

Validation of an innovative instrument for evaluating good practices regarding the use of medical gases in hospitals

Validação de um instrumento inovador para avaliação das boas práticas hospitalares com gases medicinais

Fábio Jorge Ramalho de AMORIM^{1,4}; Elisdete Maria Santos de JESUS¹; Sabrina CERQUEIRA-SANTOS¹; Lincoln Marques CAVALCANTE-SANTOS³; Izadora Menezes da Cunha BARROS²; Divaldo Pereira de LYRA-JR^{1,4*}.

¹Departamento de Farmácia/Laboratório de Ensino e Pesquisa em Farmácia Social, Universidade Federal de Sergipe, 49.000-000, São Cristóvão–Sergipe, Brasil.

²Departamento de Farmácia, Universidade Federal de Sergipe, 49.400-000, Lagarto–Sergipe, Brasil.

³Centro de Pesquisa em Assistência Farmacêutica e Farmácia Clínica, Faculdade de Ciências Farmacêuticas de Ribeirão Preto, Universidade de São Paulo, 14.040-903, Ribeirão Preto–São Paulo, Brasil.

⁴Programa de Pós-graduação em Ciências da Saúde, Universidade Federal de Sergipe, 49060-108, Aracaju–Sergipe, Brasil.

*lepfs.ufs@gmail.com.

Abstract

Objective: Medicinal gases are used in the diagnostic, surgical, and preventative treatment of several diseases, such as COVID-19. Currently, there are no instruments available in the literature to assess compliance with good practices regarding the use of medicinal gases in the hospital environment. The purpose of this study was build and validate an instrument to assess compliance with good practices regarding the use of medicinal gases in hospitals. **Methods:** A methodological development and content validation study was carried out from May to November 2018 and was comprised of three distinct stages: (I) development of the instrument for assessing compliance with good practices regarding the use of medicinal gases in hospitals; (II) content validation of the instrument using the nominal group technique; and (III) classification of each standard based on performance categories and their respective scores. **Results:** An instrument with 54 “compliance standards” was developed and divided into two domains: structure (29) and process (25). In the applicability assessment test, the instrument obtained 100% agreement regarding its usefulness in hospital practice. Four categories of performance were defined: satisfactory with excellence, satisfaction, little satisfaction, and unsatisfactory. **Conclusion:** The instrument obtained a satisfactory evaluation among the specialists regarding content, as well as the classification of each compliance standard according to criticality, scores, and performance categories. Therefore, a pioneering instrument was generated in accordance with national and international protocols for evaluating good practices regarding the use of medicinal gases in hospitals. The developed instrument may contribute to patient safety and reduce healthcare costs.

Keywords: Validation; medicinal gases; Good practices.

Resumo

Introdução: Os gases medicinais são utilizados no diagnóstico, cirurgia e tratamento preventivo de diversas doenças, como a COVID-19. Atualmente, não existem na literatura instrumentos que avaliem a adesão às boas práticas de uso de gases medicinais em ambiente hospitalar. **Objetivo:** Construir e validar um instrumento para avaliar a adesão às boas práticas quanto ao uso de gases medicinais em ambiente hospitalar. **Métodos:** O estudo de desenvolvimento metodológico e validação de conteúdo foi realizado no período de maio a novembro de 2018 e compreendeu três etapas distintas: (I) elaboração do instrumento de avaliação do cumprimento das boas práticas de uso de gases medicinais em ambiente hospitalar; (II) validação de conteúdo do instrumento pela técnica de grupo nominal; e (III) classificação de cada padrão com base nas categorias de desempenho e suas respectivas pontuações. **Resultados:** Foi elaborado um instrumento com 54 “padrões de conformidade”, dividido em dois domínios: estrutura (29) e processo (25). No teste de avaliação de aplicabilidade, o instrumento obteve 100% de concordância quanto à sua utilidade na prática hospitalar. Quatro categorias de desempenho foram definidas: satisfatório com excelência, satisfação, pouca satisfação e insatisfatório. **Conclusão:** O instrumento obteve avaliação satisfatória entre os especialistas quanto ao conteúdo, bem como a classificação de cada padrão de conformidade segundo criticidade, pontuação e categorias de desempenho. Dessa forma, foi gerado um instrumento pioneiro de acordo com protocolos nacionais e internacionais de avaliação de boas práticas quanto ao uso de gases medicinais em hospitais. O instrumento desenvolvido pode contribuir para a segurança do paciente e reduzir custos com saúde.

Palavras-chave: Validação; Gases medicinais; Boas práticas.

Introduction

In 1992, France recognized gases or mixtures of medicinal gases as medicines or medical devices, followed by the European Union, Asia, and the Americas¹⁻³. Since then, medicinal gases have been used in disease diagnosis, as life support, and for the treatment and prevention of diseases, such as hypoxemic respiratory failure caused by the SARS-CoV-2 virus⁴. These gases are prescribed as anesthetics, analgesics, drug vehicles, and pneumatic energy sources for surgical and dental instruments^{2,5}.

In hospitals, healthcare professionals must be trained in accordance with good practices regarding the use of medicinal gases to be able to monitor their use and provide adequate management of these drugs in patient care⁶⁻⁸. However, audits suggest that the administration of medicinal gases, such as oxygen, by healthcare professionals is not compatible with international protocols^{9,10}. According to the literature, these gases may cause adverse events, thereby requiring extensive attention from production to use^{11,12}.

For example, the audits highlight that oxygen is often prescribed without clinical recommendations and is used incorrectly (i.e., without titration and due monitoring); patients may thus be exposed to high doses, which are associated with clinical complications, ultimately increasing costs and wasting this essential medicine for maintaining life^{13,11,14}. To avoid such problems, it is necessary to periodically evaluate the quality of pharmaceutical services (structure, processes, and results), identify problems, and propose interventions, with the active participation of those involved^{15,16}.

Although pharmacists are legally responsible for the management of medicinal gases in several countries, guidelines and instruments for assessing their work processes are scarce^{8,17,3}. In 2008, Brazil began regulating medicinal gases as medicines, with the pharmacist as the professional responsible for their management. However, little is known about compliance with good practices in hospitals, among other reasons for the lack of specific assessment instruments¹⁸⁻²⁰. This is relevant because the use of gases, such as oxygen, is one of the main resources for the treatment of patients with more severe forms of COVID-19^{21,4}. Therefore, this study aimed to validate an instrument for assessing compliance with good practices regarding the use of medicinal gases in hospitals.

Methods

A methodological development study of the type development and content validation was carried out from May to November 2018 and was comprised of three distinct stages: development of the instrument to assess compliance with good practices regarding the use of medicinal gases in hospitals; validation of the content of the instrument using the nominal group technique, which seeks consensus on the opinions of a group of experts for decision-making^{22,23} and classification of each standard based on performance categories. This categorization was carried out in three stages: (I) assessment of the degree of criticality of each compliance standard by a panel of experts; (II) submission of the instrument to pharmaceutical professionals from 26 Brazilian states and the Federal District to assess the degree of criticality of each compliance standard followed by a comparative analysis with the initial classification; and (III) definition of the performance categories and their respective scores regarding compliance with good practices for the use of medicinal gases in hospitals.

Stage I – Development of the instrument

The instrument was developed based on the identification of compliance standards, which are items that can be used to assess compliance with good hospital practices regarding the use of medicinal gases and were identified after a scientific literature search (LILACS, PUBMED/Medline, Scielo, EMBASE) using the following descriptors: “Medicinal Gases”, “Good Practices”, “Hospitals”, “Hospital Pharmacy Service”, as well as the guidelines, manuals, and legislation recommended by national and international regulatory agencies published in or before September 2018.

The compliance standards identified were used to generate a questionnaire, thereby configuring the first version of the instrument. This questionnaire was subsequently submitted to a panel of experts who served as the nominal group for validation. Standards related to non-hospital environments were excluded.

Stage II - Validation of the instrument

The nominal group technique was used to validate the instrument ²⁴. This group consisted of a panel of experts previously defined based on the scoring criteria adapted from Fehring ²⁵, who were invited and accepted to participate in the study. At the first meeting, the participants signed a free and informed consent form and answered a questionnaire to enable characterization of the group. The panel was composed of seven professionals (CSR, RCS, GCC, SMS, JGPL, HFL, and AFSL): four females and three males; one professional between 20 and 30 years old, four professionals between 31 and 40 years old, and two professionals between 41 and 50 years old; five pharmacists, one hospital administrator, and one occupational safety engineer; three with professional experience between five and ten years, three with experience between 15 and 20 years, and one with experience between 20 and 25 years; and five worked in hospitals and two worked in health surveillance.

