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Original Article

Standard operating procedure: implementation, critical analysis, and validation in the Audiology Department at CESTEH/Fiocruz

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Keywords

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ABSTRACT

Purpose: Evaluate three standard operational procedures (SOPs), regarding the application of the brainstem auditory evoked potential (BAEP) test, implemented by the Audiology Department of the Center for Studies in Occupational Health and Human Ecology (CESTEH) through the application of a questionnaire and to verify whether the SOPs are effective and assess the necessity for improvement. **Methods:** The study was conducted in three phases: in the first phase, eight speech-language pathologists and seven physicians, with no experience in BAEP, were instructed to read and perform each SOP, eventually all individuals evaluated the SOPs by responding to a questionnaire; in the second phase, the questionnaires were analyzed and the three SOP texts were reviewed; in the third phase, nine speech-language pathologists and six physicians, also with no experience in BAEP, read and re-evaluated the reviewed SOPs through a questionnaire. **Results:** In the first phase, difficulties in understanding the texts were found, raising doubts about the procedures; however, every participant was able to perform the procedure as a whole. In the third phase, after the review, all individuals were able to perform the procedures appropriately and continuously without any doubts. **Conclusion**: The assessment of the SOPs by questionnaires showed the need for adaptation in the texts. After the texts were reviewed according to the suggestions of the health professionals, it was possible to observe that the SOPs assisted in the execution of the task, which was conducted without any difficulties or doubts, being regarded effective and ensuring quality to the service offered.

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INTRODUCTION

Since the Industrial Revolution, quality has been increasingly important in organizations. This issue was particularly important in the 1930s[1]. Quality is known as the set of criteria a product and/or service should meet to satisfy or exceed customer expectations[2].

As of the 1950s, according to the concepts introduced by Juran, Deming, and Feigenbaum, quality should not be associated only with the degree of technical perfection, but also with the degree of customer satisfaction[3].

A theory that stands out as paramount to the total quality management process, the Juran Trilogy, developed by Joseph Juran, consists of three managerial tools: quality planning, quality control, and quality improvement[4].

Another very important theory in the quality management process is the Deming Cycle, devised by William Deming in 1950, which is a continuous cycle that advises the straightening of relationships and elimination of barriers in research, design, production and sales, proposing a systemic, integrated, multidisciplinary approach in organizations[2].

The Japanese, through Kaoru Ishikawa, have perfected the Deming Cycle leading to the PDCA cycle. The acronym PDCA stands for "Plan", "Do", "Check", "Act". "Plan" refers to strategic planning and the organization's quality taking customer satisfaction into consideration. "Do" corresponds to the definition of processes, their priorities, and the standardization of routines through documentation. "Check" deals with the development of indicators and data analysis. "Act" mentions the verification of process conditions and taking corrective and preventive actions[2].

Quality is a matter of such importance that the International Organization for Standardization (ISO), the largest developer of voluntary standards worldwide, has in its collection the ISO 9001 standard, which establishes requirements for the Quality Management System (QMS) of an organization.

Standardization is understood as establishing a single way to perform an activity or task, that is, to develop and implement technical standards[3].

The best way to begin standardization is through the understanding of all mechanisms involved in a process. To this end, a systematic representation of the process, called Standard Operating Procedure (SOP), is required. The SOP describes each critical and sequential step to be taken by the operator to ensure the expected output[5].

The SOP aims to standardize and minimize the occurrence of deviations in the execution of daily tasks for the correct operation of the process. An SOP warrants customers that, at any time they go to a particular establishment, actions will be taken to ensure that the quality of service is the same, regardless of day or time. Thus it increases the predictability of the results, minimizing possible variations caused by malpractice and random changes, regardless of fault, partial absence, or vacation of an employee, for example[6].

Concerns about quality in the provision of health services are also not new. In recent decades, mobilization around the implementation of quality programs to improve the efficiency of these services in hospital organizations has been observed in many countries[7].

