NURSING AND INFECTION CONTROL IN INJECTABLE MEDICATIONS: PREPARATION AND VALIDATION OF INSTRUMENT

ENFERMAGEM E CONTROLE DE INFECÇÕES EM MEDICAÇÕES INJETÁVEIS: ELABORAÇÃO E VALIDAÇÃO DE INSTRUMENTO

ENFERMERÍA Y CONTROL DE INFECCIONES EN MEDICAMENTOS INYECTABLES: PREPARACIÓN Y VALIDACIÓN DEL INSTRUMENTO

Thais Roberto Magalhães Fittipaldi¹
Camila Eugenia Roseira²
Raissa Silva Souza³
Rosely Moralez de Figueiredo⁴

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Objective: to develop and validate an instrument for measuring nursing professionals' knowledge about safe practices for infection prevention in injectable medications Method: methodological study, conducted in a municipality of São Paulo, between March 2018 and December 2019, according to stages: establishment of the conceptual structure and construction of the instrument; validation by specialists with experience of care or infection control or researchers in the area, with >80% agreement rate and content validity index \geq 0.78; and semantic analysis with the target audience, recruited through the snowball technique. Results: an instrument was constructed with 27 items, including: preparation of the environment, preparation and administration of injectable medications and disposal of sharp-cutting materials. There was a high rate of agreement among the 10 specialists and semantic refinement after response from 34 participants from the target audience. Conclusion: consolidated tool to measure, in a standardized way, the knowledge of nursing professionals on the subject, allowing specific educational interventions, according to situational diagnosis.

Descriptors: Infection Control. Nursing. Validation Study. Injections. Knowledge Management for Health Research.

Objetivo: elaborar e validar instrumento para mensuração de conhecimento de profissionais de enfermagem sobre práticas seguras para prevenção de infecção em medicações injetáveis. Método: estudo metodológico, realizado em município paulista, entre março de 2018 e dezembro de 2019, conforme etapas: estabelecimento da estrutura conceitual e construção do instrumento; validação por especialistas com experiência assistencial ou controle de infecção ou pesquisadores na área, com taxa de concordância >80% e índice de validade de conteúdo ≥0,78; e análise semântica junto ao público-alvo, recrutado por meio da técnica bola de neve. Resultados: construiu-se

Nurse. MSc in Health Sciences. Nurse at the Irmandade da Santa Casa de Misericórdia de Rio Claro. Rio Claro, São Paulo, Brazil. https://orcid.org/0000-0001-8389-1985

Nurse. PhD in Health Sciences. Professor at the Centro Paula. São Carlos, São Paulo, Brazil. roseira.camila@gmail.com. https://orcid.org/0000-0002-9114-6579.

Nurse. PhD in Nursing. Professor at the Universidade Federal de São João Del-Rei. Divinópolis, Minas Gerais, Brazil. https://orcid.org/0000-0002-7843-0495.
 Nurse. PhD in Mental Health. Head Professor at the Universidade Federal de São Carlos, São Carlos, São Paulo, Brazil. https://orcid.org/0000-0002-0131-4314.

instrumento com 27 itens, contemplando: preparo do ambiente, preparo e administração de medicações injetáveis e descarte de materiais perfurocortantes. Houve alta taxa de concordância entre os 10 especialistas e refinamento semântico após resposta de 34 participantes do público-alvo. Conclusão: consolidada ferramenta para mensurar, de forma padronizada, o conhecimento de profissionais de enfermagem sobre o tema, permitindo intervenções educativas específicas, conforme diagnóstico situacional.

Descritores: Controle de Infecções. Enfermagem. Estudo de Validação. Injeções. Gestão do Conhecimento para a Pesquisa em Saúde.

Objetivo: desarrollar y validar un instrumento para medir el conocimiento de los profesionales de enfermería sobre prácticas seguras para la prevención de la infección en medicamentos inyectables. Método: estudio metodológico, realizado en un municipio de São Paulo, entre marzo de 2018 y diciembre de 2019, según etapas: establecimiento de la estructura conceptual y construcción del instrumento; validación por especialistas con experiencia en atención o control de infecciones o investigadores en el área, con >80% de tasa de concordancia e índice de validez de contenido ≥0,78; y análisis semántico con el público objetivo, reclutado a través de la técnica de bola de nieve. Resultados: se construyó un instrumento con 27 ítems, entre ellos: preparación del ambiente, preparación y administración de medicamentos inyectables y disposición de materiales de corte afilado. Hubo una alta tasa de acuerdo entre los 10 especialistas y refinamiento semántico después de la respuesta de 34 participantes del público objetivo. Conclusión: berramienta consolidada para medir, de manera estandarizada, el conocimiento de los profesionales de enfermería sobre el tema, permitiendo intervenciones educativas específicas, de acuerdo al diagnóstico situacional.

