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Original article

Self-applicable instrument for internal auditing of Pharmaceutical Supply Centers

Instrumento autoaplicável para auditoria interna das Central de Abastecimento Farmacêutico

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ABSTRACT

Objectives: To adapt an assessment instrument for the CAF to a self-administered questionnaire so that it can be used in the CAF routine as a tool for managing this service. **Methods**: This is a cross-sectional study, carried out in four stages: 1st reorganization of the original questionnaire, 2nd update of the instrument, 3rd adaptation of the instrument/pilot test, 4th application of the instrument. Results: In the 1st stage, the committee of experts modified the constructs to four (structure, process, results and documentation) and selected the issues considered most relevant to the CAF service. In the 2nd stage, it was ensured that the instrument remained in accordance with current legislation. In the 3rd stage, the pilot test was carried out, resulting in the modification of the questions to dichotomous ones and the development of a glossary. As a result, the self-administered instrument was developed, consisting of forty-three questions, dichotomous (yes/no), distributed across the constructs: structure, process, results and documentation. In the 4th stage, the self-administered instrument developed in the previous stages was answered in the CAF. Statistical analyzes of reliability (Cronbach's alpha) and validity (Spearman's correlation coefficient) were performed. As a result, (α) = 0.623 and (ρ) = 0.952 were obtained, showing that the self-administered instrument is reliable and valid. **Conclusion:** The proposed self-applicable Instrument to Evaluate the Pharmaceutical Supply Center is a simple and lean tool capable of evaluating CAFs, and is therefore useful for their management.

Keywords: Pharmaceutical Services; Drug Storage; Surveys and Questionnaires; Primary Health Care

RESUMO

Objetivos: Adaptar um instrumento de avaliação para a CAF para questionário autoaplicável de forma que possa ser utilizado na rotina da CAF como ferramenta para gestão desse serviço. **Métodos:** Trata-se de um estudo transversal, realizado em quatro etapas: 1° reorganização do questionário original, 2° atualização do instrumento, 3° adaptação do instrumento/teste piloto, 4° aplicação do instrumento. **Resultados:** Na 1° etapa o comitê de especialistas realizou a modificação dos constructos para quatro (estrutura, processo, resultados e documentação) e seleção das questões consideradas mais relevas para o serviço da CAF. Na 2° etapa assegurou-se que o instrumento se mantinha de acordo com a legislação vigente. Na 3° etapa realizou-se o teste piloto, resultando na modificação das questões para dicotômicas e desenvolvimento de glossário. Como resultado desenvolveu-se o instrumento autoaplicável composto por quarenta e três questões, dicotômicas (sim/não), distribuídas nos constructos: estrutura, processo, resultados e documentação. Na 4° etapa o instrumento autoaplicável desenvolvido nas etapas anteriores foi respondido nas CAF. Realizou as análises estatísticas de confiabilidade (alfa de Cronbach) e validade (coeficiente de correlação de Spearman). Como resultado obteve-se (α) = 0,623 e (ρ) = 0,952 mostrando que o instrumento autoaplicável é confiável e válido. **Conclusão:** O Instrumento autoaplicável para Avaliar a Central de Abastecimento Farmacêutico proposto é uma ferramenta simples e enxuta capaz de avaliar as CAF, sendo, portanto, útil para a gestão das mesmas.

Palavras-chave: Assistência Farmacêutica; Armazenamento de Medicamentos; Inquéritos e Questionários; Atenção Primária em Saúde.

Introduction

For the effective implementation of Pharmaceutical Services (PS), it is essential to adopt the Pharmaceutical Services Cycle as a guiding basic principle, which is a system composed of the stages of selection, programming, acquisition, storage, distribution, and dispensing.[1] Storage comprises the set of technical and administrative procedures involving the activities of receiving, stocking, and conserving medicines.[2] It is known that the inadequate execution of any of these stages may compromise the others and, therefore, failures in the storage stage may impact the management of PS.

