Revista CEFAC

eISSN 1982-0216

DOI: 10.1590/1982-0216/20242619223 | Rev. CEFAC. 2024;26(1):e9223

Review articles

Analysis of age criteria for provision of the personal frequency-modulated system: An integrative review

Vanessa Boldarini de Godoy[1]
Isabela Spin Rondina[1]
Paulo Roberto Regini[2]
Thyago Cezar[3]
Lilian Cassia Bórnia Jacob-Corteletti[1]
Kátia de Freitas Alvarenga[1]

[1] Universidade de São Paulo, Faculdade de Odontologia de Bauru - FOB/USP, Departamento de Fonoaudiologia, Programa de Pós-Graduação em Fonoaudiologia, Bauru, São Paulo, Brasil.

[2] Centro Universitário Teresa D'Avila - UNIFATEA, Programa de Pós-Graduação em Design, Lorena, São Paulo, Brasil.

[3] Hospital de Anomalias Craniofaciais - HRAC-USP, Programa de Pós Graduação em Ciências da Reabilitação do Hospital de Reabilitação de Anomalias Craniofaciais, Bauru, São Paulo, Brasil.

ABSTRACT

Purpose: to critically analyze whether the legislation regarding the Personal Frequency-Modulated (FM) System device encompasses most of the students with hearing impairment to facilitate the development of skills required for communication, literacy, and learning.

Methods: a legislative analysis of the norms regarding the use of the Personal Frequency-Modulated (FM) System device. Relevant legislations were searched on public databases such as the Planalto and the Ministry of Health portals. Brazilian laws, ordinances, and relevant guidelines were consulted as well.

Literature Review: Ordinance n. 1,274 of June 25, 2013, the CONITEC Report on FM in 2020 and GM/MS Ordinance No. 2,465, of September 27, 2021, which regulate the Personal Modulated Frequency System device, were identified.

Conclusion: the initial ordinance of 2013, which regulated the Personal Frequency-Modulated (FM) System, was revised and updated, because it did not include children under six years of age, who are in the peak phase of oral language learning.

Keywords: Jurisprudence; Hearing Loss; Health Planning Guidelines; Enacted Statutes; Public Policy

A study conductet at the University of São Paulo, Faculty of Dentistry of Bauru - FOB/USP, Department of Speech Therapy, Postgraduate Program in Speech Therapy, Bauru, São Paulo, Brazil.

Financial support: National Council for Scientific and Technological Development Process no. 88887.802630/2023-00.

Conflict of interests: Nonexistent.

Corresponding author:
Vanessa Boldarini de Godoy
Faculdade de Odontologia de Bauru, Universidade de São Paulo
Alameda Dr. Octávio Pinheiro Brisolla, 9-75
CEP: 17011-220 - Bauru, São Paulo, Brasil
E-mail: van_godoy_@hotmail.com

Received on: May 12, 2023
Accepted on: October 2, 2023

INTRODUCTION

The World Health Organization (WHO) currently uses two reference classifications to describe health: the International Statistical Classification of Diseases and Related Health Problems, which is in its tenth revision (ICD-10), and the International Classification of Functioning, Disability, and Health (ICF)[1].

Regarding disability, the lack of an explicit, objective definition has hindered, prevented, and even caused controversy regarding the potential health promotion for individuals with disability[2]. However, the International Convention on the Rights of Persons with Disabilities and its Optional Protocol—signed in New York and converted into a Constitutional Amendment by Decree 6,949 of August 25, 2009—states that disability is an evolving concept. It results from the interaction between people with disabilities and societal barriers that impede their full and equal participation in society[3].

The WHO[4] states that, "disability is complex, dynamic, multidimensional, and questioned" (p. 4). In this context, among various disabilities, hearing impairment affects a significant number of Brazilian citizens. According to the 2010 demographic census by the Brazilian Institute of Geography and Statistics (IBGE), there were 5,750,809 people with some degree of hearing impairment in the country[5].

According to the official Brazilian Census[5] data, in 2000, there were 2,161,333 people aged 0–14 with at least one type of disability. Of these, 1,602,660 attended daycare centers or schools, implying they were in early childhood (ages 0–5) and compulsory primary education (ages 6–14)[6].

According to the annual School Census conducted by the National Institute of Educational Studies and Research Anísio Teixeira (INEP), there were 66,334 enrollments of students with some degree of hearing impairment in early childhood and elementary education in 2005 alone[7].