Descriptores: Control de Infecciones. Enfermería. Estudio de Validación. Inyecciones. Gestión del Conocimiento para la Investigación en Salud.

Introduction

Guidelines and recommendations of good practices for the prevention and control of health care-related infections (HCRI) are part of the agenda of agencies and governmental institutions, national and international (1-3). Among these recommendations, these are included in safe injection procedures, including phlebotomy, lancet or intravenous devices (4).

The practice of safe injection is a component of standard precautions aimed at maintaining a basic level of protection in relation to avoidable risks, both for patients and for health professionals⁽⁴⁻⁶⁾. In summary, it contemplates the proper administration of injection by a qualified and trained professional, using aseptic technique and sterile and disposable material, and the disposal is done safely in a container for needle-sharps⁽⁴⁻⁵⁾.

Compliance with the guidelines relevant to the practice of safe injection, as well as those aimed at the control and prevention of HCRI is the responsibility of health professionals⁽⁴⁾. However, it is the role of health institutions to create conditions for the implementation of these practices in the different health care scenarios⁽¹⁻²⁾.

In this regard, educational interventions of different natures have proved to be paramount in this process of transposition of official texts into the concrete spaces of care practice. However, little is prioritized the specific needs of health professionals in their different places of activity⁽⁶⁾.

Among nursing professionals, the process of preparation and administration of medicines is a daily care activity, often performed in a way that is different from what is recommended.

The adoption of good infection prevention practices in this process is essential for the safety of the recipient, also preventing the exposure of the professional to avoidable risks⁽¹⁻³⁾. Despite this, evidence on the adhering to these good practices, as well as on knowledge gaps in this regard, is scarce⁽⁷⁻⁸⁾.

A study that evaluated knowledge, attitudes and practices of professionals about good practices in the administration of medicines identified that 15.8% of professionals (12.4% of physicians and 3.4% of nurses) reported the reuse of syringes for more than one patient in the work environment, and about 5.3% of professionals (5% of physicians and

0.3% of nurses) indicated that this practice occurs "always" or "normally"⁽⁹⁾. Another study, which evaluated the reported practices of safe injection of medications, revealed low nurses' support for recommendations, such as hand hygiene, and high rate of adhering to unauthorized conducts, such as needle recap⁽¹⁰⁾.

There are also reports in the literature about the reuse of syringes for more than one patient⁽⁹⁾, storage of occluders and connectors for intravenous devices in places prone to contamination, sharing of container with connectors of different patients⁽¹¹⁾ and insufficient antisepsis for venous puncture⁽¹²⁾.

Thus, among the potential risks, from the perspective of good safe injection practices, which may represent a direct danger to the patient and the professional, are the reuse of equipment for injection and disposal of sharp materials⁽⁴⁾. As a consequence, the literature shows outbreaks of human immunodeficiency virus (HIV), hepatitis B and C and bacterial infections⁽⁴⁾. In addition, bloodstream infection (BSI) associated with peripheral venous catheters (PVC) is cited, although more rarely⁽¹³⁾.

In a literature review, the existence of a specific instrument on good infection prevention practices in the administration of medications was not identified. It is understood that instruments such as these are able to identify knowledge gaps, contributing to the generation of standardized and comparing data. This is of great value, both for the expansion of knowledge on the subject in Brazil, and in the implementation of individualized educational interventions to solve problems in specific scenarios.

The aim of the study was, therefore, to develop and validate an instrument for measuring the knowledge of nursing professionals about safe practices for the prevention of infection in injectable medications.

Method

This is a methodological study developed from March 2018 to December 2019, in a municipality in the interior of the state of São Paulo. The path of elaboration of the instrument followed the steps: establishment of the conceptual structure; definition of objectives and population; construction of items and response scale; selection and organization of items; and structuring of the instrument⁽¹⁴⁾.

