic, and small incentives were offered per patient and per tenotomy to help motivate the staff.

In this model the physician does not need to be available at all times to perform Ponseti casting, rather they simply need to be available to perform tenotomies as needed. For those institutions where a physician is not in residence (such as rehabilitation organizations), schedules are established for regularly visiting physicians to perform the tenotomies.

2. Affordability of Treatment for Families

In countries where the majority of the population lives in poverty, most families are severely limited in their capacity to fund their own health care. The cost of the supplies required to receive serial plaster casting, let alone the service, is more than most families can afford. CCW has observed in various programs high dropout rates for those who have started the treatment process but lack funds for continuing casting. Experience indicates that even in countries where clubfoot clinics are being operated at governmental facilities most patients are expected to pay for the treatment and/or the supplies. Our limited experience indicates that in many cases neither the hospitals nor the patients can afford to fund clubfoot treatment.

For a countrywide program to be able to quickly build necessary capacity and credibility, this crucial barrier to care must be removed. CCW's strategic approach to this issue is to provide the full treatment at no charge to all patients over the initial three years. This considerably eases the burden on families who only have to find money to cover the cost of transport to the clinic. Providing free care in the early years of the program is also necessary to build critical volume, capacity and establish sustainability.

3. Establishing a critical minimum volume

As with any medical procedure, a critical minimum volume is needed to attain competence and ongoing quality treatment results (Urbach, 2004). Low patient numbers do not allow new Ponseti clinicians the opportunity to practice, perfect the technique and maintain their expertise.

CCW has found that the improved success rate attained by a perfected technique bolsters parent satisfaction and boosts ongoing compliance. CCW has also found that this creates a positive reputation for the program within the medical community and Ministry of Health. The support of both bodies is critical for long term success. Anecdotal experience has indicated that staff at low volume clinics (with less than 30 patients per year) often lose interest in treating patients, leading to a decline in results and an eventual cessation of the service.

In CCW's experience, in order to assist clinics to reach and maintain a minimum volume of successful cases, clinic sites must be chosen carefully for their patient accessibility, staff capacity and organizational interest. They must also be able to offer services in a consistently available location at a regularly scheduled weekly treatment time. Clinics meeting these criteria should be equipped and supported in such a manner that they can build patient volume quickly to reach a minimum of at least 30 patients annually (five per week).

4. Adequacy of Training

CCW has chosen to follow the curriculum, protocols and training established by the Ponseti International Association (PIA) for its training workshops. CCW has added to the curriculum a key component of practical sessions. Adult education literature suggests that the most effective learning is garnered when a trainee is able to physically perform a technique or activity (Rogers and Freiberg, 1993). With this in mind, the second day of a training workshop is completely practical, using models and then children to build on and consolidate the knowledge acquired during the theory focus of the first day.

Actual Patients – CCW procedures have established that a training workshop should take place at or near a clinic site already practicing Ponseti, so that regularly scheduled patients can be casted by trainees under the watchful eye of trainers. The number of children attending the workshop should be managed so that there is one clubfoot per trainee, allowing all attending the opportunity to both cast and 'hold' while someone

else casts. If too many patients attend the workshop we have found that it can lead to a feeling of pressure on the participants to ‘get through them all’, which is obviously not conducive to an optimal learning environment.

Actual Tenotomies - In addition to actual patients who require casting, organizers of a CCW training workshop are directed to ensure that there are a number of patients present who need tenotomies. The physician trainees should have a session focusing on the technique, in which several tenotomies are performed under close observation. In the early stages of the CCK program it was observed that levels of tenotomies were low, around 35% compared to the 70% reported in the literature (Ponseti, 1992). One researcher hypothesized that the reason for this difference was lack of physician comfort with the procedure (Lavy et al., 2007). This issue is a real one, and thus time must be invested in following up, one-on-one, with trained physicians to supervise and assist with initial tenotomies until they become comfortable with the technique.

Experienced Trainers – CCW has established that trainers at its Ponseti training workshop should be medical professionals who have been trained by the Ponseti International Association or its designates, who regularly and competently practice the technique, and who preferably have experience within the context of a developing nation’s health system. As a CCW program develops over time, the medical director also identifies in-country health professionals from the successful clinics who have demonstrated excellence in the technique to deliver certain training sessions. The use of successful national professionals serves both as a motivational tool and as a way of delivering information in a culturally competent and credible way.

Strict Adherence to Established Ponseti Techniques – CCW believes that as with all training, ongoing supervision is essential. The Ponseti method is a precise technique to which even minor changes can negatively impact on treatment outcomes. Our practical experience has shown that in many instances poor treatment results can lead to parental discouragement and discontinuation, which risks bringing a clinic and the method into local disrepute. CCW asks that the medical director of a program visit a

clinic location every few months in the first year after training to ensure the technique is being properly and consistently applied. The director should also monitor the records received for negative trends (such as a low percentage of tenotomies performed or a high percentage of cases with excessive numbers of casts required before correction). Regular analysis of this data allows ineffective treatment to be identified and addressed early.

5. Physician Leadership - Gaining the support of the Medical Community

The introduction of a countrywide program using the Ponseti Method to treat children with clubfoot can be met with resistance from medical and public health individuals as well as organizations. No program can afford to be viewed as affluent expatriates pushing their ideas on the local medical community. CCW has found it important to only work in countries where there is a well respected orthopedic surgeon trained in the Ponseti method who is willing to serve as the program Medical Director. This person becomes the spokesperson and advocate for the technique, generating debate and consensus within the medical community and the public health structure.

