Care for cleft lip and palate patients: modeling proposal for the assessment of specialized centers in Brazil

Atenção à pessoa com fissura labiopalatina: proposta de modelização para avaliação de centros especializados, no Brasil

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ABSTRACT This study has designed a logic model of care for individuals with cleft lip and palate in order to subsidize the assessment of rehabilitation centers in the Country. International guidelines, as well as publications by experts from the Hospital for Rehabilitation of Craniofacial Anomalies – University of São Paulo and from the Ministry of Health have been reviewed. The logic model comprises two dimensions – Care Management and Patient Rehabilitation – and defines objectives, interventions and necessary results for the integral rehabilitation of the individual. The intervention modeling is an essential step for the design of the assessment tool, which may be replicated in other Brazilian states.

KEYWORDS Cleft lip. Cleft palate. Program evaluation. Health policy.

RESUMO *Este estudo elaborou um modelo lógico de atenção à pessoa com fissura labiopalatina, para subsidiar avaliações em centros de reabilitação do País. Foram revisadas as diretrizes internacionais da área, publicações de especialistas do Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo e do Ministério da Saúde. O modelo contempla duas dimensões – Gestão da atenção e Reabilitação do paciente –, além de demarcar objetivos, atividades e resultados necessários para a reabilitação integral do indivíduo. A modelização da intervenção é passo essencial para a elaboração do instrumento de avaliação dessa atenção, que poderá ser reproduzida nos vários estados brasileiros.*

PALAVRAS-CHAVE *Fenda labial. Fissura palatina. Avaliação de programas e projetos de saúde. Política de saúde.*

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Introduction

The cleft lip and/or palate (CLP) is the most common diagnosis of craniofacial malformation in newborn babies (MARTELLI *ET AL.*, 2012). The worldwide prevalence is 1.53 cases for every thousand live births and in Brazil it ranges from 0.19 to 1.54 for every thousand live births (MARTELLI *ET AL.*, 2012; SOUZA-FREITAS *ET AL.*, 2004).

The CLP results from failures in the anatomical fusion of facial processes between the second and twelfth weeks of intrauterine life, and may be classified according to the anatomical involvement as: cleft lip, cleft palate, cleft lip and palate, and rare facial clefts. Concerning the extent, defects may be considered as: complete or incomplete, unilateral or bilateral (BORGES *ET AL.*, 2014). The etiological factors cited are genetic, mainly those related to the individual (mutations and polymorphism) that interact with environmental factors such as: nutritional deficiency, alcoholism, and tabagism (SOUZA-FREITAS *ET AL.*, 2004).

For the complete rehabilitation of individuals with CLP, a multidisciplinary approach is needed, involving medicine, dentistry, speech therapy, psychology, nursing, and social service. Health care in this area reaches all levels of complexity and in several countries the interventions dealing with this problem are performed in specialized centers and in public and private hospitals (WHO, 2002). In Brazil, the history of craniofacial anomalies care is represented by the struggle of professionals, researchers, and families who, in the last 35 years, have strived for the inclusion of these congenital defects in the agenda of health policies (MONLLEÓ; GIL-DA-SILVA-LOPES, 2006).

In the 1990s, the first initiatives for the care of individuals with CLP in the Unified Health System (Sistema Único de Saúde – SUS) took place. In 1993, there was the introduction of procedures for the correction of the CLP table in the Hospital Data System (Sistema de Informações Hospitalares of SUS – SIH/SUS) (BRASIL, 1993), followed by the publication of the Directive Nr 62, of April 19, 1994, of the Secretariat of Health Care/Ministry of Health (Secretaria de Atenção à Saúde/Ministério da Saúde – SAS/MS), that established the norms for the registration of hospitals and services of rehabilitation in the area (BRASIL, 1994). Subsequently, the Reference Network for the Treatment of Craniofacial Anomalies (Rede de Referência no Tratamento de Deformidades Craniofaciais – RRTDC) (BRASIL, 2002) was created and currently it has 28 registered centers (BRASIL, 2015).

