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# Clinical protocol for Hearing Health Services for the care of adults and elderly

## *Protocolo clínico para Serviços de Saúde Auditiva na atenção a adultos e idosos*

### Keywords

Hearing Aids  
Clinical Protocols  
Hearing Loss  
Adult  
Elderly  
Correction of Hearing Impairment

### Descritores

Auxiliares de Audição  
Protocolos Clínicos  
Perda Auditiva  
Adulto  
Idoso  
Correção de Deficiência Auditiva

### ABSTRACT

**Purpose:** To develop a clinical protocol for patient care in the selection, verification, and validation process of hearing aids; to verify the viability of the protocol during its use by specialists in the field; to establish the graphical representation of the protocol by means of a flowchart with algorithms. **Methods:** We conducted a literature review to collect the procedures required for developing clinical protocols in healthcare services and the main procedures at each step along the process of fitting hearing aids. Subsequently, we developed the protocol, which was evaluated by eight audiologists in terms of its content and ease of use. We considered the issues raised by the professionals and then drew up a final document, as well as a flowchart with process algorithms. **Results:** A protocol after having conducted an extensive survey of the literature was developed; all audiologists reported that the use of the instrument was of great value in their clinical practice; finally, we created the flowchart with algorithms after having developed the protocol and, by extension, we also created the Standard Operational Procedure for the selection, verification and validation process of hearing aids. **Conclusion:** The clinical protocol for the care of patients in the selection, verification and validation process of hearing aids was developed and validated by means of its use by professionals. The information and data we collected allowed a graphical representation of the protocol and its steps as a flowchart with algorithms.

### RESUMO

**Objetivo:** Desenvolver um protocolo clínico para o atendimento ao paciente no processo de seleção, verificação e validação das próteses auditivas e estabelecer a representação gráfica do protocolo por meio de um fluxograma com algoritmos. **Método:** Foi realizado um estudo bibliográfico para levantamento dos procedimentos necessários na elaboração de protocolos clínicos em saúde e quanto aos principais procedimentos em cada etapa do processo de seleção e adaptação de próteses auditivas. Posteriormente, foi realizada a elaboração por extenso do protocolo, que passou pela avaliação de oito fonoaudiólogos quanto ao conteúdo e aplicabilidade. Houve a adequação dos fatores levantados pelos profissionais e elaboração do documento final, além da constituição de um fluxograma com algoritmos do processo. **Resultados:** O protocolo foi desenvolvido após extenso levantamento de literatura; todos os fonoaudiólogos participantes referiram ser de grande valia a utilização do instrumento em sua prática clínica; e, ao final, houve a constituição do fluxograma com algoritmos, realizada após a elaboração do protocolo por extenso, originando o Procedimento Operacional Padrão no processo de seleção e adaptação de próteses auditivas. **Conclusão:** O protocolo clínico para o atendimento ao paciente no processo de seleção, verificação e validação do uso das próteses auditivas foi desenvolvido e validado por meio de sua aplicação por profissionais, o que gerou, posteriormente, a representação gráfica do protocolo e suas etapas por meio de um fluxograma com algoritmos.

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## INTRODUCTION

Hearing impairment is one of the most prevalent sensory deficits in the population. In Brazil, according to data from the 2010 census, 5.1% of the population, or approximately 9.8 million people, has some degree of hearing impairment<sup>(1)</sup>.

In order to minimize the consequences of hearing impairment, fitting hearing aids is essential to the individual's rehabilitation process, since it allows for the best possible use of one's auditory function, improves speech perception and reduces communication difficulties that can often impede social interactions of the hearing-impaired<sup>(2,3)</sup>.

There is great variability in the process of selection and fitting hearing aids. However, not always some important and critical aspects are observed, even though there is a consensus on the standardization of conduct and main procedures in the guidelines of the scientific societies, such as the American Academy of Audiology (AAA), the American Speech-Language-Hearing Association (ASHA), and the International Society of Audiology (ISA)<sup>(4)</sup>.