6. Utilizing a Multiple Channel Strategy

In many countries there are networks of existing non-governmental organizations and in-country institutions serving physically disabled children and adults. The CCW experience has shown that these organizations are an ideal resource and potential partners to the establishment of a country wide clubfoot treatment program, offering country-specific insights and potential clinic locations and treatment staff. In addition, these organizations are key assets in patient recruitment and educational activities. Potential partners and supporters should be identified and consulted during the preparation phases of a countrywide clubfoot effort to gain essential country-specific information about health and disability and to ensure that services are not being duplicated.

In the establishment of a program, CCW has found it crucial to meet with representatives from the Ministry of Health to understand what is already being done

and to work together to advance clubfoot treatment in that country. Unfortunately many ministry of health institutions are already overstretched by existing needs and cannot be easily expand their capacity. A multiple channel strategy has proven successful in achieving critical scale of volume that is essential for high success rates, which then lead to high confidence of parents and credibility within the medical community. Whenever possible, CCW prefers to keep expectations realistic-- to focus on establishing a small number of highly successful clinic sites before committing to a large number of locations.

7. Quality of Program Management

The ongoing review and management of already established treatment programs in the developing world has been variable and largely under-addressed in the literature. CCW has found that a countrywide program requires considerable administration and coordination in order to carry out regular training workshops, keep clinics supplied with materials, collect and report on clinical data, manage funds and to maintain relationships with partnering organizations. To ensure accountability and transparency, CCW countrywide programs employ a program coordinator to work together with the medical director to promote coordination and strategic growth.

Additionally, CCW's experience has demonstrated that the use of its centralized database system provides valuable data for program management. In Kenya, analysis of this information allowed the CCK Medical Director to identify a trend of lower than expected numbers of tenotomies. The identification of this trend prompted the Medical Director to focus on following up with surgeons at each site to help them overcome fears that they had related to the procedure, as well as alter the training curriculum to include actual tenotomies during surgeon training sessions.

8. Medical Supplies and Materials

As with any medical procedure, the availability of supplies is critical to the treatment. Anecdotal evidence gathered by CCW indicates that this supply is often compromised in developing countries because of lack of funds for plaster and padding, corruption

within the health system or due to sporadic availability of local supply. Because the Ponseti treatment relies on regular and consistently applied plaster casts, interruption to the availability of supplies can have direct negative implications on treatment outcomes.

In the CCK program model, the supply of plaster, padding and braces are managed by the coordinator of the program, who is able to monitor the supplies at each clinic location and replenish them when required. Though eventually it is anticipated that local governments will take responsibility for all CCW projects, in the early phases of a countrywide model it is important that supplies be consistent to give the program the best chance of acceptance and success.

9. Referral Sources and Parent Awareness of the Availability of Treatment

High rates of illiteracy are common in most developing countries (SIL International, 2007), as a result, health education and awareness is limited. In some countries, health awareness is further compromised by superstition and pervasive, inaccurate traditional beliefs (Abang, 1988). Thus, when babies are born with clubfoot, parents, traditional birth attendants, and even local health workers may not be able to identify the deformity, or be unaware that treatment is available.

CCW believes that this issue is one which Ponseti programs in developing countries must address through the development of more robust parent education components and public awareness efforts than would be required in a western program. Research is currently underway in Uganda to identify social issues and attitudes and successful strategies for educating the general medical community (Clubfoot: Ponsetti Management, 2006)). Future plans for CCK center around raising the awareness of health personnel through inclusion in training curricula, and implementing broad public educational activities. The need for parent and medical community awareness should be addressed on a country by country basis, taking into account the unique social, institutional, geographical and cultural features of each setting.

Conclusion

“Good intentions are not enough, the act of charity is not enough, society depends on us to use our time, relationships and financial contributions to do the most possible good. The act of giving is laudable but not the end. We must be effective in our work.”

Michael E. Porter, Harvard University
Doing Good: Do You Have a Strategy?
Willowcreek Association August 2007

The need for treatment of children with clubfoot in the developing world is undeniable – at current rates it is estimated that 2 million children will be disabled by clubfoot in the developing world within 10 years. This is a burden that can be eliminated for those who are able to access the services of a health professional using the simple and effective Ponseti technique.

Due to the inadequate supply of orthopedic surgeons, the already overwhelmed health care systems and the lack of funds available to health professionals and institutions in developing nations, the wide application of the Ponseti method will only become possible through the use of an integrated and coordinated approach. While there has been individual Ponseti training sessions in more than 21 developing countries in 2006 (and efforts to develop 5 – 8 full countrywide programs underway), the overwhelming majority of children with clubfoot in the developing world--97%, do not have access to Ponseti treatment. The critical challenge in treating clubfoot in the developing world today is to create broadly applicable, affordable and effective countrywide treatment model(s).

This paper discussed the issues that need to be addressed by such a model and the way these issues are managed within the CURE Clubfoot Worldwide programs. The core strengths of this model are; the use of paramedical health workers to improve access, making treatment free for families, attaining a critical minimum volume, ensuring training and follow up is comprehensive and relevant, partnering with others in the field,

ensuring good management structures are in place, gaining the respect of the local medical community, and raising awareness about the deformity and its treatment.

If the goal is to eradicate clubfoot as a lifetime disability, the need for strategic, countrywide programs is undeniable. It is hoped that the CURE Clubfoot Worldwide model presented will find success in broad application in developing countries around the world.

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