Hearing impairment primarily involves difficulty in perceiving speech sounds. The constant variation in frequency and intensity during communication compromises their intelligibility and makes it challenging to predict the performance of affected individuals based solely on their tonal thresholds. The degree of hearing loss is typically quantified by the quadritonal arithmetic mean of the frequencies of 0.5, 1, 2, and 4 kHz of each ear's tonal threshold. When compared to the reference hearing level, this allows for classification, which varies based on the author referenced in hearing pathology studies[8].

Hearing impairment hinders children's language development by causing difficulties in speech discrimination and perception, limiting communication, and potentially compromising development if early interventions are not implemented[9]. As demonstrated in a study of 110 children using Individual Sound Amplification Devices (referred here simply as hearing aids) with late intervention, experiencing a longer period of auditory deprivation and reduced auditory processing, most had alterations in vocabulary, phonology, and inferior school performance[10]. Oral children with hearing impairment undergoing speech therapy have similar results to those without hearing impairments[11]. Furthermore, auditory processing is a fundamental element required for language acquisition to begin its productions[12]. The WHO (2020) classifies hearing loss from mild to profound[13].

The education of individuals with hearing impairment is significant because potential cognitive difficulties related to attention, reasoning, and memory are associated with language development. Thus, this impairment does not inherently cause any cognitive deficit. If there are no associated cognitive deficiencies, people with hearing impairment tend to perform well at school, provided specific language difficulties are addressed. In case cognition, and, consequently, academic performance of individuals with hearing impairment depend on language qualification and rehabilitation processes, then development of programs to address this issue should be prioritized[14,15].

Preschool-aged children with hearing loss may lack consistent access to necessary high-quality linguistic input, which is fundamental for language development[16]. Expression capacity is determined by intrinsic factors such as genetics and brain maturation, and extrinsic ones, corresponding to the quality of environmental stimuli. The Personal Frequency-Modulated (FM) System is a crucial tool for perceiving stimuli in the academic environment[17].

In this context, the Unified Health System implements public collective health policies based on the fundamental principles of universalization and equity for all citizens. Universalization implies everyone's right to service, ensuring equal access. The aim of equity is to reduce inequalities by treating the unequal differently according to their disparities[18]. This implies creating and targeting initiatives or programs to mitigate the impact of specific inequality.

Given the significant portion of the population involved, the State must implement its established

public policies, requiring public authorities to ensure everyone's right to health, education, equality, thus guaranteeing full social inclusion[19]. Additionally, public policies have to align with these assumptions guiding full access and equity in the education system[19].

The Personal Frequency-Modulated (FM) System is a crucial tool for aiding the learning of individuals with hearing impairments. It eliminates school environment noise using a lapel microphone and an ear-adapted receiver. This significant advancement promotes school inclusion by maintaining attention on the teacher, thus facilitating knowledge acquisition.

This research problematizes the age range of schoolchildren entitled to use the Personal Frequency-Modulated (FM) device. The aim of this study is to critically analyze if the legislation for the Personal Frequency-Modulated (FM) device includes the suitable age group of students with hearing impairment, to promote the development of necessary communication, literacy, and learning skills for these children.

METHODS

This study examines the current national legislation on FM use and its age-related scope. The integrative review comprised five steps: first, determining the guiding research question; second, establishing the inclusion and exclusion criteria for regulations according to the proposed theme; third, defining the information to be extracted from the selected texts; fourth, evaluating the included legislation; and fifth, knowledge synthesis.

The guiding question was: What is the age-range criteria in the legislation for studying the use of the Personal Frequency Modulation (FM) System? Relevant legislation was searched on public databases such as the Planalto portal (http://www.planalto.gov.br/) and the Ministry of Health portal (http://bvsms.saude.gov.br). The used keyword was: Sistema de Frequência Modulada Pessoal (FM) [Personal Frequency-Modulated (FM) System]. Therefore, relevant Brazilian laws, ordinances, and guidelines were consulted and selected for the study.

During selection, the standards' review was read, followed by a thorough reading of the material. Standards that did not include the use of the Personal Frequency-Modulated (FM) System and its age scope were chosen as exclusion criteria.

LITERATURE REVIEW

Regulations identified: Ordinance No. 1.274 of June 25, 2013[20] and GM/MS Ordinance No. 2.465 of September 27, 2021[21] regulate the Personal Frequency-Modulated (FM) System device as described in Chart 1.

