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CREATION AND CONTENT VALIDITY OF *5R-MEDSAFE*: ASSESSING ADHERENCE TO THE SAFE DRUG ADMINISTRATION "FIVE RIGHTS"

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ABSTRACT

Objective: to present the creation and content validity stages of a questionnaire to assess the determinants of adherence to the safe drug administration five "rights" "*x*", based on the Theory of Planned Behavior integrative model.
Method: a methodological study to create and validate a self-reported measuring instrument for psychosocial variables. It took place in two public university teaching hospitals: one located in the South and the other in the Southeast of Brazil.
Results: the results were organized according to each stage of the *5R-MEDSAFE* content validation process.
Conclusion: the results obtained in this creation and content validation study of the *5R-MEDSAFE* indicated that the tool presented diverse content validity evidence. Its application can be useful in different contexts as a way of assessing adherence to these behaviors among Nursing workers. This will make it possible to identify which elements of the behaviors are amenable to intervention, as well as to implement the most appropriate intervention, according to the Theory of Planned Behavior constructs.

DESCRIPTORS: Patient safety. Drug administration. Behavior. Nursing beliefs.

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CONSTRUÇÃO E VALIDADE DE CONTEÚDO DO *5R-MEDSAFE*: AVALIAÇÃO DA ADESÃO AOS CINCO CERTOS DA ADMINISTRAÇÃO SEGURA DE MEDICAMENTOS

RESUMO

Objetivo: apresentar as etapas de construção e validade de conteúdo de um questionário para avaliaçãbo dos determinantes da adesão aos cinco certos da administração segura de medicamentos – *5R-MEDSAFE*, baseado no modelo integrador da Teoria do Comportamento Planejado.
Método: estudo metodológico de construção e validação de instrumento de medida autorrelatada de variáveis psicossociais. Desenvolveu-se em dois hospitais-escola universitários, públicos, um localizado na região Sul e outro na região Sudeste do Brasil.
Resultados: os resultados foram organizados conforme cada etapa da validação de conteúdo do *5R-MEDSAFE*.
Conclusão: os resultados obtidos neste estudo de construção e validação de conteúdo do instrumento *5R-MEDSAFE* indicaram que o instrumento apresentou evidências de validade de conteúdo. Sua aplicação pode ser útil em contextos distintos como forma de avaliar a adesão a esse comportamento entre trabalhadores de enfermagem. Isso permitirá identificar qual elemento do comportamento é passível de intervenção, bem como implementar a intervenção mais adequada, conforme os construtos da Teoria do Comportamento Planejado.

DESCRITORES: Segurança do paciente. Administração do medicamento. Comportamento. Crenças enfermagem.

ELABORACIÓN Y VALIDEZ DE CONTENIDO DEL INSTRUMENTO *5R-MEDSAFE*: EVALUACIÓN DE LA ADHESIÓN A LOS “CINCO CORRECTOS” DE LA ADMINISTRACIÓN SEGURA DE MEDICAMENTOS

RESUMEN

Objetivo: presentar las etapas de creación y validez de contenido correspondientes a un cuestionario para evaluar los determinantes del nivel de adhesión a los “Cinco correctos” de la administración segura de medicamentos – “*5R-MEDSAFE*”, sobre la base del modelo integrador de la Teoría del Comportamiento Planificado.
Método: estudio metodológico para crear y validar un instrumento de medición autoinformado de variables psicosociales. Se desarrolló en dos hospitales-escuela universitarios y públicos: uno situado en la región Sur y el otro en la región Sudeste de Brasil.
Resultados: los resultados se organizaron conforme a cada etapa de la validación de contenido de *5R-MEDSAFE*.
Conclusión: los resultados obtenidos en este estudio de creación y validación del contenido del instrumento *5R-MEDSAFE* indicaron que la herramienta presentó diversa evidencia de validez de contenido. Su aplicación puede resultar útil en diferentes contextos como una forma de evaluar el nivel de adhesión a estas conductas entre trabajadores de Enfermería. Eso permitirá identificar los elementos de los comportamiento que son pasibles de intervención, al igual que implementar la intervención más adecuada, conforme a los constructos de la Teoría del Comportamiento Planificado.

DESCRIPTORES: Seguridad del paciente. Administración de medicamentos. Comportamiento. Creencias de Enfermería.