The validation process occurred through content and semantic analysis (pre-test)⁽⁹⁻¹⁰⁾. The stages of elaboration of the instrument⁽¹⁴⁻¹⁵⁾ were based on a broad review of the scientific literature and on the recommendations of the World Health Organization (WHO)⁽³⁾, the National Health Surveillance Agency (ANVISA)⁽²⁾ and the Center for Disease Control (CDC)⁽¹⁶⁻¹⁷⁾.

The preliminary version of this instrument was discussed and refined by peers during research group meetings of the area. In addition to the instrument itself, a small operational manual was built with guidance on the mode of application and evaluation of responses, a justified feedback and the indication of theoretical support reference.

For the validation stage of the instrument by expert judges (content validation), 23 nurses were invited, selected for convenience, according to the technique of consecutive recruitment of participants.

In the selection of the first participants (key informants), the curriculum of researchers registered in the Lattes Platform of the National Council for Scientific and Technological Development (CNPq) was consulted, using the available filters. The inclusion criteria for the specialists were: minimum professional experience of two years in nursing care; experience in infection control; have conducted research and/or scientific productions with instrument validation or infection control.

The initial contact with the judges was made by e-mail, being forwarded the link generated by the Google Form® containing presentation and objective of the research, criteria for their appointment as specialist, in addition to the Informed Consent Form (ICF) and the specific instructions on the procedures of judgment of content validity and the instrument itself. All participants (experts and representatives of the target audience) registered their consent to participate in the research, selecting the option "accept" in the forwarded electronic ICF.

The judges evaluated the scope of the 4 proposed domains, the clarity and relevance of each of the 24 items and, finally, the language, scope and relevance of the instrument in its entirety. To record the evaluation of domains and the complete instrument, dichotomous response options were used – not (1) and yes (2). For the evaluation of the items, a four-point Likert scale was used, being: I totally agree (4 points); I partially agree (3 points); I partially disagree (2 points); and I totally disagree (1 point). If the "partially disagree" or "totally disagree" options were flagged, the expert would need to suggest changes or deletion of the item.

The categorical data resulting from the evaluation of the specialists were analyzed by the researchers and the adjustments indicated were made. In order to maintain fidelity to the theoretical framework used, all possible changes to be made were previously discussed and validated in a meeting of the research group in the area.

Of the 23 specialists invited, 11 agreed to participate in the study, which, according to the literature, is consistent with the number necessary to validate measurement instruments⁽¹⁴⁾.

The data resulting from the analysis of the items of the instrument by the experts were tabulated in the Microsoft Excel for Windows® program and, later, the Content Validity Index (CVI) of each item was calculated, adding the answer options "3" and "4" and dividing the result by the total number of responses.

It was considered that items whose CVI were higher than $0.78^{(14-18)}$ would be kept in the instrument. The items below this value would be necessarily reformulated according to the judges' suggestions.

For the data resulting from the analysis of the domains and the instrument, the agreement rate of the judges was calculated, dividing the number of participants who agreed by the total number of participants and multiplying the result by 100⁽¹⁴⁾. The reference value for the agreement

rate among the judges equal to or greater than $80\%^{(18)}$ for the domain was considered.

For the second stage of validation of the instrument (semantic analysis or pre-test)⁽¹⁴⁾, 52 members of the population to which the instrument is intended were recruited for convenience and according to the snowball technique. The invitation was circulated by social media.

The 34 representatives of the target audience who agreed to participate in this stage answered the version of the instrument validated by the experts and expressed their opinions about the understanding, clarity and understanding of the statements contained in each item, as well as the understanding of the words used, which may suggest changes in the wording, if they deem it necessary⁽¹⁴⁾.

For the analysis of the results of this stage, the relative frequency of responses and the mean number of correct answers per mastery of the instrument were calculated. Thus, the higher the number of hits, the closer to the ideal. In addition, suggestions for changes in the statements were accepted, aiming at a better understanding of the sentences.

The project was approved by the Research Ethics Committee of the *Universidade Federal de São Carlos* (UFSCar), according to Resolution n. 466/12 of the National Health Council, Opinion n. 3,099,684.

Results

The final instrument elaborated included four domains, including: 1 – Environmental preparation (2 items); 2 – Preparation of injectable medications (13 items); 3 – Administration of injectable medications (8 items); and 4 – Disposal of sharp materials (4 items), totaling 27 statements with 2 answer options - correct or incorrect.