Chart 1. Presentation of the Modulated Frequency System ordinances and their characteristics

Normative Number	Year of Publication	Subject	Review	Criteria for nomination
Ordinance No. 1.274[20]	2013	Personal Frequency Modulation (FM) System	Includes the Personal Frequency Modulation System (FM) Procedure in the Table of Procedures, Medications, Orthoses, Prostheses and Special Materials (OPM) of the Unified Health System.	1. Have hearing impairment and be a user of an Individual Sound Amplification Device (AASI) and/or Cochlear Implant (CI); 2. Have command of oral language or in the development phase; 3. Be enrolled in Elementary School I or II and/or High School; 4. Present performance in the assessment of speech recognition skills in silence.
GM/MS Ordinance No. 2.465[21]	2021	Amends Ordinance No. 1,274/GM/MS, of June 25, 2013 - Personal Modulated Frequency System (FM)	Amends Annexes I and II of Ordinance No. 1,274/GM/MS, of June 25, 2013, which includes the Personal Frequency Modulation System (FM) Procedure in the Table of Procedures, Medications, Orthoses, Prostheses and Special Materials (OPM) of the Unified Health System.	Be enrolled in any academic level.

Source: Prepared by the author

Individuals with hearing impairment (HI) can benefit from hearing aids and cochlear implants (CI). They facilitate communication, are essential for oral language development, and improve the signal-to-noise ratio (S/N). However, they have limitations, especially when the sound source is distant[22].

Noise is a recurring issue for individuals with hearing impairment, hindering their communication and potentially causing physical, emotional, and educational challenges. This problem is particularly prevalent in schools with poorly designed acoustics, leading to learning difficulties. Although the Brazilian Standard (NBR) 10.152 stipulates classroom noise can range from 35 to 45 dB, actual conditions are often inadequate, compromising the quality of environmental stimuli.

Individuals with hearing impairment can benefit from the Personal Frequency-Modulated (FM) System at school. It complements the hearing aid/CI, improving speech perception in noise from distant sources. This revolutionary educational tool ensures academic performance is not compromised. Available in personal, table, and free field versions, with fixed or adaptive signal processing[23], the System primarily aims to enhance the sound connection between transmitter and receiver, highlighting the teacher's voice over undesirable sounds[24].

This system was incorporated into the Unified Health System's Table of Medicines, Orthoses, Prostheses and Special Materials (OPM) via Ordinance No. 1,274 on 25 June 2013[20], enabling its recommendation after a thorough assessment of individuals with hearing impairment by qualified professionals. The ordinance establishes the system's implementation from the Strategic Actions and Compensation Fund, incorporated into the Medium and High Complexity ceiling of the Federal District, States, and Municipalities. The Health Care Secretariat of the Ministry of Health, through the General Coordination of Information Systems of the Department of Regulation, Evaluation, and Control Systems (CGSI/DRAC/SAS), is responsible for adopting the necessary measures to adapt the management system. The ordinance also mandates that the Ministry of Health will fund the Viver Sem Limite ("Living Without Limits") Work Program [20]. This ordinance includes two annexes detailing the criteria for the Personal Frequency-Modulated (FM) System indication.

Criterion 1 specifies that only hearing-impaired individuals using hearing aids or CIs will be granted devices. Further below, when referring to the type of adaptation, it is mentioned that in the absence of an audio input feature in the hearing aid and/or CI, one should consider using magnetic induction (telecoil) "or any other wireless accessory of the hearing aid that allows for the connection to the FM system. The FM receiver can be worn as a neckloop"[20].

Criterion 2 refers to the mastery of oral language in hearing children or those who receive devices soon after early detection, up to six months of age[25]. Development typically occurs around five–six years of age, as is based on knowledge construction that begins in the early years of life with the maturation of the central nervous system, marking a phase of excellent neuronal plasticity. Both plasticity and maturation depend on stimulation[26].

According to Criterion 3, the child must be enrolled in elementary, middle, or high school. Currently, children can be enrolled in basic education (preschool) starting at age four, but for elementary school only at age six, according to a decision by the Supreme Court in the Declaratory Action of Constitutionality (Ação Declaratória de Constitucionalidade—ADC)[17]. Thus, a five-year-old child is in the final stage of preschool and oral language acquisition, which prepares them for learning to write[20].

Reading the annexes reveals that Early Childhood Education was not included in Ordinance No. 1.274 on June 25, 2013, as per the Education Guidelines and Bases Law (LDB); preschool must be provided to children aged four and five (Art. 30, II); and the pre-literacy child does not have access to the Personal Frequency-Modulated (FM) System under this Ordinance[27].