Some studies were found about the operation of the Brazilian rehabilitation centers. To be highlighted is a series of articles published by the researchers from the Hospital for Rehabilitation of Craniofacial Anomalies of the University of São Paulo (Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo – HRAC/USP) (SOUZA-FREITAS *ET AL.*, 2012A, 2012B, 2012C, 2013), that describe general aspects of the pathology and the treatment protocol used by the professionals of the institution, with emphasis on the areas of plastic surgery, speech therapy, dental pediatrics, orthodontics, maxillofacial surgery, and oral rehabilitation (dental prosthesis, dental implant). Monlleó e Gilda-Silva-Lopes (2006) have described characteristics of 25 centers that belong to the RRTDC gathered through semi-structured questionnaires sent by mail. The authors found that there is a prevalence of services in the Southeastern region of Brazil, in universities and in the cleft lip and palate field, predominately with public funding; the majority of teams follow North-American parameters and protocols are used in 70% of the sample.

The increasing number of services providing care for individuals with CLP in SUS, from 19 centers in 2008 to 28 centers in 2015 (BRASIL, 2015), indicates that assessment processes in this area may reveal how the implementation of this care in the Brazilian states has taken place, considering the

complexity of factors that may interfere with the management and operation of health interventions (CONTANDRIOPOULOS, 2006). Health assessment, understood as a value judgment of a health intervention (policy, planning, or practice (HARTZ; VIEIRA-DA-SILVA, 2005), may favor individual and collective apprenticeship and become an excellent instrument of transformation and innovation in the health system by enabling a critical view of the established norm (CONTANDRIOPOULOS, 2006).

In this sense, the Ministry of Health (Ministério da Saúde – MS) has created in 2013 a Work Group in the area of CLP, and has defined as one of its goals for 2014 the achievement of the restructuring of the specialized care, with the creation of criteria for its organization, planning, and monitoring, with specific guidelines (BRASIL, 2014). These goals have been maintained in the Management Reports for 2015 and 2016 (BRASIL, 2014, 2015), thus highlighting a gap in the improvement of this policy within the governmental agenda.

In the planning of an evaluation process, the elaboration of a logic model stands as one of the initial steps. This model can be defined as a visual scheme that presents how an intervention should be implemented and what results are expected (HARTZ; VIEIRA-DA-SILVA, 2005). The modeling also reveals the set of necessary hypotheses for the intervention to enable the improvement of a given problematic situation, with the systematization of these hypotheses as the theory of the program (CHAMPAGNE *ET AL.*, 2011). The literature on evaluation highlights that there is no consensus on the construction of these models; there are authors who make a distinction between the logic model and the theory of the program, whereas most authors use these two expressions in different ways (HARTZ; VIEIRA-DA-SILVA, 2005; CHAMPAGNE *ET AL.*, 2011). Therefore, the objective of this study was to formulate a logic model of care to individuals with cleft lip and palate that may later subsidize the evaluation of the implementation of this care in rehabilitation centers in Brazil.

Methods

This is a study of modeling the care for individuals with cleft lip and palate. This care involves prevention, diagnosis, and rehabilitation (WHO, 2002). In this study, the evaluation focused on diagnosis and rehabilitation actions, with emphasis on rehabilitation comprising early intervention, adequate use of technology, ongoing care, and several consultations aiming at the reduction of the individual's functional impairments, quality of life improvement, and social inclusion (RIBEIRO, 2010).

The logic model designed represents the modeling of the care for individuals with CLP according to the specialized literature (*figure 1*). At first, a review was made of the guidelines and international recommendations of the American Cleft Palate – Craniofacial Association (ACPA) (ACPA, 2009, 2015) and of the World Health Organization (WHO) (WHO, 2002). These are the two main organizations that have published guidelines considered to be references in the area of craniofacial anomalies, including cleft lip and palate. The ACPA is an international non-profit organization of health care professionals from the United States of America, Canada and other countries who perform research on cleft and craniofacial anomalies for over 65 years (ACPA, 2015). WHO has published the document 'Global Strategies to Reduce the Health-Care Burden of Craniofacial Anomalies', the result of a collaborative project by specialists from several countries, initiated in 2000. WHO has incorporated the guidelines for the care of individuals with CLP produced by the study Eurocleft Report, a multicentric research conducted in Europe that has stimulated the improvement of services and respective teams (WHO, 2002). The main aspects of these documents are summarized in *chart 1*.