The specialists who participated in the content validation stage of the instrument were mostly female (n=10; 90.9%), living in the state of São Paulo (n=8; 72.7%), with main performance in teaching (n=7; 63.6%), master's

degree (n=5; 45.5%), more than 10 years of academic education (n=11; 100%) and more than 10 years of professional experience in the area (n=10; 90.9%).

All items evaluated individually obtained CVI results higher than 0.78 in clarity and representativeness, not requiring reformulation, according to Table 1.

Table 1 – Descriptive analysis of the Content Validity Index by domain, obtained in the evaluation of the judges. São Carlos, São Paulo, Brazil – 2020. (N=11)

Domain	Average Content Validity Index – Clarity	Average Content Validity Index – Representativeness
1 – Environment preparation	0.95	0.90
2 - Injectable medication preparation	0.92	0.94
3 – Administration of injectable medications	0.96	0.92
4 – Needle-sharps disposal	0.90	0.90

Source: Created by the authors.

Nevertheless, discrete adjustments regarding the vocabulary and syntax of some statements were accepted. In addition, it was suggested and accepted the inclusion of an item in the domains "preparation of injectable drugs", "administration of injectable drugs" and "disposal of needlesharps", according to Chart 1.

Chart 1 – Theoretical content items added in the content validation phase, as per the judges' suggestions

Domain	Item	Added wording
2 – Preparation of injectable medications	2.2	Tearing syringe and needle wrappers for use is a safe practice.
3 – Administration of injectable medications	3.4	Tap caps (three-way) can be reused as long as they are stored in a safe place.
4 – Disposal of sharps	4.4	For administration of injectable medications at home, an adequate container for disposal of generated sharps must be ensured.

Source: Created by the authors.

Such adjustments, as well as the inclusion of items, were discussed and validated by scholars of a research group in the area.

The final version, resulting from the analysis of the specialists, was applied to 34 participants from the target audience, of which 18 (52.94%) were nurses, 9 (26.47%) nursing assistants or

technicians, 3 (8.82%) students from a nursing technical course and 4 (11.76%) undergraduate nursing students. The percentages of correct answers and errors of these participants and the average number of correct answers are presented per domain in Table 2.

Table 2 – Responses obtained in the pilot test of the instrument with a target audience, by domain. São Carlos, São Paulo, Brazil – 2020. (N=34)

Domain	Right answers (%)	Mistakes (%)	Average of right answers (%)
1 – Preparing the environment	97.06	2.94	99.78
2 - Preparation of injectable medications	87.56	12.44	94.00
3 - Administration of injectable medications	73.53	26.47	92.15
4 – Disposal of needle-sharps	88.24	11.76	98.25

Source: Created by the authors.

The most common mistakes of the participants of the semantic analysis were to consider correct the sharing of single-use articles (n=7; 20.59%), the use of the same syringe for the preparation of several medications (n=3; 8.82%), and the use of a saline bag to dilute different medications and salinize catheters (n=4; 11.76%).

Other errors identified were not considering access to vials with needles/syringes already used as an inadequate situation (n=7, 20.59%) and not recognizing the need for disinfection of the catheter connector before accessing it (n=4,

11.76%). In addition, 73.53% of the representatives of the target audience were unaware of the non-mandatory antisepsis of the skin before the administration of intradermal and subcutaneous medications, and 26.47% were unaware of the permission to put the cover on the needles again with single-hand technique.

The participants of the semantic analysis suggested changes of textual nature with a view to the more adequate understanding of information contained in some items, according to Chart 2.

Chart 2 – Main wording changes in domain 2, Preparation of injectable medications, based on suggestions from the target audience

Item	Previous writing	Final writing	
Item 2.5	Leave a needle inserted into the	Leave a needle inserted into the vial	
	multidose vial does not interfere with	does not interfere with	
	the contamination of its contents.	contamination of its content.	
Item 2.7	The administration of injectable medications should occur immediately after their preparation.	The administration of injectable medications should occur soon after their preparation.	
Item 2.13	Vials accessed by needles or syringes already used on one patient cannot be used for other patients.	Vials accessed by needles or syringes already used on one patient can be used for other patients.	