The peak phase of oral language acquisition and development occurs until five–six years of age. During this phase, "children learn to decode letters into sounds for reading, and encode sounds into letters for writing" (p.158), which is essential for the creation of meaning in texts. Therefore, the child's written language "is part of the overall language development process and occurs as a continuous cognitive elaboration, given the significance that writing assumes in the child's social integration and interaction"[28].

According to the National Pact for Literacy at the Right Age—PNAIC, established by the MEC Ordinance No. 826 on July 7, 2017, children are exposed to written culture, stories, initial writings, picture-filled books, and foundational learning for literacy early childhood[29]. Article 9 of the National Curricular Guidelines for Early

Childhood Education[21] states that the Early Childhood Education curriculum is based on various experiences, including:

> [...] II – promote children's immersion in various languages and their gradual mastery of different genres and forms of expression: gestural, verbal, plastic, dramatic, and musical; 13 III—provide children with experiences of narratives, appreciation and interaction with oral and written language, and exposure to different oral and written textual supports and genres[29].

This regulatory device is based on the Opinion of the National Education Council (CNE/CEB) No. 20/2009[29], which states that:

> Early Childhood Education curricular proposals should ensure children experience various languages, acknowledging that their world, influenced by their culture, is predominantly characterized by images, sounds, speech, and writing. In this process, valuing play, games, and children's cultures is necessary[29].

Considering the official Early Childhood Education regulations, we must analyze the need for preschool children (aged four to six) to use the Personal Frequency-Modulated (FM). Without this tool, the child may be deprived of fundamental communication and cognition skills for their learning[30].

The National Commission for the Incorporation of Technologies in the Unified Health System (Conitec) recognized the significance of providing the Personal Frequency-Modulated (FM) System for preschoolers. Accordingly, it conducted a public consultation in 2019 to examine the issue. Two electronic forms were provided: one for technical–scientific input, and another for patients to share their experiences regarding the Personal Frequency-Modulated (FM) System[31]. Additionally, the Conitec produced a report in 2020 on the proposed expansion and budgetary impact of the Personal Frequency-Modulated (FM) System for hearing-impaired individuals of all ages and academic levels[32]. In 2020, following Conitec's recommendation, the Secretary of Science, Technology, Innovation and Strategic Inputs of the Ministry of Health expanded the use of the Personal Frequency-Modulated (FM) System for hearing-impaired individuals of all ages and academic levels within the Unified Health System (SUS). This provisional measure—not yet included in law—aims to address the legislative gap that excludes preschool students, until Ordinance No. 1,274/2013 is amended.

On September 27, 2021, the GM/MS Ordinance No. 2,465 was enacted by the Ministry of Health, which removed the age criteria for the provision of the Personal Frequency-Modulated (FM) System. The only criterion that was maintained was: "Being enrolled at any academic level"[21].

This ordinance is a milestone in adapting legislation to the population's needs, aligning with studies showing that preschool provides the foundational knowledge for literacy, and is crucial for early childhood. Delay in knowledge acquisition due to hearing loss may pose challenges for the child in learning to read and write in elementary school[27]. Hearing impairment can have biopsychosocial consequences affecting the child's linguistic and cognitive development, learning, communication, and social inclusion[33].

Scientific studies have repeatedly reported the benefits of the Personal Frequency-Modulated (FM) System in schools, leading to its widespread support[34]. According to Barrera[35], children using the FM device for 10 hours daily could potentially access approximately 42% more words per day—this immersion being the foundation of language development.

Fidêncio[36] assessed the signal-to-noise ratio (S/N) in classrooms, identifying that most rooms lacked the necessary S/N for individuals with hearing impairments to understand 50% of the teacher's speech without a device. However, using the FM remote microphone achieved the audibility required for comprehension[36].

Based on Mulla's study[37], "at risk" preschool children using FM technology developed language within or close to normal learning limits. Article 205 of the 1988 Federal Constitution[38] states that education is a right of all citizens and a duty of the State, aiming for the comprehensive development of the individual, their preparation for citizenship, and their work qualification.

> Art. 206. Teaching will be based on the following principles:
>
> I - Equality of conditions for school access and retention;
>
> II - freedom to learn, teach, research, and share thoughts, art, and knowledge[38];

As stipulated in Section I of Article 206 of the Federal Constitution[38], every student is guaranteed equal conditions and freedom to learn. This includes providing those with hearing impairments, who may be at a disadvantage, with tools to ensure equal teaching and

learning conditions, in line with equity[39]-a fundamental SUS principle.

