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**Diffusion of Ponseti Method for clubfoot treatment in
Brazil – the path for adoption of a new technology**

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“...I congratulate the brazilian orthopedaedic surgeons to stabilish clubfoot treatment based on the biology of the deformity and functional anatomy of the foot...

“...Your excelent results are atribuit to the devotion of the visionary pediatric orthopaedics many of those I had the pleasure to meet in iowa. I am honored to work with you

Dr Ignácio Ponseti, 2007
Pé Torto – Tratamento pelo Método de Ponseti
Global Organization Help

ABSTRACT

Introduction and diffusion of Ponseti Method for congenital clubfoot treatment in Brazil are discussed. Ponseti Method is based on specific serial casting, Achilles tenotomy and use of abduction brace to maintain correction. This was different from standard treatment in Brazil at that time, based in many more months of serial casting and an extensive foot surgery. The Ponseti Method diffusion is analyzed in a chronological manner, with focus in the history of its diffusion in Brazil and in the world, beginning in University of Iowa. Internet influence is discussed, as well as the Program “Ponseti Brasil” for training orthopaedic surgeons in Ponseti clubfoot treatment. Populational data were used to evaluate Ponseti Method diffusion, before the Training Program. Four manners of direct evaluation of the impact of the Training Program are presented: the participants’ reaction, enquiries about clinical practice with Ponseti Method after one year, evaluation of the impact of the Training Program in two cities, São Luis and Teresina, and case series presentations of nine Brazilian Orthopaedic Clinics in a national panel in the Advanced Ponseti Course, two years after the Training Program “Ponseti Brasil”. To reinforce information about diffusion, publications in developing countries are discussed, extending indications for use of the Ponseti Method. Tendencies of medical literature about clubfoot treatment were analyzed, through written English and Latin American databases, and proceedings of two national meetings Brazilian Orthopaedic Meeting and Brazilian Pediatric Orthopaedic Meeting were revised to evaluate presentations about clubfoot treatment (Ponseti and surgical). Diffusion is also discussed in other countries, non governmental organizations, related to parents perspective, and related to costs of treatment. Diffusion of Ponseti Method is considered in expansion phase, and its discussion can help in the incorporation of this technology into the SUS (Sistema Único de Saúde – Brazilian Health System).

Keywords: diffusion, medical technology, Ponseti Method, training program, impact, literature, clubfoot, treatment.

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INTRODUCTION

The practice of medicine is determined by various factors. The development of science, and the current needs of society, influence the development of new techniques or forms of treatment (KANOUSE & JACOBY, 1988; GREER, 1988; SCOTT & CAMPBELL, 2002; DEARING, 2008).

The dissemination of medical technology is very dynamic, with innovations being quickly incorporated, and other theories and practices being promptly abandoned. One factor that influences this dynamism is the search for a more efficient, more effective procedure or device (DEARING, 2008).

The main focus of the decision on whether or not to adopt a technology or process is, therefore, based on quality measurement. Quality measurement of products and processes, studied by several authors over the past two decades, is important because in addition to the individual decision, management decisions based on population data, and the decisions of the population, depend on these assessments (GILMORE & NOVAES, 1997; NOVAES, 2004). Quality attributes, both in products and processes, i.e. efficacy, effectiveness, efficiency, equity, optimality, acceptability and legitimacy (the seven classic pillars of DONABEDIAN, 1988) play a prominent role in the choice of one technology over another, as do safety, utility, and the economic, social, ethical and political impacts (NOVAES, 2000). Therefore, considering a treatment proposal that can be classified as a process technology (treatment of congenital clubfoot by the Ponseti Method), these variables must be analyzed and compared with the previously existing technology. We shall examine and discuss these variables in this text.

An innovation, or a new health technology, goes through the stages of research, discovery of a product or process, initial dissemination (by the initial users), increasing dissemination (added to by the "champions" of use), incorporation, large-

scale adoption, and finally, the abandonment stage. The latter occurs when there is no longer any economic advantages for its continuity, or perhaps due to the emergence of a new technology that has replaced it (HILMAN, 1996; GREER, 1998; BROWNSON et al, 2006; DEARING, 2008).

The Ponseti Method can be considered a technology between the stages of dissemination and incorporation. The variables responsible for its placement at this level are discussed below.

According to DEARING (2008), and KANOUSE and JACOBY (1988), the dissemination of an innovation depends on several components, such as:

1. The innovation itself - especially the perception among those who implement it, that it truly offers an advantage in terms of cost-effectiveness, over existing treatment alternatives; it also depends on its simplicity, whether this innovation is well understood by all those involved, whether it is compatible with the social reality in which it is inserted, whether its benefits are easily observable, and whether it can be implemented successfully (the evolution of the medical literature on the Ponseti Method points in this direction (NOGUEIRA et al., 2014).
2. The behavior of the implementers; i.e. how they are motivated to adopt the new technology. In the case of orthopedists, they used the conventional treatment for congenital clubfoot, restricted to reference centers, with surgical centers to carry out procedure under general anesthesia; the results relied on specific training in this surgical procedure, and there were many complications and flawed results in these procedures. A change, simplifying the treatment and including more professionals capable of performing it, can be seen as attractive by orthopedists devoted to the application of this treatment.
3. Society and its opinion leaders, and perceived social pressure to adopt new ways of solving the same problem; (parents of patients with clubfoot have access to information on the least invasive method of treatment, and they question the doctors about its use).

4. The process of individual adoption, which depends on knowledge, persuasion, decision, implementation, and finally, the adoption of new guiding principles to solve old problems (as illustrated by the use of the Ponseti Method in various centers around the world)
5. The process of dissemination, including government and non-government mechanisms of dissemination, and the agents of change, which influence opinion leaders, social networks and paramedical professionals. There are also the so-called "champions of innovation" (specialized societies that establish guidelines, such as the Brazilian Society of Orthopedics and Traumatology, and the Brazilian Society of Pediatric Orthopedics) international organizations that recognize this method as an appropriate technology for the treatment: the World Health Organization (Iowa International Ponseti Meeting, 2007), National Institute of Health in the United States (Second International Conference on Birth Defects and Disabilities in the Developing World, China 2005), CURE International (Mayo et al., 2007), Ponseti International Association, Bone and Joint Decade in the United States (Bone and Joint Decade Global Network Conference, Washington, 2009), and La Vida in England, (Nogueira et al., 2011) among others, that run, or promote training programs in the use of the Ponseti Method.

As has been discussed, there are many reasons to explain why the development of new technologies is not directly incorporated into clinical practice, and it does not depend on the development and academic research in a specific area of knowledge.

This study reports on and discusses the issues concerning the introduction and dissemination of a technology in medical practice; the use of the Ponseti Method to treat congenital clubfoot; the circumstances in which this dissemination occurred, and the factors that led to this becoming the most widespread form of treatment, in terms of indications and use.

The objective of this book is to discuss and correlate aspects related to the introduction and dissemination of a health technology known as the Ponseti Method for the treatment of congenital clubfoot in Brazil.

Facts are reported and discussed based on the literature, and on the series of events that marked the spread of this technology in Brazil. They are presented chronologically, to explain the process of dissemination. The series of themes is presented chronologically to aid, which is important for understanding the process of dissemination. The methodology used in each article is discussed in the corresponding article.

Chapter 1: THE PROBLEM: CONGENITAL CLUBFOOT

Congenital clubfoot is the most common orthopedic congenital deformity, occurring in around one to every thousand live births in caucasians in around half of this proportion in Asians, and up to six times this proportion in Polynesians (Ponseti, 1996). In Brazil, LAREDO FILHO (1986) reported an incidence of two to every thousand live births in the city of São Paulo. The deformity consists of the foot being positioned inwards (adduction) and downwards (equinus), with a large curve in the forefoot (cavus) and hindfoot, which consists of the calcaneus turned inwards (varus).

Figure 1 – Bilateral congenital clubfoot



Source: Author's file

The diagnosis is often prenatal from the third month of life. The infant presents the deformity at birth which, if left untreated, carries a social stigma and severely restricts foot function, particularly from the third decade of life (PONSETI, 1996; STAHELI, 2004).

Until around twenty years ago, the treatment of this deformity consisted of the application of serial plaster casts, first to correct the adduction (with support of the calcaneocuboid joint), then to correct the varus of the hindfoot, and then to correct

the equinus, in an attempt to correct the initial deformity; this technique was described by Kite in 1939 (KITE, 2003). The plaster casts were changed weekly for a period of six to eight months, but had little success in correcting the foot, as documented by several centers, and culminating in the indication of extensive surgery, with release of all the capsules and medial ligaments of the foot and fixation in the plantigrade position (CRAWFORD, 1982; CARROLL, 1987; LARA et al, 1998; FARIA et al, 2001; HEILIG et al, 2003; DOBBS et al, 2006).

This was followed by two months of postoperative plaster casts. This surgery could only be carried out by specialized centers, with highly trained surgeons, and under general anesthesia. Furthermore, despite the “acute” alignment of the foot through various surgical techniques developed in the 80s and 90s, long-term follow-up of these surgeries did not show satisfactory results. These long-term results have only recently been reported in the medical literature (DOBBS et al, 2006) due to the difficulty of follow-up, since the surgeons that operated on the patient as a child are rarely the same ones that see the patient as an adult. A further source of difficulty in follow-up is the high level of mobility of patients in the various medical services, both nationally and internationally.

Ignácio Ponseti, a Spanish physician who worked at the University of Iowa from the late 1940s, developed a treatment method based on foot function and joint movements, and on an understanding of the elastic properties of the tissues. His method consists of specific manipulation of the foot, with five to seven weekly serial casts, followed by tenotomy (complete section) of the Achilles tendon, which can be done under local anesthesia. To prevent the recurrence that is inherent of this orthopedic condition, an abduction orthosis is used, initially for three months continuously, and then only during the night, until the patient is four years of age. (PONSETI, 1996, PERCAS-PONSETI, 2007).

Chapter 2: CONSIDERATIONS ON THE PONSETI METHOD

The word "Method" comes from the Greek "*met hodos*" and refers to the path taken to arrive at a certain result. The word "Technique" is defined as the material part or set of processes of an art (FERREIRA, 1985). Thus, these two terms are usually considered synonyms, but "method" generally has a broader sense than "technique", as is not only restricted to the practice of a procedure, but also includes the way the problem is considered and understood.

In the case of treatment of congenital clubfoot, we prefer to use the word "method", as this includes not only the method of preparing the correction casts, but also the understanding of the nature of the deformity, and how the correction is achieved. The Ponseti Method also includes guidance on how to prevent and treat relapses.

The Ponseti Method initially consists of a phase of serial casts, after specific manipulation, so that the anterior part of the calcaneus bone follows a path from medial to lateral, together with the midfoot, starting from fixation of the talus by a digital counter-support on its lateral side (PONSETI, 1996). The correction of the foot was proposed according to normal mobility of the subtalar joint (between the talus and the calcaneus). This mobility was studied in detail by Dr. Ignácio Ponseti in the early years after his arrival at the University of Iowa, in the 1940s (PERCAS-PONSETI, 2007). Besides having a good understanding of the normal biomechanics of the joint, and relating it to the maneuver required for correction, Ponseti also studied the ability of the soft parts to produce more tissue when immobilized under tension (PONSETI, 1996).

Therefore, based on an understanding of biomechanical and biological principles, the correction is done by manipulating the foot for several seconds, and positioning it in a different position each week, with greater abduction, in order to gradually correct the deformity. The casts are applied by an orthopedist, with assistance from another person (a cast technician, a nurse, or another doctor), first

over the foot and leg, carefully positioned at maximum position of correction, and then over the thigh, with the knee flexed at 90 degrees. After abduction (opening) of the angle of the foot to 70 degrees, in almost all cases, a complete section of the calcaneus (Achilles) is required, a procedure that can be performed on an outpatient basis under local anesthesia. The final cast is then applied, keeping the foot at 70 degrees of abduction, and in dorsiflexion (stretching the sectioned tendon as far as possible) for three weeks, until the tendon has healed in the elongated position. When the cast is removed, the foot is corrected – this is generally before three months of life, if the child has begun treatment in the first two weeks of life (PONSETI, 1996; HERZENBERG & NOGUEIRA, 2006).

Figure 2 - serial Casts showing gradual correction of the deformity



Source: Author's file

After removal of the cast, the child is fitted with an abduction brace, which consists of two leather shoes that open at the front, connected to a bar, which keeps the feet (or both feet in the bilateral cases) in a position of maximum abduction, but allows the mobility of the knees and hips.

Figure 3 - brace, abduction of the feet – bilateral abduction at 70 degrees



Source: Author's file

The use of an abduction brace is very important for maintaining the correction of the feet, and should be continued 23 hours a day, for three months, and then for 14 hours, at night, up to four years of age.

It is not sufficient to correct clubfeet with serial cast manipulation; if the brace is not used in the correct way, the deformity will return, as though there were some kind of "biological memory" of the initial deformity. This tendency lessens as the child grows older, therefore it is usual to advise the use of the brace until four years of age (PONSETI, 1996; MORCUENDE et al, 2004).

The Ponseti Method is simple to perform, but requires careful attention to detail. The serial cast manipulations are performed very differently from the Kite Technique (PONSETI, 1997; KITE, 2003), and their results are highly reproducible, as demonstrated in the current literature, in different clinics, under different conditions, in both developed and developing countries (CHOTEL et al., 2002; GÖKSAN, 2002; HERZENBERG et al., 2002; COLBURN & WILIAMS, 2003; SEGEV et al., 2005; CHANGULANI et al., 2006; EBERHARDT et al., 2006;

SHACK & EASTWOOD, 2006; ABDELGAWAD et al., 2007; TERRAZAS-LAFARGUE, 2007; GUPTA et al., 2008; RADLER et al., 2006).

Generally, we than prefer the word "method" because it includes the more "technical" aspects, i.e. the correct manipulation and placement of the casts, and tenotomy, but it also includes all the guidance for parents on how to maintain the correction with the abduction brace, and how to monitor it correctly.

The Ponseti Method has some prerequisites for its proper execution: identification of the deformity at birth and referral to an appropriate treatment center, with professionals trained in the technique, appropriate material and location, guidance for families, frequent visits in the first months of life, and after that, less frequent visits in the maintenance phase.

Contact between doctor and patient (or health professionals and patient, or the patient's parents, in this case) is crucial for the success of the treatment. This form of treatment brings a more humanized approach to the medical treatment, reflecting a current trend in medicine. This form of approach helps build relationships with the participants in the treatment, and leads to stronger ties, which contributes to the success of the treatment and the appreciation of the medical profession.

The problems of application of the Ponseti Method relate to two main factors: inadequate training of medical professionals, and non-involvement of the family in raising awareness of the importance of the use of the abduction brace – a factor that is responsible for the highest incidence of recurrence of the deformity – and a breakdown in the relationship of trust between the doctor and the health professionals, and the families (Nogueira et al., 2013).

Chapter 3: SURGICAL TREATMENT AND ITS PROBLEMS

According to PONSETI (1996), surgery for clubfoot should be avoided if there is another less-invasive option. Posterior-medial release includes resection of the joint capsules and ligaments of the foot, and positioning of the cartilaginous structures in a position of reduction, fixed in an incongruous position.

The surgical results were examined in detail in a study by DOBBS et al (2006), in Saint Louis, and proved to be unsatisfactory, both from an orthopedic point of view, with greater rigidity and a higher number of surgeries per foot treated, and in terms of quality of life, with indices of SF 36 (LOPES et al., 2007), which are similar to indices of patients with chronic renal failure on dialysis, or congestive heart failure. A study by VITALE et al. (2005), carried out at the International Center for Health Outcomes and Innovation Research in New York, showed good "long-term" results with a 16-year follow-up. This was based on questionnaires, and on the specific evaluation instrument used for the pathology, as well as x-rays. However, the poor results arising from extensive surgical release occur after from the third decade of life, and are therefore not documented in this study; these limitations have a significant impact on quality of life.