In Brazil, the concern with this issue is so important that the Brazilian Health Surveillance Agency (ANVISA) published the Resolution no. 36 on July 25, 2013, which establishes actions for patient safety in health care and other measures. The purpose of this resolution is to institute actions to promote patient safety and the continuous improvement of processes in health services. The resolution also refers to the adoption of principles and guidelines, such as the promotion of mechanisms for identification and evaluation of nonconformities in the processes and procedures performed and the use of equipment, devices, and inputs, proposing corrective and preventive actions in the health facilities[8].

Institutions that are more prepared and more focused on quality will certainly ensure the best service to its customers and their consequent health recovery through more defined and widespread practices, considering that this also implies the ongoing training of professionals, humanized patient care, technical competence, and employee satisfaction[9].

Currently, it is possible to adapt the concepts of quality used in the industry to the health sector with relative ease, giving concrete examples of the use of traditional quality tools[10].

Following the trend of quality tools, such as the PDCA cycle, the Department of Audiology of CESTH, concerned to ensure the best quality in patient care and safety, devised SOPs for high complexity audiological tests such as brainstem auditory evoked potential (BAEP), vector electronystagmography (ENG), transient-evoked otoacoustic emissions (T-EOAE), and distortion product otoacoustic emissions (DPOAE) in order to standardize procedures and minimize errors in the execution of tests offered to the population.

Concerned with continuous improvement, the purpose of this study is to evaluate three SOPs, regarding the application of the BAEP examination, implemented by the Audiology Department of the CESTEH through a questionnaire and to verify whether the procedures are effective and assess the need for improvement.

METHODS

This study was approved by the Research Ethics Committee of the National School of Public Health (ENSP) under protocol no. 440605154.7.0000.5240.

Study participants were thirty-five volunteers of both genders aged 25 to 58 years, with average schooling time of 14 years, divided into three groups: Group 1 included 15 legally qualified professionals (eight speech-language pathologists and seven physicians) that performed the BAEP test according to the SOPs implemented by the Audiology Department of the CESTEH; Group 2 comprised 15 legally qualified professionals (nine speech-language pathologists and six physicians) that conducted the BAEP examination according to the revised edition of the SOPs; Group 3 included five speech-language pathologists that participated as volunteers, this time under patient simulation situation or as referees of the task performers.

All volunteers that agreed to participate in the study were informed about its purpose, importance, and benefits both for the Department of Audiology and the service users. After initial instructions, an Informed Consent Form was read and signed by all participating professionals (task performers and referees/patients).

The research was divided into three phases.

The first phase aimed at critically analyzing the texts of the three SOPs: SOP AUDI-01 on the guidance for patients undergoing the BAEP test, SOP AUDI-02 on the preparation of patients undergoing the BAEP test, and SOP AUDI-03 on the execution of the BAEP test of short latency using clicks to define the site of auditory nerve or brainstem injury and establish a minimal auditory response level by air conduction. In this first phase, 15 volunteers (Group 1) were instructed to read each SOP and execute the procedure as described by simulating the BAEP test. During the procedure, two referees observed the SOP execution for each volunteer and noted, individually, the critical points or failures according to the difficulties presented by the task performer. Eventually, each volunteer responded to a questionnaire (Appendix A) with open and closed questions on the three SOPs performed in order to assess their texts.

The second phase focused on the analysis of the observations and suggestions made by each volunteer task performer described in the questionnaires. A compilation of all referees' suggestions was conducted (Group 3) so that the SOP texts could be rewritten. After writing, the new texts were referred to the CESTEH Quality Management System for the publication of a revised version of each SOP.

For the third phase, other 15 volunteers were invited (Group 2). The methodology was the same used with Group 1, that is, reading, application, and evaluation of possible critical points. The purpose of the third phase was to determine whether the adjustments made in the SOP texts were effective, mitigating or eradicating the doubts that the former group had identified.