According to Article 4 of the Child and Adolescent Statute[39], children and adolescents must be comprehensively protected, prioritizing the realization of their rights to life, health, and education. Furthermore, Article 53 of the same regulation states that children and adolescents have the right to education, which aims for their comprehensive development, preparation for citizenship, and work qualification by ensuring equal conditions for school access and retention[39].

CONCLUSION

Evidently, Ordinance No. 1,274 of June 25, 2013[20] did not encompass preschool-age children in the active stage of oral language learning and pre-literacy. The 2020 Conitec report[31] advocated legislative changes, leading to the promulgation of Ordinance GM/MS No. 2,465 on September 27, 2021[21]. This altered the Personal Frequency-Modulated (FM) System's provision, removing the minimum age requirement. It now applies to all students with hearing impairment enrolled at any academic level, using hearing aids and/or bilateral CI, which can be adapted with the bilateral Personal Frequency-Modulated (FM) System.

REFERENCES

1. Organização Mundial da Saúde. CIF: Classificação Internacional De Funcionalidade, Incapacidade e Saúde. São Paulo: Edusp; 2003.
2. Nubila HBV, Buchalla CM. O papel das Classificações da OMS - CID e CIF nas definições de deficiência e incapacidade. Rev Bras Epidemiol. 2008;11(2):324-35. https://doi.org/10.1590/s1415-790x2008000200014
3. Brasil [homepage on the internet]. Decreto Nº 6.949, de 25 de agosto de 2009. Promulga a Convenção Internacional sobre os Direitos das Pessoas com Deficiência e seu Protocolo Facultativo, assinados em Nova York, em 30 de março de 2007 [accessed 2023 jul 04]. Available at: http://www.planalto.gov.br/ccivil_03/_ato2007-2010/2009/decreto/d6949.htm
4. WHO. Relatório mundial sobre a deficiência / World Health Organization, The World Bank; tradução Lexicus Serviços Linguísticos. - São Paulo: SEDPcD, 2012.
5. Brasil [homepage on the internet]. Censo demográfico 2010: características gerais da população, religião e pessoas com deficiência. Rio de Janeiro: IBGE; 2010 [accessed 2023 jul 04]. Available at: https://www.ibge.gov.br/estatisticas/multidominio/cultura-recreacao-e-esporte/9662-censo-demografico-2010.html?=&t=destaques
6. Campos RD da S, Zazzetta MS, Orlandi F de S, Pavarini SCI, Cominetti MR, Santos-Orlandi AA et al. Handicap auditivo e fragilidade em idosos da comunidade. CoDAS. 2022;34(4):e20210080. https://doi.org/10.1590/2317-1782/20212021080 PMID: 35416836.
7. Instituto Nacional de Estudos e Pesquisas Educacionais INEP [homepage on the internet]. Available at: http://www.inep.gov.br [accessed 2023 jun 08].
8. Russo ICP, Pereira LD, Carvallo RMM, Anastásio ART. Encaminhamentos sobre a classificação do grau de perda auditiva em nossa realidade. Rev. soc. bras. fonoaudiol. 2009;14(2):287-88. https://doi.org/10.1590/S1516-80342009000200023
9. Oliveira PS, Penna LM, Lemos SMA. Language development and hearing impairment: literature review. Rev. CEFAC. 2015;17(6):2044-55. https://doi.org/10.1590/1982-0216201517611214
10. Penna LM, Lemos SMA, Alves CRL. Auditory and language skills of children using hearing aids. Braz j otorhinolaryngol. 2015;81(2):148-57. https://doi.org/10.1016/j.bjorl.2014.05.034
11. Amemiya ÉE, Goulart BNG, Chiari BM. Use of nouns and verbs in the oral narrative of individuals with hearing impairment and normal hearing between 5 and 11 years of age. Sao Paulo Med J. 2013;131(5):289-95. https://doi.org/10.1590/1516-3180.2013.1315384
12. Quintas T d' Á, Curti LM, Goulart BNG de, Chiari BM. Characterization of the symbolic game in hearing impaired people: case and control studies. Pró-Fono R. Atual. Cient. 2009;21(4):303-8. https://doi.org/10.1590/S0104-56872009000400007 PMID: 20098948.
13. Guia de Orientação na Avaliação Audiológica Volume I. Audiometria tonal liminar, logoaudiometria e medidas de imitância acústica [document on the internet]. Available at: https://www.fonoaudiologia.org.br/wp-content/uploads/2020/09/CFFa_Manual_Audiologia-1.pdf Accessed 2023 may 07.
14. Bueno JGS. A educação do deficiente auditivo no Brasil - situação atual e perspectivas. Em Aberto. Brasília, 1993.
15. Mazzotta MJS. Fundamentos de educação especial. São Paulo: Pioneira, 1982.
16. Quittner AL, Curz I, Barker DH, Tobey E, Eiseberg LS, Niparko JK. Childhood development after Cochlear Implantation Investigative Team. 2013. Effects of maternal sensitivity and cognitive and linguistic stimulation on cochlear implant users' language development over four years. J Pediatr. 2013;162(2):343-8.e3. https://doi.org/10.1016/j.jpeds.2012.08.003
17. Lamônica DAC, Silva-Mori MJF da, Ribeiro C da C, Maximino LP. Receptive and expressive language performance in children with and without Cleft Lip and Palate. Codas. 2016;28(4):369-72. https://doi.org/10.1590/2317-1782/20162015198 PMID: 27556828.
18. Ministério da Saúde [homepage on the internet]. Disppios-do-sus [accessed 2023 may 10]. Available at: http://portalms.saude.gov.br/sistema-unico-de-saude/principios-do-sus
19. Ministério da Educação [homepage on the internet]. Direito à Educação. Subsídios para a Gestão dos Sistemas Educacionais 2006 [accessed 2023 may 15]. Dispducacao.pdf Available at: http://portal.mec.gov.br/seesp/arquivos/pdf/direitoaeducacao.pdf
20. Brasil. Inclui o Procedimento de Sistema de Frequência Modulada Pessoal (FM) na Tabela de Procedimentos, Medicamentos, Órteses, Próteses e Materiais Especiais (OPM) do Sistema Único de Saúde. - Portaria Nº 1.274–Brasil - DF, 2013.
21. Brasil. Altera os Anexos I e II da Portaria nº 1.274/GM/MS, de 25 de junho de 2013 – Portaria 2.465, de 27 de setembro de 2021.
22. Rosa BC, Souza CO, Paccola ECM, Bucuvic ÉC, Jacob RTS. Phrases in Noise Test (PINT) Brazil: influence of the interstimulus interval on the performance of children with hearing loss. Codas. 2021;33(6):e20200054. https://doi.org/10.1590/2317-1782/20202020054 PMID: 34431856.