The location intended exclusively for the storage of medicines is referred to as the Pharmaceutical Supply Center (PSC) and, in Brazil, this nomenclature is used to differentiate it from other terms, such as depots and/or warehouses, which are facilities used for storing other types of materials.[3,4] The PSC must have a physical structure capable of meeting the workflow requirements inherent to this service, that is, adequate space for the proper receipt, storage, and dispatch of medicines, in accordance with the relevant health regulations.[5] RDC No. 430, dated October 8, 2020, issued by ANVISA,[6] establishes requirements for medicine storage facilities. Responsibility for the PSC lies with the pharmacist, the legally qualified and technically competent professional to carry out the activities required in this setting.[5]

When reviewing the literature on studies evaluating PSCs, a gap can be identified regarding research that deals exclusively with this service. In these studies, the facilities intended for medicine storage presented inadequate conditions and were therefore unable to provide the necessary safety, effectiveness, and quality of the medicines.[4,7–10] The study published in 2022 by Rossoni et al[4] demonstrates progress in relation to the PSC scenarios presented in other publications. This study, conducted in 26 PSCs located in the metropolitan region of Porto Alegre, observed that in 92.3% of the PSCs the medicines were stored on pallets and that in 84.6% daily temperature control was performed.

Understanding the need to seek tools that contribute to the management of the PSC and, consequently, Pharmaceutical Services (PS), studies using indicators through questionnaires emerge as an alternative for identifying problems and their causes. The use of health indicators aims to support decision-making, assisting in processes such as evaluation, monitoring, accountability, measurement of disparities, system management, and improvement of quality of care[11].

The PSC is strategic for medicine management within health services; however, the absence of standardized and easily applicable instruments for evaluating its processes compromises monitoring and managerial decision-making. Therefore, the objective of this study is to detail the development of a self-administered evaluation instrument, contributing to the management of PSCs.

Methods

This is a cross-sectional study in which the stages involved in adapting an evaluation questionnaire for the PSC were described, in order to transform it into a self-administered internal audit instrument for this service.

Original Questionnaire

The original questionnaire was developed based on the results of the project entitled "Evaluation of the Organization of Pharmaceutical Services in Primary Health Care in Municipalities of Rio Grande do Sul: Structure, Process, and Outcomes", funded by the Research Program for the Unified Health System (PPSUS). This instrument consisted of 72 multiple-choice questions distributed across the following constructs: Structure; Structure: Others; Process; Process: Others; and Other Indicators. Its application took place between January and March 2020 in municipal PSCs in Rio Grande do Sul, through interviews conducted with the respective pharmacists. Details regarding the methodology and results of this project can be accessed in other publications by the research group.[4,12]

Stages

The adaptation of this questionnaire to make it self-administered was carried out in four stages:

Stage 01: Reorganization of the Original Questionnaire

This stage aimed to reorganize the original questionnaire through the selection of questions and the recomposition of constructs, in order to obtain an initial proposal for a self-administered instrument. This process was carried out by a committee of experts, according to the Delphi Method, composed of technicians from SES/RS and professors from UFRGS. Details of this stage can be accessed in other publications by the research group.[4],[12]

Stage 02: Instrument Updating

The updating of the instrument was conducted through a review of the legislation, carried out by the authors of the present article, with the objective of verifying the existence of any changes. To ensure the reliability of the results, searches were conducted on the websites of the CFF and CRF, in addition to telephone contact and inquiries through the Council's website portal.

Stage 03: Instrument Adaptation/Pilot Testing

This stage aimed to develop the self-administered instrument based on the evaluation of its structure and content. For this purpose, the Delphi method was applied in a pilot test in which the instrument was answered by researchers from UFRGS and pharmacists from the Centro Colaborador de Serviços Farmacêuticos (CECOL-FAR/UFRGS), totaling five participants, through observation of the medication storage site at CECOL-FAR/UFRGS, and the responses were compared and discussed.

