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# Family Health Team: reports of conduct on child hearing loss

Equipe de Saúde da Família: relatos de conduta diante da perda auditiva infantil

#### Keywords

Primary Health Care Family Health Strategy Child Care Hearing Hearing Loss

#### **ABSTRACT**

**Purpose:** To analyze the performance of family health teams toward the suspicion and identification of child hearing loss. **Methods:** This is a case study. Data were collected in three focus groups with three family health teams of a health district in the metropolitan area of Recife, Brazil. All data were transcribed and analyzed based on the interview analysis model of condensation of meanings. **Results:** The family health professionals investigated made use of some resources to assess child reaction to sound stimuli, but they were mostly unaware of risk indicators for hearing loss and presented doubts about conducting referrals. Regarding child monitoring, the family health professionals reported that the lack of counter-reference by other professionals precludes the effective monitoring of children in the family health units. **Conclusion:** Despite their potential in assisting child health, the role of family health teams is still permeated by weaknesses that hinder their performance with respect to hearing health.

#### **Descritores**

Atenção Primária à Saúde Estratégia de Saúde da Família Cuidado da Criança Audição Perda Auditiva

#### **RESUMO**

Objetivo: Analisar a atuação das equipes de saúde da família diante da suspeita e identificação da perda auditiva infantil. **Método:** Trata-se de um estudo de caso. Realizaram-se grupos focais com três equipes de saúde da família de um distrito sanitário, na região metropolitana de Recife. Os dados coletados foram transcritos e analisados, tomando por base o modelo de análise de entrevistas do tipo condensação de significados. **Resultados:** Os profissionais fazem uso de alguns recursos para avaliar a reação da criança aos estímulos sonoros, mas, em sua maioria, desconhecem os indicadores de risco para a perda auditiva, bem como possuem dúvidas quanto à realização de encaminhamentos. Quanto ao acompanhamento das crianças, foi relatado que a falta de uma contrarreferência por parte dos outros profissionais impossibilita um acompanhamento efetivo da criança na unidade. **Conclusão:** Apesar das potencialidades na assistência à saúde da criança, a atuação da equipe de saúde da família ainda é permeada por fragilidades que dificultam seu desempenho no que diz respeito à saúde auditiva.

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#### INTRODUCTION

Hearing loss (HL) is a highly prevalent social problem worldwide. According to data of the World Health Organization<sup>(1)</sup>, there are approximately 32 million children in the world with disabling HL. In Brazil, it is estimated that two to seven children per thousand births present hearing disorders<sup>(2)</sup>. This is a worrisome fact, given that it is through hearing that the child acquires and develops oral language, so that HL can have serious negative effects on the development and quality of life of children.

In order to address this problem, the National Policy on Hearing Health Care was instituted by the Brazilian Ministry of Health through the order no. 2.073/2004<sup>(3)</sup>. After that, the order no. 587/2004 defined the distribution of the state network for actions in basic health care of medium and high complexities<sup>(4)</sup>. With this initiative, services aimed at establishing a network of care and support to hearing health were implemented throughout the country.

In 2010, a general hearing screening system was instituted with the publication of the federal law no. 12.303/2010<sup>(5)</sup>, which made the otoacoustic emission test mandatory and free in all hospitals and maternities in Brazil. In 2012, with the purpose of reorganizing and reinforcing actions aimed at individuals with disabilities, the "Viver sem Limites" Plan (decree no. 7.612/2011) established a new configuration for the Health Care Network for People with Disabilities within the Brazilian National Health Care System (SUS)<sup>(6)</sup>, with special emphasis on the creation of Specialized Rehabilitation Centers (CER), which began to integrate the care for people with disabilities.

The responsibility of health care for people with disabilities is distributed at the different levels of health care and performed by a multidisciplinary team. With regards to hearing impairment, the earlier the condition is identified and the intervention is conducted, the most adequately the communicative performance will occur. Its delayed identification not only impairs the individual's prognosis, but also generates high costs for the health system<sup>(7)</sup>. In the scope of Primary Health Care (PHC), the actions of the Family Health Strategy (FHS) play an important role in assisting with the early identification of HL, considering that it is one of the main accesses to the SUS.