23. Bertachini ALL, Pupo AC, Morettin M, Martinez MAN, Bevilacqua MC, Moret ALM et al. Frequency Modulation System and speech perception in the classroom: a systematic literature review. CoDAS. 2015;27(3):292-300. https://doi.org/10.1590/2317-1782/20152014103 PMID: 26222948.

24. Balen S, Soares Brazorotto J. Uso do sistema de FM no ambiente escolar [homepage on the internet]. Available at: https://audiologiabrasil.org.br/portal2018/pdf/aba-ebook-sistema_fm_amb_escolar.pdf Accessed 2023 may 08

25. Ministério da Saúde Brasília - DF 2016 [homepage on the internet]. Dispcomotor.pdf. [accessed 2023 jun 17]. Available at: https://bvsms.saude.gov.br/bvs/publicacoes/diretrizes_estimulacao_criancas_0a3anos_neuropsicomotor.pdf

26. Braga LW, Da Paz AC, Ylvisaker M. Direct clinician-delivered versus indirect family-supported rehabilitation of children with traumatic brain injury: a randomized controlled trial. Brain Inj. 2005;19(10):819-31. https://doi.org/10.1080/02699050500110165 PMID: 16175842.

27. Brasil [homepage on the internet]. Lei de Diretrizes e Bases da Educação Lei Nº 9.394, de 20 de Dezembro de 1996. Diário Oficial da União [accessed 2023 jun 23]. Disps/l9394.htm. Available at: http://www.planalto.gov.br/ccivil_03/leis/l9394.htm

28. Goulart CM. A apropriação da linguagem escrita e o trabalho alfabetizador na escola. Cad Pesqui. 2000;(110):157-75.

29. Brasil. Portaria MEC n° 826, de 07 de julho de 2017. Pacto Nacional pela Alfabetização na Idade Certa, Diário Oficial da União. Brasília, DF, jul 2017. Displterada.pdf

30. Brasil [homepage on the internet]. Parecer CNE/CEB n. 20/2009. Regulamentação das Diretrizes Curriculares Nacionais para a Educação Infantil. Diário Oficial da União. Brasília, DF, fev 2009 União [accessed 2023 may 28]. Available at: https://normativasconselhos.mec.gov.br/normativa/view/CNE_PAR_CNECEBN202009.pdf?query=INFANTIL

31. Brasil. Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde - CONITEC, 2019. Sistema de Frequência Modulada Pessoal é tema de Consulta Pública. Displta-publica.