Chart 1. Main international guidelines and recommendations for care services for individuals with CLP

WHO (2002)	ACPA (2015)
Part 1: Health care	**1. Team composition**
Neonatal emotional support and professional counseling; Neonatal nursing; Surgery: team agreed protocol; Orthodontics; Speech therapy; Otolaryngology; Clinical genetics/Pediatrics; Emotional support and professional counseling for patient and family; Periodical dental care; National register.	Presence of one coordinator; Minimum team with speech therapy, surgery and orthodontic specialties; Access to professionals in the areas of psychology, social work, audiology, general and pediatric dentistry, otolaryngology, pediatrics and nursing; The craniofacial team should include a surgeon trained in craniofacial surgery and access to a psychologist for the evaluation of cognitive and neurological development; The team should facilitate access to a neurosurgeon, an ophthalmologist, a radiologist and a geneticist.
Part 2: Service organization	**2. Team management and responsibilities**
Multidisciplinary team of specialists; Team members should have specific training and experience with cleft care; Team should agree upon the phases of treatment, including analysis, register collection and general protocols; There should be one person responsible for the improvement of quality and communication within the team; The coordination of patient's care is important; The number of patients referred to the team should be sufficient to sustain the experience and specialized competences of all team members, and to allow evaluation/team performance audit within a reasonable time period. It has been recommended that surgeons, dentists and speech therapists should treat at least 40-50 new cases per year.	Periodical meetings of team members; Mechanism of referral and communication with other professionals; Subsequent evaluations of patients at periodical intervals, based on team recommendations; Central registries shared by the team.
	3. Communication with patient and family
	The team should provide adequate information to family/caregiver on the evaluation and treatment procedures; The team should stimulate the participation of patient and family/caregiver in the treatment process; The team should support families/caregivers in obtaining the necessary financial resources to meet the demands of each patient.
Part 3: Funding	**4. Cultural competence**
Resources should be available to cover the following care aspects: Neonatal emotional support and professional counseling; Neonatal nursing; Surgery; Orthodontics/Orthopedics; Speech evaluation and therapy; Otolaryngology treatment; Clinical genetics/Pediatric medicine; Emotional support for child and parents; Travel expenses; General dental care, including prostheses.	The team demonstrates sensibility for the individual differences that affect the relationship between its dynamics and that of the patient and the family/caregiver; The team treats patients and families/caregivers in a non-biased manner.
	5. Social and psychological services
	The team has a mechanism to evaluate and treat, initially and periodically, if needed, the psychological and social needs of patients and families/caregivers, and submit them to posterior treatment, if necessary; The team has a mechanism to evaluate the cognitive development.
	6. Evaluation of results
	The team uses a process to evaluate its own performance, regarding the evaluation of the patient, treatment, or satisfaction, and a program of improvements based on the results of these evaluations; The team registers its treatment results, including the performance and changes throughout time; The team should also have a quality management system to evaluate the satisfaction of the patient/family.

Source: WHO (2002); ACPA (2009).

The proposals found in the various publications of the HRAC/USP (TRINDADE; SILVA-FILHO, 2007; SOUZA-FREITAS *ET AL.*, 2012A, 2012B, 2012C, 2013) were also analyzed. This institution has over 50 years of experience with the rehabilitation of these patients and is known as a reference all over Latin America and also by WHO (WHO, 2002). The Directive SAS/MS Nr 62 has also been analyzed for the elaboration of the logic model for the care to individuals with CLP (BRASIL, 1994).

The logic of 'if – then' was used to build the relationship between objectives, activities, and results of care to individuals with CLP in the model. Following this logic, 'if' the actions are carried out, 'then' the products are obtained, which, by its turn, enable the existence of intermediate results. If intermediate results occur, then there is a final result that will lead to the achievement of the intervention's objective, which here represents the rehabilitation of the individual with CLP (CASSIOLATO; GUERESI, 2010).

To help understanding the path that a patient has to go through during the rehabilitation process, a flow chart is presented in *(figure 2)* based on the publications reviewed for the intervention modeling (WHO, 2002; ACPA, 2009, 2015; TRINDADE; SILVA-FILHO, 2007; SOUZA-FREITAS *ET AL.*, 2012A, 2012B, 2012C, 2013).