It is the responsibility of the team of professionals working in the FHS, formed by family doctors, nurses, nursing technicians, and community health agents (ACS), among other functions, to closely monitor child growth and development milestones, monitor children exposed to risk indicators for HL, and seek partnerships with other specialists to facilitate child and family care<sup>(8)</sup>.

The team can count on the multiprofessional assistance of the Support Center in Family Health (NASF), which contributes to a greater range and efficiency of PHC. The inclusion of speech-language pathologists in the NASF teams may allow better assistance to hearing health.

The sharing and monitoring of cases by these teams allows the review of referral practice based on referral and counter-referral processes, strengthening the family health team (FHT) as the coordinator of care<sup>(9)</sup>.

Considering the high rates of hearing loss; the consequences of this disorder for the development of children; the importance

of early care; and understanding the FHS as the access to the SUS closest to the community, the present study aimed to analyze the reports of the FHT regarding the suspicion and identification of child hearing loss.

#### **METHODS**

This is a qualitative survey based on a case study. The study sample consisted of three teams of Family Health Units (FHU) of a health district in the metropolitan area of Recife, Pernambuco state, Brazil. The health units were selected randomly by lot in order to contemplate each microregion of the studied district.

Data collection was based on the formation of focus groups, which promotes a comprehensive problematization on a specific theme from group interaction. Three focus groups were formed - one for each FHU - having as inclusion criteria the teams that were complete, that is, those that included physicians, nurses, nursing technicians, and community health agents (CHA). The student interns who were practicing in the units and wanted to participate in the focus groups were accepted. When there was more than one complete team in a unit, the focus group with the greatest time availability to participate was selected.

The study sample was composed of 27 individuals, namely, three physicians, three nurses, three nursing technicians, 14 community health agents, and four student interns. The time of professional experience in the Family Health Strategy (FHS) ranged from 2 months to 20 years (mean=9.4 years), whereas the professional experience time for the team in the FHU studied ranged from 2 months to 13 years (mean=5.28 years) (Chart 1).

Prior to study commencement, visits were made to the FHUs to establish trust between collaborators and researchers - which facilitated the discussions in the focus groups - and encourage the participation of all those involved. At these times, the individuals were invited to participate in the study and the day and time for each meeting was set. The meetings were held at the FHUs where each team works.

The group of micro-region A was composed of eight individuals and lasted 93 minutes; as for the group of micro-region B, there were nine participating individuals and duration of 108 minutes; whereas the group of micro-region C contained ten individuals and lasted 97 minutes. The number of participants in a focus group should range from four to 12, so that everyone can state their opinions and bring different contributions<sup>(10)</sup>, whereas the time should vary between 90 and 110 minutes for a good use of the technique<sup>(11)</sup>.

The focus groups were led by two researchers. The researcher with the most experience in this methodology had the function of mediating, initiating, motivating, generating the discussion, and interacting with participants. The other researcher was responsible for the audio recording using an MP4 player and for the analysis of the group coordination process.

The mediator followed a debate script that contained two key questions: 1) How do you identify a child that may present a hearing problem? 2) If you suspect that a child has a hearing problem, what is the conduct of the team? To stimulate the discussion and provide elucidative information about the research

Chart 1. Characterization of study participants according to codename and professional experience (n = 27)

PROFESSIONALS		PROFESSIONAL EXPERIENCE		TOTAL
	(CODENAME*)	FAMILY HEALTH STRATEGY	FAMILY HEALTH TEAM ASSESSED	TOTAL
MICRO-REGION A	MD-A	12 years	7 years	8
	N-A	5 years	4 years	
	NT-A	5 years	5 years	
	CHA-A1	3 years	1 year	
	CHA-A2	1 year	1 year	
	CHA-A3	20 years	7 years	
₹	CHA-A4	5 years	3 years	
_	SI-A (Medicine)	3 months	3 months	
В	MD-B	6 years	1 year and 1 month	9
	N-B	10 years	3 years	
N	NT-B	13 years	9 years	
MICRO-REGION B	CHA-B1	14 years	5 years	
	CHA-B2	18 years	9 years	
	CHA-B3	11 years	7 years	
	CHA-B4	12 years	7 years	
	CHA-B5	15 years	7 years	
	SI-B (Nursing)	2 months	2 months	
MICRO-REGION C	MD-C	14 years	2 years e 9 months	10
	N-C	14 years	5 years	
	NT-C	13 years	3 years	
	CHA-C1	15 years	13 years	
	CHA-C2	13 years	13 years	
	CHA-C3	7 years	5 years	
	CHA-C4	14 years	13 years	
	CHA-C5	13 years	10 years	
	SI-C1 (Nursing)	2 months	2 months	
	SI-C2 (Nursing)	3 months	3 months	
TOTAL				27