The meeting with the nominal group was structured as follows. Initially, the participants were introduced to the theme and the first version of the instrument. After individual reading was performed, the experts wrote their opinions about the items, and then registered and presented their ideas. After the presentation of the ideas, prioritization occurred, grouping similar ideas. To clarify the opinions and suggestions presented, a discussion was held to present reasons for agreement and disagreement regarding each item. For the instrument's content validation process, experts evaluated each conformity standard against eight criteria, which were treated as the fundamental criteria for developing a construct: simplicity, clarity, objectivity, relevance, precision, variety, credibility, and behavioral aspects, through dichotomous responses: yes and no ²⁶⁻²⁹. During the performance of the nominal group technique, the instrument was subjected to appearance evaluation: whether the format and sequence of the items were adequate and facilitated application, whether the instrument and questions were very extensive, and whether the application was tiring for the evaluator, if the terminologies used were adequate for evaluating the intended items ^{27,26,30,31}. The comprehensibility of the items was also assessed, and space was created for new suggestions for improving the instrument. Finally, experts classified the standards according to the components of health quality management (structure-process-outcome) proposed by Donabedian ³². For items that had a divergent classification among experts, a discussion was held until a consensus was reached.

The final list of items was classified in the order of priorities and recorded by the facilitator for further analysis. The responses of the experts were analyzed by calculating the concordance index. The compliance standards that obtained a low index were reformulated and/or excluded, ending the first round ^{26,33}. A new meeting of the nominal group was held and an updated version of the instrument was presented to the experts. A second round of discussion

was carried out to allow experts to evaluate the modifications made and reach a consensus. After making the proposed changes, the latest version of the instrument was submitted for applicability assessment.

Applicability of the instrument

To assess the applicability of the instrument, six hospital institutions in the state of Sergipe were selected for convenience: two public, two private, and two philanthropic hospitals. One criterion was used to select hospitals: the hospital should have a structured hospital pharmacy service with a responsible pharmacist. After the application, analyses of the instrument's functional parameters were performed, such as utility in hospital practice, presence of doubts or difficulty in linguistic interpretation of each pattern, and time of application. Participants were also asked to suggest changes to the instrument to correct the eventual usability problems. The result of this step enabled the assessment of possible changes and improvements to the instrument, including the need to include performance categories ^{34,35}.

Stage III - Development of scores and performance categories to define the level of compliance with good practices regarding the use of medicinal gases in hospitals

This stage was based on the standard setting or standard definition, which was precisely based on the method of standards referenced in the criteria ^{36,37}. Compliance standards setting procedures require expert panels to determine the acceptable minimum and are considered the most appropriate when they aim to verify that those being evaluated meet the established requirements, without any hierarchy ^{38,39}. This stage was divided into three steps to facilitate the performance of the work.

1. Classification of each compliance standard according to its degree of criticality

Based on the scoring criteria adapted from Fehring ²⁵, five pharmacists (EMSJ, FJRA, IMCB, HFL, and SMS) were selected with different professional experiences to compose the panel of experts used to define the degree of criticality of the compliance standards of the instrument. There were four research pharmacists, two hospital pharmacists, two university professors, and a health surveillance inspector.

The activity was performed in three rounds. First, the instrument was presented to the participants, including the criticality assessment tool composed of a Likert-type scale with five points that obey the following classification: 1 - item not critical, 2 - item little critical, 3 - item moderately critical, 4 - item very critical, and 5 - item extremely critical ⁴⁰.

In the second round, successive discussions were held regarding the first version of the scale, enabling a readjustment of the classification of the assessment items in a consensual manner. In the third round, which had the new classification, the experts reached a consensus on the classification of each conformity standard, according to the new version of the scale, which had three points and items classified as 1 - little critical, 2 - moderately critical, and 3 - very critical.

2. Classification of each compliance standard according to its degree of criticality by pharmacists from all Brazilian states

Based on the concept proposed by Campbell and Stanley apud Isaac and Michael ⁴¹, which defines the extent to which the results of a study (regardless of whether the study is descriptive or experimental) can be generalized and be reflective of its external validity, a

consultation was performed with 27 pharmacists working in hospital pharmacies in the 26 Brazilian states and the Federal District.

To verify whether the differences in experiences and training of the participants and whether regional differences of a country of continental proportions, such as Brazil, could influence the interpretation of the degree of criticality of the studied standards, professionals were invited (convenience sample). For this stage, a discussion to reach a consensus among the participants was not foreseen. Instead, the aim was to carry out a comparative analysis of the national classification with that carried out by the local panel. If there were discrepancies, the panel would meet and reassess the rating.

After confirming participation, the guests completed the informed consent form and the questionnaire used for characterizing participants. Thereafter, they evaluated the 54 standards of conformity of the instrument according to the classification based on the criticality of the item (i.e., 1, 2, and 3), as performed by other participants. Local experts also performed the above tasks. The data were then tabulated in an Excel[®] spreadsheet and subsequently analyzed statistically.

3. Definition of scores and performance categories regarding the compliance standards for good practices regarding the use of medical gases in hospitals

The scores and performance categories for assessing compliance with good hospital practices regarding the use of medicinal gases were developed by adapting the forced distribution assessment system (through absolute classification) at the institutional level, in association with assessment methods proposed by national and international hospital accreditation⁴²⁻⁴⁴.

Accordingly, four categories of performance were defined: “satisfactory with excellence”, when the hospital complies with or exceeds 90% of the most critical standards and 100% of the least critical standards; “Satisfactory”, when the hospital meets between 80% and 90% of the most critical standards and meets or exceeds 70% of the least critical standards; “Moderately satisfactory”, when the hospital meets or exceeds 70% of the most and least critical standards; and “unsatisfactory”, when the hospital meets less than 70% of the most critical and/or least critical standards.

The panel of experts met only once to analyze the national contribution to the classification for the criticality of each standard, and to re-discuss each item until a consensus was reached, when necessary. The panel then met to validate the proposition of the scores and the respective categories of performance. For this validation, the panel received a questionnaire from the mediator to express their level of agreement with each statement using a 5-point Likert scale (ranging from 1 (strongly disagree) to 5 (strongly agree))⁴⁵. All classifications and scores were discussed (i.e., not only items with a content validity index (CVI) lower than 0.80, but all items were discussed). Two rounds of panel discussions were necessary until all adjustments were made, and a consensus was reached.

The performance categories apply to each section of the instrument and its entirety; thus, the final assessment of the assessed institution will consist of a classification from the structure section, another from the process section, and a general classification, which includes both sections. To facilitate the interpretation of the results, colors were assigned to the performance categories by adapting the risk classification proposed by the Manchester protocol⁴⁶.

Statistical analysis

The data were tabulated in a Microsoft Excel® 2013 spreadsheet and analyzed statistically. Content was evaluated by determining the CVI and interrater reliability index (IRI). Content was considered valid when the CVI ≥ 0.80 and the IRI was good or very good according to the consensus strength scale (0.00 to 0.20 = poor, 0.21 to 0.40 = weak, 0.41 to 0.60 = moderate, 0.61 to 0.80 = good, 0.81 to 1.00 = very good) (26,30,47-49).

Appearance and applicability were analyzed using descriptive statistics. The expert committee agreement rate was calculated by dividing the number of experts who agreed with the total number of judges $\times 100$, with a 90% agreement deemed acceptable (50,33,31). For the development of scores, during the phase of defining the criticality levels of each standard by the panel of local and national experts, the CVI was used for each item, each section, and the instrument (considered acceptable with an index ≥ 0.80). To assess interobserver agreement, the Kappa coefficient of agreement (ranging from -1 to 1) was applied, with its interpretation agreed upon: 0 (absence), 0 - 0.19 (poor), 0.20 - 0.39 (weak), 0.30 - 0.59 (moderate), 0.60 - 0.79 (substantial), and ≥ 0.80 (almost complete)] and the IRA. In the classification phase by national guests, the average criticality score was used for each proposed item (considering the classification closest to the calculated average; if there is a discrepancy with the initial classification, the item should be returned for discussion among the panel of experts from the previous step) ^{47,48,51}.

For the final assessment of the scores and standards of the performance categories, the level of agreement of the experts was assessed according to the result of applying the Likert-type scale, analyzed using the CVI (≥ 0.8) and the IRI (> 0.61). To calculate the CVI of the items, the total number of judges who selected four or five on the scale was divided by the total number of judges. The study was approved by the Research Ethics Committee of the Federal University of Sergipe (report number: 3.709.534 (CAAE- 22984119.9.0000.5546), respecting Resolution 466/2012 of the National Ethics and Research Committee, which provides insights regarding human studies.