Figure 1. Logic model of care for individuals with cleft lip and palate (CLP) according to guidelines from WHO (2002), ACPA (2009; 2015), publications of HRAC/USP and Directive SAS/MS Nr 62, of April 19, 1994

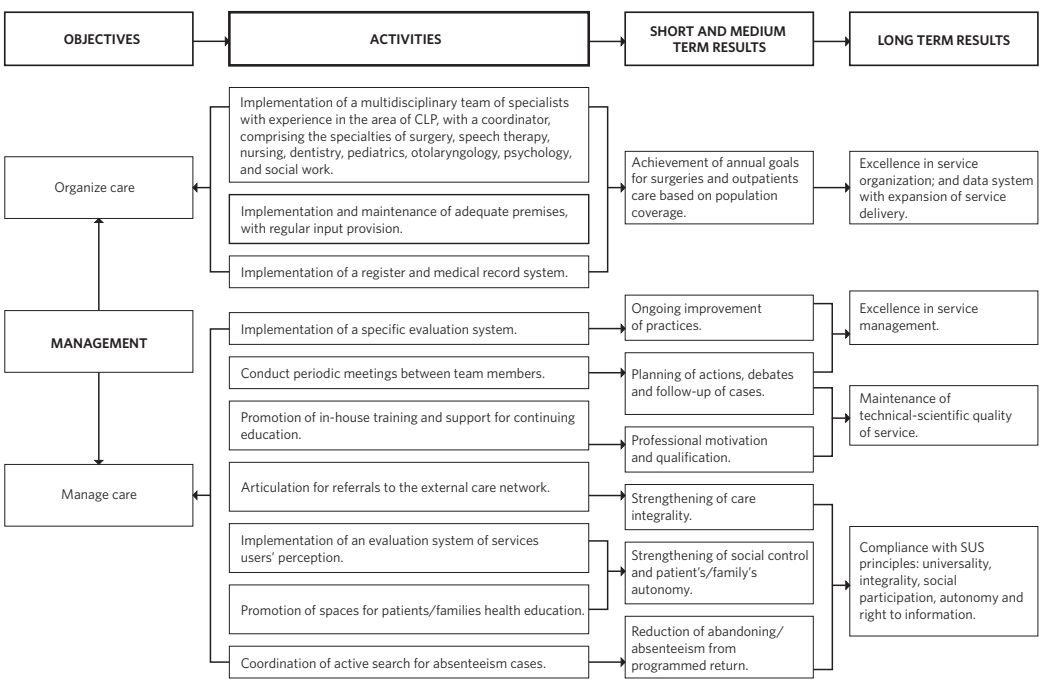


Figure 1. (cont.)