Adopting verification and validation protocols for hearing aids increases wearer satisfaction and reduces the need for returns to hearing health centers. These procedures promote practices that ensure successful fitting of these devices<sup>(5-8)</sup>.

The authors emphasize that if the essence behind the nationwide guidelines proposed for the rehabilitation of adult patients by means of hearing aids were understood and implemented by professionals, it would be possible to promote uniformity of care, decrease the variability of outcomes, promote best fitting practices, elevate clinical care to patients, increase patients' satisfaction, and reduce return rates<sup>(9)</sup>.

The use of protocols in healthcare services is very important, since they are instruments used for tackling problems that need to be overcome or organizing a better course of action. They focus on the standardization of clinical practices in outpatient clinics and hospitals, and stress the need for knowing the goals to be achieved to ensure it is properly developed<sup>(10)</sup>.

The use of a standard protocol when providing Hearing Healthcare services is considered important for ensuring better referral and greater objectivity in the conduct of the audiologist who works in those Services, which therefore leads to greater wearer satisfaction and reduces the number of returns and unnecessary appointments, as well as patient dropout rates.

In view of the above, our aims were to develop a clinical protocol for patient care in the selection, verification and validation process of hearing aids and to draw up a graphical representation of the protocol and its steps by means of a flowchart with algorithms.

## METHODS

The study was approved by the Institution's Research Ethics Committee under the number 1,422,499.

Our study resulted in a clinical protocol based on scientific evidence for the standardization of procedures in the selection

and fitting process of hearing aids in adult hearing-impaired patients.

The study was comprised of four main steps, as described below: 1- steps involved in developing the clinical protocol; 2- content of the clinical protocol; 3- validation of the Protocol by Professionals; 4- flowcharting with algorithms.

### Step 1 - Steps involved in developing the Clinical Protocol

Initially, a bibliographic survey was carried out to identify relevant studies that could assist us in defining the guidelines for developing clinical protocols in healthcare services.

We conducted a survey of the MedLine, SciElo, and Lilacs databases by using the descriptors *practice guidelines; guidelines; clinical protocols and public health; clinical protocols and unified health*, which resulted 18 studies, all of which we read and whose contents served as the basis for identifying further references. In addition, we also used online tools provided by Brazil's Ministry of Health and a common search site (Google<sup>®</sup>), which were effective in identifying healthcare service manuals and protocols from universities in Brazil, as well as specific studies from healthcare nursing centers, with the proposed description for developing healthcare Clinical Protocols in healthcare services, the step-by-step definitions and specific references for developing these instruments. We were able to identify many new studies by analyzing these references, both national and international ones.

Based on this literature review, we defined the aspects that should be taken into account when developing the Clinical Protocol – both with respect to the graphic rendering of our findings and the guidelines on the search for scientific evidence for adapting content.

For developing the protocol, we considered the criteria presented in a previous study<sup>(11)</sup>, which comprise the following summarized steps: 1) defining the desirable situation for the protocol; 2) reviewing the literature and searching for evidence; 3) preparing the protocol document; 4) using and discussing the protocol in group; and 5) disclosing the protocol.

After analyzing the criteria, and still based on the literature review we had conducted on developing protocols, we decided to follow the procedures adopted by authors<sup>(10,12)</sup> proposing graphical representations for the development of clinical protocols by means of flowcharts with algorithms. These consist of descriptions of the processes detailed in the flowcharts and use a standard set of symbols.

A procedure checklist was prepared as per a method proposed by authors in the field<sup>(13)</sup>, according to which all professionals granted access to the medical records should be able to have a quick view of the tests run and actions taken.

### Step 2- Content of the Clinical Protocol

After defining which steps would be included in the Clinical Protocol, we conducted a literature survey on the main steps involved in the process of selecting and fitting hearing aids relative to patient evaluation; selection of hearing aid features;

verification of the selected features; evaluation of outcomes; guidance, counseling, and follow-up.