INTRODUCTION

Drug administration is one of the Nursing team competencies and is considered the basis of nurses' work, as it requires clinical reasoning on the part of the professionals[1–2]. However, errors in the drug administration process are one of the most frequent in health care, and represent an important cause of increased costs in health services, varying from R$ 31.00 to R$ 21,500.00, according to a Brazilian study[3].

Drug administration is routinely in charge of the Nursing team, although it is not an exclusive action of these workers. Some authors assert that more failures occur in drug administration than in the other stages of this process, such as prescription and dispensing[4].

It is known that the new logic is that patient safety should be conducted and seen from the perspective of the success of actions, rather than failures[5]. In addition to that, the magnitude of the problem is reinforced by under-reporting of incidents, which can be explained by the punitive culture still present in health services, either due to the fear of identifying those who have reported them[6] or to the absence of a strengthened safety culture.

The safety culture can be defined as a set of group and individual values, attitudes, perceptions and competencies that determine an institution's pattern of behavior and commitment to safety[7]. A positive safety culture is important for identifying interventions to reduce the occurrence of incidents, especially medication errors.

Although clinical reasoning underpins safe drug administration[1], using the Five "rights" (5Rs) in this process is essential to prevent incidents. Some authors assert that the 5Rs (right patient, administration route, dose, medication and administration time) are essential for safe drug administration[2,8]. Currently, there has been an expansion to 12 Rs (guidance, recording, indication, interaction and response to the correct therapies, the patient's right to refuse and the right to a correct prescription); however, there is no evidence that these new Rs in safe drug administration exert an impact on drug administration safety[8]. There is no consensus on the "rights" included, but the attempt is to add system-related barriers as a way of increasing patient safety in this process[1,8].

Although efforts have been made in the clinical practice to train teams to adhere to patient safety protocols, including safe drug administration, they do not seem to be sufficiently effective in promoting an effective change in behavior. In fact, the design of more effective interventions with health workers, aimed at patient safety by reducing the occurrence of incidents, requires understanding the factors underlying worker's behaviors.

The Theory of Planned Behavior (TPB) has been widely used to understand health professionals' different behaviors. Described on the basis of studies[8], this theory, which comes from the Social Psychology field, assumes that a large part of human behavior is, at least in part, under volitional control, at least partially, immediately determined by intention, i.e., the motivation to adhere (or not) to a given behavior. Some authors[10] define these constructs as follows: intention, in turn, is determined by attitudes, perceived norms and perceived behavior control.

According to the theory[9], attitudes represent a person's favorable or unfavorable evaluation of a given behavior, resulting from the personal assessment of a group of beliefs, which is based on *behavioral beliefs*. Behavioral beliefs are related to expectations of obtaining favorable or unfavorable results from performing the behavior.

The perceived norm consists of the perception regarding the social pressure exerted to carry out the behavior, which results from a set of *normative* beliefs. Such beliefs refer to specific people or groups who exert an influence on the performance of a given behavior. They are classified as injunctive, when there is social pressure to perform the behavior, or as descriptive, when a given behavior is performed based on the perceived prevalence of its behavioral adoption in a given reference group.

In addition to these, the *professional norm* has been reported in the work context, referring to the assessment of performing a behavior dictated by professional statutes, codes or protocols[9].

Perceived behavior control refers to the perception about the extent to which the behavior is under the person's control, and is supported by *control beliefs*. These beliefs are related to the perception of the presence (or not) of resources and opportunities to carry out the behavior, i.e., barriers and/or facilitating factors for performing a given behavior[9].

Considering its widespread use in understanding health professionals' behaviors, the TPB becomes an interesting model for understanding professionals' behaviors related to patient safety, more specifically safe drug administration.

In this context, assessing adherence to the 5Rs protocol for safe drug administration might represent another step towards care quality and patient safety in this process, thus preventing incidents. As the initial 5Rs involve individual aspects[2] and their execution is the main strategy for preventing drug administration failures reported in the literature[6], it was decided to study these behaviors.

Although adherence to the 5Rs is undeniably important and its relevance as a subsidy for safe drug administration is well known, there is a gap in the international and national literature in terms of knowledge construction, specifically in relation to studies aimed at understanding the factors that determine this adherence by Nursing professionals. In addition to that, no questionnaire with validity evidence for assessing these behavioral determinants from the TPB was found in any review study. Although drug administration is not a procedure exclusive to the Nursing team, it is routine for these workers to carry out this activity.