\*Physician: MD-A, MD-B, MD-C; Nurse: N-A, N-B, N-C; Nursing Technician: NT-A, NT-B, NT-C; Community Health Agent: CHA-A1, CHA-A2, CHA-A3, CHA-A4, CHA-B1, CHA-B2, CHA-B3, CHA-B4, CHA-B5, CHA-C1, CHA-C2, CHA-C3, CHA-C4, CHA-C5; Student Intern: SI-A (Medicine), SI-B (Nursing), SI-C1 (Nursing), SI-C2 (Nursing)

objective, the mediator made use of manga questions, deepening the theme of each questioning.

At the beginning of the focus groups, the mediator created an atmosphere of comfort, arranging the participants in a circle, which allows good eye contact and better interaction<sup>(12)</sup>, in addition to facilitating the audio recordings. Subsequently, the mediator explained the research objectives, data collection procedures, and the involved ethical aspects to the group members. Soon after the volunteers signed the Informed Consent Form (ICF), the theme and the script points were presented, and the volunteers could freely express their opinions and present contributions.

The speeches of all participants were transcribed in full, classified, and prepared based on the interview analysis model of condensation of meanings<sup>(13)</sup>. We opted for the condensation of meanings because this analysis was considered the most appropriate for the purposes of the study. This technique allows condensed summarization of meanings without losing the essence of the content of discourses.

After transcription of all the speeches, a cautious reading was performed in order to understand the meaning of the whole and then determine the units of meanings and define the central themes in the simplest possible way. The units of meanings were assessed aiming to establish a relationship with the objective

of the research. Thus the essential description of the identified themes was accomplished, using clippings from the discourse lines of the teams.

The main categories of analysis previously identified were: identification of children with hearing loss and conduct adopted in the cases of children with hearing loss. Anonymity of the participants was guaranteed by the adoption of acronyms referring to the initials of each profession, followed by the letter that indicates the microregion of the team, and the number, in sequential order, according to the speech of each professional. The sequence adopted in the identification of each microregion is not associated with the order presented by the sanitary district studied.

The present study was approved by the Research Ethics Committee of the aforementioned Institution under protocol no. 532.851/2014.

#### **RESULTS**

The performance of the family health teams towards the suspicion and identification of child hearing loss (HL) in the family health units (FHU) was analyzed according to the following key categories: 1. Identification of children with hearing loss; 2. Conduct

Chart 2. Distribution of the categories and subcategories of analysis

0 7				
Key Categories	Subcategories			
Identification of children with hearing loss.	Assessment. Risk indicators.			
Conduct adopted in the cases of children with hearing loss.	Conduct of referrals for diagnosis and intervention. Guidance to parents. Child monitoring.			

adopted in the cases of children with hearing loss. Within these main categories, other subcategories were explored (Chart 2).

#### Identification of children with hearing loss

The following subcategories were explored in the description of results of this category: assessment and risk indicators. As for assessment, we tried to understand how the professionals proceed, in each function that they perform daily, to identify a child with HL. In the speech of one of the nurses (N-A), it was possible to observe that some members of the teams are attentive to the complaints of parents, both during the home visits and during assistance at the unit. Such complaints serve as a basis for directing actions.

[...] usually, the persons accompanying the child in the appointment report that they sometimes call the child by name and the child does not listen, that they emit some sounds and the child does not pay attention... (pause) Usually, the complaint comes from one of the parents (N-A).

In addition, nurses N-B and N-C stated in their reports that, during childcare consultations, they use some resources to evaluate the child's reaction to sound stimuli; physician MD-A asks parents or caregivers about the reaction of children to environmental sounds; whereas some community health agents (CHA), during home visits, show concern about the sound volume and the speech and school performance of children.

- [...] we usually ask: Do they react when the door slams? (MD-A).
- [...] we make sounds: clap our hands, snap our fingers, and see if they follow, participate, react (N-B).
- [...] in childcare, my identification is that way: I carry a rattle, I make noise (N-C).