32. Brasil [homepage on the internet]. Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde - CONITEC, 2020. Dispo0_final.pdf. União [accessed 2023 jul 4]. Available at: https://www.gov.br/conitec/pt-br/midias/relatorios/2020/relatorio_sistemafm_estudantes_506_2020_final.pdf

33. Speri MRB. The child with hearing impairment: from suspicion to the speech therapy rehabilitation process. Verba Volant. 2013;4(1):40-64. Available at: https://wp.ufpel.edu.br/laboratorioelo/files/2014/05/speri.pdf

34. Anderson KL, Goldstein H. Speech perception benefits of FM and infrared devices to children with hearing aids in a typical classroom. Language, Speech, and Hearing Services in Schools. 2004;35(2):169-84.

35. Carlos R, Benítez B, Gina PA, Anne MT. Remote microphone system use at home: impact on caregiver talk. JSLHR. 2018;61(2):399-409. https://doi.org/10.1044/2017_JSLHR-H-17-0168 PMID: 29330553

36. Fidêncio VLD. Avaliação digital do efeito do ruído sobre a fala: relação sinal/ruído [dissertation]. Bauru (SP): Universidade de São Paulo, Faculdade de Odontologia de Bauru; 2013.

37. Mulla I, McCracken W. The use of FM technology for pre-school children with hearing loss. A sound foundation through early amplification. 2014;8(2):71-6.

38. Brasil. Constituição 1988. Constituição da República Federativa do Brasil. Diário Oficial da União. Brasília (DF): Senado; 1988.

39. Brasil. Estatuto da Criança e do Adolescente - Lei nº 8.069, de 13 de julho de 1990. Diário Oficial da União. Brasília (DF): Senado; 1990.

Authors' contributions:

VBG: conceptualization, project administration, analysis, original draft writing, writing, review and editing;

ISR: investigation, analysis, validation, writing of the original draft;

PRR: conceptualization, formal analysis, visualization, writing of the original draft;

TC: formal analysis, validation, original draft writing, writing, review and editing;

LCBJC: methodology, supervision, writing of the original draft;

KFA: visualization, supervision, writing of the original draft.

ANNEX I

Ordinance no. 1,274 of June 25, 2013 - Annex I

Procedure:	SISTEMA DE FREQUÊNCIA MODULADA PESSOAL
07.01.03.032-1	PERSONAL FREQUENCY MODULATED SYSTEM
Description:	Device for people with loss of hearing quality who use an Individual Sound Amplification Device (AASI) or Cochlear Implant (CI). Composed of transmitter with microphone to capture the signal via Frequency Modulation (FM) and receiver with adaptation for audio input from hearing aids or IC. The prescription must be carried out by a qualified healthcare professional.
Complexity:	Medium Complexity
Modality:	01 - Outpatient
Registration Instrument:	06 - APAC (Main Process)
Type of Financing:	04 - Strategic Actions and Compensation Fund (FAEC)
Financing Subtype:	0009 - Assistance/monitoring in physical, mental, visual, auditory rehabilitation and multiple disabilities
SA Outpatient Value:	R$ 4,500.00
Total Outpatient Value:	R$ 4,500.00
Complementary Attribute:	09 - Requires CNS
Sex:	Both
Minimum age:	5 years
Maximum Age:	17 years
Maximum Quantity:	1
CBO:	223810, 225275
CID:	H83. 3, H90.0, H90.1, H90.2, H90.3, H90.4, H90.5, H90.6, H90.7, H90.8, H91.0. H91. 1, H91.2, H91.3, H91.8, H91.9, H93.2
Service/Classification:	164 - Service of Orthoses, Prostheses and Special Materials in Rehabilitation:005 - Dispensing of Hearing OPM006 - Maintenance and Adaptation of Hearing OPM

ANNEX II

Ordinance no. 1,274 of June 25, 2013 - Annex II

STANDARDS FOR PRESCRIPTION OF PERSONAL MODULATED FREQUENCY (FM) SYSTEM

The dispensation of the Personal Modulated Frequency System (FM) must be indicated after complete evaluation by trained professionals who are covered by the codes established by the Brazilian Classification of Occupations defined in this Ordinance. These prescriptions must follow criteria and standards that determine their safe indication.