The survey we carried out of the main databases (MedLine, Scielo, Lilacs) was based on international best practices for procedures (which ones and how they are performed), totaling 17 studies. We also sought access to the best practice manuals from the main international and national institutions for analyzing the procedures performed and verify a consensus among them (a total of 6 guides).

Following the literature review, we prepared the clinical protocol in question so that its content and its applicability could be evaluated by professionals in the field, as described below. Subsequently, we rendered it graphically (flowchart with algorithms) so as to facilitate its understanding and handling.

The target population for this protocol is that comprised of adult patients (over 18 years of age) with sensorineural hearing loss (mixed, conductive, unilateral or bilateral impairment), ranging from mild to profound, potential hearing aid wearers as assessed and referred by an otorhinolaryngologist.

The protocol must be handled by a trained audiologist with appropriate training both as an undergraduate, graduate/specialization course student to ensure that aspects of quality in patient care are prioritized.

### Step 3- Validation of the Protocol by Professionals

In order to ensure content validity, clarity, applicability and usage, ten professional audiologists having at least one year of working experience in the field of selecting and fitting hearing aids at several Hearing Health Centers that also provide treatment, as secured by Brazil's publicly funded Health System (the so-called *SUS – Sistema Único de Saúde*), were selected for receiving the protocol content.

All participants signed the Informed Consent Form (ICF) and then received copies of the following documents:

- a) a full printed copy of the Protocol;
- b) a checklist for checking the procedures contained in the protocol that were actually employed;
- c) a copy of the questionnaire evaluating the content and applicability of the protocol, developed by us, with questions on the importance, ease of understanding and application of the procedures selected, possibility of applying those procedures in the work environment, effectiveness of this proposed intervention in the clinical practice, and management of the adult patient who is a hearing aid wearer.

The professionals were briefed on the objectives of the study, use of the protocol, completion of the checklist and questionnaire in person. All of them were also instructed to feel free to fill out the protocol with notes as they used it, so as to more easily indicate any required changes as well as their opinion on what was being proposed.

All copies of the documents delivered to the participants were then handed back to the researchers – the protocol, in

order that the notes could be considered; the checklist, to assess whether it had been effectively checked; and, finally, the answered questionnaire containing the critiques, suggestions and evaluation remarks made by audiologists were taken into account when they might indicate that any adjustments and possible changes to steps described in the protocol and/or to the flowchart with algorithms were needed.

The protocol provides for full patient care and can be used in six sessions, each of which being 45 minutes long and divided according to each step described in the protocol.

### Step 4- Flowcharting with Algorithms

The professionals evaluated the content of the protocol and, after their final suggestions, the flowchart was prepared (upon a final version of the protocol had been drawn up) as described<sup>(12)</sup>, so as to ensure quick understanding and objective instructions, leaving no room for different interpretations.

The graphical rendering by means of the flowchart with algorithms was prepared by using a standard set of symbols<sup>(12)</sup>.

## RESULTS

The protocol was developed after we surveyed the literature and encompassed aspects related to its preparation and steps involved therein, the relevant procedures required in the process of selecting and fitting hearing aids, as well as the most frequently used questionnaires cited in the literature as being pertinent to each step.

After the evaluation conducted by the professionals was completed, the protocol had the following steps: assessment of the potential hearing aid wearer, survey of the hearing aids selected and their features, verification of the hearing aids, guidance and counseling to the patient, evaluation of the outcomes (Validation).