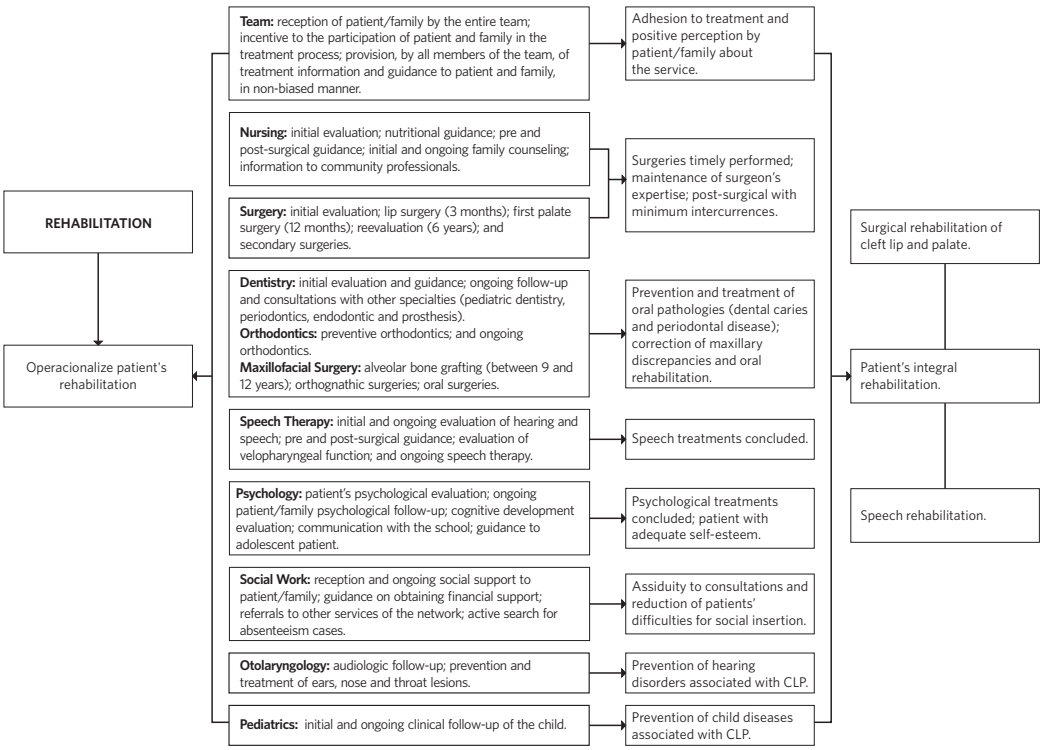
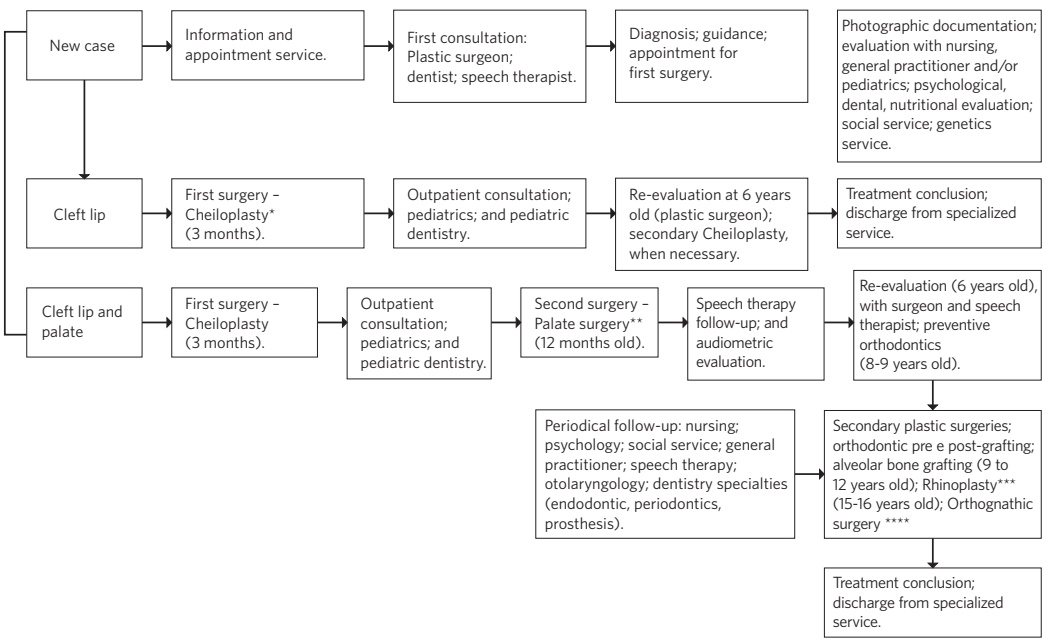


Figure 2. Flow chart of the rehabilitation of the individual with cleft lip and palate



Source: ACPA (2009); SOUZA-FREITAS *et al.* (2012a, 2012b, 2012c, 2013); TRINDADE; SILVA FILHO, 2007.

*Cheiloplasty: lip repair surgery.

**Palate surgery: palate repair surgery.

***Rhinoplasty: nasal repair surgery (performed when necessary).

****Orthognathic surgery: surgery of the mandibular/maxillary complex (performed when necessary).

Results and discussion

Logic model of care for individuals with cleft lip and palate

The logic model of care for individuals with cleft lip and palate (CLP) created *(figure 1)* comprises in the first part the objectives related to the management dimension based on the international recommendations (WHO, 2002; ACPA, 2009, 2015). Management refers to the political-administrative conduction of a system and in this study it has been divided in two sub-dimensions: organization and management of interventions. In the second part of the model are the objectives of the dimension rehabilitation of the patient (SOUZA-FREITAS *ET AL.*, 2012A). Hartz and Vieira-da-Silva (2005) point out that in the logic model of a program or intervention there should be: essential and secondary components, services related to practices required to carry out the components, and expected outcomes, as well as goals and effects on the populations' health conditions.