This process took place in four meetings held during May 2023. For the analysis of the instrument structure, the following aspects were observed: the number of questions and the response options (single or multiple choice). In the analysis of the instrument content, each question was evaluated regarding its comprehensibility and its relevance to the routine of services in the CAF.

Stage 04: Instrument Application

The application occurred in two ways: a) the pharmacist responsible for the CAF self-completed the questionnaire on site, and b) a researcher, blinded to the pharmacists' responses, self-completed the questionnaire on site. Finally, the responses were compared in order to verify the comprehensibility of the instrument and the psychometric characteristics of reliability (Cronbach's alpha) and validity (Spearman's correlation coefficient).

Data Collection

Data collection took place from June to July 2023 and was conducted through direct observation of the PSC, in which the pharmacist responsible for the PSC and the UFRGS researcher independently self-completed the instrument. The responses provided by the pharmacist responsible for the PSC and by the UFRGS researcher were independent. The visit of the UFRGS researcher to the PSC, in order to complete the instrument, occurred after prior scheduling.

Statistical Analysis

To evaluate the psychometric properties of the instrument, reliability and validity were analyzed. Reliability refers to the ability to consistently reproduce a result over time and across different settings, whereas validity refers to the property of an instrument to measure exactly what it is intended to measure[13]. In the present study, Cronbach's alpha (α) was used to determine reliability, and Spearman's correlation coefficient (ρ) was used to verify the validity of the instrument.

Ethical Aspects

The research was approved by the Ethics Committee of the Research, Teaching, and Extension Council of the Federal University of Rio Grande do Sul (UFRGS), under opinion No. 2.437.516. The managers and pharmacists responsible for the PSCs who participated in this research formally expressed their agreement. The invitation, con-

taining information about the study, identification of the researchers, the objectives of the project, and the data collection procedures, was sent by e-mail. The anonymity of the participants was duly ensured.

Results

In the first stage, the committee of specialists identified the need to select the questions, maintaining, by consensus, those considered essential for the service performed in the PSC. This process resulted in a reduction in the number of questions from the original questionnaire, which initially contained seventy-two questions, leading to an instrument composed of fifty questions. In addition to this modification, the constructs were also reorganized in order to make the subject addressed by each question clearer. In this process, the proposal by the author Donabedian and the approach adopted in the study conducted by the Ministério da Saúde and the Pan American Health Organization[16] were followed, grouping the questions into the constructs of structure, process, and outcome. The inclusion of a specific construct for PSC documentation was suggested. Thus, by consensus of the committee, the questions were reorganized into four constructs: structure, processes, outcomes, and documentation.

In the second stage, the following regulations related to the PSC were identified: RDC No. 430/2020[6] issued by ANVISA, RDC No. 679/2019[14] issued by the CFF, and RDC No. 50/2002[15] issued by ANVISA. After reading these documents, the information identified was compared with the instrument. In this comparison, it was verified that the instrument was in accordance with the current legislation, and no modifications were necessary.

In the third stage, during the analysis of the instrument structure, the committee of specialists unanimously identified the need to modify the questions into dichotomous items, allowing the respondent to answer only "yes" or "no". In this evaluation, the possibility of merging questions addressing the same topic was also identified. In the content analysis, the importance of ensuring the proper interpretation of each question was verified, since the respondent would not have the immediate presence of the researcher to resolve possible doubts. By consensus among the committee members, the development of a Glossary was approved, in which each question includes a brief description to support its interpretation.

As a result of this process, the final version of the Self-administered Instrument for Evaluation in the Pharmaceutical Supply Center was developed. It is organized as a simple questionnaire composed of 43 dichotomous questions (yes/no), with their respective descriptions, distributed across four constructs: structure, process, outcome, and documentation. To facilitate its application, the self-administered instrument was designed to be completed online using the Google Forms platform together with the description of each question.