RESULTS

The first phase of this study evaluated, using questionnaires, the text of the three SOPs implemented by the Department of Audiology: the SOP that refers to guidance to patients undergoing the BAEP test; the SOP that refers to the preparation of patients undergoing the BAEP; and the SOP that refers to the BAEP examination itself.

The responses to the 15 questionnaires are shown in Table 1.

The following was observed regarding the quality of the SOP texts: all volunteers understood the text as a whole, the language used was appropriate, the task performers managed to complete the task described in a systematic way, and all participants regarded the SOPs as useful.

With respect to the running time of three SOPs sequentially, the volunteers, both physicians and speech-language pathologists, spent 70 minutes to complete the task on average.

Failures were identified during the implementation of the SOPs and the photos were not effectively helpful. The volunteers made several suggestions regarding the texts of the SOPs.

After analyzing the questionnaires, the referees improved the written texts and produced new photos for the three SOPs. Next, a revised edition of the three SOPs was published considering the suggestions made.

In the third phase, new volunteers participated in the assessment the three revised SOP texts. The results are shown in Table 2.

The following was observed regarding the revised versions of the SOPs: all volunteers understood the text as a whole, the language used was appropriate, all task performers managed to complete the task described in a systematic way, the text was in logical sequence, the photos were effectively helpful, and all participants regarded the SOPs as useful.

Only one volunteer presented difficulties during task execution. There were no failures in the execution of the SOPs and the photos effectively assisted task execution. Only one volunteer suggested changes in the SOP texts.

As for the running time of the three SOPs sequentially, the volunteers, both physicians and speech-language pathologists, spent 55 minutes to complete the task on average, that is, there was a 15-minute reduction in execution time.

DISCUSSION

The International Standard ISO 9001:2008 presents the requirements for a Quality Management System (QMS) of an organization, whatever the area of activity. Total Quality Management comprises a management model that involves the entire organization in order to meet the needs of employees and customers, thereby offering more efficient services.

The Department of Audiology of CESTEH, aiming to ensure quality service and safety to patients, formulated SOPs for the

Table 1. Evaluation of the SOPs by questionnaire

	SOP guidance	SOP preparation	SOP execution
Did you understand the text as a whole?	100%	100%	100%
Was the information clear?	100%	94%	94%
Was language appropriate?	100%	100%	100%
Were the photos helpful?	not applicable	80%	80%
Was the text in logical sequence?	94%	100%	100%
Could you fully perform the SOP?	100%	100%	100%
Did you have any difficulties?	20%	46%	26%
Were there failures in the SOP execution?	93%	13%	6%
Do you believe the SOP is useful?	100%	100%	100%
Do you have suggestions regarding the text?	33%	53%	6%

Table 2. Reassessment of the SOPs by questionnaire. Reassessment by questionnaire after revision and adequacy of the SOP texts

	SOP orientation	SOP preparation	SOP execution
Did you understand the text as a whole?	100%	100%	100%
Was the information clear?	100%	100%	100%
Was language appropriate?	100%	100%	100%
Were the photos helpful?	not applicable	100%	100%
Was the text in logical sequence?	100%	100%	100%
Could you fully perform the SOP?	100%	100%	100%
Did you have any difficulties?	0%	0%	6%
Were there failures in the SOP execution?	0%	0%	0%
Do you believe the SOP is useful?	100%	100%	100%
Do you have suggestions regarding the text?	0%	0%	6%

BAEP examination to standardize tasks and minimize possible errors during the execution of this service offered to the public.

Following the same principle, researchers advocate the importance of establishing SOPs in a Clinical Research Center to ensure service improvements, including training, professionalism, credibility, and quality assurance through standardization routines. They also recognize that an SOP should be written in a clear, objective and detailed way so that there is uniformity in the procedure[11].