The organization of care of cleft lip and palate is internationally consolidated through specialized centers (WHO, 2002; ACPA, 2009), based on evidences, especially in the biomedical perspective. The reviewed literature shows that for the rehabilitation of this defect the best results are produced by interventions at specific moments of craniofacial growth and development, with ongoing rehabilitation treatment, allied to the existence of specialized and qualified multi-professional team with clinical and surgical experience (WHO, 2002; SOUZA-FREITAS *ET AL.*, 2012A).

In this study, besides the prevailing biomedical perspective in the sphere of care for the individual with CLP, there was the aggregation to the logic model of elements of service management that may potentiate the compliance with SUS principles and guidelines, from the understanding that the social support of SUS political project is one of the dimensions of management (SOUZA, 2009).

There is consensus in the literature on the need and relevance of the assessment of health interventions; however, it is necessary to broaden the debate on the theoretical-conceptual approaches and the most adequate models (COSTA *ET AL.*, 2015). The modeling proposal presented here may contribute for the improvement of this policy, considering that since 1993 SUS provides resources for the expansion of these services but has not yet achieved the establishment of a policy for the assessment of their implementation. Work and power relationships and disputes between the various stakeholders present in the social space of these rehabilitation centers require deepening and complexification of the logic model; they have not been included in the object of this article and may be studied in the future.

The management dimension

Regarding care organization, the following items were highlighted: establishment of the multidisciplinary team of specialists with a coordinator; implementation and maintenance of adequate premises, with regular input provision; establishment of clinical treatment protocol agreed upon between the team members; and implementation of a register and medical record system (ACPA, 2009; WHO, 2002). In the long term these aspects would result in the achievement of excellence in the organization of the service and the data system with the expansion of care delivery.

The review of the international guidelines showed that the documents published by ACPA (2009, 2015) comprise more information on the service and role of each professional in the team of care for the individual with CLP in comparison with WHO publication (2002). Another aspect is the minimum

composition of the service team regarding specialties. In the North-American proposal, the team should comprise professionals from the following areas: surgery, orthodontics, otolaryngology, speech-language pathology, psychology, social work, and nursing (STRAUSS, 1998). ACPA (2009) does not include a geneticist in the minimum team, but considers that clinical genetic evaluation is a key component in the management of patients with congenital craniofacial anomalies and should include: diagnosis; recurrence risk counseling; and counseling regarding prognosis. OMS (2002) includes the clinical genetics professional in the minimum service team.

In Brazil, the Directive SAS/MS Nr 62, of April 19, 1994, defines that the services of care to CLP should have specialists in the areas of medicine (anesthesiology, plastic surgery, medical clinic, otolaryngology, pediatrics); dentistry (maxillofacial surgery, prosthodontics, pediatric dentistry, orthodontics, prosthesis); speech-language pathology; psychology; social work; nursing; physiotherapy; nutrition; and family assistance (BRASIL, 1994). Monlleó and Gil-da-Silva-Lopes (2006) have carried out a study with 29 care centers for craniofacial anomalies taking part in RRTDC of SUS and verified that the specialty clinical genetics had the lower frequency in most part of the sample. The authors suggest that this may highlight the interference of the rule for obtaining the credential at SUS that does not require this specialty. Another referred hypothesis is that the characteristic of these centers is essentially rehabilitation interventions, and the role of the geneticist is mostly directed to diagnosis and counseling (MONLLEÓ; GIL-DA-SILVA-LOPES, 2006).

In the sub-dimension of care management the proposed relations comprise the following activities and respective results expected in the short/medium terms: the implementation of a system for monitoring by the team of the outcomes of treatment would guarantee the longitudinal follow-up of the patient (ACPA, 2009) and a periodic assessment of the practices developed in the sphere of care would favor their improvement (CONTANDRIOPOULOS, 2006); periodic meetings between team members would result in collective planning of interventions and debate of cases (ACPA, 2009); the promotion of in-house training and support to continuing education (WHO, 2002; ACPA, 2009) would increase professional motivation and qualification. In the long term, these results would promote management excellence and maintenance of technical-scientific quality of the service.