Results

After conducting a literature search, 70 compliance standards were identified, which assessed compliance with good hospital practices regarding the use of medicinal gases and served as the first version of the instrument ^{8,52-59}. The content of this prototype was evaluated by a panel of experts.

The compliance standards, according to the triad proposed by Donabedian ³², were classified into structure (34 items; 48.6%) and process (36 items; 51.4%). No standard was classified in the outcome domain; thus, an evaluation instrument comprising of only two sections (structure and process) was proposed. The content evaluation was carried out for each section, presenting a CVI of 0.90, and is described in Tables 1 and 2.

The compliance standards related to good practices regarding the use of medicinal gases in hospitals and the analysis of agreement between the judges are shown in Table 1 (structure section) and Table 2 (processes).

After two rounds of discussion among the nominal group, suggestions for changes and evaluations were assessed. After extensive discussion and consensus building among the judges, 54 of the initial 70 standards were retained in the version of the instrument subjected to assessment for applicability, 29 of which were of structure and 25 of process.

In this study, 12 items (17.14%) had a CVI below 0.80. Some of these standards were excluded from the instrument because they were covered by other similar standards or needed

a new wording; this was performed after a consensus was reached among experts (Table 3). Other excluded items, although having a CVI above 0.80, were excluded as the specialists understood that they were included in other standards or should be added to others due to their similarities.

The assessment of the instrument's appearance included questions regarding the adequacy of the format, terminology used, applicability, and the order of the standards of conformity in the instrument (Table 4). During the evaluation of the instrument, the experts did not suggest any adjustment to its structure, but proposed a change in the sequence of the questions to provide items that dealt with the same subject in a consecutive manner.

The instrument was then subjected to the applicability assessment test in six hospitals in the state of Sergipe (two private, two philanthropic, and two public hospitals). However, the public hospitals did not respond. Among the participating hospitals, three were medium-sized, and three were large. The instrument was applied by seven different professionals, five pharmacists, a clinical engineer, and a maintenance officer between ages 26 and 45 years, and professional experience between four and 12 years. The average time spent applying the instrument was 18 min. Only one professional did not understand the text of four standards (10, 14, 15, and 53) due to a lack of knowledge regarding the technical terms, resulting in a 99% agreement rate. All agreed on the usefulness of the instrument analyzed in hospital practice, and none suggested changes.

The classification of each standard of conformity for the final version of the instrument according to its degree of criticality, the CVI resulting from the classification carried out by the panel of experts, and the CVI and the average of the classification derived from the evaluation carried out by professionals from all states of Brazil and the Federal District, are described in Tables 5 (structure section) and 6 (process section). Standards with a CVI lower than 0.80 were discussed by experts until a consensus was reached. For the national assessment, the panel met again to discuss standards with a CVI lower than 0.80; however, the initial classification was retained as it represented the assessment of most participants. Further, the average of the classifications was compatible with the initial classification proposed by the panel.

The assessment of the degree of criticality of the compliance standards by the local panel of experts and the national assessment resulted in CVI values (referring to the entire instrument) of 0.87 and 0.88, and Kappa coefficient values of 0.69 (substantial agreement) and 0.70 (substantial agreement), respectively. In parallel, the IRI for the instrument was 0.78, which is considered a good level of agreement.

The assessment of the scores for compliance with good practices regarding the use of medicinal gases in hospitals and their respective performance categories, as well as changes made after a consensus was reached by experts, are shown in Table 7.

Table 8 shows the final version of the performance categories and their respective scores after the second round of panel discussion. This also includes the colors defined for each performance category.

Discussion

Medicinal gases constitute one of the most recent pharmacotherapeutic groups included in the list of hospital pharmacist intervention activities^{3,60,61}. Similar to any medicine, the risks associated with its use must be considered and, consequently, an appropriate process of use in the hospital environment must be implemented, guaranteeing the safety of professionals and patients, with lower care cost⁶⁰. This necessitates the use of specific assessment instruments and quality management tools, which can serve as a reference for the planning, training, execution, and monitoring of professional practices^{60,62,15,17}.

In the literature, there are instruments used to evaluate good hospital pharmacy practices in general; however, to our knowledge, none of these instruments apply to medicinal gases

^{17,62,63}. On the other hand, studies that presented evaluations related to medicinal gases highlighted consumption and cost or described only the activities or responsibilities when these medicines are applied as an assistive treatment ^{3,6,10}. Thus, the instrument developed and validated in this study was designed to contribute to the routine compliance of hospital pharmacists with good practices regarding the use of medicinal gases and to fill the gap in the literature.

For the development of instruments, studies have mentioned bibliographic research as the most used strategy, such as the triangulation of methods, including literature review, interviews, and focus groups; when instruments already exist in other countries, a cross-cultural adaptation strategy is employed ^{33,64-66}. According to Silver *et al.* ⁴⁵, development is a rigorous process that is based on the generation of items, with content validation using expert feedback and a pre-test. Owing to a lack of instruments for this purpose, this study established and validated a tool based on information identified in the literature and national and international standards.

For the instrument validation process, the nominal group technique was selected instead of the Delphi technique as it presents a final result in the short term, even if there is disagreement among specialists. Of note, this method allows the resolution of divergent opinions through a consensus reached for each item of the instrument via a debate among the invited experts ^{24,27,33}. Therefore, the use of this technique proved to be favorable for the construction of the instrument, as the consensus for maintenance, modification, or exclusion of the items facilitated the development of a more reliable instrument in its final version.

Despite the longevity of national and international legislation, there are still few pharmacists working in this area, especially in Brazil. As a result, the use of the criteria adapted from Fehring ²⁵ was the most rigorous approach for establishing a panel of experts. Notably, the groups of experts in this study had a number of participants and characteristics similar to those described in the literature ^{23,67,37}. In practice, the definition of specialists, considering professionals from different backgrounds with a high degree of qualification and different lengths of professional experience, contributed to the quality of the final product.

Dargahi and Khosravi ⁶⁸ recommend that an instrument of this nature should be subdivided into three sections: structure, process, and result, which are elements of health quality assessment that make up the triad proposed by Donabedian ³². In this study, experts did not classify compliance standards identified in the literature as result indicators; thus, the instrument developed and validated only had two sections (structure and process). Therefore, future studies with medicinal gases should prioritize the inclusion of outcome indicators that can serve as a reference for hospital pharmaceutical practice.

In the content assessment, most of the instrument compliance standards had a CVI value ≥ 0.80 . However, some standards, such as the 17th structure (i.e., is the area for medical gas tanks suitable for the activities carried out?) and the 25th process (i.e., is the use of cylinders with confirmed leakage discontinued?), achieved a relatively low rating compared to other studies that evaluated themes common to the pharmacist's routine, reinforcing the benefits of a consensus among specialists in a short timeframe ^{24,33,69,70}. Thus, the main contribution of this stage is related to the way the items were built and the indicators that needed improvement ⁶². McMillan *et al.* ²⁴ highlighted that the ideas of all participants must be discussed, allowing them to make the best decision and reach a consensus.

The literature presents studies with validated content based on only four criteria ³³. However, this study used eight criteria that were considered fundamental for the proper elaboration of a construct proposed by Pasquali ²⁸, thereby increasing the complexity of the evaluation and the robustness of the results. Based on the premise that validity is a characteristic supported by degrees of evidence and determined to the extent that the evidence exists, the instrument proposed in this study was considered valid in terms of its content. Accordingly, it

should be used to guide pharmacy activities in the management of medicinal gases and contribute to the promotion of patient safety.

The analysis carried out in the appearance evaluation revealed that the developed instrument has a compatible format (disposition of questions) for the proposal and uses of appropriate terminologies, even for those who do not work routinely with medicinal gases, thereby making its use less tiring and more feasible. According to the literature, appearance validation means that the instrument must be related to what is being proposed and show agreement between the specialists regarding the wording of the items and their form of application, which should be improved by the specialists when relevant ^{30,31}. In addition, Echevarría-Guanilo *et al.* ⁷¹ stressed that the instruments must be objective and dynamic, with a short application time. Therefore, the developed instrument has satisfactory psychometric characteristics, but needs to be further tested in other real conditions to assess specificity, reliability, and stability ^{72,73}.

In this validation, the applicability measurement test was necessary to obtain the opinions of hospital pharmacists, and in their absence, of other professionals regarding the functional aspects of the management of medicinal gases. In this test, the instrument showed excellent agreement in terms of understanding the text of the standards and usefulness in the hospital environment. Other studies on the validation of instruments capable of measuring structure and processes in pharmaceutical services also evaluated the adequacy of the items and the format of the instrument ^{62,74,75}. However, Rocha *et al.* ⁶⁹ suggest that although not all content validation studies include this test, its absence could be a weak point. Therefore, employing this test gave greater methodological rigor to the study, favoring a more concrete assessment of the proposed items.