In the fourth stage, pharmacists from six PSCs and the UFRGS researcher self-completed the instrument developed in the previous stages. The participating PSCs are located in the metropolitan region of Porto Alegre, including four municipal PSCs and two hospital-based PSCs. Chart 1 describes the stages involved in the development of the proposed instrument.

As a result of the statistical analysis, a Spearman's correlation coefficient value of 0.952 (RV=1) was obtained for the instrument as a whole. This result demonstrates that the instrument is valid and, therefore, capable of measuring what it is intended to measure. Spearman's correlation coefficient was also calculated for each PSC individually, as presented in Table 1. Upon examining this table, divergences can be observed between the responses provided by the PSC pharmacists and the UFRGS researcher in PSC No. 4 and PSC No. 5. These divergences occurred in the responses to question 2 in PSC No. 4, and questions 2 and 9 in PSC No. 5. Question 2 addresses "Are the floor/walls/ceiling impermeable?" and question 9 "Do the windows have protective screens against insects?".

The statistical result for Cronbach's alpha observed for the instrument as a whole was 0.623 (RV >0.6). This value indicates that the instrument is reliable and, therefore, capable of reproducing results consistently.

Chart 1. Description of the stages involved in the development of the Self-administered Instrument for Internal Auditing of Pharmaceutical Supply Centers.

Stages		Constructs	N° of Participants	Application	N° of Questions	Questions
1	Reorganization of the original questionnaire	Structure; Process; Outcomes; Documentation	26	Interview	72	Multiple choice
2	Instrument update	Structure; Process; Outcomes; Documentation	2	Self-administered	50	Multiple choice
3	Instrument adaptation/ Pilot test	Structure; Process; Outcomes; Documentation	5	Self-administered	43	Dichotomous; Glossary
4	Instrument application	Structure; Process; Outcomes; Documentation	7	Self-administered	43	Dichotomous; Glossary
Final Instrument		Structure; Process; Outcomes; Documentation	NA	Self-administered	43	Dichotomous; Glossary

Source: Elaborated by the author (2023)
Legend: (NA) not applicable

Table 1. Spearman's Correlation Coefficient (ρ) for each PSC.

PSC	ρ
01	1,000*
02	1,000*
03	1,000*
04	0,952*
05	0,857*
06	1,000*

Source: Elaborated by the author (2023)
Legend: (*) p-value <0.001.

Discussion

The use of questionnaires in health evaluation is widely recognized; however, these instruments are often not assessed appropriately[13]. It is essential that, before being used, the instrument demonstrates its suitability for application, ensuring that the data obtained are accurate, valid, and interpretable.[17]

In the statistical analysis, the results obtained indicate that the instrument is valid and reliable within the parameters established in the literature. This means that the instrument is capable of measuring what it is intended to measure and reproducing this result consistently over time and across different settings[13]. It should be emphasized that the instrument was developed with the objective of contributing to the routine activities of the PSC and, therefore, presents a simplified and concise structure, which may justify the strong correlation found between the PSC responses and the researcher's responses, demonstrated by $\rho = 0.952$. It is important to recall that the responses to the instrument were collected independently, without knowledge of or interference between the PSC and the researcher. Cronbach's alpha of 0.623 suggests that reliability may be further improved, while also possibly being associated with the reduced number of participating PSCs and the use of dichotomous variables, which were necessary in this study to simplify application and encourage the universal adoption of the proposed instrument.

When addressing the development of self-administered questionnaires, it is important to consider the aspects required by this different application dynamic.[18] Gunter[19] suggests that the instrument should contain all the information necessary for the respondent to act in the manner expected by the researcher. Thus, the development of the Glossary emerged as a tool to ensure the proper understanding of the questions. It is also suggested that the questions be more objective, in agreement with the need identified during the third stage, which resulted in the modification of the questions into dichotomous items.