Surgery is usually performed with a tourniquet of the limb, adding a greater risk of vascular complications and postoperative edema. It is a procedure that is performed in major urban centers, in tertiary hospitals, and by orthopaedic surgeons who are highly trained in the technique. This surgery for congenital clubfoot is not usually done by a generalist orthopedist, and requires general anesthesia. In addition, the costs of this treatment, with serial casts by the Kite Technique followed by posterior-medial release surgery, are six times higher than the costs of treatment by the Ponseti Method (Nogueira et al., 2011; Ferreira et al., 2011).

Chapter 4: THE PONSETI METHOD AND ITS APPEARANCE IN BRAZIL

In 2000, we came into contact with the Ponseti technique through one of its first advocates, Dr. John Herzenberg, in Baltimore, who was obtaining good results with the technique, and taught his trainee in pediatric orthopedics and reconstruction in congenital alterations, Monica Nogueira, to perform the technique.

During this year of training in the United States, we also heard a very important debate for the observation of this important shift of paradigm in the treatment of clubfoot. At the most important course in American child orthopedics, the so-called Tachdjian course, in San Francisco in 2000, the main discussion presented during the morning session was the conservative treatment of congenital clubfoot. The participants were Dr. Ignácio Ponseti himself, of the University of Iowa, Dr. Ken Noonan (NOONAN, 2000), and Dr. Alain Dimeglio (DIMEGLIO, 2000), also an advocate for conservative treatment, but through physiotherapy, continuous passive movement, and the application of bandages. The American pediatric orthopedic surgeon discussed conservative treatment of congenital clubfoot, and placed less emphasis on treatment with extensive surgeries. This was not a focal discussion at a university center, but a debate within the main discussion forum of a medical specialty in the United States. Medical conducts were truly changing and it was very interesting to be able to witness this moment of transition.

We returned to Brazil at the end of 2000, eager to apply the new concepts we had learned, and report on the changes. Back at the university in the city of São Paulo, the proposed Ponseti Method was not well-accepted in orthopedic practice; this and other centers of excellence in the treatment of clubfoot were still heavily focused on the good preliminary results of extensive surgeries, their high rates of resolution, and the high complexity of these surgeries (SODRÉ, 1994, 1997; CARVALHO JR et al., 1997; LARA & SODRÉ, 1998, FARIA et al., 2001). Thus, there was resistance, in the main university centers of São Paulo, to the adoption of the Method, as extensive surgery was the standard procedure.

The development of surgical techniques for correction of clubfoot occurred through contact between Brazilian doctors and American doctors, mainly on the East coast of the United States. Thus, doctors like Alain Crawford, Douglas McKay, George Simons, Vincent Turco, and Norris Carroll (TURCO, 1979; CRAWFORD, 1982; MCKAY, 1983, SIMONS, 1985, CARROLL, 1987) became patrons (and trained several orthopedists Brazilian pediatrics), and had been proponents of extensive surgeries for the treatment of clubfoot (HEILIG, 2003).

Children's clubfeet were corrected, but the number of surgeries per child varied, and multiple procedures were required, making the feet more rigid with each intervention. In addition, due to the complexity of its implementation, the complication rates varied according to the experience at each center, and over-corrections were, and still are, difficult to treat clinically (ARONSON, 1990; SODRÉ, 1996). All the doctors agreed on the indication of serial casts at birth, but the conservative treatment, both in Brazil and in the major international centers, was not resulting in adequate correction in most cases (SODRÉ, 1994, FARIA et al, 2001; CUMMINGS et al, 2002; MERLOTTI, 2006; MORRISSY & WEINSTEIN, 2006).

Given that there were no doubts as to the start of treatment with manipulations and changes of casts during the first weeks of life, a clinical protocol was proposed for the treatment of congenital clubfoot, comparing the Ponseti technique with the Kite technique (KITE, 2003) in use at that time. The protocol was not considered valid, and was never sent to the ethics committee. This comparative study was subsequently conducted abroad by other institutions (HERZENBERG, 2002; SUD et al., 2007; SANGHVI e MITTAL, 2009; MATOS & OLIVEIRA, 2010; RIJAL et al., 2010), and found that treatment by the Ponseti Method was more efficient and more effective in terms of time and percentages of correction.

The School of Medicine of Universidade Estadual Paulista Júlio de Mesquita Filho, UNESP, in Botucatu, in the State of Sao Paulo, was the first to pay attention to information about the new technique: Dr. Reinaldo Volpi, an orthopedic surgeon

specializing in bone reconstruction, and also trained in public health, saw the Ponseti technique as a good treatment option. In 2001, the UNESP was the first university to exchange this information, promoting scientific meetings to explain the technique, and discussion of patients. It also became the first university clinic to perform treatment of congenital clubfoot by the Ponseti technique, performed by assistant and resident doctors of the department. Since then, meetings have been held each year to discuss cases and difficulties in relation to the application of the Ponseti Method.

In 2001, faced with the difficulty of acceptance, both of the Ponseti technique and the techniques of planning and correction of deformities in the São Paulo state capital and in the university environment, we accepted an invitation from Dr. Jorge Borges, a pediatric orthopedic surgeon with training in pediatric trauma and an interest in bone lengthening and reconstruction, to work in the city of Passo Fundo, in the state of Rio Grande do Sul, in the South of Brazil.

The work in the Rio Grande do Sul enabled direct use of the principles learned at the American center in Baltimore; Jorge Borges was, himself, a great follower of the innovations at this center and at various other North American, European, and Latin American centers.

The opportunity provided by this working environment led to direct application of the principles and a steep learning curve, not only in the implementation of the Ponseti technique, but also in the concepts of reconstruction treatment, with measurement of the angles of alignment and radiographic joint guidance according to the North American School, and in the follow-up and analysis of cases in which the same strategies had been used. North American orthopedics differed in principle from that of Brazil and its European influence: American orthopedics was more informal and reproducible, based on following specific rules: through the "step-by-step" procedures passed on by the North American Masters, it was possible to reproduce the same good results.

Our European heritage in orthopedics reflected, and still reflects a decision-making based mainly on acceptance or rejection of the principles by the medical university hierarchy. Scientific evidence is important, but sometimes, despite being demonstrated through publication, this evidence is often considered less relevant, as discussed by GREER (1988).

The work in the city of Passo Fundo was characterized by an open environment, with little resistance to the adoption of the new principles learned in Baltimore; it was also shaped by the presentation of these new principles to students, medical residents and other professionals interested in the new approaches to the orthopedic problems typical of our practice, clubfoot being one of them.

The work in the South of Brazil was also influenced by the working structure, which had orthopedic surgeons with two professionals per specialization group, one generally more senior, with good training and more experience, but nevertheless actively participating in continuing education activities, acting as an opinion former in his or her area, and another professional, generally younger, almost all having received different types of training abroad, and active proponents in the rational use of technologies and forms of treatment widely discussed in the centers of excellence.

To all this was added the application of all these concepts in three different contexts, all at the same institute: one, a private clinic with private patients, the second, a medical group, and the third, patients of the *Sistema Único de Saúde* (the Brazilian national healthcare system – SUS). The Ponseti Technique was applied in the three healthcare modalities, and the initial results showed no differences between the groups. In most patients, the Ponseti Method offered greater effectiveness in the correction of the deformity, and greater efficiency, as it obtained the correction with far less cost and less time (NOGUEIRA, 2002b).

In 2001, we returned to Baltimore for the annual course in correction of deformities, and also to participate in monitoring the practice sessions in a preliminary course on the Ponseti technique, with the participation of renowned

American orthopedics. These included Dr. Norris Carroll (a great champion of extensive surgical treatment of clubfoot), and also J Norgrove Penny (Kampala, Uganda), Richard Davidson (Philadelphia, Pennsylvania), Noam Bor (Afula, Israel), Fred Dietz (Iowa City, Iowa), David Feldman (New York, NY), and Didier Moukoko (St Gely du Fesc, France, representing Dr. Alain Dimeglio), all invited by Dr. Herzenberg, who defended the Ponseti technique as the most appropriate for the treatment of clubfoot. The title of Dr. Norris Carroll's lecture was "The wound, I believe, is the disease" (CARROLL, 2001). At the same Congress, a Chilean orthopedic surgeon and opinion former, Dr. Dalia Sepúlveda, also informally expressed her enthusiasm for the Ponseti technique.

Another highlight of this symposium, in addition to the workshops with plastic models for manipulation and manufacture of casts, was the presence of Dr. J. Norgrove Penny, a Canadian pediatric orthopedic surgeon who has lived and worked in Uganda, Africa.

Dr. Penny presented the results of a project to treat clubfoot in Uganda, where out of a population of twenty million inhabitants, there are a thousand cases of clubfoot each year, and around ten thousand cases were left untreated (PENNY, 2001).

Dr. Penny and Shafique Pirani's project has attracted great interest, Brazil being a developing country. Despite the universal health system adopted by Brazil, the population not reached by medical attention, mainly non-emergency cases, is very large, resulting in many cases of children with untreated clubfoot.

The strategy they presented in Africa was to develop a health policy on prevention of the deformity, informing and guiding maternity units and children's hospitals, training professionals to carry out the operations and perform cast manipulations, training local doctors to perform percutaneous tenotomies, and developing a locally-produced brace that would be more accessible to these patients.

They chose to use the Ponseti Method in Uganda for the treatment of clubfoot deformity, as this is the most appropriate method for a developing country and does not require costly resources. In addition, the method does not require extensive surgery, or the higher costs associated with this. The results of long-term follow-up were demonstrably better (COOPER and DIETZ, 1995), and the method could be systemized for mass training. This treatment had already been performed in this way in Uganda for four years, and received support from international organizations, such as Rotary International and the Canadian International Development Agency (CIDA), in association with the Ministry of Health of Uganda and the Department of Orthopedics of the University of Makerere, in Kampala, Uganda (PENNY, 2001).

At this symposium, there was an opportunity to present to Dr. John Herzenberg the results obtained with this method here in Brazil, in the state of São Paulo, and in Passo Fundo, in the state of Rio Grande do Sul. He approved it, reporting the results to Dr. Ponseti. As a result, Brazil gained academic support from the University of Iowa and Dr. Ponseti's group, and we continue to collaborate on different projects.

From 2002, back in São Paulo and following a visit to the University of Iowa to attend the Annual Symposium on the Ponseti Method, it was necessary to establish a new practice. Due to the resistance to the dissemination of the method observed in academic circles, and the need for a national reference in Portuguese that could be consulted by patients' parents, we decided to create a website with the same content as that of Dr. Ponseti in Iowa, with his permission, but in Portuguese. And so, the website www.petorto.com.br was created, with the protocol of the Ponseti Method, containing a section with explanations about the cause, another with FAQs, and a link to the website of the University of Iowa.

This website provided parents with a forum for medical education, to learn more about the method, and was used mainly by young families in cases where there was a prenatal diagnosis of the deformity.

The first clinical results of treatment of clubfoot in southern Brazil, which formed the learning curve, were presented at the Brazilian Congress of Orthopedics in November 2002 (NOGUEIRA, 2002 b). In that same year, a group from Curitiba also presented a poster on the results of treatment by the Ponseti Method at the Hospital Pequeno Príncipe (FORLIN et al, 2002).

Due to the resistance to the introduction of the Ponseti Method in orthopedic circles, the First International Symposium on the Ponseti Method was organized in 2003, with the support of the University of Iowa, through Dr. José Morcuende. The event was also attended by Dr. Shafique Pirani of the University of British Columbia in Canada, and Dr. Dalia Sepúlveda from Santiago in Chile, enabling the Brazilian doctors to learn more about the method. This course was based at the School of Medicine of the Universidade Estadual Paulista Julio de Mesquita Filho - UNESP in Botucatu, and was co-organized by Dr. Reinaldo Volpi. Dr. Pirani presented to the course the results of his work with magnetic resonance imaging in neonates, demonstrating total remodeling of cartilages in just a few weeks, with maintenance of joint congruence (PIRANI, 2001). Another important contribution he made was the method for quantifying clubfoot deformity, which is now widely used in various centers (DYER, 2006). Dr. Pirani also presented the preliminary results of the project developed in Uganda, with focus on public health.

In 2004, the Brazilian Pediatric Orthopedic Society, in a guidelines book, recognized the Ponseti Technique as appropriate and indicated for the treatment of congenital clubfoot, describing good results (SANTILI, 2004).

In that same period, Dr. Edilson Forlin, an orthopedic doctor at Hospital Pequeno Príncipe in Curitiba, reported that he had learned about the Ponseti technique during his visit to the University of Iowa, in 1992. He stated, however, that the technique for the treatment of clubfoot by the Ponseti technique, especially percutaneous tenotomy of the Achilles tendon, was not well accepted in his environment; even so, he reported on 49 children treated with the technique, with posterior medial releases in 13% of the feet treated (SANTILI, 2004).

Following the International Symposium on the Treatment of Clubfoot by the Ponseti Technique at UNESP, and the official visit of Dr. José Morcuende, (representing Dr. Ponseti) to the three departments of orthopedics (the Institute of Orthopedics and Traumatology of Hospital das Clínicas of the Universidade de São Paulo School of Medicine, Santa Casa de São Paulo, and the Association of Assistance to the Disabled Child - AACD - São Paulo), there followed a year of affirmation of the Ponseti technique, both at the Brazilian Congress of Pediatric Orthopedics, in Belo Horizonte, and at the Brazilian Congress of Orthopedics, in Recife.

In 2005, the second International Symposium on the Ponseti technique was organized, once again at UNESP, in Botucatu, by Dr. Reinaldo Volpi (an orthopedic doctor and public health professional) and Dr. Monica Nogueira. The invited international speakers were those who had already participated in the previous symposium at UNESP, Dr. José Morcuende (University of Iowa), Dr. Shafique Pirani (University of British Columbia, Canada), and Dr. Dalia Sepúlveda (Hospital de Niños, Roberto del Río, Santiago, Chile), and also two orthopedic surgeons, Dr. Anna Ey (Hospital San Juan de Deu, Barcelona, Spain), and Dr. Cristina Alves (Hospital Geral do Funchal, Madeira, Portugal).

This symposium, which had fifty delegates, focused on the Ponseti Method and the details of how to perform it, and also presented a new topic: a national panel on the preliminary results of the orthopedic doctors who had participated in the first symposium in 2003.

Fourteen services presented cases in summary form, from four Brazilian states: São Paulo, Minas Gerais, Alagoas and Rio Grande do Sul (Hospital da Beneficência Portuguesa - SP; Hospital da Escola Paulista de Medicina – São Paulo – SP, PUC de Campinas, Faculdade de Medicina do ABC, Hospital Municipal de São José dos Campos - SP, Hospital da Baleia, and UFMG, Belo Horizonte, Minas Gerais, Institute of Orthopedics and Traumatology of Passo Fundo, Rio Grande do Sul, Hospital do Açúcar in Maceió, Alagoas, Hospital das Clínicas de São Paulo, Hospital

Universitário of the campus of USP, SP, UNESP Botucatu – SP, Santa Casa – SP, UNICAMP – Campinas, SP, and Faculdade de Medicina de Taubaté – SP).

All these services, together, presented a total of 1293 feet treated, in 853 children, with a 94% success rate in the initial correction by the Ponseti Method. This result was considered very important, and following the two-day symposium in 2003, it was possible to reproduce the good results of the Method in various services.

Based on these results, the idea for a project with national coverage was sown.

Chapter 5: THE ROLE OF THE INTERNET

The internet today is a means of information used by 28.7% of the world's population, according to a US website Internet World Stats (<http://www.internetworldstats.com/stats.htm>) i.e. approximately 1.9 billion people.