In this study, the time spent on applying the instrument was short, but markedly varied among the participants. This can be justified by studies by El-Hmoudova ⁷⁶ and Santos and Mognon ⁷⁷, who showed that people with a reflective learning style need more time to assess the information received. Despite the variation, the time spent on the application did not influence the quality of the final result, suggesting that it will not interfere in the decision making of hospital managers regarding the adequacy of the structure and processes in the institutions they represent, avoiding a waste of time and resources to solve problems that may arise due to non-compliance with good practices.

Given the number of compliance standards proposed by the instrument, it is natural that some are more critical than others and that failure to comply with these standards can have a negative impact on the reestablishment of the health of health service users. This forced the definition of scores and performance categories. Of note, the scores and categories were developed based on the criteria used in health service assessment instruments for classifying the criticality of each item of the instrument carried out locally and across the country, with the final assessment carried out by a panel of experts. This was corroborated by Kannan *et al.* ⁷⁸, who emphasized the need to rethink the scoring approach and the need to adopt a more realistic, rational, reproducible, and generalizable approach. Ultimately, a situation that provides health service managers with decision-making based on scientific evidence is warranted.

Although institutions can be ranked based on scores and performance categories, this was not the objective of the development of this instrument. Thus, it was appropriate to use the method of defining standards referenced in criteria or absolutes, which, according to Norcini ³⁹, seeks to verify that who is being evaluated meets the established requirements, regardless of the results of the other participants. Therefore, the proposed instrument enables situational diagnosis to be independently carried out for each institution, providing adequate planning to

derive the adequacy of the institutions' structure and processes, thereby promoting better working conditions and patient safety.

The result of the classification defined by the panel of experts for each conformity standard according to its degree of criticality was very close to the national assessment. No standard of compliance was rated as having low criticality in the assessments. Of the standards assessed with CVI <0.80, which were discussed by the panelists until a consensus was reached, most of these standards presented a higher CVI result in the national assessment. Such finding reinforces the importance of using specialists to allow panel members to reconsider their position after the arguments of other participants are proposed, to ultimately reach the best classification (36). In parallel, only one standard of conformity of the structure section and the other of the process section presented CVI in the national assessment equal to or less than that proposed by the panel of experts. These standards were re-discussed by the panel of experts; however, their classification was retained as the result represented the opinion of most participants in the national evaluation and the average value appeared close to the value for the classification initially proposed by the specialists. The data show that the proposed instrument is realistic and can be reproducible and generalizable, as proposed by Kannan *et al.* ⁷⁸. In addition to the CVI, the IRI and Kappa coefficients were used to assess the agreement between experts from the local and national panels. This combination of measures of agreement aligns with the strategy of Perroca ⁷⁹, who drew attention to the limitations of the Kappa coefficient, which they proposed should not be used as a single measure of agreement. The study revealed similar results in both methods, with good agreement between the evaluators.

The definition of scores and performance categories through the adaptation of the system of evaluation by forced distribution, more precisely by the absolute classification, was used; this is because the proposed instrument does not require application in several institutions to enable the comparison of results among them, compared with the relative classification. Individual performance was assessed against a predetermined standard ^{42,80}. The integration of the assessment methods proposed by national and international hospital accreditation systems is essential for defining the compliance percentages for each score. Despite the use of these methods for the definition of scores and performance categories, the discussions were quite intense, argumentative, and analytical. Despite a high level of agreement among specialists in most of the items analyzed, the need for definitions was observed with more than one score for the categories of satisfactory and unsatisfactory performance. Furthermore, the critical items should be considered in the definition of each category (non-compliance can have a stronger negative impact on patient safety and care costs).

At the end of the study, the developed instrument presented standards of conformity for the structure and process sections that address the receipt, storage, and distribution for pharmacovigilance in the use of medicinal gases. The instrument can be used by pharmacists and managers to promote structural and procedural adjustments, promote specific training, and corroborate the recommendations of the adopted theoretical framework ^{3,8,60}. Its use can guide decision-making processes based on systematic evaluations, ultimately reducing uncertainties regarding the effectiveness and resolution of actions, which can occur when there are no appropriate tools ^{32,81}. Thus, the instrument developed and validated in this study could contribute to compliance with good hospital practices regarding the use of medicinal gases.

Owing to more complex activities, the increased importance of hospital pharmacy in hospital management; the promotion of patient safety; the guarantee of the most appropriate, rational and comprehensive pharmacotherapy; and the lack of instruments in the literature to promote the support of hospital pharmacists regarding compliance with good practices for the routine use of medicinal gases, the ABPGasMed 1.0 instrument was established. This

instrument, which has been utilized since 2018, arrives at an opportune time with the new coronavirus pandemic. Furthermore, it is expected to be employed to qualify the pharmacy services of hospitals globally and contribute to the reduction of care costs, the quality of services, and the promotion of patient safety.

This study had the following strengths: it assumed a pioneering spirit regarding the development of an instrument that assesses good hospital practices regarding the use of medicinal gases; specialists on the panel were knowledgeable about the practice of hospital pharmacy and worker safety, and the area of sanitary inspection; all standards that initially presented a low level of agreement among experts were discussed until a consensus was reached; and professionals from all Brazilian states participated in the classification of standards of conformity based on criticality. The study also had limitations. In the evaluated literature, no result compliance standards were identified. Consequently, the developed and validated instrument did not include clinical, economic, and humanistic aspects related to compliance with good practices regarding the use of medicinal gases. Future studies may propose result indicators and should involve specialists from several countries, with greater expertise regarding medicinal gases, thereby enabling the internationalization of the instrument.

Conclusion

The instrument developed and validated in the present study to evaluate good practices regarding the use of medicinal gases contemplates the standards of compliance that must be evaluated and be adequate in any hospital. The instrument was found to be satisfactory among the experts based on its content and the classification of each conformity standard according to criticality in the defined scores and performance categories. Accordingly, this pioneering instrument, ABPGasMed 1.0, was generated in accordance with national and international protocols, as well as international standards. Ultimately, this instrument is considered to be an innovative tool for guiding the role that pharmacists play in this area, especially in the current situation where medical oxygen is vital for maintaining the lives of patients with COVID-19.

Future studies could verify the quality and reliability of the instrument, propose strategies to help improve the pharmaceutical management of medicinal gases at the outpatient and home levels, and propose new compliance standards for inclusion in the instrument.

Acknowledgments

To the administration of the public, private, and philanthropic hospital institutions in the state of Sergipe and panel of experts who agreed to participate in the study.

Funding

This work was supported by Coordination of Superior Level Staff Improvement (CAPES).

Conflict of interests

The authors declare that they have no conflicts of interest.

REFERENCES

1. Poitou P, Fouret C, Duffau E. Regulations on gases for medical use in France. *Ann Pharm Fr.* 2002;60(5):326–32.
2. Soni N, Maheshwari DG. Overview of regulatory requirements for medical gases and pharmaceutical gases. *Inter Journal of Res in Pharm and Pharma Sciences.* 2017;2(6): 61-64.
3. Luisetto M, Sahu RK. Hospital Medicine Gas Management System: The Pharmacist Role in a Pharmaceutical - Chemistry Setting-Results of a Practical Experience in an Advanced Country. *Adv Bioeng Bio Sci Res.* 2019;2(3):1–10.
4. Calligaro GL, Lallac U, Audleyd G, Gina P, Miller MG, Mendelson M et al. The utility of high-flow nasal oxygen for severe COVID-19 pneumonia in a resource-constrained setting: A multi-centre prospective observational study. *E Clin Med.* 2020;28:100570.
5. De-Juilio PA, Jenkins MB, Huml JP. Evaluation of Safety and Cost of an Open-Design Oxygen Mask in a Large Community Hospital. *Resp care.* 2018;63(4):412–416.
6. Sangiorgi E, Carati D, Mazzolani M, Mazzetti I, Fraticelli A. Safety Management of Medical Gas Plants in Healthcare Structures of the Emilia Romagna Region. *Ital J of Clin Pharm,* 2015.
7. Herve-Bazin M, Durand D, Cardona F, Maison P. Medication errors related to the administration of medicinal gases in France: one of the 12 french never events. *Congreso de la Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM).* 2016.
8. Associação Portuguesa das Empresas Químicas - APEQ. Manual hospitalar: boas práticas de gestão de gases medicinais. 1ªed. Lisboa: APEQ; 2017. Portuguese.
9. Salah M, Osman H, Hosny O. Performance-Based Reliability-Centered Maintenance Planning for Hospital Facilities. *J. Perform. Constr. Facil.* 2018;32(1):1–7.
10. Gómez-Chaparro M, García-Sanz-Calcedo J, Márquez LA. Analytical Determination of Medical Gases Consumption and Their Impact on Hospital Sustainability. *Sustainability.* 2018;10(8):2948.
11. Kamran A, Chia E, Tobin, C. Acute oxygen therapy: an audit of prescribing and delivery practices in a tertiary hospital in Perth, Western Australia. *Internal medicine journal.* 2018; 48(2):151–157.
12. Hatling D, Hogset A, Guttormsen AB, Müller B. Iatrogenic cerebral gas embolism: A systematic review of case reports. *Acta Anaest Scand.* 2019;63:154–160.
13. Gunathilake R, Lowe D, Wills J, Knight A, Braude P. Implementation of a multicomponent intervention to optimise patient safety through improved Oxygen prescription in a rural hospital. *Aust. J. Rural Health.* 2014;22:328–333.
14. Rioseco PS, Rodríguez NO, Skog SM, Rozas, EC, Sepúlveda AN. Auditoría de oxigenoterapia de pacientes hospitalizados en establecimientos del Servicio de Salud Talcahuano. *Rev Chil Enferm Resp.* 2017;33:91–98.
15. Salamano M, Palchik V, Botta C, Colautti M, Bianchi M, Traverso ML. Seguridad del paciente: aplicación de gestión de calidad para prevenir errores de medicación en el circuito de uso de medicamentos. *Rev Calid Asist.* 2013;28(1):28–35.