The children do not respond when called by the name, [...] want to watch TV at a louder volume [...] sometimes are not doing well at school [...] and, especially, when they reach the age of one, [...] two years old and still can't speak (CHA-B1).

Some factors reported by the team members were highlighted in the risk indicators.

[...] it is important to investigate if there is someone with a history of hearing loss in the family [...]. If it is a little baby, investigate if he/she has any congenital disease: syphilis, rubella, cytomegalovirus, which can cause hearing loss (SI-A).

You should be alert for a child who had had a sequence of otitis (CHA-B1).

Only one family health team reported inadequate ear care during hygiene as a risk indicator for HL.

[...] people that like to wash the ears, clean them with a cotton swab, hair clip, pen cap, you know? With all these, we all know that there are people who can even go deaf (N-C).

In contrast, two other aspects were mentioned several times by all the teams as risk indicators for HL: the use of headphones and the habit of listening to loud music, rather common in the community.

What can draw attention is the matter of headphones, isn't it? Which, now-a-days, children are already using [...] (CHA-A3).

[...] I'm really concerned about the noise from loud music, television... (pause) the habit that the community, in general, has to listen to very loud sounds (MD-A).

### Conduct adopted in the cases of children with hearing loss

The assessment adopted by the family health teams towards child HL emerged from the speeches to conduct referrals for diagnosis and intervention, guidance to the parents, and child monitoring. The professionals differed in some procedures in conducting referrals for diagnosis and intervention. Nurse N-A reported that, when a child is identified with HL, she promptly requests support from NASF to assist in the diagnostic process and makes referrals for intervention, whereas the physician from the same team (microregion A) would refer the child directly to an otolaryngologist.

Generally, when I identify a child at risk for hearing loss, I automatically refer he/she to the speech-language pathology department of NASF for assessment [...] Hence, they make the referrals if that's the case (N-A).

I refer the child to an otorhinolaryngologist. It's more urgent, isn't it? You can't miss the opportunity to recover the problem (MD-A).

The physician and the nurse in micro-region B reported that they would make evaluations to confirm the suspicion and conduct the necessary referrals. The question that appeared subsequently for the physician and the nurse, for example, was to which specialty and where the case would be referred to. The choice between a pediatrician or an otorhinolaryngologist would be based on the age of the child and the ease of access to the specialty in the health network.

The first step would be to confirm it with the parents [...] this suspicion of mine, [...] could speak with the CHAs for monitoring, but I would conduct the referral. My doubt is whether I would refer the child to a pediatrician or an otorhinolaryngologist. If we could find an otorhinolaryngologist, if we had regulation for that (N-B).

Physical examination, otoscopy [...] so that we could check for some obstruction, some foreign body, or if the child had had otitis [...] then I wouldn't know where to refer them to. Depending on the age, if the child were a little older, I would refer them to an otorhinolaryngologist [...] but if they were younger, I would refer them to a pediatrician (MD-B).

The nurse in the micro-region C addressed the difficulty in making referrals to other professionals, except for those of medical specialties.

[...] From here we can't refer a child directly to a speech-language pathologist for evaluation. [...] It is easier for us to refer a child to the otorhinolaryngology outpatient clinic and there, depending on the need, they refer them to another outpatient clinic (N-C).

It was possible to notice that the professionals know about the existence of the Neonatal Auditory Screening (NAS), which allows identification of HL as early as possible, although it is not yet widely performed.

SUS makes the ear test, doesn't it? A screening test conducted in the first months of life to identify whether the child is deaf (MD-B).

We are aware of this test, that we have to refer the child, but it's a process. I believe that it will soon be available for everybody, won't it? But it isn't yet (MD-A).

Some maternity hospitals even require it, [...] It's just too difficult to actually refer a child for this service (NT-A).

Regarding guidance to parents, only the team of micro-region C reported, as one of the first approaches during the case assistance, providing orientation to parents and reassuring them.

[...] I believe that in the first approach [...] we should inform the mother and reassure her. [...] make her aware of the possibility of having a child with disability and refer her to a specialist (MD-C).

In turn, in the micro-regions A and C, some guidance with a focus on the habit of listening to very loud music or sounds and sanitizing the ear were mentioned.

[...] when we make a visit, we hear the noise, [...] we immediately alert for the problem (MD-A).