Source: Created by the authors.

Discussion

The rigor of the theoretical review of the theme, as well as the refinement of the initial version of the instrument after exhaustive discussions with members of the research group in the area, may have contributed to the high levels of acceptance by the experts. Therefore, all items, when evaluated individually, as well as the instrument, in its entirety, obtained CVI higher than 0.78 in relation to clarity and representativeness⁽¹⁴⁾. These values show the harmony and robustness of the instrument elaborated.

In addition to the wide acceptance of the specialists, their contributions, as well as those of the representatives of the target audience, allowed the textual improvement of the instrument, making its language more familiar and meaningful for the respondents.

One of the items included as the experts' suggestion was how to open the casing of syringes and needles. According to the

recommendations of regulatory agencies⁽²⁾, such packages should be opened following aseptic technique, without contact between the sterile surface of the syringe and/or needle and other non-sterile surfaces; which can be compromised if such b are randomly torn.

Another item included was the reuse of the lids of turners (three-way), which is also something that, in practice, may differ from the literature. The recommendation⁽²⁾ in force is for the lids of the three-way to be discarded with each use. However, in practice, this does not always happen, due to the unavailability of spare caps in adequate quantity. The reuse of three-way may compromise patient safety, since they, in general, end up being stored in inappropriate places, such as lab coats pockets, bedside table of the patient's bed, among others, which may lead to contamination⁽¹¹⁾.

The disposal of sharp residue generated in the administration of injectable medications at home was another item included based on the suggestions of the specialists. Immediately discarding used syringes and needles in a safe reservoir and within reach of the hands is considered the first step in the process of safe management of waste from health services⁽³⁾. However, adequate reservoirs are not always available and accessible to professionals who provide home care. In this regard, a study points to the need to regulate the management of these wastes generated in households, because the lack of norms favors inappropriate disposal⁽¹⁹⁾.

Regarding the pre-test, the application of the instrument allowed the identification and analysis of the participants' errors. The most frequent occurred in the stages of preparation and administration of injectable, portraying actions that, if performed incorrectly, can compromise the aseptic barrier and trigger complications such as HCRI. Thus, the realization of these errors in health services would have repercussions on unsafe practices in the administration and preparation of injectable, according to the literature ^(9,20). One of these points was the sharing of single-use articles.

A recent study pointed out that the practice of sharing single-use articles, such as syringes and needles, for more than one patient is a reality still reported by 3.4% of nurses and 12.4% of physicians in the United States⁽⁹⁾. Another study, in turn, related the sharing of these articles to the occurrence of outbreaks of infection⁽²¹⁾ in developing countries. The sharing of any single-use article, whether syringe, needle, lancet or the like, is closed by the high risk of dissemination of microorganisms⁽³⁾.

Another critical point identified in the pretest was the safety of using the same syringe for the preparation of medications. Reusing syringes and needles consists of an activity related to the transmission of diseases, such as viral hepatitis, and should therefore be ratified as unsafe and mitigated practice⁽²²⁾.

Detailed investigations conducted in India and Pakistan have identified the reuse of syringes as one of the main contributors to the transmission of these hepatitis, associated with the origin of 50% of these infections in Pakistan and 38% in India⁽²³⁾.

Just as it is not advisable to use the same syringe for the preparation of medications, access to multi-dose vials with needles and syringes already used is also contraindicated by official guidelines. A study conducted in Michigan (United States of America) identified that the access of a vial with a needle and syringe already used and the sharing of the contents of the vial to other patients was associated with hepatitis C transmission (24).

Access to a multidose vial should be performed by a syringe and needle set at once and disposed of in a suitable reservoir immediately after the procedure. This recommendation is valid, even if the set was previously used in the same patient⁽²⁻³⁾. The fact that the participants of the pre-test of this study judged this practice as "adequate", in addition to contradicting the official recommendations, indicates the need to consider the inclusion of the discussion of this topic in professional qualifications.

The use of saline solution in a larger volume pouch to dilute different medications and salinize catheters is, in general, another critical point pertinent to the practice. The official recommendations contraindicate the use of a common source of diluents for several patients, due to the high probability of contamination, except in pharmacies with the use of laminar flow cabinets⁽²⁻³⁾. However, the use of this type of presentation of the saline solution is still recorded.