Worldwide internet usage in the last 10 years has grown by 444.8%. It is interesting to note that while the growth of internet usage in North America was 146.3%, in Latin America and the Caribbean, this growth was 1032%, and today includes 34.5% of the population, or more than 204 million people. In Brazil, despite the label of "digital exclusion", statistics show that it has the highest concentration of internet users in Latin America; more than 75 million people (37.8% of the country's population).

Brazil accounts for 37.9% of all users in Latin America, followed by Mexico (15.3%), Argentina (13.3%) and Colombia (10.8%). Due to the popularity of virtual communication in the country, and its participation in the social networks, Brazil was called a "Schmooze Nation", or country of informal communication, by Newsweek magazine [Http://www.newsweek.com/2007/09/18/schmooze-nation.html](http://www.newsweek.com/2007/09/18/schmooze-nation.html)

In the area of health, there is more and more information available. Access to information, together with the increase in levels of education of the population, has led to patients seeking information about their disease, symptoms, medications and costs of hospitalization and treatment, a phenomenon which GARBIN et al (2008) terms the "patient-expert".

Compared to television, a mass communication medium with absolute permeability in our country, the Internet is an information medium that contains an infinite number of available information sources, and is characterized by the proactive participation of the individual as an active agent in the process of acquiring information.

Recent Studies include groups such as women (PANDEY, 2003), or young people (Skinner, 2003) as the highest Internet users when it comes to health information. In the case of congenital clubfoot, the diagnosis of deformity by ultrasound is common from the third month of life, and is carried out in 33% of the pregnancies in which children are born with clubfoot, according to recent data (NOGUEIRA, and FARCETTA, 2010).

Families search the Internet for more information on the subject, given that in the majority of cases (77% in a Brazilian study with seven centers - NOGUEIRA et al, 2010g) the occurrence is unique and unheard of in the family. Pregnancy is a time when the woman is more emotional, and has more free time, and the time spent searching for information on the Internet for her family or friends is greater. Therefore, it is not difficult to see why 49.7% of consultations for orthopedic treatment of clubfoot, whether pre- or postpartum, by physicians with experience in the Ponseti technique, were referenced via the Internet (NOGUEIRA and FARCETTA, 2010). These Brazilian data are comparable to the North American statistics, presented at the Meeting of the Ponseti International Association in Washington in November 2009. In that study, 74% of American parents contacted the University of Iowa seeking treatment for their child by the Ponseti Method after researching on the Internet, and 51% of parents of other nationalities who sought this same service also did so via the Internet (TREVILLIAN, 2009).

In 1996, the University of Iowa and Dr. Ponseti's group created a website with information on treatment, which led to a tenfold increase over just four years, in the number of patients who sought Dr. Ponseti's services (MORCUENDE et al, 2003) and one year later, the first Internet discussion group for parents was organized. Four years later, other countries such as Australia, England, France, Finland and Germany followed suit, and Brazil followed this trend in 2002, with the first discussion group for parents on the treatment of clubfoot by the Ponseti method. In the years that followed, other countries such as South Africa, Spain, Portugal, Israel, Holland, Switzerland, Bulgaria, Lithuania, and Lebanon, also set up discussion groups on the

treatment of clubfoot, and there is now a total of thirty-six Internet discussion groups, in sixteen countries (EGBERT, 2009).

Thus, the "patient-expert" is searching for information about treatments, whether adequate or inadequate (ASLAM et al, 2005). According to GARBIN et al (2005), this fact greatly influences the doctor-patient relationship (or in this case, the patient's parents), as this individual is potentially less willing to passively accept the medical decisions. These authors point out the reasons why the patient is able to interfere in the authority and social prestige of the doctor, and consequently, change the doctor-patient relationship, which has traditionally been based on information asymmetry. They also discuss the empowerment that could lead, in extreme cases, to deprofessionalization of the doctor. However, these arguments would hold true if doctors were ignorant of the events, rather than acting as interactive and participatory agents in these changes. The increased information available on professionals and their academic careers is also an important source of information for patients, who previously had only the diplomas on the walls of doctors' offices.

In this situation, the dissemination of knowledge and the electronic media have influenced, and still influence clinical practice, and in the case of treatment of congenital clubfoot, they provide an important contribution for furthering the Ponseti Method.

Chapter 6: WHY HAVING THE PROGRAM PONSETI BRAZIL: THINKING NATIONALLY

Given the favorable results with the Ponseti Method in 2005, demonstrating good reproducibility in fourteen different services, and also based on the repercussions of the Ponseti Project for the Treatment of Clubfoot in Uganda (PENNY, 2001; PIRANI, 2006), in 2006, a plan was developed to expand the training of doctors nationwide.

Successful doctor training projects have the advantage of standardizing the content, since well-developed and properly reproduced content can lead to the reproduction of good outcomes based on the correct practice of the principles. A typical example in medicine is the Advanced Trauma Life Support Course (ATLS). The ATLS courses are standardized, constantly updated, and reproduced in several countries, with different social conditions and features, but with very positive results (ALI et al, 1987, 1998; VAN OLDEN et al, 2004). The impact of these training courses is seen in the improvement in mortality rates in initial care of the polytraumatized patient of each institution where professionals have undergone training.

In orthopedics, we see the example of the Association for the Study of Osteosynthesis (treatment of fractures), which also runs standard-courses through the "AO Foundation" (MATTER, 1988), and which has a very active participation in Brazil, initially at its center in Ribeirão Preto - USP, and with courses in different Brazilian cities. The assessment of the impact of these courses in Brazil has not yet been documented, but it is believed they can also help improve the care of patients with fractures.

In relation to the course on the treatment of congenital clubfoot by the Ponseti Method, we find it difficult to obtain an "instant" measurement of its impact because instead of a situation of acute management, as in the case of multiple traumas or fractures (where maintenance of life is an immediate observable outcome of the

training), the initial treatment (serial cast phase) lasts around two months, and follow-up of at least one year or even more is required to determine whether doctors are successfully performing both the initial phase of application of casts and the tenotomy, and the control and prevention of recurrences.

The content of the training courses was therefore prepared with these characteristics in mind, so that what was taught was not a modification of the Method or personal preference of the expert teacher of the Ponseti Method. Another concern was the official aspect of the course through the Brazilian Society of Pediatric Orthopedics, which is linked to the Brazilian Society of Orthopedics and Traumatology, so that the project could officially include the entire country. With the resources obtained (as we describe below), the planning carried out, and the group of teachers of the organized Method, we gained official consent from the Society of Pediatric Orthopedics to carry out the Project.

An English non-government organization was created based on the presentation of idea of a national training project for orthopedic doctors throughout the country, to two people from the investment banking sector. The association was called La Vida (Vital Investment for Development Aid in Latin America www.lavida.org.uk), and held numerous events to raise funds for this Brazilian project in the United Kingdom.

This institution donated 126 thousand Brazilian reais, through the Brazilian Society of Pediatric Orthopedics, to officially set up a Study Group on the Ponseti Method. Orthopedists who had already had contact with the Ponseti Technique, or training recognized by the University of Iowa, traveled in groups of three to the cities selected for the project, most of which were capitals of the twenty-one Brazilian states, to give the training courses.

The Program consisted of twenty-one Symposiums, carried out from January 2007 to December 2008. Each Symposium followed a standardized format: one session during the Friday morning dedicated to classes on the Ponseti Method,

another session in the afternoon with practical work using plastic models, and on the following day, in the morning session (a Saturday), the local organizers led patients and their parents who attended voluntarily, in a discussion on the Ponseti Method, often followed by the application of casts in real patients.

The lectures were also standardized, i.e. seven lectures, each lasting about twenty minutes, consisting of material provided by the University of Iowa, with translation and adaptation into Brazilian Portuguese.

The sessions were as follows:

- Opening of the Symposium – presented the Project, how it was developed, explanation of its purpose, and its work proposal.

- History of the Ponseti Method – discussed the treatment of clubfoot, and the historical evolution of its treatment, emphasizing the circumstances that led Dr. Ponseti to develop the Method and discussing of the role of the Internet in the dissemination of the method. The session also commented on the long-term follow-up of extensive surgical releases of clubfoot (DOBBS et al, 2006);

- Ponseti Method in detail - with emphasis on the biological properties of the foot, and also the characteristic of the biomechanics of the subtalar joint as key factors of the correction during the cast phase.

- Classification and quantification of Clubfoot deformity and Magnetic Resonance Studies – discussed the two more important studies for understanding the deformity, how to manipulate it for gradual control, and how the remodeling that could not be demonstrated in the radiographic evolution could be elegantly demonstrated by magnetic resonance studies; (PIRANI, 1999).

- Recurrences: diagnosis and treatment – a fundamental part of the discussion, qualifying the deformity with potential for recurrence, how it decreases over time, and how to identify and treat it.

- Complex clubfoot - discussed the identification of clubfoot with different characteristics from common clubfoot, and the changes in manipulation necessary for its treatment.

- Limits of the Method - this innovative lecture, promoted by the University of Iowa, presented the preliminary results obtained in our country among older patients with deformities, and other difficult cases, such as patients with extremely rigid feet, as in arthrogyrosis, or patients with myelodysplastic diseases, where the lack of sensitivity due to lesion of the spinal cord had previously virtually contraindicated the use of the Ponseti Method.

Slides of the lectures were sent to thirteen orthopedists trained in the Ponseti Method (and constituting the Brazilian Ponseti Method Study Group), together with the script of information to be cited and discussed in each of the slides.

This was done to standardize the form of teaching in the Symposium, and to ensure that any one of the Study Groups could teach any of the seven lectures. The content was approved by the group.

The reference manual for this Project was developed based on the adaptation of the content of the manual of GLOBAL HELP (STAHელი, 2004), an American nonprofit foundation that organized the necessary information for a quick and illustrated reference to knowledge on the Ponseti Method. The adaptation for Portuguese, and some modifications, were made based on a joint work with Dr. Lynn Staheli, and the Brazilian Society of Pediatric Orthopedics. A page was added with specifications of the brace, and both Dr. Ignácio Ponseti and Dr. José Morcuende wrote a preface encouraging the initiative. The print run of 6,000 copies of this manual was funded by the English NGO La Vida. The manuals were distributed at the symposiums, free of charge, to all the participants.

The practical session was the most important part of the Symposium, as it consisted of an explanation by the three teacher-monitors of the Ponseti Method to smaller groups of participants on how the deformity was corrected visually through the specific correction maneuver of the Method. This was possible using plastic models that simulated the deformity, with elastic bands to demonstrate the effect of the correction with the appropriate handling. It was also possible to demonstrate the

harmful effects of incorrect manipulation of the foot. This was a very interactive session, in which all the participants had an opportunity to manipulate the models. Many were also able to prepare casts, under the supervision and guidance of the teachers, on another type of rubber model mimicking a clubfoot in a newborn infant with the deformity.

These ten models of each type were developed by a company that manufactures orthopedic braces in Iowa, together with Dr. Ponseti himself. The models were donated to the Ponseti Brazil Project by Mr. Michael Braunstein, who was present at the presentation of the proposal of the Ponseti Brazil Program during the International Symposium on Clubfoot by the Ponseti Method, in Iowa, in 2007.

On the following day, the discussion of cases with patients presented by the local doctors consisted of "interviews" with the parents of children with clubfoot who had come voluntarily to the event, examination of feet in treatment or already treated, and sometimes, preparation of casts. On this day, the participants also filled out a course assessment survey.

The symposiums took place in twenty-one cities in Brazil, mostly state capitals but also some non-capitals, seeking to decentralize knowledge of technique, which was already present in the state capitals. The cities that hosted the symposiums were: Belo Horizonte - MG, Campina Grande - PB, Fortaleza - CE, Recife - PE, Aracaju - SE, Maceió - AL, São Luis - MA, Manaus - AM, Belém - PA, Uberlândia - MG, Londrina - PR, Vitória - ES, Rio de Janeiro - RJ, Florianópolis - SC, Porto Alegre - RS, Campo Grande - MS, Teresina - PI, Salvador - BA, Brasília - DF, Goiânia - Go and Natal - RN.

The different states were contacted through the Brazilian Society of Orthopedics and its regional branches, and the local organizers took care of the arrangements at the site, the publicity, and the clinical cases to be presented. The English NGO funded the travel expenses of three orthopedic monitor-teachers of the Method to each of the symposium sites. The symposium delegates enrolled free of

charge, and their participation was voluntary and open to all. Publicity for the event was the responsibility of each region, and was done by means of posters, direct mail, and electronic media.

The monitors consisted of a group of thirteen doctors from various parts of Brazil, with good training in the Ponseti technique, good teaching skills, and acting as opinion formers in Pediatric Orthopedic circles. (Dr. Monica Paschoal Nogueira, of the Hospital Beneficência Portuguesa, São Paulo; Dr. Alexandre Lourenço, of the Universidade Federal de São Paulo, Dr. José Luis Zabeu, of the Pontifícia Universidade Católica (PUC) de Campinas, Dr. Maria Henriqueta Rennó Merlotti, of the Hospital Municipal de São José dos Campos - SP, Dr. Eduardo Novaes, of the Universidade Federal de Minas Gerais, in Belo Horizonte – MG, Dr. Gilberto Brandão, of the Hospital da Baleia, Belo Horizonte and Universidade Federal de Minas Gerais, Dr. Laura Fernanda Alves Ferreira, of the Hospital Universitário da Universidade de São Paulo, Dr. Ana Paula Tedesco Gabrieli, of the Hospital Universitário de Caxias do Sul – RS, Dr. Jung Ho Kim, of the Instituto de Ortopedia e Traumatologia de Passo Fundo - RS, Dr. Carlos Aguiar and Dr. Edilson Forlin of the Hospital Pequeno Príncipe, in Curitiba – PR, Dr. Reinaldo Volpi, of the School of Medicine of Universidade Estadual de São Paulo Julio de Mesquita Filho, Botucatu – SP, and Francisco Violante, of the AACD - Associação de Assistência à Criança Deficiente, São Paulo - SP).

The participants were asked to fill out a form at the start of the symposium, with their identification data and contact information, and answering the following questions:

1. Do you treat clubfoot?
2. Do you perform posterior medial release surgery?
3. How many children have you treated in the past year?
4. Have you heard about the Ponseti technique?
5. What are your expectations of this symposium?

After the symposium, at the end of the second day, the participants filled out the assessment form below, with Likert scales (Table 1).

Table 1: Assessment of the Ponseti Symposium

- Did the symposium meet your expectations?				
1	2	3	4	5
No	a little	reasonably	yes	exceeded
- Was the Ponseti Technique well presented?				
1	2	3	4	5
Not	a little	reasonably	yes partially	yes fully
- Based on the information from this course, do you consider yourself capable of treating patients with the Ponseti technique?				
1	2	3	4	5
No	may be capable	reasonably	yes, probably	Certainly
- After taking part in the symposium, are you convinced that the Ponseti Technique is the most indicated for the treatment of clubfoot?				
1	2	3	4	5
No	not sure	indifferent	possibly	yes
- Do you believe that this symposium could change the way you treat children with clubfoot?				
1	2	3	4	5
No	a little	reasonably	possibly	yes
Suggestions and comments:				

Chapter 7: THE PONSETI BRAZIL PROGRAM: HOW TO EVALUATE IT

Following the symposiums of the Ponseti Brazil Project, we sought to evaluate the impact on the treatment of congenital clubfoot throughout the country. The hypothesis was that following the training courses on the treatment of clubfoot, the success of the correction and maintenance of the deformity by the Ponseti Method would cause the number of posterior-medial release surgeries to drop significantly. Four means of gathering information to test this hypothesis are presented below.

Evaluation of a Health Program is, in itself, a discipline that is already structured within the overall discipline of Health Evaluation. The formal assessment, or the systematic use of information and criteria for attributing values and justifying value judgments, has its own scientific value and can serve as a basis for decision-making on whether to change or maintain a situation in health care, seeking to improve its conditions. A simple way to assess a program is to determine its value or merit (WORTHEN et al, 2004).