During childcare, we advise the mother not to clean the child's ears with a cotton swab. They should clean the outside with a cloth diaper (N-C).

With respect to the issue of language development, two community health agents (CHA-B1 and CHA-A3) reported their experience in guiding mothers when children are in the process of acquisition.

- [...] when they begin to talk to their children, teach them how to speak, they should speak in front of their children, at the same height, so that they can also see this lip movement (CVH-B1).
- [...] we advise the mother to speak correctly, to stimulate the child to speak correctly (CHA-A4).

Regarding child monitoring, all the teams reported that when they conduct referral to a specialty, they have no return, which hinders their knowledge on the procedures that were performed and, consequently, the monitoring of children in the unit.

[...] even if there is referral to a specialty or to an emergency service, the return never happens [...] There's no way to monitor (SI-B).

The professional team only becomes aware of what is being done when parents provide team members with feedback, either during a visit or an appointment.

We become aware of the whole process that is going on over there. [...] We make a visit, the speech-language therapist also makes a home visit together with the CHA [...] and we also have the answer of the mother here in the unit (NT-A).

Another addressed issue was that, because the process of referrals in the health unit is slower, parents often seek the specialties directly, and are not screened by the family health strategy (FHS).

Parents go straight to the place where they can find specialists. Some people come to us to find out where that reference is offered and look for them [...] because, unfortunately, we know that the access to a specialty through the FHU takes a longer (CHA-B1).

#### DISCUSSION

Child health care is among the essential actions conducted by the family health team to ensure healthy child growth and development<sup>(8,14)</sup>.

When questioned about the assistance focused on auditory aspects, the professionals reported careful interest in the children and their families during the visits, aiming at listening to and receiving their complaints. This attitude establishes a connection between child, family, health service<sup>(15)</sup>, favoring better assistance.

Assessment of child auditory acuity is part of the nurses' routine. This evaluation is performed through the observation of the children's reaction to sound stimuli<sup>(16)</sup>, and allows data collection on hearing health. In addition, it is important that aspects associated with the behavior of children at home, the development of their language, their performance in school, and their socialization be surveyed during care, because if the children are not awakened by noises in the environment, do not react to them while sleeping, do not respond when being asked or only do so when they are looking at the person asking them, speak little or do not speak at all, there is suspicion of hearing loss (HL)<sup>(17)</sup>.

In contrast, when questioned about the risk indicators for HL, the professionals' responses were incipient. The most precise information on the indicators described in the Joint Committee on Infant Hearing (JCIH)<sup>(8,18)</sup> were given by a medical student intern (SI) and a community health agent (CHA) who has a deaf daughter. It is pertinent to discuss the training of these professionals regarding child developmental milestones, including the auditory ones, considering that they assist the health needs of children on a daily basis.

The Brazilian Ministry of Health promotes training in the Comprehensive Care for Childhood Illnesses (AIDPI) directed mainly to professionals assisting children in primary health care (PHC) services. With regard to hearing health care, one of the aspects addressed is how to assess and classify hearing disorders; however, this activity does not contemplate the universe of hearing loss entirely<sup>(19)</sup>. The approach is focused on ear problems owing to infections, not considering, for instance, aspects of behavioral alteration and speech and language development, which would facilitate the identification of changes in growth and development.

The risk indicators for HL that professionals should be aware of are as follows: parents' concern with child development in terms of hearing, speech, or language; family history of HL in childhood or consanguinity; ototoxic medications; congenital infections such as rubella, syphilis, cytomegalovirus, Human Immunodeficiency Virus (HIV), herpes, or toxoplasmosis; head trauma; various syndromes<sup>(8,18)</sup>, among others.

Nurses should be aware of the aspects of healthy development and their variations, identifying children with a need for specialized treatment<sup>(20)</sup>. However, this knowledge should not be restricted to nurses, considering that it is the joint work of the team that will facilitate the identification, monitoring, and approach of the various developmental changes<sup>(21)</sup>.

It can be noticed that some family health teams are more attentive to other aspects, such as the use of headphones, listening to loud sounds, and improper ear hygiene habits. This information can be justified by the current campaigns focused on these aspects.