Thus, considering the importance of the process of creating and validating instruments, this study aims at presenting the creation and content validity stages of a questionnaire to assess the determinants of adherence to the 5Rs of safe drug administration – "*5R-MEDSAFE*", based on the Theory of Planned Behavior (TPB) integrative model[10].

METHOD

A methodological study regarding the creation and validation of a self-reported measuring instrument for psychosocial variables. It took place in two public university teaching hospitals: one located in the South and the other in the Southeast of Brazil. Data collection took place from July 2021 to March 2022.

Nursing workers that were active in hospitalization units and involved in the drug administration process took part in the study, namely: nurses, technicians or nursing assistants. Workers on leave during this research stage were excluded. Inclusion of the workers was based on the "snowball" technique, in which an initial key worker, selected on the basis of their professional category and role in drug administration, indicated a second worker and so on. Inclusion also took into account proportionality of the teams, professional categories and type of unit (critical and semi-critical).

The creation of *5R-MEDSAFE* based on the TPB was the first methodological step. In this stage, the "Questionnaire for assessing the psychosocial determinants of adherence to the five principles of safe drug administration – *5R-MEDSAFE*" was created and validated based on the TPB, consisting of a subjective assessment of behaviors, indirect measures (beliefs – identified in stage 1 of the study, see Figure 1) and direct measures of the psychosocial variables that predict it.

The following definition was proposed to obtain the subjective measurement of behaviors: "Considering that adhering to safe drug administration means adopting the five rights, i.e. administering the right medication, to the right patient, at the right dose, administration route and time, how often have you adhered to these behaviors over the last two weeks?".

It was proposed to use an answer scale with percentage ranges: [1] “20% or fewer times; [2] between 30% and 40% of the times; [3] between 50% and 60% of the times; [4] between 70% and 80% of the times; and [5] between 90% and 100% of the times”. This measure was elaborated on the basis of a previous study[11]. It is noted that if a worker answered “No” to this question, it was considered that they had not administered any medication in the last two weeks.

To measure the psychosocial variables that determine the behaviors, items were created for direct and indirect measures. The direct measures refer to items that measure each component of the TPB theoretical model and their creation followed the predefined model instructed by the author[12]. The indirect measures incorporate items prepared from the qualitative analysis of the salient modal beliefs obtained from the target population (results from stage 1), considering those with prevalence greater than 10%[13].

Considering these assumptions, items were formulated to measure each TPB construct, as specified below: – Behavioral Intention (Int): it refers to the person’s motivation to perform a given behavior; – Attitude (At): it is considered to be the person’s favorable or unfavorable assessment of the behavior in question; – Perceived Norm (PN): it refers to the social pressure perceived by the person to engage or not in a given behavior; – Perceived Behavior Control (PBC): it refers to the perceived ease and/or difficulty performing a given behavior; and – Behavioral, Normative and Control Beliefs: items were prepared to assess beliefs based on the salient modal beliefs identified in the target population.

A Likert-type scale was used to measure each of the TPB constructs, with scores varying from [1] Definitely not to [5] Definitely. The mean score was calculated for each variable, obtained from the arithmetic mean of the scores of the items that comprise it. The higher the score, the more likely the subject is to adopt the behavior. For the items derived from negative beliefs, which reveal the disadvantages of the behaviors, the scores are later on inverted so that higher scores indicate greater favorability for adherence.

The preliminary version of *5R-MEDSAFE* was sent to the panel of experts, who evaluated it in terms of the comprehensibility and relevance properties of each item and comprehensiveness of the total number of items. Five experts were invited, two from Canada and three from Brazil, who met the criteria of having in the TPB or patient safety areas.

To check agreement among the experts, the CVI-I and the CVI for the questionnaire as a whole (CVI-Total) were calculated. The items with CVI values below 0.80 were excluded or reworked[14].

The Fleiss Kappa test[15] was also performed to assess inter-observer agreement of the instrument’s attributes.

After the evaluation stage by the expert’s committee, the researchers held a discussion to review and reach consensus on the items for the preliminary version of the scale to be pre-tested with the target population.

5R-MEDSAFE pre-test

The questionnaire was applied to Nursing workers from both institutions who were active in direct patient care and drug administration, regardless of the time they had been working in the institution and in the unit. Workers on leave during the data collection period were excluded.

The technique used to assess understanding and presentation of the instrument was cognitive interview[16]. This technique is applied to a sample of 10 to 15 individuals from the target population, in order to assess comprehension of the items and calibrate the answer pattern, to avoid errors or distortions either in comprehension, in the search for information memory or in distorting the answers due to a supposed judgment (social desirability)[17].