For the assessment of a training program, the most relevant dimension is its impact, i.e. the effect of this intervention. In this training program (the Ponseti Brazil Program), the direct result would be more doctors trained to treat congenital clubfoot by the Ponseti method in Brazil. However, the most important final outcome or impact would be an increase in the number of children successfully treated by the Ponseti Method. Another less direct and more extensive impact would be greater dissemination of Ponseti Method in Brazil following the training program.

According to WORTHEN (2004), an assessment focused on objectives (goals) lends itself to this purpose. If the goal of the program is a greater number of children with congenital clubfoot successfully treated, then indicators are needed to measure this variable.

In the case of our main objective i.e. whether the Ponseti Method was used more frequently, and in an appropriate way, with satisfactory results, by the

participants of the training courses, two indicators of impact – one direct and one indirect, can be used.

The direct indicator of impact would be an increase in the number of children successfully treated, based on the compilation and assessment of the results of the treatment of children by the participating orthopedists. The indirect indicator of impact would be a comparison of the number of posterior-medial release surgeries performed before the training, and after it.

If the correct application of the Ponseti Method by more professionals results in more children successfully treated, then the number of posterior-medial release surgeries should decrease, representing more children with clubfoot treated without extensive release surgery to the foot.

This was the indicator used by the American study of ZIONTS (2010), which was able to demonstrate, in the databases of procedures coded in the United States, that in the last decade, the number of posterior-medial release surgeries performed by American doctors had declined substantially, at a rate of 6.7% per year, from just over 70% in 1996 to just over 10% in 2006.

In terms of the use of this variable (number of posterior-medial release surgeries) as an indicator for the extent of impact of the training program, we have the problem that not all the reduction in the number of posterior-medial release surgeries can be accredited to the training program (PPB). This decrease may be attributable to factors other than the training, such as other forms of dissemination of the Ponseti Method, courses, meetings, lectures, books and periodicals.

As mentioned earlier, the direct form of measuring the impact would be constant observation of the treatment centers with professionals trained by the Program where the success in the treatment of each patient was observed, for each trained physician, thereby tabulating all the data. By monitoring of the number and observing the results of patients with clubfoot successfully treated by professionals

before the Program, and the follow-up of patients treated after the Program, we would arrive at an accurate measurement of the direct impact of the program. Because the number of trained professionals was 556, working in different treatment centers in more than twenty-one cities (many orthopedists who attended the symposiums were from other cities), this study would be possible in a wider evaluative study, with appropriate resources and adequate structure.

Chapter 8: ASSESSMENT OF THE SITUATION PRIOR TO THE PROGRAM: NUMBER OF POSTEROMEDIAL RELEASE SURGERIES

In the Brazilian statistics obtained from data from the Ministry of Health website www.datasus.gov.br, there are three procedure codes that relate to congenital clubfoot: 39023176 - surgical treatment of clubfoot.

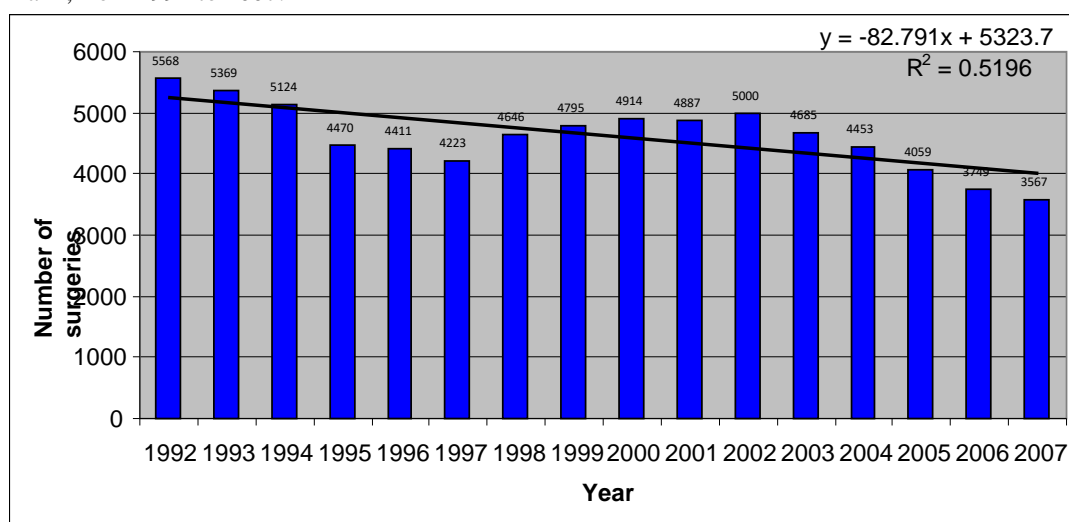
39050173 - review of congenital clubfoot, and

39051170 - treatment of inveterate congenital clubfoot.

The last two codes (review of congenital clubfoot and treatment of inveterate congenital clubfoot) were each investigated in isolation, each year, and it was observed that the data were numerically equal, even though they represented two completely different findings. We therefore opted not to evaluate these data in the analysis, and considered only the code relating to "treatment of congenital clubfoot".

The number of surgeries for clubfoot by the SUS (code 39023176) relating to "surgical treatment of clubfoot" per year, up to 2007, is shown in the figure below:

Figure 4: Number of procedures under the SUS code for "surgical treatment of clubfoot" per year, in Brazil, from 1992 to 2007.



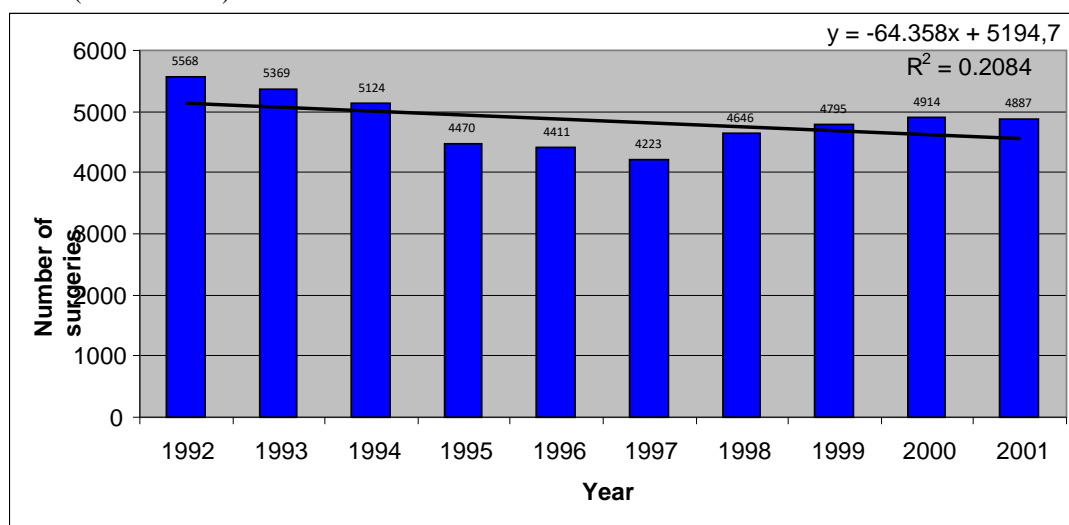
Source: TABNET DATASUS 06-11-2010

Using the Datasus database, we searched on the number of procedures coded as surgical treatment of clubfoot in the time interval available for analysis; from 1992 to 2007.

As the graph shows, in the sixteen years from 1992 to 2007, the number of surgeries for clubfoot by the SUS in Brazil fell slightly, but did not change significantly ($R = 0.51$). However, if we compare the absolute number of surgeries performed in 1992 alone (5568) with the absolute number of surgeries performed in 2007 (3567), we see a 36% reduction in this procedure.

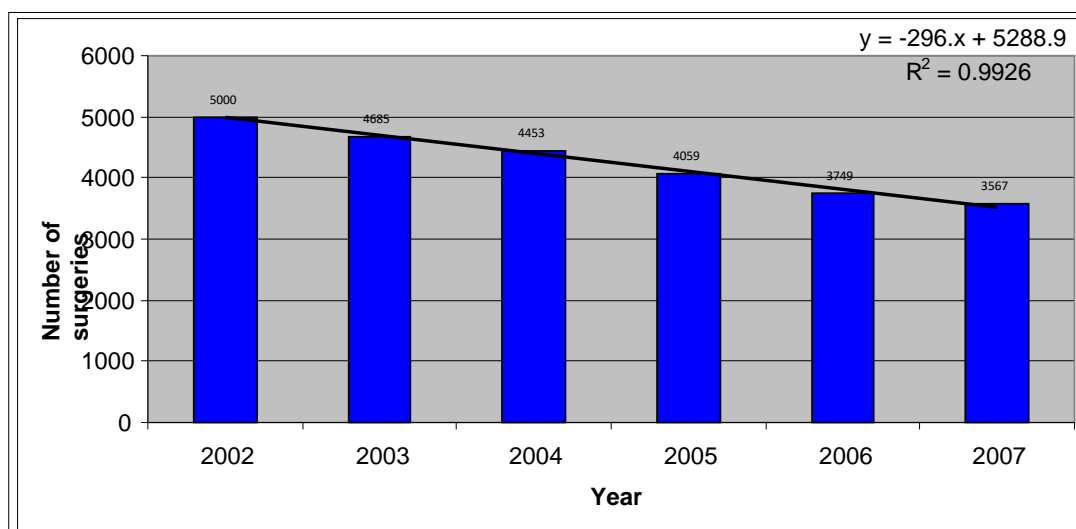
We therefore chose to analyze the trend in the number of surgeries per year in two separate periods: from 1992 to 2001, and from 2002 to 2007. The graphs of these two time periods in this historical series are shown in the figure below.

Figure 5: Number of procedures under the SUS code for "surgical treatment of clubfoot" per year, in Brazil (1992 to 2001).



Source: TABNET DATASUS 06-11-2010

Figure 6: Number of procedures under the SUS code for "surgical treatment of clubfoot" per year, in Brazil (2002 to 2007).



Source: TABNET DATASUS 06-11-2010

The two periods shown in figures 4 and 5 show different trends in relation to the number of surgeries of clubfoot carried out under the *Sistema Único de Saúde* (SUS). In the ten-year period from 1992 to 2001, there was no significant change in the number of surgeries of clubfoot performed each year ($R^2 = 0.21$). In the six-year period from 2002 to 2007, there was a trend toward a reduction in the number of surgeries ($R^2 = 0.99$).

A possible explanation for the change in these trends in the two periods is the dissemination of the Ponseti Method, with more centers publishing their results, according to the medical literature (Nogueira, 2013 Barcelona) The Ponseti Brazil Program, carried out in 2007 and 2008, cannot be regarded as the cause of the downward trend in the number of surgeries in this analysis, since this number was already declining approximately four years before the completion of the Program. For this, it would be necessary to analyze the future trend in the number of surgeries, in order to correlate it with the periods studied.

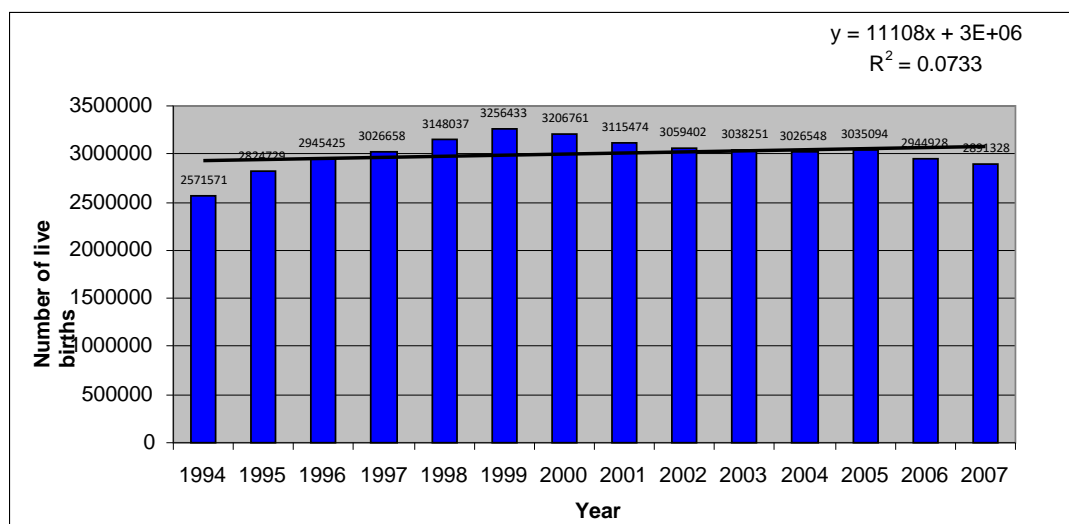
However, in Brazil there is a difficulty with the use of the code for congenital clubfoot by the orthopedic services. The code for "surgical treatment of clubfoot",

both in the public service (*Sistema Único de Saúde - SUS*) and in the private services (insurance companies) is incorrectly used for any type of surgery of the feet and as a result, the records of these surgeries are clearly overestimated. Thus, a tendon transfer, or a simple percutaneous Achilles tenotomy (part of the treatment by the Ponseti Method) is commonly coded as "surgical treatment of clubfoot", undermining the accuracy of any search on these health statistics, both in the public services information system (www.datasus.com.br) and in information from databases of the private services.

In view of this limitation, there is still a lack of correlation between the number of surgical procedures with the total number of live births, and the total number of live births diagnosed with congenital clubfoot.

In relation to the number of children born in Brazil from 2000 to 2007, (datasus.gov.br), we identified that the number of live births has not changed in the last decade, as shown in the graph below.

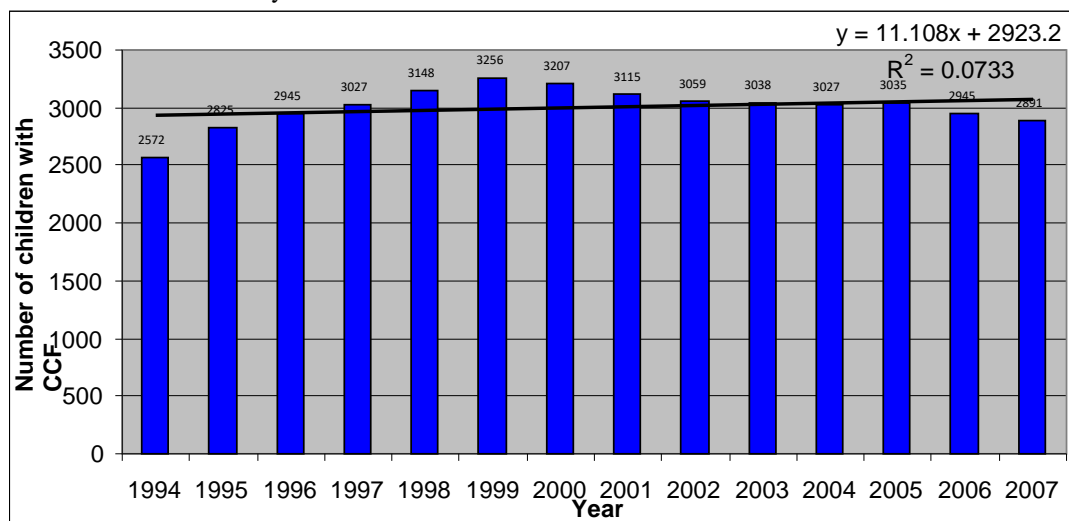
Figure 7: Number of live births in Brazil, each year, from 1994 to 2007.



Source: TABNET DATASUS 06-11-2010

With the estimated global average in the population of one occurrence of clubfoot deformity to every 1000 live births, we estimate that around 2800 children were born with one, or two clubfeet in 2007.

Figure 8: Estimated incidence of clubfoot in Brazil, from 1994 to 2007, based on a global incidence of one occurrence to every 1000 live births.