The Municipal, State and/or Federal District manager must require documentation that proves the indication and skills necessary to use the device, which must be clearly exposed in the justification of the clinical report/report containing patient data and multidisciplinary assessment with diagnosis and history of the evolution of the dysfunction.

Prescription of the FM System Kit to children and/or young people with hearing impairment must follow the following criteria:

1. Have hearing impairment and be a user of an Individual Sound Amplification Device (AASI) and/or Cochlear Implant (CI);

2. Have command of oral language or in the development phase;

3. Be enrolled in Elementary School I or II and/or High School; and

4. Present performance in the assessment of speech recognition skills in silence. It is suggested, when possible, IPRF (Speech Recognition Percentage Index) better than 30%, in silent situations. In the case of children in the oral language development phase, when it is not possible to perform the IPRF, or the use of tests with words due to their age, a Voice detection threshold (LDV) equal to or lower than 40 (with hearing aids or CI).

Adaptation Type:

1. Every elementary or high school student with hearing impairment, user of hearing aids and/or bilateral CI, can be fitted with the bilateral FM System (one receiver for each hearing aid and/or CI);

2. The adaptation must preferably occur through the audio input feature of the hearing aid and/or IC;

3. In the absence of an audio input feature on the hearing aid and/or IC, adaptation via a magnetic induction feature (telephone coil) or any other type of wireless accessory on the hearing aid that allows connection to the FM System must be considered;

4. The receiver must be adapted to ear level, with the exception of the cases already mentioned in Item 3, where the receiver is used as a neck collar; and

5. The lapel microphone should preferably be indicated, thus enabling the FM System to be used by different teachers and in different school environments.

Main clinical indication for the use of the Personal Frequency Modulation (FM) System:

Mild, moderate, severe and profound sensorineural hearing loss for students enrolled in Elementary School I or II and/or High School.

ANNEX III

GM/MS ORDINANCE No. 2,465, OF SEPTEMBER 27, 2021

Amends Annexes I and II of Ordinance No. 1,274/GM/MS, of June 25, 2013, which includes the Personal Frequency Modulation System (FM) Procedure in the Table of Procedures, Medications, Orthoses, Prostheses and Special Materials (OPM) of the Unified Health System.

THE SUBSTITUTE MINISTER OF STATE OF HEALTH, in the use of the powers conferred on him by items I and II of the sole paragraph of art. 87 of the Constitution, and considering Ordinance No. 3,011/GM/MS, of November 10, 2017, which establishes resources to be transferred from the Strategic Actions and Compensation Fund - FAEC to the Annual Financial Ceiling for Ambulatory and Hospital Assistance of Medium and High Complexity-MAC of the States and the Federal District, resolves:

Art. 1 Annexes I and II of Ordinance GM/MS No. 1,274, of June 25, 2013, published in the Official Gazette of the Union (DOU) No. 121, of June 26, 2013, Section 1, page 61, become come into force with the following changes:

ANNEX I

Code/Name Procedure:	Changes
07.01.03.032-1 - PERSONAL MODULATED FREQUENCY SYSTEM	Minimum Age: 0 months Maximum age: 130 years

ANNEX II

STANDARDS FOR PRESCRIPTION OF PERSONAL MODULATED FREQUENCY (FM) SYSTEM

"The prescription of the FM System Kit to people with hearing impairment must follow the following criteria:" (NR).

"3. Be enrolled in any academic level;" (NR).

Adaptation Type:

"1. Every student enrolled at any academic level, with hearing impairment, user of hearing aids and/or bilateral CI, can be fitted with the bilateral FM System (one receiver for each hearing aid and/or CI);" (NR).

Main clinical indication for the use of the Personal Frequency Modulation (FM) System:

"Sensorioneural hearing loss of mild, moderate, severe and profound degrees, as long as the student is enrolled at any academic level." (NR).

Art. 2 The General Coordination of Management of Health Information Systems of the Department of Regulation, Evaluation and Control of the Secretariat of Specialized Health Care of the Ministry of Health (CGSI/DRAC/SAES/MS) is responsible for adopting the necessary measures to adapt the SUS Table of Procedures, Medications and Orthoses, Prostheses and Special Materials Management System (SIGTAP) and the Health Terminology Repository (RTS), with a view to implementing the change defined by this Ordinance.

Art. 3 This Ordinance comes into force on the date of its publication with operational effects from the period following its publication.