Another study on the validation of SOPs described each step to be followed by a professional performer in conducting a task in order to ensure a certain expected result. They also emphasize that an SOP is directly related to a specific professional technique. The authors conclude that SOPs are important technological resources in health practice and should, therefore, be validated, thus gaining scientific credibility[12].

During the preparation of the SOPs in the Department of Audiology of the CESTEH, there was concern about preparing them in a detail-oriented manner, so that any legally qualified professional, experienced or not, could perform it entirely, without damage to the quality of the services. Because of its constant concern for continuous improvement, the Department of Audiology sought to validate the SOPs on BAEP through this study.

In a study conducted to analyze the management tools used in the nursing practice, the participants reported that the SOP allows the provision of standardized care within technical and scientific principles. Also, it contributes to resolve distortions acquired in practice, in addition to its educational purpose. For the authors, these results indicate that the use of SOPs shows the organization of the service by means of detailed guidelines that reveal the care recommended for specific situations. As a result, the improvement of their processes and outcomes is evident. They also claim that the rationalization, due to standardization of routines, provides greater safety to the procedures[13].

In the CESTEH, concerns about customer satisfaction are a key factor to the process of continuous improvement. This unit specialized in outpatient care ensures maintenance and continuous improvement in customer service, as well as quality and safety. The use of SOPs proposed by the Department of Audiology and the validation of standardization of instruments are based on the Deming Cycle, always seeking to evaluate certain processes and find solutions for continuous improvement; a fact also observed in another study[13].

"When it comes to quality management in manufacturing and food handling, it is mandatory to remember the Standard Operating Procedures (SOPs), Good Manufacturing Practices (GMPs), and Hazard Analysis and Critical Control Points (HACCP)". In this research note, after conducting training, awareness, and adoption of SOPs, important changes were observed, such as a significant reduction in microbiological requirements searched. These results confirm the effectiveness of the use of SOPs and employment of best practices in the tasks performed[14].

Results show that, in the first phase of the study in the Department of Audiology, difficulties in implementing the SOPs were observed, generating doubts in the volunteers, resulting in task interruption and increased runtime. With the review of the SOPs and their validation in the third phase of this study, the mean execution time decreased and all volunteers were able to complete the task without difficulties, questions, or interruptions.

The standardization matter can also be observed in police institutions. These institutions have verified the importance of SOPs and have invested in them as a reference source for the police work. A study addressing vehicles reports that the creation and use of SOPs in compliance with legal standards establish parameters that enable decision to be discretionary, not arbitrary. The SOPs guide the individual conduct of the police officer during the approach, increasing the safety level for those involved, thus reducing the likelihood of abuse[14].

A study conducted with post-cardiorespiratory arrest resuscitated patients showed the benefits of implementing a standard operating protocol in the care for these individuals. According to the authors, the development of a protocol using therapeutic hypothermia routinely adapted to this group of patients presented great support to professionals. It provided significant improvement in hypothermia and rewarming times. They also emphasize that new revisions in the protocol should be made aiming to adapt the procedures to the literature[15].

A survey on protocol reviews was conducted in the nursing service of three hospitals. The study found the main causes cited to justify a review of the SOPs and the updating of techniques, and that some procedures are specific to certain units, deserving adaptations. Verifying the existence, revision, and updating of SOPs were among the study objectives. The authors conclude

that the revision and updating of SOPs should be conducted by a specific committee or individually by the nurses, that is, those that directly perform the SOPs[5].

The implementation of standardized procedures contributes to the uniform execution of tasks, as it can be observed in the Department of Audiology. Different professionals have performed the task described in the SOPs, maintaining the techniques and ensuring quality in the health care provided to the population serviced.

Some authors observed that the implementation of SOPs in the dairy sector, complemented with Good Manufacturing Practices, contribute to ensure hygienic and sanitary conditions for food processing. A team previously unaware of the existence of the SOPs began to value the guidance document as a tool to clear doubts. The authors also emphasized that the commitment of the staff to the manufacturing process was one of the basic conditions for the successful implementation of this tool[6].