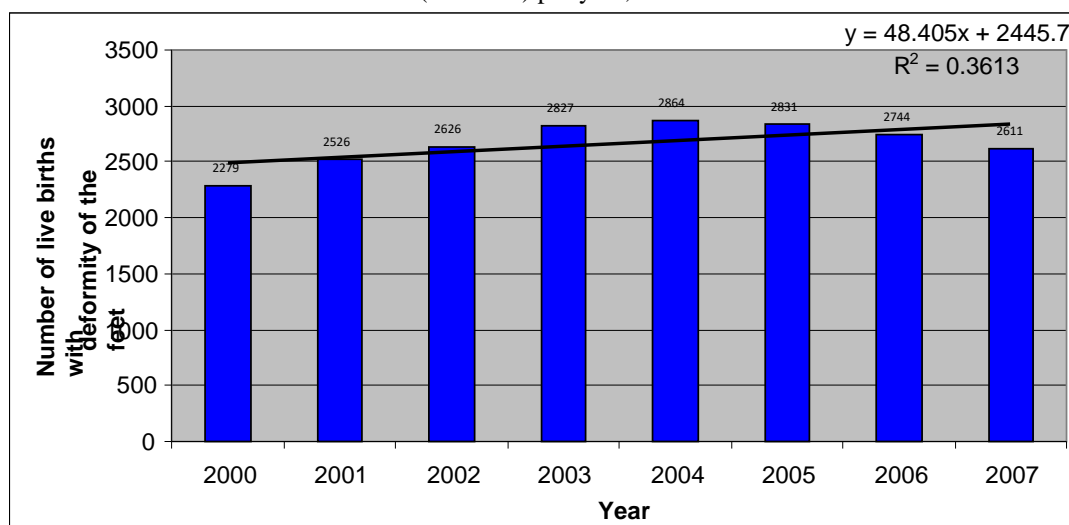
Source: Created by Monica Paschoal Nogueira based on data from <http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sinasc/cnv/nvuf.def>

The registration of congenital deformity relating to field number 34 of the registration of live births is the official documentation of children born with deformities. It is usually filled out by the pediatrician, or the nurse in the delivery room, and indicates the occurrence of deformities. With regard to congenital foot deformities, this record is annotated, regardless of the congenital deformity (congenital clubfoot, vertical talus foot, metatarsus varus, polydactyly, transverse defects). Therefore, there is no official record of children born with clubfoot, but at least congenital changes in the feet are recorded. There was a high level of underreporting (SILVEIRA et al, 2007 – around 40%, according to a study by LUCHETTI and KOIFMAN (2010), in 2004 in seven cities, and repeated in 2007. This study tested the validity of the information on congenital deformities recorded in the SINASC (the Portuguese acronym for Live Births Information System), and compared these data with those of the Latin American Collaborative Study of

Congenital Malformations (ECLAMC) database. This center aims to record congenital anomalies in live births and stillbirths, and to promote health policies for the establishment of preventive measures to avoid these developmental anomalies.

Through a search of the SINASC, we obtained the occurrence of congenital alterations in the feet, as shown in the chart below:

Figure 9: Total number of live births with congenital deformities of the feet, based on data from field 34 of the record of live births in Brazil (SINASC) per year, from 2000 to 2007.



Source: TABNET DATASUS SINASC 06-11-2010

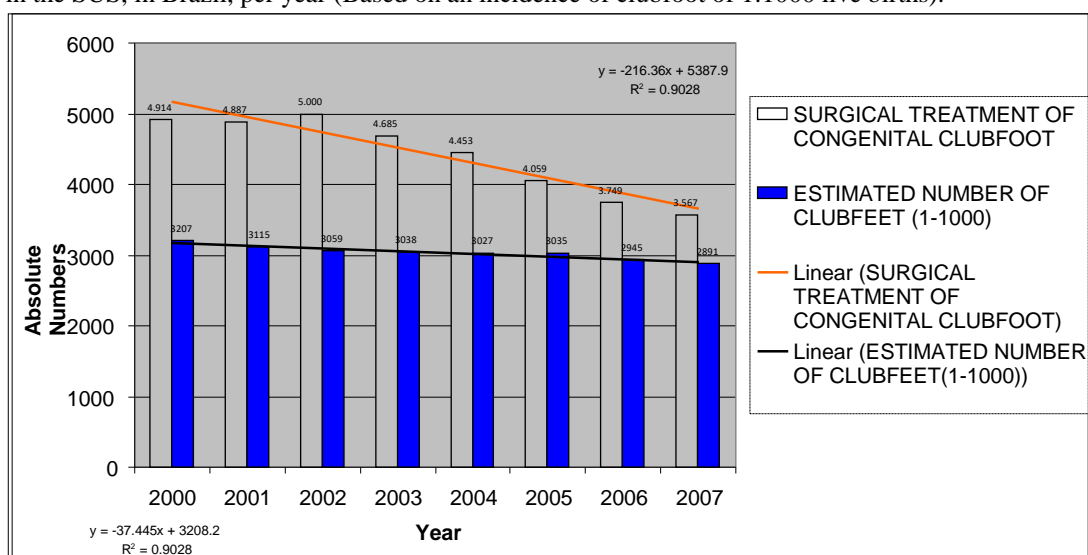
We observed that the SINASC data also show no significant change in the number of children born with congenital deformities of the feet. If we consider the correct estimate through the known incidence one child born with clubfoot to every thousand live births, we arrive at an average underreporting of 10% in 2007.

However, if we compare the number of surgeries for clubfoot performed, with the number of live births with the deformity, we find a much higher number of surgeries for clubfoot than the number of live births. As the surgery for the treatment of clubfoot is generally indicated in the first year of life, this great discrepancy could indicate that in addition to the underreporting of children born with congenital deformities of the feet, the number of surgeries for the treatment of clubfoot may also be overestimated.

We therefore estimated the number of infants born with clubfoot based on the incidence of one child born with clubfoot to every thousand live births in the general population (as shown in Figure 7), and compared these data with the number of procedures coded as "surgical treatment of clubfoot".

A comparison of the trends, reflected by linear equations, of estimated live births per year (using a population incidence of 1 clubfoot to every 1000 live births) with the trend in the number of procedures coded as "surgical treatment of clubfoot" per year, is shown in the figure below.

Figure 10: Comparison of the frequency and linear equations between the estimated number of live births with clubfoot per year and the number of procedures coded as "surgical treatment of clubfoot" in the SUS, in Brazil, per year (Based on an incidence of clubfoot of 1:1000 live births).



Source: DATASUS

Even considering the highest number of surgical procedures for clubfoot in the SUS, in relation to the estimated number of children born with congenital clubfoot deformity (with the previous explanations on the underreporting of children born with clubfoot and the surgical procedures for correction of clubfoot overestimated), it can be seen that the number of live births with congenital deformities of the feet in the period from 2000 to 2007 did not change ($R^2 = 0.36$) while the number of surgeries decreased from 2000 to 2007 ($R^2 = 0.90$).

Based on these data, in an attempt to better understand the decrease in the number of surgical procedures coded as treatment of clubfoot, and to evaluate the impact of the Ponseti Brazil Program on this trend, four assessment forms were proposed: first assessment – participants' reaction; second assessment - after 1 year, by email; third assessment: gathering information in two cities (*in situ*), and fourth assessment, an advanced course and clinical data of the national panel.

The first, more immediate assessment, relating to the participants' reactions, consisted of a questionnaire which was applied immediately after the end of the Symposium, to be completed by the participants. Based on the analysis of the responses before the symposium, given in the registration form and the questionnaire with semi-open questions after the symposiums, information was gathered about the participants' reactions to this exposure to the training program in the Ponseti Method. The results are presented in the next topic.

Chapter 9: FIRST DIRECT ASSESSMENT OF IMPACT: PARTICIPANTS' REACTION (PRELIMINARY RESULTS OF THE PONSETI BRAZIL PROGRAM)

At the end of the Ponseti Brazil Program, the results of the questionnaires and assessments of the orthopedist participants were compiled together.

Among the participants, which also included, in lower numbers, medical students, orthopedic residents, physiotherapists and nurses, 556 orthopedic surgeons were trained in this Program – approximately seven percent of the 8000 Brazilian orthopedic surgeons accredited as specialists by the SBOT- Brazilian Society of Orthopedics and Traumatology, according to data from 2007.

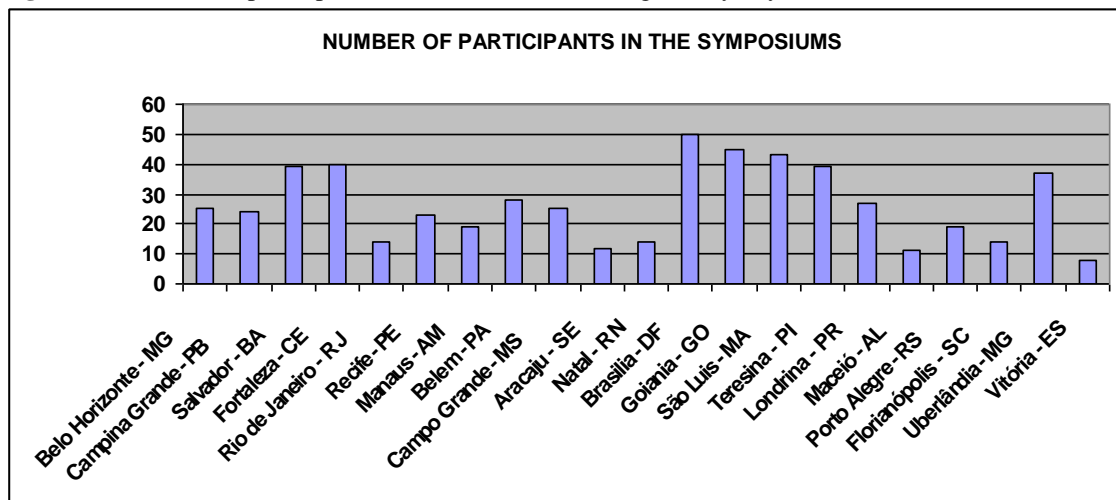
All the participants filled out the initial form with their information. All together, they reported having treated a total of 4905 children in the previous year using the Kite technique and posterior-medial release. Seventeen percent of the participants did not know about the Ponseti technique before the training, and 88% reported that after the training, they felt they would be able to treat children with the Ponseti method. It is also important to highlight that 94% of the orthopaedic surgeons reported that the symposium in their city has changed the way they considered the options for the treatment of congenital clubfoot.

The symposiums were an important forum for exchanging experiences in the treatment of clubfoot, and the qualitative assessment of the participating physicians was positive.

In many of these cities, doctors described limitations to treating their patients, because the posterior-medial release surgery performed as a complement to the Kite Technique could not be carried out due to limitations of the hospitals (lack of availability of surgical rooms for elective surgeries or access to general pediatric anesthesia), or even a lack of technical skills to perform the surgery.

In terms of the number of participants per symposium, the average was 26, ranging from 8 (Vitória) to 50 (Brasília). This number depended on the commitment and influence of the local event organizer, often appointed by the regional director of the Brazilian Society of Orthopedics. In many cities, orthopedic residents, a few rehabilitation professionals, some nurses, and some medical professors (less than 2% of the total) took part in the symposiums, but the vast majority consisted of orthopedists, some pediatric orthopedists and other general orthopedists and other subspecialties. As the application of plaster casts and tenotomy are considered medical procedures (Lisbon, 1994), only the orthopaedic surgeons received the evaluation and the final questionnaires for assessment. 73% of the participating orthopaedic surgeons (408 of the total of 556 orthopaedic surgeons) worked in public services, and more than 80% of those who worked in public services also worked also in private services.

Figure 11: Number of participants in the Ponseti Brazil Program, by city.



Source: Initial forms filled out by the participants.

All the participants filled out the initial form with their contacts and responses to the initial questions, but the final assessment was completed by only 52% of them. The main reason for this is that many did not remain in the course until the end of the discussion of cases on day two. Another reason may have been the lack of administrative structure of the symposiums, as the instructors were responsible for applying both the initial and final forms. On day two, the instructors were busy

attending to the patients brought by the local organizers, which caused a disturbance in the course dynamics, often resulting in a failure to complete the assessment forms.

In fourteen of the twenty-one cities, all the orthopaedic surgeons responded that the way they considered the treatment options for congenital clubfoot had changed after the training. In the remaining seven, the number of orthopedic surgeons who reported a change in the way they considered the treatment options for clubfoot represented more than 75% of the participants. It is interesting to note that despite this, 83% of the participants responded that they had already heard of the Ponseti Method before the training. 99% of the participants said they thought the symposium and training were well presented and conducted by instructors.

In the descriptive assessments and suggestions, some comments are notable, with emphasis on the participants' enthusiasm:

"...It is a good time for my patients with clubfoot. I was convinced; now I know that the method is, at the moment, the best alternative..." (Symposium in Salvador);

or reporting the need for support and assistance

"...Total satisfaction. Trained teachers, suitable format. It's important that we are always in contact to clear up any doubts..." (Symposium in Vitória);

or concerning for the practical side of the symposium, and some even felt able to go back and treat congenital clubfoot:

"...For me it was important to improve my technique in cast placement by the Ponseti method. It was very good, they literally got our hands on to teach ..."

"...had stopped treating CCF, after this course I will start treating clubfoot again, by the Ponseti method. I learned about the techniques at meetings, but did not feel confident about using them..." (Symposium in Aracaju);

or highlighting their change of practice:

"...I am from a technique where the Clubfoot Congenital Foot is just prepared for surgery with the application of casts, but I have changed my mind..." (Symposium in Sao Luis).

or showing interest in supporting the development of centers of reference :

"...Enable centers as reference in treatment of Clubfoot Congenital Foot by the Ponseti Method. These centers evaluate bad and difficult cases, and also train professionals and update them..." (Symposium in Fortaleza).

Some orthopedic doctors needed more training, as they still did not feel confident in applying the concepts, despite recognizing their value:

"...I want to change my practice, but I need experience it to fully believe it..." (Symposium in Goiânia)

Others reflected on the role of the *Sistema único de Saúde* in implementing the Method:

"...I believe we should fight to try lowering the cost of the brace, or to provide this aid on the SUS, because due to the social condition of our patient, this may perhaps be an obstacle..." (Symposium in Sao Luis);

"...I think that the SBOT should bring it to the notice of the Ministry of Health to carry out a program with public backing..." (Symposium in Teresina).

The program was, therefore, very important for disseminating the Ponseti Method among orthopaedic doctors, but what is still unknown is how many of them had really learned how to carry out the method correctly. Perhaps because there was no registration fee for the training, many participants were curious, but without any real commitment to correctly follow the entire two-day training program; some of

them attended the training to improve their orthopedic education, but did not treat children with clubfoot in their clinical practices.

Some consequences of the symposiums could not be measured through the assessment forms, but were detected by the instructors. One of these was the ability to offer, to all the participants, an important tool for use in clinical practice that is used in reference centers worldwide for the treatment of children with congenital clubfoot. This gave the Brazilian orthopedic surgeons an opportunity to treat congenital clubfoot, the same way as the most developed and well-equipped centers around the world did, with the prospect of obtaining the same good treatment results. In a heterogeneous country like Brazil, this is very important.

High levels of motivation and interaction were observed between the local orthopaedic surgeons and the instructors at the end of symposiums when, following the symposium in Campo Grande, and an informal assessment was carried out, in which the participants openly reported their experiences and their informal assessment of the training. This was done to document the symposiums for the English institution collaborating in the Ponseti Brazil Project. Many experiences were exchanged informally, which contributed to the positive results reported by the participants and instructors.

Chapter 10: SECOND DIRECT ASSESSMENT OF IMPACT: SURVEY AFTER ONE YEAR - VIA THE INTERNET

Due to the difficulty of obtaining information on the impact of the training on the clinical practice of the real orthopaedic surgeons, assessment forms were sent out by email, one year after a year of the symposium. An email address was created exclusively for this purpose *simposiosponseti@gmail.com* and along with the submission of the form, the proposal was to send out the official symposium certificates, with the seal of the International Ponseti Association, and another from Bone and Joint Decade, an organization of the American Academy of Orthopaedic Surgeons.