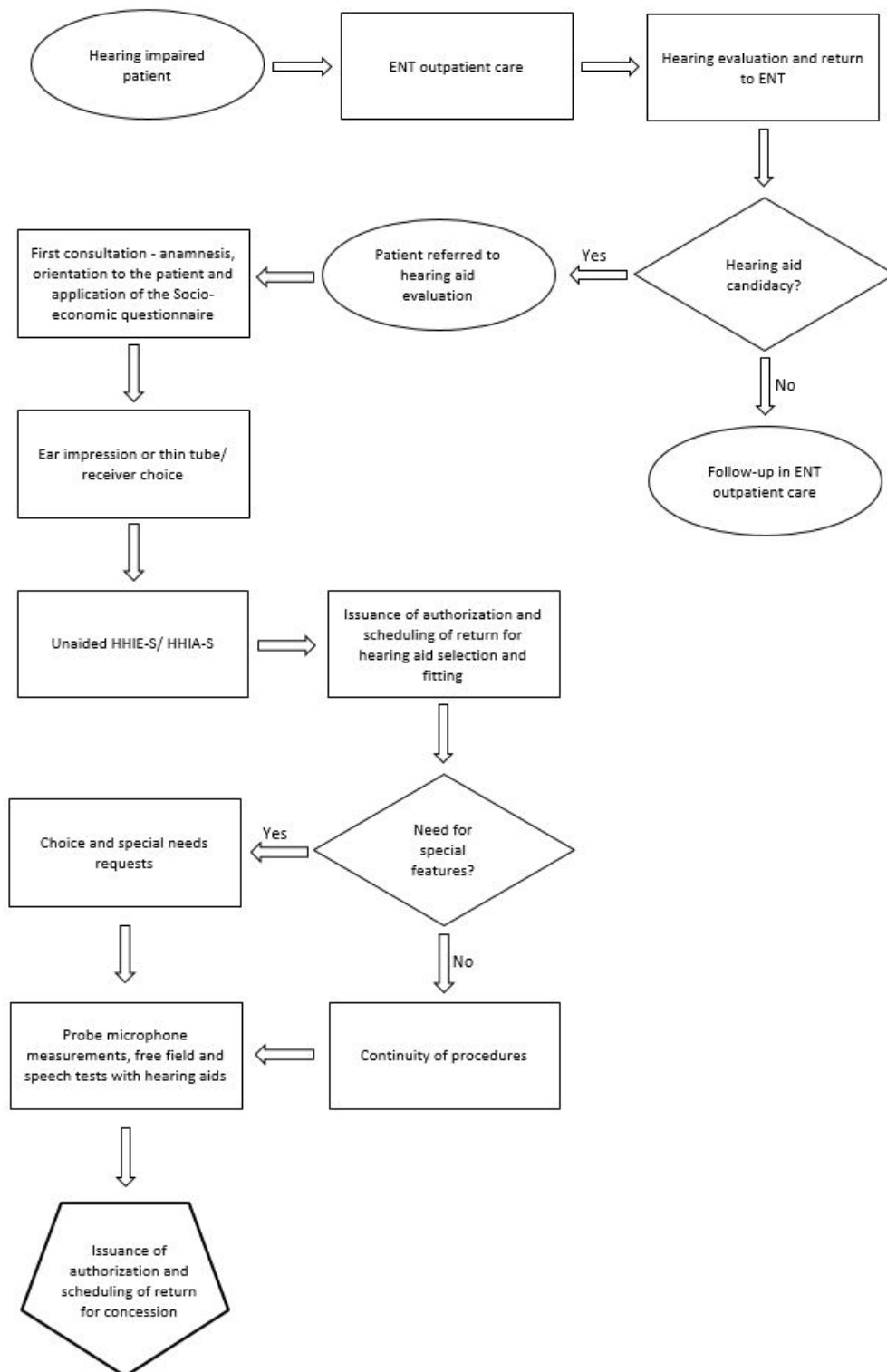
All participating audiologists reported that the use of the instrument in their clinical practice was of great value. Additionally, with the proposed use of the procedure checklist, the visualization of tests, guidelines and protocols used becomes easier, as mentioned by 85% of the professionals participating in the study.