Even so, it is important to highlight the divergence identified in the response to question 2, which addresses whether the "floor/walls/ceiling are impermeable". This disagreement may be justified by the lack of clarity regarding the meaning of the word "impermeable". It is known that an impermeable material is one that prevents the penetration of liquids; however, confirmation of this characteristic solely through observation may be difficult. When reviewing the legislation related to PSCs, it can be observed that there is no definition of what constitutes an impermeable surface or examples of such material.[6,14,15]

RDC N°. 430/2020[6] issued by ANVISA is the main reference for Pharmaceutical Supply Centers and establishes Good Practices for the Distribution, Storage, and Transportation of Medicines. This resolution establishes, among other requirements, that medicines cannot be stored in direct contact with the floor/wall and that temperature and humidity control and monitoring of the facility must be carried out. However, it is noteworthy that the term Pharmaceutical Supply Center (PSC) is not used in this resolution.

RDC N°. 679/2019[14] issued by the CFF establishes the responsibilities of pharmacists in the logistical operations of medicine/pharmaceutical supply distribution and storage. In this resolution, the PSC is defined as the specific facility linked to a health unit and intended for the activities of receiving, storing, distributing, and dispatching medicines. Nevertheless, there are no specifications regarding how the PSC should be organized or details concerning its structure.

RDC N°. 50/2002[15] issued by ANVISA establishes the Technical Regulation for the planning, programming, development, and evaluation of physical projects for healthcare facilities. In this regulation, only the size of the physical structure required for a PSC is defined. Thus, it can be stated that there is a gap regarding legislation specifically directed toward PSCs. Therefore, in the absence of exclusive legislation, recommendations developed for pharmacies are extrapolated for application to PSCs.

Question 9, which addresses the "presence of protective screens against insects", also generated questions; however, in this case, the divergence arose from the fact that, in the participating PSCs, there were no windows or the windows were permanently sealed and, therefore, the most appropriate response would be "not applicable". Thus, the inclusion of the option "not applicable" as a possible response was suggested by the pharmacists who participated in the study.

It is noteworthy that, to date, no evaluation instruments for Pharmaceutical Supply Centers (PSCs) with self-administered characteristics and intended for routine use as a management tool have been identified in the literature. Most available instruments require application by external evaluators or present a high degree of complexity, which may limit their adoption within health services. In this regard, the instrument proposed in this study fills a relevant gap by offering a simple, concise, and validated alternative, favoring the systematic monitoring of PSC processes and supporting managerial decision-making.

Among the limitations of the study, the reduced number of participating PSCs can be highlighted, resulting from the lack of response from pharmacists and managers. This factor may restrict the generalization of the findings obtained. Another limitation is the possibility that pharmacists may have felt evaluated by the study, despite the clarification that the objective was to evaluate the instrument itself. The fact that the PSCs belonged exclusively to the public sector may also be considered a limitation, since there is no perception regarding the private sector.

Conclusion

The results of the present study demonstrate that the Self-administered Instrument for the Evaluation of the Pharmaceutical Supply Center is current and applicable and may be used as a reliable and valid tool for PSC management. However, it is important to highlight that the reduced number of PSCs included may limit the extrapolation and generalization of the results obtained.

As future perspectives, the developed self-administered instrument may be systematically used by PSCs as a management support tool, allowing the

continuous monitoring of their processes and the identification of weaknesses. Furthermore, its application in different contexts may contribute to the improvement of the instrument, as well as to the generation of indicators, supporting planning and service qualification actions within the scope of Pharmaceutical Services (PS). It should be noted that the original questionnaire, as well as the developed self-administered instrument, will be made available to readers upon request to the author.

Finally, this study stands out for proposing, in an unprecedented manner, a self-administered instrument for the evaluation of PSCs, filling a gap in the literature and offering a practical and self-administered management support tool.

Authors' Contributions
LPK contributed to the conception, design, or analysis and interpretation of the data, as well as acting in the writing of the article or relevant critical review of the intellectual content and was responsible for all aspects of the text in ensuring the accuracy and integrity of any part of the work. DP contributed to the final approval of the version to be published.

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The authors declare no conflicts of interest.

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The data underlying the research text are contained within the manuscript.

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