However, only twenty-two participants completed the email assessment, representing 4% of all the symposium participants. They stated they had treated a total of 160 patients during this period using the Ponseti Method; two of the respondents said they had not treated any patient using the Method.

The responding participants had treated only 60% of the children with clubfoot in their care using the Ponseti Method. A possible reason for this relatively low percentage of correction may have been the treatment of children with non-idiopathic clubfoot, in which the correction is more difficult to obtain: these would be syndromic patients in which the choice of conventional surgery was considered. In patients treated by the Ponseti Method, the participants reported that they had obtained initial correction after the cast phase in 90% of cases.

The average number of casts used in the correction of clubfoot by this group of orthopedists was eight, ranging from four to fifteen casts. This average can be considered high, as is common during the learning curve of the Ponseti Method. The average number of casts in the treatment of children at centers of reference is around five.

Among the main difficulties reported by participants in the application of the method, the difficulty in the application of the casts was the most common, followed by the difficulty of obtaining abduction braces in some centers. In other cases, the braces obtained were inadequate for maintaining the correction of the deformity. Difficulties in removing the casts, and identifying and treating recurrences, were also mentioned.

Due to the small number of forms returned by email one year after the symposiums, it was not possible to infer again how much the training had contributed to the dissemination and appropriate use of the Ponseti Method for the treatment of clubfoot. However, the data were representative as they included ten of the twenty-one cities where symposiums had been held. They reported good results with the use of the Ponseti Method, with a good number of casts used in each correction. Even with this very small sample, it was observed that many of the physicians trained were having problems applying the basic principles of the Ponseti Method: how to correctly apply the correction cast. This finding reinforces the need to expand knowledge and training for those who are actually treating children with congenital clubfoot. One way to improve the use of the Ponseti Method would be to hold an "advanced course", where professionals could clear up any doubts that have arisen with the use of the Ponseti Method.

Chapter 11: THIRD DIRECT IMPACT ASSESSMENT - IN LOCO (VISIT AFTER ONE YEAR TO TWO CITIES)

The difficulties in obtaining results on the impact of the training of the Ponseti Brazil Project in the actual practice of orthopedic doctors led to the third form of impact assessment: fieldwork to observe the clinical practice in two cities where the symposium was held.

The cities of São Luis in Maranhão, and Teresina, in the State of Piauí, were selected due to the fact that the symposiums in these cities represented a radical change in the local conventional treatment of congenital clubfoot in general, due to a certain homogeneity in the training of doctors, and the existence of ideal conditions to implement the Ponseti Method. Another reason for this choice was the motivation observed in the symposiums, the existence of teams who worked in public university hospitals that were regional references for the treatment of children, and the availability of doctors to receive the visit by this author one year after the symposium in his city.

In São Luis, the symposium was coordinated locally by the staff of the Hospital Materno-Infantil Maternidade Benedito Leite, a pediatric hospital that was already a reference in humanized care of newborn infants, through its project Mãe Canguru (Mother Kangaroo) (ARAUJO et al, 2010).

The symposium was held on April 11 and 12, 2008, at the Hospital Materno Infantil.

Forty-three orthopedists attended this symposium; of this group, sixteen were considered "senior orthopedists", i.e. they had graduated at least nine years previously. The time since graduation ranged from 9 to 34 years, with an average of 17 years.

Only six participants had obtained information about the symposium through the official means i.e. email, publicity leaflets and posters. The remaining participants had attended the symposium after informal contact with colleagues involved with the organization. They worked in fifteen Public Hospitals and fourteen private services. Almost all worked in public and private health services. Of the 43 participants, 15 reported treating children with congenital clubfoot, of which only eight were posterior-medial release surgeries. All together, they had treated 520 children in the year preceding the symposium. Most of the symposium participants worked in the city of São Luis. The distances in the state of Maranhão are very great, which made it difficult for orthopedists from other cities to attend.

Only 10 of the 43 participants had not heard of the Ponseti Method prior to the Symposium. Of the 23 delegates who responded to the symposium assessment form delivered at the end of the second day of training, all evaluated the symposium as well-presented, 10 reported that they felt they had been trained to deal confidently with children with clubfoot by the Ponseti Method, seven still had doubts, and six were not yet confident in using the method.

Twenty Respondents reported that the Ponseti Method seemed the most appropriate for the treatment of clubfoot; three responded that "yes, maybe" (with less emphasis) the Ponseti Method seemed the most appropriate for the treatment of clubfoot. Fifteen respondents pointed out that the symposium had changed the way they considered the treatment options for congenital clubfoot (5 on the Likert scale), six with less emphasis (between 4 and 3 on the Likert scale), and only 2 said that the symposium had not changed their way they considered the treatment options for congenital clubfoot.

The author returned to São Luis for the assessment one year after the symposium on March 13, 2009, having obtained authorization from the president of the regional Maranhão branch of the Brazilian Society of Orthopedics and Traumatology to use clinical data on patients treated by doctors who had attended the symposium (Annex17).

The Hospital visited in São Luis was the Hospital Materno Infantil de São Luis, Maternidade Benedito Leite (of the Universidade Federal do Maranhão). This is the public reference hospital, and is the reference center for the majority of births in São Luis (total of nineteen thousand labors per year) (DATASUS 2004).

The visit to the outpatient clinic of the Hospital Materno Infantil da Universidade Federal do Maranhão occurred in the morning, and sixteen children were assessed, along with Dr. Leopoldina Milanez Leite and Dr. José Simões. It was observed that the Ponseti Method was being used correctly in many cases, with very good results, but children with recurrences were also observed, and problems obtaining and using the abduction brace. Children with neglected deformity constituted a difficult problem, not so much due to the ability to correct it, which the outpatient clinic certainly had, but due to logistical imitations, as these patients lived more than 800 km from the treatment, and their ability to travel each week to change the casts was limited.

One family whose father had bilateral neglected Clubfoot was assessed, and the son was in treatment, with near total correction of the deformity. Syndromic Children were also being treated without too many difficulties, with the use of the correct manipulation technique. They presented adequate data collection, and had a unified congenital clubfoot outpatient clinic with three senior doctors, residents and interns, and a very engaged cast technique in the dynamic of the outpatient clinic. There was also a "brace bank" with orthoses donated by patients who no longer had use for them.

All the participants of the Ponseti symposium of 2008 were invited to take part in an exchange of experiences and discussion of possible problems with the Ponseti Method at the end of the afternoon on the day of the visit. Only nine orthopedic doctors attended, and of these, only five had attended the 2008 symposium. The other four were interested in learning more about the subject.

Responding to the assessment questionnaire after one year, the five orthopedic surgeons were asked how many patients with clubfoot they had treated in the year since the symposium. Compiling the responses, it was found that they had collectively treated 67 patients since the symposium. They all said they had used the Ponseti Method in these patients. Three mentioned that they had treated syndromic patients. Concerning their experience in the treatment of older children, the five orthopedic doctors reported that in the year since symposium, they had treated eleven patients over the age of one year. All five reported good results with the Method, and better correction with this method in relation to their previous practices.

The most important part of the meeting was to establish the correct completion of the prospective protocols for the treatment of patients with clubfoot using the Ponseti Method (Annex 16).

Compilation of data was also encouraged, on patients treated for presentation at the Brazilian congress of pediatric orthopedics, in the following year.

At the IX Congress of Pediatric Orthopedics, held in Campos do Jordão - SP in June 2010, the preliminary results of the Hospital Materno Infantil on the Treatment of Clubfoot were presented (LEITE et al., 2010), and then re-presented on the national panel of experiences with the Method, as part of the Advanced Course on the Ponseti Method in Belo Horizonte - MG, in August 2010.

In this work, carried out from April 2008 (soon after the first visit to São Luis) to April 2010, 74 patients (107 feet) were treated in the clubfoot outpatient unit of the orthopedic service of the Hospital Materno-Infantil de São Luis. There was a prevalence of males, representing 81% of cases, bilateral clubfoot in 30% of cases, being right clubfoot in 21.4% of cases, and left clubfeet in 18.6% of cases. The mean age at the start of treatment was 4.7 months.

The majority of the patients (53%) were from cities in the interior of Maranhão (many of these were referred from birth at the hospital itself, and others were referred

from other regions of the state). Thirteen patients (a total of 16 feet) abandoned the treatment, mainly due to transport difficulties, but also due to difficulties in maintaining the weekly plaster cast, or the abduction brace. The vast majority of these children had had no previous treatment (69%) and in the treatment of all cases, the Ponseti Method was performed without modifications. The casts were changed weekly; the casts were removed in the outpatient clinic and percutaneous achilles tenotomies were performed under general anesthetic at the surgical center.

A hundred and seven feet were followed up until the end of the correction, and at the end of two years. For the assessment scale, the convention agreed at the second International Symposium on Clubfoot by the Ponseti Method in Botucatu in 2005 was used (Annex13).

Of the 107 feet treated, 102 feet showed total correction of the clubfoot deformity, with results ranging from very good (91 feet) to good (12 feet). The definitions of very good, good, fair and poor, as already explained were agreed on by the Second International Symposium on the Ponseti Method, held in Botucatu in 2005. "Very good" was used for feet without any deformity and presenting total correction, with dorsal flexion greater than 10 degrees; "Good" was used for feet without deformities and dorsal flexion less than 10 degrees, with a Pirani classification of zero or one. The results of four feet (3.7%) were "regular"; these included deformities with indication for complementary treatment, either conservative or surgical. Percutaneous achilles tenotomy was performed in 94% of cases; an average of eight casts was used in the correction by three different professionals; and none of the children underwent posterior-medial release surgery that would be rated as "poor".

Two years after the training symposium, this public hospital outpatient clinic had exclusively local resources, treating children with clubfoot by the Ponseti Method with a 96% success rate in terms of correction, a result that is comparable with the results in the specialized medical literature (NOGUEIRA et al, 2009).

The symposium in Teresina was held on May 9 and 10, 2008, and was attended by 39 orthopedists. In total, they responded that they had treated 407 children with clubfoot in the past year, using the Kite technique and posterior-medial release surgery. All those who completed the final assessment form (only 38% of the participants) reported that the Symposium had been well-presented, and that it had changed the way they considered the treatment options for congenital clubfoot. 72% of the participants had already heard of the Ponseti Method, and 63% of the respondents of the final assessment reported that they felt able to treat children with congenital clubfoot by the Ponseti Method after the Symposium. There were four orthopedists from the city of Paranaíba, PI and one orthopedist from the city of Picos, PI. This symposium was attended by the city mayor, who is also an orthopedic doctor.

This author returned to the city of Teresina on June 19 and 20, 2009, and the meeting was held at the Hospital São Paulo, a private hospital. Of the 39 participants in the first symposium, 17 orthopedists participated in this second meeting, including two orthopedists from the interior of the State. On that same visit, there was a meeting at the municipal department of health, with the secretary of health Assis Carvalho and Mr. Noah Fortes, director of the largest public university hospital of the region, the Hospital Getúlio Vargas (connected to the Universidade Federal e Estadual do Piauí) to discuss the proposal for an clubfoot outpatient unit, newly created and headed by Dr. Osvaldo Mendes de Oliveira Filho. Hospital Getúlio Vargas is a high complexity hospital, with 330 beds and 12 clinical medical specialties, and acts as a reference for patients from Piauí, in the South of Maranhão, southern Pará, and northern Tocantins. The Hospital is also a reference center in the treatment of leprosy.

According to local data, (www.saude.pi.gov.br), the department of health maintains three health units that are reference in the State for the care of children from before birth. It serves 25 thousand women in its prenatal services, and follow-up of children up to five years of age. The Maternidade Evangelina Rosa has two

residency programs, and is responsible for 63% of births in the city of Teresina, with 88% of these mothers coming from the State of Piauí and 12% from other states.

Authorization was obtained from the president of the SBOT Piauí, Dr. Osvaldo Mendes de Oliveira Filho and from the director of the Hospital, Dr. Noah Fortes, to collect and present data on patients of the hospital Getúlio Vargas in this work (Annex18).

The outpatient clinic for clubfoot of the Hospital Getúlio Vargas was visited, and together with five orthopaedic surgeons, headed by Dr. Osvaldo Mendes de Oliveira Filho, 12 patients were evaluated, many of them had good correction, while others were referred for the application of new casts.

A rehabilitation center for children with neurological disorders, the CEIR - Center for Integrated Rehabilitation, under the command of the SEID - state secretary for inclusion of people with disabilities, was also visited. This center which is managed by the wife of the state governor. This center provides care for children with neurological clubfoot, and also local production of abduction braces, through the Public Health System.

According to a local publication from 2007 and 2008, 96% of the population depends on the public health system (Piauí Saúde, April 2009).

The presence of only 17 doctors at the meeting meant we were not successful in collecting data from the participants after one year, because only five completed the assessment form. In total, they had treated 35 patients by the Ponseti Method; only four syndromic and three myelodysplastic. An average of eight casts were used. Reported difficulties included transport logistics across large distances, which led many patients to abandon the treatment, and also difficulty in following the guidelines and using the abduction brace. These orthopaedic surgeons were reticent about the two last questions on the form: they believed that the Ponseti Method often led to good results; one said “always” (having treated 10 patients in the year since

the symposium), and one said “no”, the Ponseti Method had not led to good results in their patients (however, the number of patients treated by this doctor was very small, only five during the year).

This city did not represent a good sample, as the only person who was really more involved with the work was the president of the regional SBOT himself, and his specialty (hand surgery) may have contributed to his lack of full dedication to the project of the outpatient clinic. This would have required continued contacts and supervision of the clinic, which had favorable political support for its implementation.

Chapter 12: EXPANSION OF KNOWLEDGE IN THE METHOD - THE IMPORTANCE OF BRAZIL AND DEVELOPING COUNTRIES

During the training symposiums, we saw that many feet treated by Brazilian orthopedic surgeons were not of newborn infants; many children were not referred directly for treatment, or were on long waiting lists to be evaluated by specialists at other centers. Due to the good results obtained with the use of the Ponseti Method, Brazilian physicians have begun to apply the Method for the treatment of older patients not initially indicated for treatment by this method.

The results of the application of the Ponseti Method were observed in the discussion of cases presented by local orthopedists at the national symposiums; they were surprising in terms of the number of children with clubfoot treated successfully; these results were reported in three Brazilian studies (NOGUEIRA et al 2007b, LOURENÇO e MORCUENDE, 2007, HAJE DP, 2010; NOGUEIRA et al., 2011) The successful results with the Ponseti Method in a sixteen-year-old girl, treated in Maceió, were presented internationally and attracted significant interest among the international scientific community (NOGUEIRA, Germany 2005, Baltimore 2006, Iowa 2006 and 2007, Cuba 2007, Switzerland 2008, China 2009, Colombia 2009; Finland 2009, MORCUENDE, 2010).

In the international literature, other developing countries have published a contribution to extended the indication of the Ponseti Method in its use in older children, (TINDALL, et al, 2005; LAVY et al, 2007; GUPTA et al, 2008; CULVERWELL e TAPPING, 2009; PIRANI, 2006, EVANS and VAN THANH, 2009, AVILUCEA et al, 2009; HALANSKI et al, 2009).

Another Brazilian contribution to the study of clubfoot treated by the Ponseti Method in more difficult cases was that of a multicenter study, with the collaboration of a Portuguese and a Spanish center, which addressed the correction of clubfoot deformity in older children who had already been treated with posterior-medial

release surgery. It was believed that feet already operated on are more rigid, therefore in principle, these could not be corrected with the Ponseti Method. The study showed that not only can these difficult-to-treat feet actually be treated, but also that this treatment is reproducible in different centers, with the same success rate (NOGUEIRA et al, 2009). This study was preceded by another study with a smaller case series (GARG and DOBBS, 2008), which also showed good results.