It is the role of physicians and nurses, when identifying children with suspicion of HL, to refer them to another level of complexity for diagnosis and intervention and seek articulation with other specialized services to provide better care for the children and their families<sup>(8)</sup>. In this study, it was possible to observe that some professionals diverged with respect to referrals and presented doubts about their accomplishment, which may delay the adoption of intervention measures. It is recommended that identification of HL occur within the first three months of life, so that intervention measures can be adopted before six months of age<sup>(8)</sup>. Nevertheless, some studies<sup>(22-23)</sup> have described that the time between the suspicion of auditory alteration and its confirmation can reach 48 months.

Furthermore, when referring children to other levels of complexity, the basic health units do not receive formal counter-reference from the other specialties<sup>(24)</sup>, which precludes adequate monitoring of the children, because by knowing the planning and the treatment that is being used, the FHS could provide comprehensive care. This communication gap is only alleviated with the information transmitted by the family to the professionals of the unit.

As previously commented by a CHA, the FHS is often not sought by the parents because they feel that the basic health unit is not likely to resolve the problem. This can be justified by the fact that the resolution is related to the user's perception about the solution of their health problem by specialized care<sup>(25)</sup>. As there are difficulties in conducting the referrals and delay in scheduling the consultations - which compromise the integrality of the assistance, the PHC can be seen as having little resolution power.

However, this level of resolution can reach 80% when health problems are adequately addressed<sup>(26)</sup>. This fact extrapolates the narrow idea of effectiveness based on the cure of diseases, but it also considers effectiveness with respect to relief of symptoms and minimization of suffering, as well as the promotion and maintenance of health<sup>(25)</sup>.

Concerning the Neonatal Auditory Screening (NAS), the teams are knowledgeable about the test as a way to detect possible auditory changes, but they claim lack of access to it. In Brazil, the performance of the ear test achieved significant growth between 2008 and 2012. The northeast region of the country presented the highest growth rate with 189.70%, followed by the north (63.36%), southeast (46.43%), midwest (11.92%), and south (1.52%) regions. Despite the great advances in coverage, the northeast region cannot meet the needs of the existing demand<sup>(27)</sup>. In the state of Pernambuco, there are four auditory health services accredited by SUS: two of medium complexity<sup>(28)</sup> and two of high complexity<sup>(29)</sup>.

As predicted by the Brazilian Ministry of Health<sup>(30)</sup>, this scenario is likely to change. It is estimated that, at the beginning

of 2017, maternity wards be equipped with established care flows and 100% coverage for the ear test, which currently presents coverage of 33% in Brazil.

Regarding guidance to parents, only one team elucidated the importance to support and orient parents at the first moment, whereas the other teams reported providing guidance related to the habit of listening to very loud sounds and ear hygiene, which can be justified by the demand of that population.

It is worth emphasizing that parents should be properly guided by the health unit professionals with respect to language development - as previously reported by one of the CHAs, the procedures that will be performed, and the therapeutic prognosis. The specific scientific literature shows that good guidance allows greater care and support to the parents<sup>(23)</sup>, making them more reassured and co-responsible for the health of their children<sup>(14)</sup>.

The professionals have experience times of over 10 years in the FHU and of almost 10 years in the FHS. This information indicates a certain stability of the health team at this level of complexity, which may favor teamwork improvement. In contrast, practice time may represent a distance from graduation training and, often, absence of continuing education.

A limitation to the present study is the absence of a non-probabilistic sample, which includes three FHUs of a health district, narrowing the inferences with interpretations in the context of the teams. Further studies with larger samples in other regions of the country need to be conducted to confirm the findings herein presented.

The outcomes of the present study can subsidize the directing of actions developed by family health teams in relation to child hearing loss.

#### **CONCLUSION**

Despite their potential in assisting child health, the role of family health teams is still permeated by weaknesses that hinder their performance with respect to hearing health.

Family health teams evaluate the auditory acuity of children, but they are mostly unaware of risk indicators for hearing loss and present doubts about conducting referrals. In addition, the lack of counter-reference by other professionals precludes the effective monitoring of children in the family health units.

Permanent health education actions are required for all the professionals involved, as well as an effective health care network, to ensure the provision of services and attend to the various actions required by the team.

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#### **Author contributions**

JFPS was responsible for the collection, classification, and analysis of data and writing of the manuscript; FOSS collaborated in the collection of data and revision of the manuscript; MLLTL and CFT collaborated in the literature review, analysis and interpretation of data, and revision of the manuscript; SMSG was the study adviser, responsible for its design and execution.