Considering the main points raised in the observations and suggestions made by the professionals, who might prevent the proposed procedures from being performed, we categorized the difficulties we found within the following factors (with the number of participants reporting the issue being given):

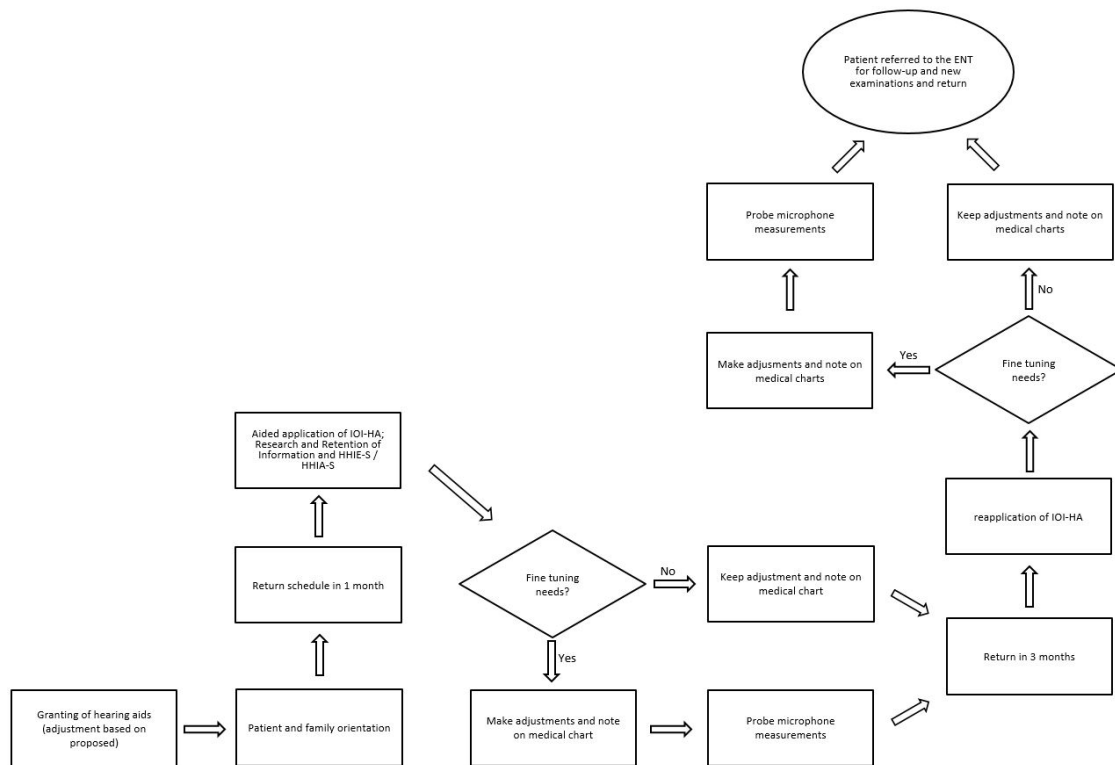
- time constraint (8 participants – 100%);
- infrastructure (availability of test materials and equipment – 4 participants – 50%);
- external factors (patients not showing up for the appointments, being late for them, or presenting with limitations – 3 participants – 37.5%).

Within the factors time constraint and infrastructure, the speech perception in noise and discomfort level tests were those mentioned as the most difficult ones to run, followed by probe microphone measurements.

At the end, the flowchart with algorithms was created after the protocol had been fully prepared, which resulted in the creation of the Standard Operational Procedure for the hearing aid selection and fitting process, as shown in Figures 1 and 2.



**Figure 1.** Algorithm containing the steps for Assessing potential hearing aid wearers, Selecting the Features of hearing aids and Verification of hearing aids



**Figure 2.** Algorithm containing the steps for Guidance and Counseling, Evaluation of outcomes (validation) and Follow-Up

## DISCUSSION

Protocols contain the description of a specific healthcare situation, with the definitions of what should be done and by whom, when and how, in order to guide professionals through their decision making and action to be taken both in terms of prevention and health intervention<sup>(12)</sup>.

With respect to the clinical protocol developed, we can consider that each step of the process of selecting and fitting hearing aids was thoroughly described along with its main procedures, which tests should be run and when. An audiologist is the professional that should be responsible for carrying out all steps in the protocol.