Chapter 13: “IS IT POSSIBLE TO TREAT RECURRENT CLUBFOOT WITH THE PONSETI TECHNIQUE AFTER POSTERIOR-MEDIAL SURFACE RELEASE?”¹

In relation to the application of the Method Ponseti in difficult-to-treat feet, arthrogryptic feet were not initially indicated for treatment by this method. These feet are, by definition, very rigid, and the most widely-accepted cause of deformity is very different from the causes proposed for so-called idiopathic clubfoot. Due to a reduction in intrauterine mobility, the joints have a smaller range of movement from birth, and the musculature and its control can be affected to different degrees and involve diverse topography (Bevan et al, 2007).

Conservative treatment of arthrogryptic clubfoot by conventional techniques did not result in correction, which was traditionally obtained in the literature only by extensive foot release surgeries, even talectomy (excision of the talus, the bone connection between the leg and the foot) as the recommended treatment option, and this is true even today (SIMIS et al, 2010). However, recent studies report good results for the correction of arthrogryptic feet (KOWALCZYK et al, 2008; BOEHM et al, 2008; JANICKI et al, 2009, MORCUENDE et al, 2008, VAN BOSSE et al, 2009) which has also prompted the compilation of arthrogryptic cases treated with the Ponseti Method in our country (NOGUEIRA et al, 2005 and 2010). The treatment by the Ponseti Method in arthrogryptic feet showed an initial correction of 100% of cases (11 out of 11 patients in this series), with a higher percentage of recurrences (71%), but avoiding extensive releases and major bone resections.

It was possible to obtain good results in the correction of arthrogryptic clubfoot due to the development and improvement of the manipulation technique, modified for the correction of significant pes cavus deformity in these children. In these patients, a group of doctors, led by the group from Iowa, combined their experiences in the treatment of so-called “complex” feet or feet that are "more

¹ Nogueira MP, Ey Battle AM, Alves CG. Is it possible to treat recurrent clubfoot with the Ponseti technique after posteromedial release?: a preliminary study. Clin Orthop Relat Res. 2009 May;467(5):1298-305.

resistant to conservative treatment". This group described the maneuver of positioning of the hand in order to elevate the entire forefoot, applying counter pressure to the neck of the talus using both hands (PONSETI, et al, 2006).

The cause of myelodysplastic clubfoot (equinovarus adductus) also differs from those of idiopathic clubfoot. In children with myelomeningocele, the feet will only have innervation of the levels not affected by neural tube defects; in the thoracic and upper lumbar levels, the foot can take on any deformity, because it is not innervated.

In the lower lumbar levels, clubfoot deformity is very common, due to the presence of innervation to the fourth or fifth lumbar root, which frequently leads to a position of foot inversion, and thus, structuring of the deformity in this position. The most common foot deformity in neural tube defects is, therefore, equinovarus adductus of the feet (MORRISSY and WEINSTEIN, 2006).

The treatment of this disorder is often surgical, with extensive foot releases to obtain proper positioning of the feet in these patients, who are often able to walk. Conservative treatment with casts, to maintain the correction achieved with manipulation and positioning, may be recommended as an initial approach, (MORRISSY and WEINSTEIN, 2006) but various skin complications have been described, due to the lack of skin sensitivity in these patients.

FERNANDES (2007) reported that there has been no work in the literature that would justify the use of serial casts, since the corrective cast did not allow for full correction, and could produce pressure sores.

Despite this study, and the traditional approach to dealing with extensive release surgery of Myelodysplastic clubfoot, recent studies show the use of the Ponseti Method with good preliminary results in initial cast correction, with 35 out of 35 feet being corrected. However, they report a recurrence rate of 68%, in which the feet were corrected again using the Method (GERLACH et al, 2009; JANICKY et al, 2009). Based on these studies, national groups have also reported good results with

the method in Brazilian children with myelodysplasia (NOGUEIRA et al, 2010d; VOLPI and VOLPI, 2010; NAVARRO and LIZA, 2010).

The Ponseti Brazil Project led us to highlight, in the discussion of cases presented by local orthopedist surgeons from various cities visited (Maceió, Salvador, Belo Horizonte, São Luis, Teresina, Campina Grande, Recife), a relatively high incidence of a specific syndrome – Moebius Sequence – which is clinically characterized as paralysis of the sixth cranial and seventh cranial nerve..

Children with this syndrome have rigid, arthrogryptic feet, absence of facial mimicry and limited ocular mobilization. This syndrome is currently highlighted as the only causal association between congenital clubfoot and use of the drug misoprostol during the first weeks of pregnancy (GONZALES, 1993, 1998).

Misoprostol is used by pregnant women to induce abortion, as reported by ALMEIDA (2007) in 59.5% of their case series in Brazil. Observing this change in Brazilian children may reflect the social conditions involved in the genesis of this alteration, and should motivate future studies.

The type of treatment of clubfeet in these children is the same as that used for the treatment of arthrogryptical deformities (BOEHM et al, 2008; MORCUENDE et al, 2008) also described for the management of complex feet (PONSETI et al, 2006).

Chapter 14: FOURTH DIRECT IMPACT ASSESSMENT: ADVANCED PONSETI COURSE AND NATIONAL PANEL

Due to difficulties encountered in assessing the impact of the Ponseti Brazil Project described previously (assessments by electronic means, assessments in two cities), this fourth form of assessment was proposed, which involves collecting data from patients treated by doctors who attended the symposiums in each city where the symposiums were held.

Ideally, this data collection would be carried out by some of the local representatives with more practice in the treatment of clubfoot by the Ponseti Method, and this case series would be presented at a national panel, in the Advanced Course on the Ponseti Method, as a pre-course to the 17th Orthopedics Congress of Minas Gerais.

Financial support was gained for the implementation of this symposium, from the American company MD Orthopaedics, through its owner John Mitchell, following a presentation of the preliminary results of the symposium at the end of 2007, in Iowa. He donated twenty thousand US dollars to the Brazilian Society of Orthopedics and Traumatology, Minas Gerais regional division, the organizer of the Minas Gerais Congress and Advanced Course. This support was used to fund international tickets and accommodation for the same teachers who had been involved with the Ponseti Symposiums held at the School of Medicine of the Universidade Estadual Paulista Júlio de Mesquita Filho, in Botucatu, in 2003 and 2005. The international teachers invited were: José Morcuende of the University of Iowa in the United States, the group of Dr. Ponseti; Shafique Pirani of the University of British Columbia, Vancouver, Canada; Dalia Sepúlveda of the Hospital de Niños Roberto del Rio, Santiago, Chile; Anna Ey Battle, Hospital San Juan de Deu, Barcelona, Spain, and Cristina Alves, Hospital Central do Funchal, in Madeira, Portugal. These guest speakers gave theoretical lectures on the Method, and

participated in a session that showed the international situation of the Method, as well as acting as moderators for the national presentations (Annex 13).

The orthopaedics surgeons of the Brazilian Study Group on the Ponseti Method participated in workshop sessions using plastic models. Thus, it was possible to form twelve working tables, with ten participants in each. Orthopedists enrolled in the national panel as speakers had priority in the discussion, and in the attention to the preparation of casts.

The English Non-Governmental Organization La Vida, which had helped paying pay for the travel expenses of the doctors during the Ponseti Brazil Project, printed Pirani classification posters, and paid for the printing of certificates and the mailing of these to all the symposium delegates, along with an invitation to register for the Advanced Course, and the compilation and presentation of case studies in the national panel. The invitation was also extended to orthopedists who had participated in programs prior to the Ponseti Brazil Program, such as the International Symposiums on the Ponseti Method at the Universidade Estadual Paulista Júlio de Mesquita Filho, in Botucatu, in 2003 and 2005, and other Ponseti symposiums held by this same group of teachers, in Cuiabá, Joinville and Belo Horizonte, in previous years.

The organization's intention was simply compile the cases of each city in a more active way, just as we had done at the International Symposium on the Ponseti Method in Botucatu, 2005, which resulted in the presentation of 1293 feet treated in 853 children. This would give a national extension of the treatment of clubfoot by the Ponseti Method.

Another goal of this event was to answer any questions in the initial practice of the Ponseti Method by Brazilian orthopedic doctors, through a discussion forum with international and national specialists in the Method.

All the material was sent in advance, and some telephone and email contacts were made, to encourage the orthopedists' to take part. We had 120 students enrolled in the course, and nine orthopedists from eight Brazilian states took part in the national panel. Although representatives from Salvador, Cuiabá and Goiânia attended the course, they did not present their case series, The results presented are summarized in the table below:

Table 1: Compilation of data submitted by nine orthopedics departments in the national panel for the treatment of clubfoot by the Ponseti Method in Brazil, at the Advanced Course on the Treatment of Congenital clubfoot by the Ponseti Method, 17th Orthopedics and Traumatology Congress of Minas Gerais, Belo Horizonte, August 2010

Participant	Location	N child ren	N feet.	Teno tomy	Type	PMR	Success of treatment %
OCFF	João Pessoa – PB	48	71	54%	general	4	89
LMSL	São Luis – MA	74	107	93%	general	0	100
ACQ	Maceió- AL	55	93		local	5	84
CB	Belo Horizonte – MG	256	408	95%	local	4	99
PRM	Vitória – ES	9	14	64%	local- general	1	93
SP	Guarulhos –SP	30	45	53%	local	0	98
MA	S J Rio Preto – SP	25	42	90%	general	0	100
OS	Manaus – AM	34	50	96%	local	0	100
MPQ	Rio de Janeiro - RJ	173	271	78%	local	0	100
Total		704	1101			15	98.6

Source: Primary Data collected on the Advanced Course in the Ponseti Method, Belo Horizonte, August, 2010, by the author.

Thus, considering 15 cases of treatment failure by the Ponseti Method (posterior-medial release surgeries), the nine centers that had trained at Ponseti symposiums presented a 96% success rate with the use of the Ponseti Method, only two years after the training symposium. These results were comparable to those found in the literature (NOGUEIRA et al, 2009). In Brazil, these figures can also be compared with the initial results obtained in the Second International Symposium on the Ponseti Method in Botucatu, in 2003 (94% correction with the Method), and with the 99.4% success rate presented in the compilation of the Ponseti Brazil Project

monitors in six centers in five different Brazilian states, in 2010, with 944 feet treated out of a total of 599 children (NOGUEIRA, 2010g).

If we add these results described to the data presented (CURDIS JR, 2003; FORLIN, 2002; LARA, 2010, GENUÌNO et al, 2010) at other Brazilian congresses or publications. Overall, in the compiled data, 18 different Brazilian centers have presented their results in the treatment of clubfoot by the Ponseti Method, with correction rates in the initial cast phase of over 90%.

These data enable the dissemination of this method to be observed objectively. There are no reports in the medical literature of series of cases handled by the Ponseti Method in Brazil prior to 2002. According to the study, the medical literature and the congresses reflect this tendency to spread the Ponseti Method.

Chapter 15: RANDOMIZED TRIAL: IS IT ETHICAL?

As the conducts of medical practice can be influenced by commercial interests or attitudes common to the interest of specific groups, evidence-based medicine aims to substantiate and justify clinical decisions.

Decisions based on scientific evidence, according to DOBROW (2004), may have two strands: one is based primarily on the more philosophical, epistemological concept of evidence - the most "ideal" way to justify a decision. This strand is based on the methodological quality of the evidence, and its structural characteristics and properties (validity and reliability). This strand is hierarchical, as established by the Evidence-Based Study Group, and its emphasis is based on systematic reviews with methodological rigor, and on the study design, to characterize clinical decisions for the individual level. The other strand is more practical and context-linked, generally with a more populational focus, and is used for health policies. This aspect is not related to the methodological rigor of hermetic studies, but relates more to relevance and applicability, and the possibility of generalization in a specific context (DOBROW, 2004).

Methodologically, it was not possible to have a study design in this manuscript that could prove, with scientific rigor, the efficacy, effectiveness, and even the initial proposal i.e. the impact of the training program for the dissemination of the method. The main reason for this was the immersion and involvement of the author in the processes to be assessed. This meant that the author did not have the necessary distancing for the observation and critical judgment inherent to this approach. There was also a difficulty of obtaining responses and data from those who took part in the symposiums, which meant that the impact of the Ponseti Brazil Program could not be satisfactorily measured with the methodological design suitable for an assessment study.

The evidence discussed in this manuscript consists mostly of case series from different countries and different orthopedics departments (Annex 3). The value of

these studies lies in the second strand considered by DOBROW (2004), i.e. the overall context over time. These reflect the relevance and applicability of the Ponseti Method, and the clear national and international generalization of this form of treatment of clubfoot.

Studies related to the first aspect discussed by DOBROW (with greater methodological rigor in terms of level of evidence in randomized, controlled clinical trials) with the Ponseti Method are infrequent, but the existing comparisons (despite their many methodological flaws) indicate that the Ponseti Method is superior to the Kite technique in terms of treatment time (RIJAL et al, 2010), and cost effectiveness (HALANSKI et al, 2009; FERREIRA, 2007). The meta-analysis presented by MATOS (2010) found only four articles, and those had limitations; the comparative studies found were retrospective, and some were case series in which there was a change of conduct following the introduction of the Ponseti method to their clinical practice (HERZENBERG et al, 2002, FERREIRA, 2007).

Considering the results of these comparative studies, and the number of case studies reporting more than 1500 feet treated by the Ponseti Method (NOGUEIRA et al, 2009), it is currently difficult, from an ethical point of view, to propose a comparative study, whether with other conservative techniques, or with surgical correction of clubfoot. This is because to propose such a study, we would need to have doubts about the application of one or another proposal.

The comparative studies and case series showed greater benefits of the application of the Ponseti Method, while on the other hand, studies with a longer follow-up time with the application of surgical treatment showed greater rigidity, less range of joint movement, and a higher incidence of arthrosis in feet. The ethical principles of the Belmont Report for clinical research in human beings (respect for persons, beneficence, and justice) in the United States, were published by the US Federal Government in 1979 (CHILDRESS et al, 2004), and were also published in Brazil by CONEP - the National Committee for Research Ethics (1998), through the National Health Council Resolution of October 10, 1996 (CNS 196 III.III.1),

"...concerning the ethics of clinical research in human beings, the risks and benefits, both current and potential, individual and collective (beneficence) should be weighed, seeking to ensure the maximum benefits and the minimum damage and risks - guarantee that foreseeable damage estimates will be avoided (non-maleficence)."

Therefore, it is believed that currently, we cannot randomize patients to two treatment groups (the Ponseti Method and another surgical treatment), as we have evidence that the surgical treatment may have functionally inferior results documented in the literature (DOBBS et al, 2006). The strand of the properties of evidence related to the context, discussed by DOBROW (2004), states that in light of ethical dictates, we shall consider existing works and the dissemination of the Ponseti Method (with its efficacy, effectiveness and efficiency) as guiding factors in the decision-making for the treatment of children with congenital clubfoot.

Chapter 16: THE DISSEMINATION TO OTHER COUNTRIES (SUCH AS PORTUGAL AND SPAIN)

In Europe, the Ponseti Method also followed a path of adoption by professionals who had come into contact with the University of Iowa (Annex 3).

In Portugal, the dissemination of the Method began with a medical doctor who had specialized in Spain, Dr. Cristina Alves, and who had led many families to travel to Ilha da Madeira in search for treatment for their children by the Ponseti Method. (Second International Symposium on the Ponseti Method, of the Universidade Estadual Paulista Júlio de Mesquita Filho - Botucatu, 2005). Gradually, after presenting their results at European congresses, and with the aid of a journalist who was the mother of a child with congenital clubfoot that had been treated in Iowa, and who had created a website with information about this treatment method (www.peboto.com.pt), it spread to the whole country. In 2004, the first Ponseti symposium was organized in Portugal, Funchal, Ilha da Madeira, attended by orthopedic doctors from different parts of the country. From that time on, Portuguese groups published results on the use of the Method (ALVES et al, 2009).