16. Lasomsri P, Yanbuaban P, Kerdpoca O, Ouypornkochagorn T. A Development of Low-Cost Devices for Monitoring Indoor Air Quality in a Large-Scale Hospital. 15th ICEE.2018.
17. Sociedade Brasileira de Farmácia Hospitalar – SBRAFH. Padrões mínimos para farmácia hospitalar. São Paulo: SBRAFH; 2017. Available from: www.sbrafh.org.br/site/public/docs/padros.pdf
18. Conselho Federal de Farmácia – CFF. Resolução N° 470: Regula as atividades do Farmacêutico em gases e misturas de uso terapêutico e para fins de diagnóstico. Brasil. CFF. (28 de março de 2008).
19. Agência Nacional de Vigilância Sanitária – ANVISA. RDC n° 69: Dispõe sobre as Boas Práticas de Fabricação de Gases Medicinais. Brasil. (1° de outubro de 2008a).
20. Agência Nacional de Vigilância Sanitária – ANVISA. RDC n° 70: Dispõe sobre a notificação de Gases Medicinais. Brasil (1° de outubro de 2008b).
21. World Health Organization (WHO). COVID-19 Clinical management Living guidance. WHO, January 2021.
22. Bohren MA, Vogel JP, Fawole B, Maya ET, Maung TM, Baldé MD, et al. Methodological development of tools to measure how women are treated during facility-based childbirth in four countries: labor observation and community survey. *BMC Med Res Methodol.* 2018;(18)132:1–15.
23. Catunda HLO, Bernardo EBR, Vasconcelos CTM, Moura ERF, Pinheiro AKB, Aquino PS. Percurso metodológico em pesquisas de enfermagem para construção e validação de protocolos. *Texto Contexto Enferm*, 2017; 26(2):1–10.
24. McMillan SS, King M, Tully MP. How to use the nominal group and Delphi techniques. *Int J Clin Pharm.* 2016;38:655–662.
25. Fehring R.J. Methods to validate nursing diagnoses. *Heart Lung.* 1987;16(6):625–9.
26. Bellucci-Júnior JA, Matsuda LM. Construction and validation of an instrument to assess the reception with risk rating. *Rev Bras Enferm.* 2012;65(5):751–757.
27. Crocker L. Content Validity. *International Encyclopedia of the Social & Behavioral Sciences.* Elsevier. 2015;2(4): 2702–2705.
28. Pasquali L. Instrumentação psicológica: Fundamentos e práticas. Porto Alegre, Brasil: Artmed, 2010.
29. Pasquali L. Princípios de elaboração de escalas psicológicas. *Revista de Psiquiatria Clínica.* 1998;25(5):206–213.
30. Mousazadeh S, Rakhshan M, Mohammadi F. Investigation of Content and Face Validity and Reliability of Sociocultural Attitude towards Appearance Questionnaire-3 (SATAQ-3) among Female Adolescents. *Iran J Psychiatry.* 2017;12(1):15–20.

31. Zamanzadeh V, Ghahramanian A, Rassouli M, Abbaszadeh A, Alavi-Majd H, Nikanfar A. Design and Implementation Content Validity Study: Development of an instrument for measuring Patient-Centered Communication. *J Caring Sci.* 2015;4(2):165-178.
32. Donabedian A. Basic approaches to assessment: structure, process and outcome. Michigan: Health Administration Press; 1980.
33. Cerqueira-Santos S, Rocha KSS, Boaventura TC, Jesus SEM, Silvestre CC, Sodré-Alves BMC, et al. Development and content validation of an instrument to document the dispensing of prescribed medicines. *J Clin Pharm Ther.* 2019;1-10.
34. Coluci MZO, Alexandre NMC, Milani D. Construction of measurement instruments in the area of health. *Ciência & Saúde Coletiva.* 2015; 20(3):925-936.
35. Vedam S, Rossiter C, Homer CSE, Stoll K, Scarf VL. The ResQu Index: A new instrument to appraise the quality of research on birth place. *PloS one.* 2017;12(8):e0182991.
36. Zumbo BD. Standard-setting methodology: Establishing performance standards and setting cut-scores to assist score interpretation. *Appl. Physiol. Nutr. Metab.* 2016;41:S74-S82.
37. George S, Haque MS, Oyebode F. Standard setting: Comparison of two methods. *BMC Medical Education.* 2006;6:46.
38. Bandaranayake RC. Setting and maintaining standards in multiple choice examinations: AMEE Guide No. 37. *Med Teach.* 2008;30:836-845.
39. Norcini JJ. Setting standards on educational tests. *Med Educ.* 2003;37:464-469.
40. Angell CM, Woldetsadik MA, McDaniel JT, Armstrong NJ, Young BB, Linsner R.K, Pinter JM. Confirmatory Factor Analysis of the Enriched Life Scale Among US Military Veterans. *Front in Psychol.* 2019.
41. Isaac S, Michael WB. Handbook in research and evaluation: A collection of principles, methods, and strategies useful in the planning, design, and evaluation of studies in education and the behavioral sciences. California: Edit publishers. 1971.
42. Chattopadhyay R. Impact of Forced Distribution System of Performance Evaluation on Organizational Citizenship Behaviour. *Global Business Review.* 2017; 20(3):1-12.
43. Manual Brasileiro de Acreditação: Serviços para a Saúde – Selo de Qualificação ONA. ONA; 2020.
44. JCI. Consórcio brasileiro de acreditação (CBA). Joint Commission International (JCI). Padrões de Acreditação da Joint Commission International para hospitais. 4. ed. Rio de Janeiro: CBA; 2010.
45. Silver NC, Badenes-Ribera L, Pedroli E. Scale Development and Score Validation. Lausanne: Frontiers Media SA. 2020.
46. Roncalli AA, Oliveira DN, Silva ICM, Brito RF, Viegas SMF. Manchester protocol and user population in the risk assessment: the nurse's view. *Rev. Bai Enfer.* 2017;31(2):e16949.