The use of protocols for standardizing the procedures to be performed in the hearing aid selection and fitting process brings benefits to the patients, since it ensures uniform care, the best available practices and also reduces of return rates<sup>(5,9)</sup>. It is beneficial to Healthcare Services as well, since it can assist in reducing unnecessary expenses<sup>(10)</sup>.

All participating audiologists reported that using the instrument in their clinical practice was of great value. Still, they also reported some factors as their main concerns, such as: time constraint, infrastructure (availability of materials and equipment for conducting the tests), and external factors (patients not showing up for the appointments, being late for them, or presenting limitations). Some professionals considered that the protocol was lengthy. We believe that this is the minimum possible protocol to be used, given that it is intended for use at Hearing Health Services. Studies have shown that the less

formal the protocols, the greater the number of patients returning to the service seeking solutions for fitting-related issues<sup>(5-7)</sup>.

Should any procedure be withdrawn, there will be no guarantee that hearing aids will be properly fitted and worn. There are also studies reporting that the proper use of verification and validation procedures could result in up to a 1.2 fold reduction in the number of patient visits to the service. Accordingly, the reduction in the time unnecessarily spent on such visits allows more time to the professional, which they can use for better counseling practices or new cases – all of which ensure better results<sup>(5)</sup>. The recommendation of a “best practices” protocol for the selection, verification and validation of hearing aids ensures that each patient will gain optimal benefits<sup>(2,7,11,14)</sup>.

Within the factors time constraint and infrastructure, the speech perception in noise and discomfort level tests were those mentioned as the most difficult ones to run, followed by *in situ* measurements.

The verification carried out with probe microphone measurements is neither to be neglected nor substituted. It is rather the services that should be revised instead: the professional should get better training and/or improve their time-management skills, with this being the main and most basic test in the verification step of hearing aids<sup>(2)</sup>.

It is important to emphasize that, as already described elsewhere in the literature<sup>(12,14)</sup>, the use of the protocol is no substitute for the clinical view or autonomy of the professional, who should use them in a patient-centered fashion. At many Hearing Health Services, the patient receives care from more than only one professional, which makes it difficult to quickly

perceive and visualize the patient as a whole within the institution. Hence, tools such as protocol can ensure better quality in the care being given to this patient.

We believe that the use of procedures based on best practices, having well-described steps and relying on the use of well-designed protocols; the constant search for training and continuing education on the part of the professionals (especially with respect to conducting tests); familiarity with and full usage of all the required equipment (which is provided for in the official Ordinances and Instructions and should there for be demanded by patients and all main stakeholders involved) should all facilitate the routine of these professionals and increase patient satisfaction.

Flowcharting with algorithms, as recommended by different authors and Institutions<sup>(11,12)</sup>, was performed once the protocol had been completed, thereby resulting in the Standard Operating Procedure for the hearing aid selection and fitting process. It is intended to improve how the patient's path unfolds in the Service, from their referral to the time they start wearing their hearing aids and their follow-up.

Looking at the recommendations proposed in this way makes this path clearer, and thus the tasks throughout the process can be duly systematized with no room left for misunderstandings on the part of the various stakeholders. This, in turn, allows for greater clarity in the professionals' conduct, which helps keep public health expenditures within the appropriate levels and thus ensures greater satisfaction and best practices to patients<sup>(15)</sup>.

## CONCLUSION

We developed a clinical protocol for patient care in the selection, verification and validation process of hearing aids and evaluated its applicability by professionals, which resulted in a graphical rendering of the protocol and its steps as a flowchart with algorithms.

## REFERENCES

1. IBGE: Instituto Brasileiro de Geografia e Estatística. Censo Demográfico 2010 - Resultados Gerais da Amostra. Rio de Janeiro: IBGE; 2012.
2. AAA: American Academy of Audiology [Internet]. Guidelines for the audiologic management of adult hearing impairment. USA: American Academy of Audiology; 2007 [citado em 2016 Jan 22]. Disponível em: [https://audiology-web.s3.amazonaws.com/migrated/haguidelines.pdf\\_53994876e92e42.70908344.pdf](https://audiology-web.s3.amazonaws.com/migrated/haguidelines.pdf_53994876e92e42.70908344.pdf)
3. Almeida K. Seleção, verificação e avaliação de resultados na adaptação de próteses auditivas em adultos. In: Lopes, O., Fo., Campioto, A. R., Anelli,

W., Levy, C. C. A. C. Novo tratado de fonoaudiologia. 3. ed. Barueri: Manole; 2013. p. 389-402.