The development of SOPs assists in the execution of daily tasks and SOPs must be written by professionals with knowledge on the tasks so that they can be described in detail. However, this does not guarantee that the text is clear and objective, because one who is experienced in a particular subject and procedure may fail to pay attention to small details that are obvious but deserve to be described, as noted in the first phase of this study. Therefore, we felt the necessity to review the SOPs according to the doubts and difficulties described in the questionnaires.

After a critical analysis of the SOPs in the Department of Audiology, a corrective action (reviewing the wording with a focus on the procedure and adding photos) has reduced the runtime of procedures and eliminated problems that occurred in the first phase of this study, corroborating the findings of previous research. Therefore, an SOP is a professional training tool; in addition to eliminating or mitigating errors, it ensures a higher quality level of health care, reinforcing the idea that standardization provides benefits both for patients and for health professionals.

CONCLUSION

Assessment conducted by health professionals through questionnaires of three standard operational procedures (SOP) showed the need for adaptations in their texts. This can be understood as a continuous improvement process, i.e., corrective actions through the publication of reviewed editions of the SOPs. After text revision, it was possible to observe that the SOPs assisted in the execution of the proposed task, which was appropriately conducted without difficulties or doubts by health professionals with no experience in BAEP, being regarded as effective and ensuring quality of the service offered.

The results of the present study show the need for scientific research to confirm the effectiveness of innovations proposed in health care organizations.

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Author contributions

ELQ contributed with the invitation of the 30 volunteers and the confirmation of their attendance on the appointed day and scheduled time to conduct this research, as well as with his studies on the theme to write the introduction; VFS contributed with the writing of the methodology and of the results, in addition to being responsible for the reception of the volunteers at CESTEH and the application of questionnaires after conducting the standard operating procedure; VMF and GRSL contributed with the bibliographic search on the issue which created the introduction of this article; they also accompanied the volunteers during the research; AVMF conducted the research and writing of the discussion and conclusion of this article and the accompaniment of the volunteers during the research. All the authors contributed to the organization of the text as a whole and revision of the article.

Appendix A. Questionnaires to evaluate the SOPs

Referee: ( ) Speech-language pathologist ( ) Physician				
Evaluation date: ___/___/__ Age: _____ Time of professional experience: _____ Gender: F ( ) M ( )				
EVALUATION OF SOP ORIENTATION FOR THE BAEP TEST				
	YES	NO	MAYBE	NOTES
Did you understand the text as a whole?				
Was the information clear?				
Was language appropriate?				
Were the photos helpful?				
Was the step by step clearly organized?				
Could you fully perform the procedure?				
	Open Response			
What were the difficulties				
Were there any flaws? Where?				
Do you believe this SOP is useful?				
How could this SOP be improved?				
Would you like to suggest further questions for this questionnaire?				
EVALUATION OF SOP PREPARATION FOR THE BAEP TEST				
	YES	NO	MAYBE	NOTES
Did you understand the text as a whole?				
Was the information clear?				
Was language appropriate?				
Were the photos helpful?				
Was the step by step clearly organized?				
Could you fully perform the procedure?				
	Open Response			
What were the difficulties				
Were there any flaws? Where?				
Do you believe this SOP is useful?				
How could this SOP be improved?				
Would you like to suggest further questions for this questionnaire?				
EVALUATION OF SOP EXECUTION FOR THE BAEP TEST				
	YES	NO	MAYBE	NOTES
Did you understand the text as a whole?				
Was the information clear?				
Was language appropriate?				
Were the photos helpful?				
Was the step by step clearly organized?				
Could you fully perform the procedure?				
	Open Response			
What were the difficulties?				
Were there any flaws? Where?				
Do you believe this SOP is useful?				
How could this SOP be improved?				
Would you like to suggest further questions for this questionnaire?				