47. Almanasreh E, Moles R, Chen TF. Evaluation of methods used for estimating content validity. *Res Social Adm Pharm.* 2019;15(2):214–221
48. O'Neill TA. An Overview of Interrater Agreement on Likert Scales for Researchers and Practitioners. *Frontiers in Psychology.* 2017;8:1-15.
49. James LR, Demaree RG, Wolf G. An Assessment of Within-Group Interrater Agreement. *J of Appl Psychol.* 1993;78(2)306–309.
50. Alexandre NMC, Coluci MZO. Content validity in the development and adaptation processes of measurement instruments. *Cien Saude Colet.* 2011; 16(7):3061–3068.
51. Gorostiaga A, Aliri J, Ulacia I, Soroa G, Balluerka N, Aritzeta A, et al. Assessment of Entrepreneurial Orientation in Vocational Training Students: Development of a New Scale and Relationships With Self-Efficacy and Personal Initiative. *Front. Psychol.* 2019;10:1125.
52. The American Institute of Architects Academy of Architecture for Health - AIA. Guidelines for design and construction of hospital and health care facilities. 2001.
53. Argentina. Ministerio de Salud. Resolución 1130/2000: Apruébase el Reglamento para la fabricación, importación, comercialización y Registro de gases medicinales. (15 de diciembre de 2000).
54. Brasil. Agência Nacional de Vigilância Sanitária – ANVISA. Resolução - RDC n ° 50: Dispõe sobre o regulamento técnico para planejamento, programação, elaboração e avaliação de projetos físicos de estabelecimentos assistenciais de saúde. Brasil (21 de fevereiro de 2002).
55. European Medicines Agency - EMEA. Guideline on medicinal gases: pharmaceutical documentation. including recommendation on nonclinical safety requirements for well established medicinal gases. EMEA. London; 2008.
56. European Union. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). *Official Journal.* 2000;262:21–45.
57. The facility guidelines institute - FGI. Guidelines for design and construction of health care facilities. 2010.
58. French Red Cross. A source of design reference standards: handbook to build an hospital. Maldives. 2006.
59. Autoridade Nacional do Medicamento e Produtos de Saúde, I.P - INFARMAD. Circular informativa infarmed nº236/CD: Sistemas para a distribuição de gases medicinais. Lisboa, 2012.
60. Amor-García MA, Ibáñez-García S, Díaz-Redondo A, Alonso AH, Sáez MS. Estrategia multidisciplinar para reducir errores en el uso de los gases medicinales. *Farmacia Hospitalaria.* 2018;42(3):103–7.
61. Food and Drug Administration - FDA. Compliance program guidance manual: compressed medical gases. 2015.

62. Jesus EMS, Onozato T, Cardoso AV, Santana RS, Santos AS, Silva DT, et al. Development and validation of a hospital pharmaceutical services assessment tool. *Rev. Bras. Farm. Hosp. Serv. Saúde*. 2015; 6(4):6–11.
63. Joint Commission International. Joint Commission International accreditation: standards for hospitals. 2017; 6^a ed.
64. Epstein J, MiyukiSanto R, Guillemin F. A review of guidelines for cross-cultural adaptation of questionnaires could not bring out a consensus. *J of Clin Epid*. 2015; 68(4):435–441.
65. Li J, Denise L, Li Y, Luo Y. Development and initial validation of a clinical measure to assess early symptoms of post-stroke depression in the acute stroke patient. *J Clin Nurs*. 2018;27(3-4):784–794.
66. Sureda X, Espelt A, Villalbí JR, Cebrecos A, Baranda L, Pearce J, Franco, M. Development and evaluation of the OHCITIES instrument: assessing alcohol urban environments in the Heart Healthy Hoods project. *BMJ Open*. 2017;7:e017362.
67. Vargas-Porras C, Roa-Diaz ZM, Barnes C, Adamson-Macedo EM, Ferre-Graul C, Molina-Fernandez MI. Psychometric properties of the spanish version of the perceived maternal parenting self-efficacy (PMP S-E) tool for primiparous women. *Mater and child health j*. 2020;24(5):537–545.
68. Dargahi H, Khosravi SH. Hospitals pharmacy quality assurance system assessment in Tehran University of Medical Sciences, Iran. *Iranian J Publ Health*. 2010; 39(4):102–113.
69. Rocha KSS, Santos SC, Boaventura TC, Santos-Júnior GA, Araújo DCSA, Silvestre CC, et al. Development and content validation of an instrument to support pharmaceutical counselling for dispensing of prescribed medicines. *J Eval Clin Pract*. 2020;26:134–141.
70. McBride AJ, Pates R, Ramadan R, McGowan C. Delphi survey of experts' opinions on strategies used by community pharmacists to reduce over-the-counter drug misuse. *Addiction*. 2003; 98:487–497.
71. Echevarría-Guanilo ME, Gonçalves N, Romanoski PJ. Psychometric properties of measurement instruments: conceptual bases and evaluation methods – part I. *Texto Contexto Enferm*. 2017;26(4):e1600017.
72. Asunta P, Viholainen H, Ahonen T, Rintala P. Psychometric properties of observational tools for identifying motor difficulties – a systematic review. *BMC Pediatrics*. 2019;19:322.
73. Souza AC, Alexandre NMC, Guirardello EB. Psychometric properties in instruments evaluation of reliability and validity. *Epidemiol. Serv. Saude*. 2017;26(3):649–659.
74. Gonçalves AMRF, Campos MSA, Bernardes A, Gabriel CS, Pereira LRL. Development and validation of an instrument to measure the professional's knowledge of dispensing medication (CDM-51) in community pharmacies. *Plos One*. 2020; 15(3):e0229855.
75. Vo TH. Evaluation of the potential impact of pharmacist interventions: development and validation of the CLEO multidimensional tool [these]. L'Université Grenoble Alpes; 2016.

76. El-Hmoudova D. Assessment of individual learning style preferences with respect to the key language competences. *Procedia-Social and Beh Sci.* 2015;171:40 – 48.
77. Santos AAA, Mognon JF. Estilos de aprendizagem em estudantes universitários. *Boletim de psicologia.* 2010; 60(133): 229-241.
78. Kannan P, Sgammato A, Tannenbaum RJ, Katz IR. Evaluating the Consistency of angoff-based cut scores using subsets of items within a generalizability theory framework. *Appl. Measure. Edu.* 2015; 28:169–186.
79. Perroca MG, Gaidzinski RR. Assessing the interrater reliability of an instrument for classifying patients – kappa quotient. *Rev Esc Enferm USP.* 2003; 37(1):72–80.
80. Stewart SM, Gruys ML, Storm M. Forced distribution performance evaluation systems: Advantages, disadvantages and keys to implementation. *J of Man & Org.* 2010; 16:168–179.
81. Health and Food Safety Directorate-General. Tools and methodologies to assess the efficiency of health care services in Europe. European Union, 2019.

Tables**Table 1. Judges' agreement on the compliance standards which compose the structure domain from the application of CVI and IRA tests.**

Item	Compliance standard	CVI *	CVI **	IRA ***
1	Does the hospital have a pharmacist registered as responsible or technical reference for this activity in the local Pharmacy Council?	0.91	0,9	0,85
2	Does the hospital use transportable cylinders?	0.98		
3	Does the hospital use a central reservoir with cylinders?	0.89		
4	Does the hospital use a central reservoir by cryogenic tank?	0.93		
5	If the hospital uses the reservoir by cryogenic tank, does it have at least two reserve cylinders?	0.89		
6	Does the hospital use oxygen concentrate generators?	0.98		
7	Is the installation site of the generator or generator located above the ground? (It should never be installed underground or in building roofs)	0.93		
8	Does the installation site of the central reservoir or generator comply with the minimum distance of five meters from the building area?	0.98		
9	Does the installation site of the central reservoir or generator comply with the minimum distance of five meters from the combustible materials area or storage of flammable materials?	0.98		
10	Does the installation site of the central reservoir or generator comply with the minimum distance of five meters from an audience meeting place?	0.98		
11	Does the installation site of the central reservoir or generator comply with the minimum distance of three meters from doors or passageways that do not have a view and that give access to the storage area?	0.64		
12	Does the installation site of the central reservoir or generator comply with the minimum distance of three meters from vehicle traffic area?	0.88		
13	Does the installation site of the central reservoir or generator comply with the minimum distance of three meters from public sidewalks?	0.96		

Table 1. Judges' agreement on the compliance standards which compose the structure domain from the application of CVI and IRA tests. (continuation)

Item	Compliance standard	CVI *	CVI **	IRA ***
14	Is the installation site of the central reservoir or generator located outdoors (when it is not possible, is it in a fireproof shelter)?	0.86		
15	Is the installation site of the central reservoir or generator distant or protected from electric power transmission lines, transformers and electrical switches?	0.93		
16	Are cylinders kept away from sparks, flames and other sources of heat (maximum temperature 54°C)?	1.00		
17	Is the area for medical gas tanks suitable for the activities that are being carried out? (Depending on the number of tanks and the actual need)	0.71		
18	Is the central reservoir area (cylinders) suitable for the activities that are being carried out? (Depending on the number of cylinders and the actual need)	0.66		
19	Is the storage area dry, clean and well ventilated?	1.00		
20	If the hospital uses flammable gases (hydrogen and acetylene), are they stored at a minimum distance of eight meters from oxidizing gases (oxygen, nitrous oxide), or does it use sealed and fire-resistant barriers?	0.96		
21	In the centralized gas system, are signs used to indicate the persons authorized to have access, with the procedures to be adopted in case of emergencies, the telephone number to be used in these cases and with signs adverting to danger?	0.70		
22	Are the cylinders stored upright by a strap, chain or other similar material?	0.98		
23	Does the gas storage location have a fire extinguisher?	1.00		