In the same sub-dimension of care management, the articulation of patient referral to other services of SUS network would favor care integrality and continuity (BRASIL, 1990); the evaluation of services users' perception and the promotion of spaces for health education would strengthen social participation, the autonomy of this segment, and the right to information, which are included in the Health Organic Law (Lei Orgânica da Saúde) (BRASIL, 1990); and, finally, the coordination of active search for absent cases would reduce the number of non-attendance to programmed follow-up and treatment abandoning, besides contributing with greater social insertion of people with CLP (WHO, 2002; TRINDADE; SILVA-FILHO, 2007).

The rehabilitation dimension

The second part of the logic model comprises the attributions and responsibilities of the health team and professionals involved in the rehabilitation of cleft lip and palate. If nursing and plastic surgery perform the recommended activities there are greater changes that the corrective surgeries will be timely carried out, there may be a reduction in post-surgical intercurrences, and it will contribute to the maintenance of the surgeon's expertise (WHO, 2002; ACPA, 2009;

SOUZA-FREITAS *ET AL.*, 2012A). The accomplishment of the roles of dentistry and its respective specialties will result in the reduction of the occurrence of oral pathologies throughout the rehabilitation and in the correction of maxillary-mandibular discrepancies (SOUZA-FREITAS *ET AL.*, 2012B, 2012C, 2013). If the actions of speech therapy and psychology are performed throughout the CLP rehabilitation process they will contribute to the conclusion of the interventions and the discharge of the patient from the respective therapeutic areas (WHO, 2002; ACPA, 2009; SOUZA-FREITAS *ET AL.*, 2012A). If social work promotes psychosocial rehabilitation of patient and family it favors the assiduity to consultations and treatments, and social and economic difficulties of patients will be mitigated (TRINDADE; SILVA-FILHO, 2007). And finally, if otolaryngology and pediatrics provide the care pertaining to the respective specialties they will favor prevention and treatment of hearing impairments and child diseases associated with cleft lip and palate (ACPA, 2009).

In the long term, the main result of all the dimensions and activities approached in the logic model designed is the patient's integral rehabilitation, which comprises surgical correction and speech rehabilitation – the two major CLP after-effects – and, furthermore, social inclusion and improvement of health and life conditions of the people involved.

As a graphic representation of how the care for the individual with CLP 'should be' (CASSIOLATO; GUERESI, 2010), the logic model does not therefore contemplate the complexity of factors involved in the patient's rehabilitation, among which those factors associated with the social determinants in health (BUSS; PELLEGRINI-FILHO, 2007) and with the context of the implementation of actions. However, by explicating the hypotheses on how an intervention should supposedly operate, in various contexts, it creates the main reference on which management and assessment are based (CASSIOLATO; GUERESI, 2010). By providing information on how the activities may be connected with the expected results, the logic model appears as an efficient tool for supporting the management of intervention, resource allocation, and actions planning (HAYES; PARCHMAN; HOWARD, 2011). Considering the existing gap in the national administration sphere regarding assessing and monitoring SUS policy for the care of cleft lip and palate (BRASIL, 2015), the logic model may also offer support in identifying appropriate evaluation issues to be prioritized by managers (HARTZ; SILVA, 2005; CASSIOLATO; GUERESI, 2010).

Final considerations

The proposed modeling of care for individuals with CLP is a partial representation of a complex reality that makes evident several issues that deserve debate and investigation: Are the Brazilian centers linked to SUS complying with the guidelines systematized in this study? Which local context aspects are influencing the implementation of those services? To what extent are those centers capable of working on health prevention, considering the etiologic factors associated with tabagism, alcoholism, and nutritional deficiency? What happens to the cases that go through surgeries in hospitals and services that do not pertain to the reference network?

Conducting researches with evaluative approaches in the Brazilian states may contribute to the construction of answers on these and other gaps involving the care for individuals with CLP in SUS. The logic model designed also contributes to clarify to the Brazilian government what is expected from a care center for individuals with CLP, according to SUS principles, such as access universality and integrality. The formulation of indicators and assessment patterns constitutes the next stage to be achieved, based on the modeling proposed in this study. ■

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