An example of this is published in a study conducted at a cardiology clinic in West Virginia (United States of America), which identified an association between hepatitis B and C outbreak and the sharing of saline vials for more than one patient. After these results, only medications and intravenous solutions for single use began to be used in the clinic, with no more case records⁽²⁵⁾.

Unsafe health care practices, including injectable administration, remain one of the main modes of hepatitis C transmission, accounting for most new infections in 2015. In the Eastern Mediterranean region, the most common cause of infection transmission is unsafe injections in health care⁽²⁶⁾.

The association between hepatitis B and C and unsafe practices in injectable administration is a challenge for researchers, as long incubation periods (more than 6 months) and absence of prodromal clinical manifestation make investigations long and inaccurate. So much so that the Morbidity and Mortality Weekly Report (MMWR) of the Centers for Disease Control and Prevention (CDC) in the United States reported that some of the viral hepatitis outbreaks identified in the years 2017 to 2019 are still under investigation (277).

With regard to the non-recognition by the participants of the pre-test of this study on the need to disinfect the catheter connector (hub) before accessing it, it can also be considered a topic to be addressed in educational contexts aimed at the qualification of workers. It is known that, like vials and ampoules, the catheter connector requires disinfection before use, as it is considered an immediate gateway for bacteria, with the potential to contaminate the lumen of the catheter and cause infections, even in peripheral catheters⁽²⁸⁾.

Regarding this, an observational study identified that disinfection of the connector before access reduced the number of catheter-related bloodstream infections in a dialysis unit⁽²⁹⁾. Another study related the high incidence of catheter connector colonization to the number of positive blood cultures⁽³⁰⁾.

Another aspect identified in the pre-test was the participants' ignorance about the non-mandatory skin antisepsis before intradermal and subcutaneous medications were given. The WHO recommends that, in clean skin, there is no need for routine antisepsis before the administration of intradermal, subcutaneous injections and vaccines. This recommendation is based on studies in which no evidence of infection was found, when insulin injections were administered without previous skin antisepsis with 70% alcohol^(3,31).

A recent review study on skin preparation for injections also did not identify evidence that skin preparation with 70% alcohol reduces local skin infections before vaccination⁽³²⁾.

For intramuscular injections, the recommendation remains to perform previous skin antisepsis, except for vaccines⁽³⁾.

Another subject that the pre-test participants were unaware of was the possibility of recapping needles with a single-hand technique. The most indicated measure for the prevention of accidents with sharp materials is to avoid the manipulation and recapping of needles, besides having a collector near the place of use. However, in special situations, when the sharp-cutting manifold is unavailable, needle recapping with single-hand technique is a possible option. It is noteworthy that the use of both hands to put the cover on the needle is related to a high number of accidents and is strictly prohibited^(12,33).

Considering the relevance of the theme for the safety and quality of care, it is understood that the application of the validated instrument can support the implementation of specific educational strategies both in academia and in services, to address gaps and weaknesses identified, since the pre-test stage has already evidenced points that can be improved theoretically and practically.

As a limitation of this study, it is understood that, because it is a methodological study, the answers obtained in the semantic analysis stage (pre-test) were part of the validation process of the instrument and, therefore, did not present sample representativeness. Thus, it is not possible to extrapolate their results to other populations.

As contributions of this study, it is found that the instrument constructed and validated allows standardized data collection, which can be compared, in addition to obtaining specific panoramas about the knowledge of nursing professionals regarding safe practices for infection prevention in injectable medications, in different health care scenarios.

Conclusion

The instrument elaborated proved to be an adequate tool for measuring knowledge on the theme "Safe Practices for Infection Prevention in Injectable Medications", presented high agreement

among the judges and comprehensibility after its application to the target audience, undergoing a small refinement prior to its final availability.

Finally, it is noteworthy that new versions of this instrument may be necessary as recommendations are updated.

Collaborations:

- 1 conception, design, analysis and interpretation of data: Thais Roberto Magalhães
 Fittipaldi and Rosely Moralez de Figueiredo;
- 2 writing of the article and relevant critical review of the intellectual content: Thais Roberto Magalhães Fittipaldi, Camila Eugenia Roseira, Raissa Silva Souza and Rosely Moralez de Figueiredo;
- 3 final approval of the version to be published: Thais Roberto Magalhães Fittipaldi and Rosely Moralez de Figueiredo.

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