Table 1. Judges' agreement on the compliance standards which compose the structure domain from the application of CVI and IRA tests. (continuation)

Item	Compliance standard	CVI *	CVI **	IRA ***
24	Is the surface, where the gas plant is located, made of non-combustible material and compatible with cryogenic temperatures?	0.88		
25	Is there sufficient lighting to provide a night view of instruments?	0.98		
26	Are the places where life support equipment is usually used provided with emergency supply for each centralized system?	0.75		
27	Does the institution use an alarm system to monitor the system?	1.00		
28	Is the installation site for the oxygen and other gas storage reservoirs easily accessible to maintenance and supply personnel?	0.98		
29	Is medical air supplied primarily through a central supply, with secondary supply through cylinders?	0.82		
30	Is the suction of medical air compressors located outside the building, capturing atmospheric air free of any contamination from exhaust systems, such as ovens, combustion engines, hospital vacuum discharges and solid waste removal?	0.89		
31	Is the air intake point for medical air compressors located at a minimum distance of three meters from any door, window, building entrance or other access point?	0.96		
32	Is the air intake point of medical air compressors located at a minimum distance of 16 meters from any ventilation exhaust, vacuum pump discharge or bathroom exhaust?	0.89		

Table 1. Judges' agreement on the compliance standards which compose the structure domain from the application of CVI and IRA tests. (continuation)

Item	Compliance standard	CVI *	CVI **	IRA ***
33	Does the air intake point of medical air compressors maintain a distance of six meters above the ground, with the end of the air inlet protected by a screen and facing downwards?	0.88		
34	If the hospital uses a central with a special supply of 21% of oxygen and 79% of liquid nitrogen to produce and distribute synthetic compressed air, does it have a backup supply and a continuous analysis system that blocks the supply when out of specifications ?	0.82		

* Content Validity Index applied to the items (CVI)

** Content Validity Index applied to the domain (CVI)

*** Interrater Agreement applied to the domain (IRA)

Table 2. Judges' agreement on the compliance standards which compose the process domain from the application of CVI and IRA tests.

Item	Compliance standard	CVI *	CVI **	IRA ***
1	Is the pharmacist responsible for scheduling the purchase of medical gases?	0.96	0,90	0,80
2	Is the supplier supervising the adequacy of gas transport?	0.73		
3	Is the reception of medicinal gases carried out or supervised by a pharmacist?	0.89		
4	In order to guarantee safety and quality, is the quality control report of the liquid oxygen manufacturer evaluated every time there is a batch change?	0.95		
5	Is pharmacovigilance of medicinal gases performed by a pharmacist?	0.88		
6	Is a specific tool used to change the valves (avoiding the presence of grease and other combustible materials)?	0.98		
7	Are cylinders handled with hands or gloves free from grease contamination?	0.95		
8	Does the hospital never use oxygen as a way to replace compressed air in pneumatic systems?	0.91		
9	Are the identification, colors (according to ABNT - NBR 12176/2004) and other characteristics of the cylinders preserved?	1.00		
10	Are cylinders without identification or with doubtful identification denied on delivery to the hospital?	0.82		
11	Is the helmet or seal removed only when the cylinder is to be used?	0.93		
12	Was the team that handle the cylinders properly trained?	1.00		
13	Are adaptations to cylinder connections prohibited?	0.89		

Table 2. Judges' agreement on the compliance standards which compose the process domain from the application of CVI and IRA tests. (continuation)

Item	Compliance standard	CVI *	CVI **	IRA ***
14	Are cylinders, like non-critical items, cleaned before being taken to the operating room?	0.98		
15	Are cylinders stored away from grease or other combustible materials, as well as from flammable gases?	1.00		
16	If the hospital uses flammable gases (hydrogen and acetylene), are they stored together with carbon dioxide?	0.96		
17	Are the cylinders stored protected from rain and sunlight?	1.00		
18	Are empty cylinders stored separately from the full ones?	1.00		
19	Are defective cylinders or those suspected of malfunction flagged, returned to the distributor, and your problem reported?	0.89		
20	Is the certificate with the batch analysis protocol, signed and dated by a legally qualified professional, required and made available when delivering liquid oxygen?	0.79		
21	Is the certificate provided by the company at the time of delivery filed for a minimum period of one year after the product expires?	1.00		
22	Is the inspection of the product batch and its invoice performed at the time of delivery?	0.95		
23	Does the hospital have the package insert or the safety information sheet for the chemicals of the available gases?	0.98		
24	Are the manufacturer's recommendations available to workers in the workplace?	0.96		
25	Are cylinders with a confirmed leak removed from the storage? (Prohibited use)	0.77		

Table 2. Judges' agreement on the compliance standards which compose the process domain from the application of CVI and IRA tests. (continuation)

Item	Compliance standard	CVI *	CVI **	IRA ***
26	Are cylinders without gas identification and safety valve not received or used?	0.79		
27	Does a pregnant woman only work in the area with anesthetic gases or vapors with the written authorization of the occupational physician?	0.98		
28	Are the cylinders moved with the use of the appropriate Personal Protective Equipments (colorless safety goggles, boot with protective toecap and leather scrape gloves or vanguard)?	0.79		
29	Are oxygen and compressed air used only for the purposes for which they are intended?	0.80		
30	When an oxygen cylinder is identified without the check valve or other appropriate device to prevent reverse flow, is it separated for a later return?	0.77		
31	Are cylinders transported securely, upright and with helmets or seals?	0.98		
32	Is the transfer of gas from one cylinder to another prohibited in the institution? (Prohibited procedure)	0.82		
33	Are the maintenance programs and their reports (signed by the professional who performed them) available to the work team directly involved?	0.73		
34	Are all oxygen cylinders in the backup supply connected to the collector and with the respective open valves?	1.00		
35	Does the reserve supply automatically start operating when the minimum safety pressure of the primary supply is reached?	0.96		
36	Does the hospital have a standard operating procedure for receiving, storing and distributing medical gases?	0.86		

* Content Validity Index applied to the items (CVI)

** Content Validity Index applied to the domain (CVI)

*** Interrater Agreement applied to the domain (IRA)

Table 3. Compliance standards that presented a CVI value below 0.80 in the content evaluation.

Item	Compliance standard	Excluded from the instrument	Added to another compliance standard	Modified until consensus among judges
1	Structure 11			X
2	Structure 17	X		
3	Structure 18	X		
4	Structure 21			X
5	Structure 26			X
6	Process 02			X
7	Process 20			X
8	Process 25		X	
9	Process 26		X	
10	Process 28			X
11	Process 30		X	
12	Process 33			X

Table 4. Expert panel agreement rate in relation to appearance validation of the instrument.

Item	General evaluation	Answer	%
1	Is it in an acceptable format?	Yes	100.00
2	Does the format facilitate its use?	Yes	100.00
3	Is the sequence of questions appropriate?	Yes	57.14
4	Is filling the instrument exhausting?	Yes	57.14
5	Are the questions repetitive?	No	71.42
6	Is the instrument too extensive?	Yes	85.71
7	Are the questions too extensive?	No	85.71
8	Was the terminology used appropriate?	Yes	100.00

Table 5. Assessment by the expert panel and national evaluation to define the degree of criticality of the structure compliance standards of the proposed instrument.

Compliance standards		Expert panel assessment		National evaluation	
		Final criticality degree	CVI	CVI	Average rating
Q1	Does the hospital have a pharmacist registered as responsible for medicinal gases in the local Pharmacy Council?	3	0,80	0,78	2,66
Q2	If the hospital uses a medical compressed air supply unit with a compressor, does it have another central unit with a compressor, or at least two cylinders connected to a network?	3	1,00	1,00	3,00
Q3	Is the suction of medical air compressors located outside the building, capturing atmospheric air free of any contamination from exhaust systems, such as ovens, combustion engines, hospital vacuum discharges and solid waste removal?	3	1,00	1,00	3,00
Q4	Is the air intake point for medical air compressors located at a minimum distance of three meters from any door, window, building entrance or other access points?	3	0,60	1,00	3,00
Q5	Is the air intake point of medical air compressors located at a minimum distance of sixteen meters from any ventilation exhaust, vacuum pump discharge or bathroom exhaust?	3	1,00	0,93	2,90
Q6	Does the air intake point of medical air compressors maintain a distance of six meters above the ground, with the end of the air inlet protected by a screen and facing downwards?	3	0,60	0,89	2,85
Q7	If the hospital uses a central with a special supply of 21% of oxygen and 79% of liquid nitrogen to produce and distribute synthetic compressed air, does it have a backup supply and a continuous analysis system that blocks the supply when out of specifications?	3	1,00	1,00	3,00
Q8	If the hospital uses the reservoir by cryogenic tank, does it have at least two reserve cylinders connected to a network?	3	1,00	0,93	2,90
Q9	Is the installation site of the central reservoir or the oxygen concentrating generator located at ground level?	2	0,40	0,48	2,29
Q10	Does the installation site of the central reservoir or oxygen generator comply with the minimum distance of five meters from the building area?	3	0,60	0,81	2,74
Q11	Does the installation site of the central reservoir or oxygen generator comply with the minimum distance of five meters from the combustible materials area or storage of flammable materials?	3	1,00	0,96	2,96