In Spain, the method was disseminated following the contact of Dr. Anna Ey Battle with the Ponseti Method, explained by Dr. Ponseti himself, in Barcelona, (PERCAS-PONSETI, 2009). Dr. Anna Ey Battle organized, with the Spanish orthopedic community, four international symposiums, (Madrid 2007 - with Dr. Paloma Cervera - and Barcelona 2008, Seville 2009 and Madrid 2010 - Annex 15) where the number of participants has been growing. The last symposium presented a case series from six different cities (Palmas de Canarias, Madrid, Málaga, Valencia, Santander and Barcelona), reporting 281 feet treated by the method, with only 2.5% posterior-lateral release surgeries.

Chapter 17: EFFICIENCY: COSTS OF THE TREATMENT

FERREIRA (2007), in her study on the costs of treating clubfoot in the Sistema Único de Saúde, compared the hospital costs of five patients treated in the conventional way for clubfoot (Kite technique followed by posterior-medial release) with the costs of five patients treated by the Ponseti Method, at the University Hospital of USP, Butantã campus. Considering only the hospital costs of each technique, the cost of the Ponseti treatment was 2.8 times lower than that of the conventional treatment for children with unilateral clubfoot. In terms of treatment time, the Ponseti Method was 6.6 times faster than the conventional method (for unilateral clubfoot), and it is believed that for children with bilateral clubfoot, this difference is even greater, since both feet were not operated on at the same time, due to the complexity of the surgery and the time under anesthesia.

In this work, only hospital costs were included: it is therefore estimated that the highest number of treatment days results in higher cost, due to the higher number of medical visits. These, in turn, lead to an increase the overall transport costs and lost days of work for the parents (ANDERSON et al, 2007).

Another European study (GÖKSAN, 2002) states that the costs of treatment with the Kite technique and surgery are five times higher than the cost of treatment by the Ponseti Method.

Chapter 18: NON-GOVERNMENTAL ORGANIZATIONS

The Ponseti Method is a rapid, low-cost form of treatment that is easy to teach, and has a great impact on the treatment of clubfoot deformity. In addition, clubfoot deformity is easy to identify, as are the effects of treatment. These components have led to the Method being publicized and promoted by non-government institutions in different countries.

Programs for the treatment of clubfoot, like CURE INTERNATIONAL (MAYO, 2007) (www.give.helpcurenow.org), or Christ Blind Mission (CBM) (www.cbm.org), and LA VIDA (www.lavida.org) in England have emphasized the treatment of clubfoot in developing countries. Other organizations, such as STEPS in England (www.steps-charity.org.uk), STEPS - SA, (www.steps.org.za) in South Africa, MIRACLE FEET in the United States, or the newly created Brazilian organization, PRIMEIRO PASSO (FIRST STEP) (www.primeiropasso.org.br) were formed by parents of children with clubfoot, with the aim of promoting the dissemination of information and treatment of children by the Ponseti Method.

These organizations have an important role in creating social pressure to gain referrals for the treatment by means of a well-developed social network, and permeation in various sectors of society.

Non-government organizations that work with children with congenital clubfoot and education for health professionals have focused on actions in developing countries. CURE INTERNATIONAL has programs in Kenya, Ghana, Zambia, Malawi, Afghanistan, India, Cambodia, Haiti, and Honduras. CBM (Christian Blind Mission) has partnerships in many countries, organized based on blindness prevention programs, but in recent years, expanding its operations to other forms of disability, including congenital clubfoot.

In Brazil, both the manufacture of casts and tenotomy are considered medical procedures (Lisbon, 1994); the use of the method by other health professionals, as

occurs with physiotherapists in England and Canada (SHACK and EASTWOOD, 2006; JANICKI et al, 2009), or technical orthopedics (PIRANI, 2006; CULVERWELL and TAPPING, 2009; TINDALL et al, 2005) are not possible in our country.

The cooperation of non-governmental organizations for the treatment of clubfoot in Brazil must therefore be done differently from what is done in the countries of Africa or Central America. The *Sistema Único de Saúde* (the Brazilian national health system) is regionalized, and this characteristic can be a positive aspect for the work in the national network. The existence of access to healthcare for all Brazilians (universality), the eagerness to disseminate the method among patients' parents, and the high efficiency and low cost of the Method, are all favorable conditions for the official incorporation of the treatment in our health system.

The combined and coordinated work of non-governmental organizations, civil society, academics, doctors and government entities can give the Ponseti Method ideal conditions for development, dissemination and incorporation, extending the coverage of the treatment for children with the deformity.

Chapetr 19: GOVERNMENT CONSENSUS IN HEALTH

The consensus in decision-making in health is the result of the work of the scientific community, and the interface of medicine with management professionals in the area of evaluation of health technologies. After the consensus, implementing decisions requires a dissemination strategy, and interaction with health professionals.

Well-developed health policies have a positive impact on the health of the populations. In China, the introduction of folic acid in the diets of women of childbearing age resulted in a 41% reduction in the incidence of neural tube defects; (BERRY et al, 1999). Policies to eradicate poliomyelitis were another example of the effectiveness of the adoption of behaviors, radically reducing this debilitating disease that has serious orthopedic consequences (BUCK, 2004).

Consensus of government entities on the treatment of congenital clubfoot was achieved by the Ponseti Project in Uganda, involving the Ministry of Health (PIRANI, 2006), and also in Latin America, with the health consensus achieved in Chile (CHILEAN MINISTRY OF HEALTH, 2010). In two countries (Uganda and Chile) the Ponseti Method was indicated as the preferential form of treatment for congenital clubfoot, due to its simplicity, effectiveness and low cost.

Chapter 20: HOW TO INCORPORATE THE PONSETI METHOD IN THE SUS?

The Ponseti Method is already being carried out in the Brazilian Public Health System, albeit gradually, due to medical education on the method as a form of treatment for congenital clubfoot in residence programs, since its good results were first recognized by the Brazilian Society of Pediatric Orthopedics in 2004 (SANTILLI, 2004). It is taught to medical interns, and their knowledge is tested in an examination for the title of specialist in orthopedics. Thus, it is already being used for the treatment of clubfoot in children in this country, both in the public and private services, as documented by FERREIRA et al (2009).

As described earlier in this manuscript (item 12), different orthopedics departments have already achieved and reported good results with the Ponseti Method, and some public hospitals even have a specific day of the week in their outpatient clinics for clubfoot patients (Hospital Materno Infantil and Maternidade Benedito Leite - São Luis, Hospital São Zacharias, Rio de Janeiro, Hospital Municipal de Guarulhos, São Paulo, Hospital Infantil Alzir Bernardino Alves, in Vitória, Espírito Santo, Hospital da Baleia in Belo Horizonte, Minas Gerais, Hospital Martagão Gesteira in Salvador, Bahia, Hospital do Açúcar, Maceió, Alagoas). This organization resulted from the Ponseti Brazil Program in some locations, or the organization of the outpatient clinic was influenced by it (PPB).

The Ponseti Brazil Program also trained orthopedic doctors, the majority reporting that they work in the public services (73%), which also contributed to the dissemination of the method in the *Sistema Único de Saúde*. While not all trained physicians use the Ponseti Method, at least the dissemination and clarification on this form of treatment has been expanded, as well as its application in the public healthcare network.

Despite the observation that the Ponseti Method is being used in various services throughout the country, there is still no organized system for its correct

application and proper treatment by the *Sistema Único de Saúde* in our country. This form of treatment is not covered by the classification codes, making it more difficult to document.

There is no exchange of knowledge between hospitals that perform the treatment with the supply of abduction orthoses, and referrals of newborn infants with the deformity are still insufficient. The provision of orthoses and prostheses, which is done efficiently for neurological and orthopedic disorders (such as cerebral palsy, or complications of poliomyelitis and scoliosis), is not as efficient when it comes to the treatment of congenital clubfoot, due to a lack of knowledge of this form of treatment among health managers.

Another component to be studied, and possibly modified, is the payment for each procedure performed (payment, in the case of clubfoot, for each cast and not per child treated), which is the current form of payment, both in the public system and the private system in our country, and which is subject to distortion in the quality of healthcare.

Several fronts need to be developed so that the orthopedists can make better use of the Ponseti Method and effectively treat more children.

Better records are needed on children with the deformity, which is currently under-notified (LUQUETTI et al, 2010). This can be done through a direct work of education of professionals who work with the newborn infant; it is necessary to continue the proper training of orthopedic doctors who treat children with clubfoot. What is needed is the development of reference centers, and correct referral of these children, to improve access and ensure the universality of healthcare. The coding of this procedure should be revised, so that accurate public records of the procedures can be made.

Educating parents on for the correct use of the abduction brace should be expanded to an interdisciplinary network (social workers, physical therapists, nurses,

and other health professionals). This would ensure that children are detected and referred to reference centers without delay, for treatment. This integration of the various disciplines is one of the biggest successes of the SUS. Thus, we would adjust and optimize the treatment of clubfoot, within the logic of the Health System: expanding access, promoting equality of access to healthcare, and improving the coverage of treatment. The treatment of clubfoot by the Ponseti Method is relatively simple, reproducible, effective and efficient, with better functional results in long follow-up time for patients, and better use of economic resources. In terms of public health, the Ponseti Method is a great tool for preventing neglected deformity, which carries a social stigma and physical limitation for the patient, and a stigma of abandoning our national healthcare system.

Concerning public health, the Ponseti Method represents achievement of better clinical outcomes by simplifying the healthcare hierarchy, moving from highly complex treatment in the tertiary network, to outpatient treatment in the secondary network. The treatment of congenital clubfoot, when applying the treatment with Kite technique and surgery, is focused on the tertiary network (which enabled extensive posterior-medial release surgery of the foot, under general anesthesia and hospitalization); the Ponseti Method now offers the possibility to perform the treatment of clubfoot in the outpatient clinic (secondary network), enabling it to be carried out in various regional centers. The costs, as discussed previously (Annex 4) are minimized, and the results are better, because it enables the participation of various professionals (social workers, physiotherapists, nurses) who can assist in the medical care and maximize its effects (e.g. in relation to adherence to the use of the abduction brace, or explanations to parents).

It is necessary to continue registering and monitoring children undergoing treatment for clubfoot, and continue carrying out research at joint centers so that the problems identified can be resolved; for example, the difficulty of obtaining abduction orthoses, centers with greater difficulty in obtaining good results, and with a demand for more training of professionals, among others.

Also, we must not forget older children with neglected deformities, including those already operated on: they can be referred to reference centers that are achieving good results with the application of the Ponseti Method, and can be treated for those debilitating deformities.

According to PORTER and TEISBERG (2007), the best way to retain health costs is to improve the quality and effectiveness of healthcare; according to this author, health is less costly than disease, and therefore the effective results of an intervention or treatment are the best tools for reducing costs and ensuring better health for the population.

The authors reinforce the 14 pillars of quality in health care, expanding the concept of DONABEDIAN (1988). One of the pillars reinforces the importance of the prevention of diseases and health problems. In our study, this is reflected in the prevention of untreated deformities, i.e. the detection of children with the deformity at birth, by obstetricians, pediatricians and other healthcare professionals working in pre- and perinatal healthcare; treatment of clubfoot in the neonatal period easier to perform more reproducible than treatment in older children (prevention, early detection, diagnosis, and treatment to halt the causal chain of the disease early on).

PORTER reinforces the concepts of "correct treatment for the correct patient", "lower incidence of treatment errors, and their repetition", "reduction of the delay in the start of the treatment", "less invasive treatment methods", "faster recovery", "lower disability", "lower rates of recurrence", "less disease progression" and "less need for healthcare". All these concepts are well substantiated by the use of the Ponseti Method, therefore the treatment not only offers the possibility of obtaining feet that are functionally and aesthetically close to normal for the rest of their lives, but also offers the possibility of eradicating untreated deformity in our country.

According to this author, competition in the health services is positive, and should be based on results, which are rarely measured in health administration. The

value of healthcare should be measured in the patients' results in relation to the costs of this healthcare.

The reward, for the best centers and services, could be recognition, or allocation of resources. This reward could then be considered by observing the best results of these centers, or even, in the variable rarely measured, the level of adhesion of professionals or services to the process, in this case, a given modality of treatment and its correct performance. Professionals are very different in their ways of working, and have the freedom to be so; therefore, the best way to provide the best health care should be through monitoring of the results obtained.

Also, according to his point of view, it would be more appropriate to ensure that the patients were taken to reference centers for treatment; this could be more effective than expecting each outpatient clinic to be able to treat clubfoot with the same efficiency.

Chapter 21: FINAL CONSIDERATIONS

This study discusses the history of dissemination of the Ponseti Method in Brazil, and has detected a paradigm shift in this treatment. The treatment of congenital clubfoot by the Ponseti Method is an important tool for preventing a neglected deformity that carries physical and social stigma for untreated patients. Clubfoot is a public health problem due to its frequency – around three hundred thousand children are born with clubfoot every year – due to the incapacitating and stigmatizing effects on untreated patients, and the social and financial cost that this deformity can create, reducing the individual's capacity to work, and restricting their mobility.

In addition, the focus of public health is important because through a specific intervention, treatment by the Ponseti Method, the cycle of deformity, disease and disability can be halted in childhood, giving the individual a healthy life, free of deformity, stigma and burden on society. Serial casts, tenotomy and maintenance of the correction with a brace in the first years of life can be seen as a "vaccine" against the physical disability.

The Ponseti Method is a form of preventing neglected deformity (receiving the label of secondary prevention) since we are not yet able to combat the occurrence of the deformity itself, but we can certainly minimize it through early treatment. Tertiary prevention or rehabilitation can be applied with the use of the Ponseti Method in older, untreated children, or even those previously operated on, or who have undergone some form of previous treatment that failed to correct the deformity.

The treatment of congenital clubfoot by Ponseti Method is reproducible, and should be accessible to all children. For it to be effectively integrated as part of the *Sistema Único de Saúde*, it should be performed by regional reference with trained professionals, integrated into the network of services, with interconnections with the maternity hospitals, centers of primary care, brace workshops, and centers of

education and health for family members. The current stage of development of the *Sistema Único de Saúde* is conducive to the dissemination of the Ponseti Method: the health pact promotes regionalization, and the consolidation of these health regions. Thus, the treatment by Ponseti Method will be able to promote universality, comprehensiveness and equality of access to healthcare for all children with congenital clubfoot.

The impact assessments reported in this study did not, by themselves, present a good way of measuring the impact of the Ponseti Brazil Program. This was due to problems encountered with the methodology in each of these assessment attempts, but was mainly due to the immersion of the author in coordination and teaching activities in each of symposiums, which made an objective analysis of the Ponseti Brazil Program and its impact impossible. However, considering the wider context surrounding the dissemination of the Method discussed above, the attempts at assessment can be considered as forms of recording events related to the dissemination of the Method.

The perception that only a few of the professionals trained in the Ponseti Brazil Program truly learned the correct application of the Method, mastering their difficulties and its technical details, does not undermine the importance and scope of the Program. The majority of the professionals trained worked in the public services (73%). If each region of the country had a center of expertise in the use of this treatment, it would be possible to treat these deformities much more efficiently. And if all these treatment centers were coordinated, and working together, it would be possible to improve the quality of care and the effectiveness and the recognition of reference centers for treatment.

Based on the points discussed in this manuscript, the Ponseti Method is in the process of dissemination in the life-cycle of technologies, to go back to DEARING's proposal mentioned in the introduction to this manuscript; this cycle will continue until this form of treatment of clubfoot is replaced by another, more advantageous

method that gives even better results. The future may point towards genetic studies and gene therapies.

The contribution of this study is in furthering understanding of the processes related to the dynamics of incorporation and dissemination of technology in medicine, the treatment of congenital clubfoot by the Ponseti Method. It may also provide another tool for analyzing the subject, for its presentation to and official incorporation by the *Sistema Único de Saúde*.

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