4. Kochkin S, Beck DL, Christensen LA, Compton-Conley C, Fligor BJ, Kricos PB, et al. MarkeTrak VIII: the Impact of the Hearing Healthcare Professional on Hearing Aid User Success. Correlations between dispensing protocols and successful patient outcomes. *The Hearing Review*. 2010;17(4):12-34.
5. Kochkin S. MarkeTrak VIII: reducing patient visits through verification and validation. *Hearing Review*. 2011;18(6):10-2.
6. Abrams H. A concise guide to hearing aid verification and validation [Internet]. USA: Hearing Loss Association of America; 2012 [citado em 2016 Jan 22]. Disponível em: <http://hearinghealthmatters.org/hearingviews/2012/verification-and-validation-how-they-differ-and-why-its-best-practice-to-do-both/>
7. Jorgensen JE. Verification and validation of hearing aids: opportunity not na obstacle. *J Otol*. 2016;11(2):57-62. <http://dx.doi.org/10.1016/j.joto.2016.05.001>. PMID:29937811.
8. Tecca JE. 20Q: outcomes measures in clinical practice [Internet]. Houston: AudiologyOnline; 2018 [citado em 31 Ago 2015]. Disponível em: [www.audiologyonline.com](http://www.audiologyonline.com)
9. Valente M. Guideline for audiologic management of the adult patient [Internet]. Houston: AudiologyOnline; 2006 [citado em 31 Ago 2015]. Disponível em: <http://www.audiologyonline.com/articles/guideline-for-audiologic-management-adult-966>
10. Werneck MAF, Faria HP, Campos KFC. Protocolos de cuidados à saúde e de organização do serviço [Internet]. Belo Horizonte: Nescon-UFGM; Coopemed; 2009 [citado em 19 Jun 2015]. Disponível em: <https://www.nescon.medicina.ufmg.br/biblioteca/imagem/3914.pdf>
11. Enders BC, Davim RMB. Elaboração de protocolos clínicos: problemas no uso da evidência. *Rev. RENE*. 2003;4(2):88-94.
12. Pimenta CAM, Pastana ICASS, Sichieri K, Gonçalves MRCB, Gomes PC, Sollha RKT, et al. Guia para construção de protocolos assistenciais em enfermagem [Internet]. São Paulo: COREN-SP; 2015 [citado em 2015 Out 12]. Disponível em: <http://portal.coren-sp.gov.br/sites/default/files/guia%20constru%C3%A7%C3%A3o%20protocolos%2025.02.14.pdf>
13. Cox RM, Mendel LL, Bell VH. The University of Memphis Speech and Hearing Center Guidelines for Provision of Amplification for Adults [Internet]. Memphis: University of Memphis; 2011 [citado em 2016 Abr 4]. Disponível em <http://harlmemphis.org/files/6913/4625/3220/protocol2011.pdf>
14. Kochkin S. MarkeTrak VI: on the issue of value: hearing aid benefit, price, satisfaction, and brand repurchase rates. *The Hearing Review*. 2003;10(2):12-26.
15. Oh SH, Lee J. General framework of hearing aid fitting management. *J Audiol Otol*. 2016;20(1):1-7. <http://dx.doi.org/10.7874/jao.2016.20.1.1>. PMID:27144226.

## Author contributions

*LCCBRs: drawing up of the study, schedule, survey of the literature, data collection and analysis, manuscript writing, submission and paperwork; KA: supervision, drawing up of the study, schedule, survey of the literature, data collection and analysis, manuscript revision, approval of its final version, submission and paperwork.*