Table 5. Assessment by the expert panel and national evaluation to define the degree of criticality of the structure compliance standards of the proposed instrument. (continuation)

Compliance standards		Expert panel assessment		National evaluation	
		Final criticality degree	CVI	CVI	Average rating
Q12	Does the installation site of the central reservoir or oxygen generator comply with the minimum distance of five meters from an audience meeting place?	3	1,00	0,93	2,88
Q13	Does the installation site of the central reservoir or oxygen generator comply with the minimum distance of three meters from doors or passageways that give access to the storage area?	2	0,60	0,59	2,18
Q14	Does the installation site of the central reservoir or oxygen generator comply with the minimum distance of three meters from vehicle traffic area?	3	0,80	0,89	2,81
Q15	Does the installation site of the central reservoir or oxygen generator comply with the minimum distance of three meters from public sidewalks?	3	1,00	0,85	2,85
Q16	Is the installation site of the central reservoir or oxygen generator located outdoors or in a fireproof shelter?	3	1,00	0,96	2,96
Q17	Is the installation site of the central reservoir or oxygen generator protected from the risk of falling electric power transmission lines or pipes containing flammable liquids or fuel, or flammable gases?	3	1,00	0,89	2,88
Q18	In the centralized gas system, are signs used to indicate the persons authorized to have access?	2	1,00	0,63	2,14
Q19	In the centralized gas system, are signs used to indicate the procedures to be adopted in case of emergencies, the telephone number to be used in these cases and with signs adverting to danger?	3	1,00	0,85	2,85
Q20	Is the surface, where the gas plant is located, made of non-combustible material and compatible with cryogenic temperatures?	3	1,00	0,96	2,96
Q21	Is there sufficient lighting to allow adequate viewing of the supply center at night?	3	0,40	0,85	2,85
Q22	Does the institution use an alarm system for failure monitoring in the supply center?	3	0,80	0,96	2,96
Q23	Is the installation site for the oxygen central reservoir easily accessible to maintenance and supply personnel?	2	0,40	0,56	2,44

Table 5. Assessment by the expert panel and national evaluation to define the degree of criticality of the structure compliance standards of the proposed instrument. (continuation)

Compliance standards		Final criticality degree	Expert panel assessment	National evaluation	
			CVI	CVI	Average rating
Q24	Is the cylinder storage area covered, dry, clean, well ventilated and protected from sunlight?	3	1,00	0,93	2,88
Q25	Does the gas storage location have a fire extinguisher?	3	1,00	0,93	2,90
Q26	Does the hospital have a package insert or chemical safety information sheet for the available gases?	3	1,00	0,89	2,88
Q27	Does the institution provide personal protective equipment (colorless safety goggles, boot with protective toecaps and leather scrape gloves or vaquel exclusive for this purpose and free of oil or grease) for the transportation of cylinders?	3	1,00	0,93	2,9
Q28	Are the places, where life support equipment is usually used, provided with an emergency supply of oxygen and compressed air for each equipment?	3	1,00	0,93	2,9
Q29	Does the hospital have a standard operating procedure for receiving, storing and distributing medical gases?	3	1,00	0,96	2,96

Q=question.

Table 6. Assessment by the expert panel and national evaluation to define the degree of criticality of the process compliance standards of the proposed instrument.

Compliance standards		Expert panel assessment		National evaluation	
		Final criticality degree	CVI	CVI	Average rating
Q1	Is the pharmacovigilance of medicinal gases performed by a pharmacist?	3	0,8	0,70	2,55
Q2	Is the prior authorization of the occupational physician required for pregnant women to carry out activities in the area with medicinal gases or anesthetic vapors?	3	1	0,78	2,7
Q3	Is the reception of medicinal gases carried out or supervised by a pharmacist?	3	0,8	0,67	2,51
Q4	During the reception of medicinal gases, is there an evaluation regarding the compliance of transport practices?	2	0,6	0,67	2,26
Q5	When receiving liquid oxygen, is the product quality certificate required, with batch analysis, dated and signed by a legally qualified professional?	3	1	0,81	2,81
Q6	Is the certificate provided by the company at the time of delivery filed for a minimum period of one year after the product expires?	2	0,6	0,78	2,07
Q7	When the cylinder is received, is its batch, validity and identification checked?	3	1	0,96	2,9
Q8	Are all cylinders of the piped system backup supply connected to the collector and with the respective valves open?	3	1	1,00	3
Q9	Are tests performed periodically to evaluate the automatic activation of the reserve supply when the minimum safety pressure of the primary supply is reached?	3	1	0,89	2,88
Q10	Are the gas central reservoir maintenance programs and reports available to the work team?	3	0,8	0,81	2,81
Q11	Are cylinders stored away from grease or other combustible materials, as well as from flammable gases?	3	1,00	1,00	3
Q12	Are the cylinders stored upright by a strap, chain or other similar material?	3	1,00	0,96	2,96
Q13	If the hospital uses flammable gases such as hydrogen and acetylene, are they stored at a minimum distance of eight meters from oxidizing medicinal gases, such as oxygen and nitrous oxide, or separated by fire-resistant barriers?	3	1,00	1,00	3

Table 6. Assessment by the expert panel and national evaluation to define the degree of criticality of the process compliance standards of the proposed instrument. (continuation)

Compliance standards		Expert panel assessment		National evaluation	
		Final criticality degree	CVI	CVI	Average rating
Q14	Are cylinders kept away from sparks, flames and other sources of heat above 54°C?	3	1,00	1,00	3
Q15	Are empty cylinders stored separately from the full ones?	3	0,60	0,96	2,96
Q16	Are damaged or suspected cylinders identified, segregated and reported?	3	1,00	1,00	3
Q17	Are the safety recommendations provided by the manufacturer accessible to workers?	3	1,00	0,93	2,9
Q18	Was the team that handle the cylinders properly trained?	3	1,00	1,00	3
Q19	During the process of changing the cylinder valves, is a specific tool used to avoid the greases and other combustible materials?	3	1,00	0,96	2,96
Q20	Is the helmet or seal removed only when the cylinder is to be used?	3	1,00	1,00	3
Q21	Are adaptations made to the cylinder connections?	3	1,00	0,81	2,81
Q22	Are the cylinders cleaned before being taken to the operating room?	3	1,00	0,85	2,81
Q23	Are the cylinders transported in an upright position?	3	0,80	0,96	2,96
Q24	Are oxygen, compressed air and other gases used only for the purposes for which they are intended?	2	0,60	0,52	2,48
Q25	Is the prohibition on transferring gas from one cylinder to another respected?	3	0,80	0,96	2,96

Q=question.

Table 7. Evaluation of performance categories and corresponding scores.

Performance categories	Corresponding color	Expert panel assessment	
		CVI	Nomenclature changes after consensus
1. “Excellent” ($\geq 90\%$ compliance with the most critical compliance standards and 100% compliance with the least critical compliance standards).	Blue	1,00	-
2. “Satisfactory” ($\geq 80\%$ and $< 90\%$ compliance with the most critical compliance standards and $\geq 70\%$ compliance with the least critical compliance standards).	Green	1,00	-
3. “Moderately satisfactory” when the hospital meets or exceeds 70% of the most and least critical compliance standards.	Yellow	0,60	“Little satisfactory”
4. “Unsatisfactory” when the hospital meets less than 70% of the most and least critical compliance standards.	Red	0,80	-

Table 8. Performance categories, their respective scores and colors.

Performance category	Color	Extremely critical	Moderately critical
“Excellent”	Blue	$\geq 90\%$	100%
“Satisfactory”		$\geq 90\%$	$\geq 50\%$ e $< 100\%$
“Satisfactory”	Green	$\geq 80\%$ e $< 90\%$	$\geq 50\%$
“Satisfactory”		$\geq 70\%$ e $< 80\%$	100%
“Little satisfactory”	Yellow	$\geq 80\%$ e $< 90\%$	$< 50\%$
“Little satisfactory”		$\geq 70\%$ e $< 80\%$	$< 100\%$
“Unsatisfactory”	Red	$< 70\%$	$\leq 100\%$