The stages in the creation and content validation of the Questionnaire for assessing the psychosocial determinants of adherence to the safe drug administration 5Rs – *5R-MEDSAFE* are summarized in Figure 1.

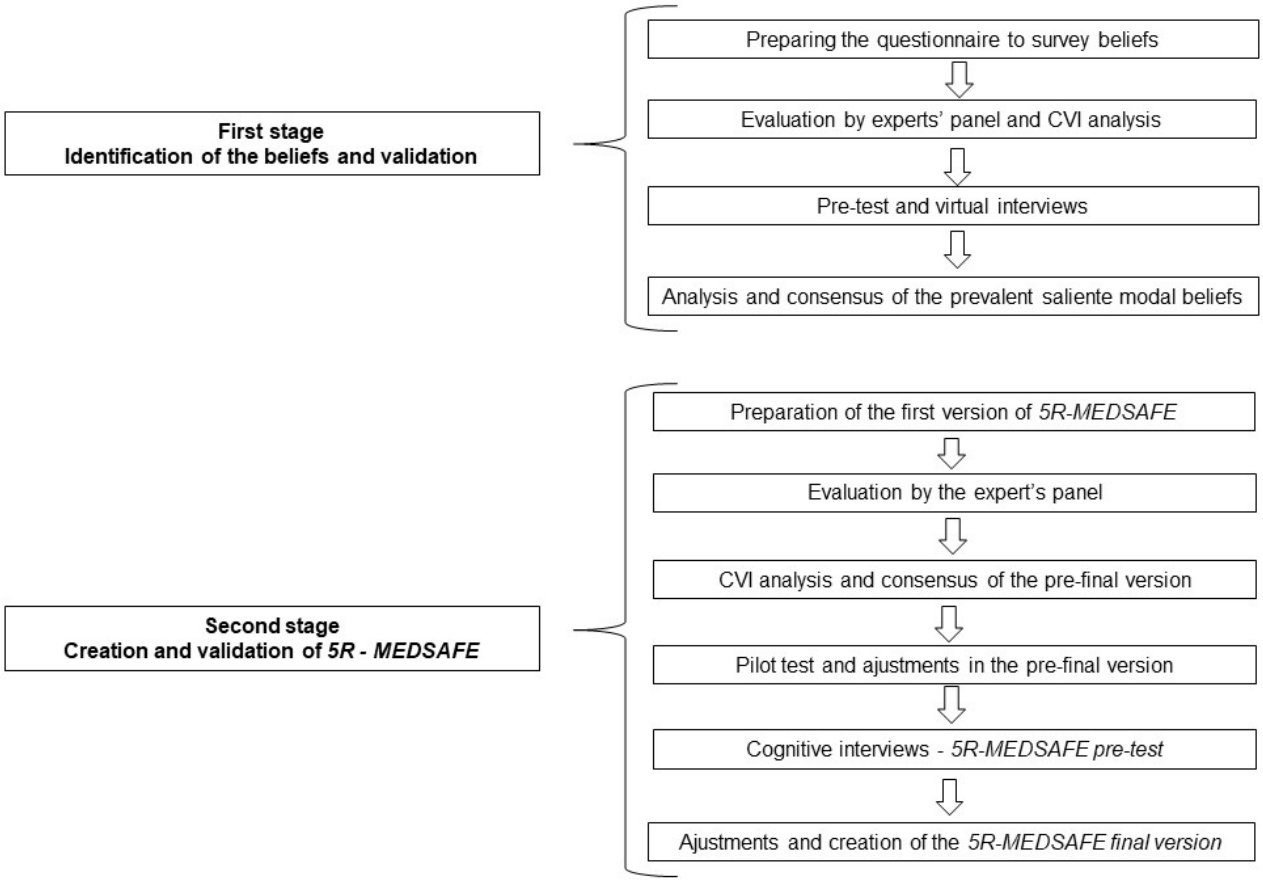

Figure 1 – Flowchart corresponding to the process of preparing and validating the instrument for assessing the direct and indirect psychosocial factors of adherence to the safe medication protocol: *5R-MEDSAFE*.

The study was approved by the ethics committees of both institutions involved, and data collection was only initiated after due approval, according to the following records.

RESULTS

The results will be presented according to the *5R-MEDSAFE* content validation stages.

Experts' committee results

Five experts took part in the content validation process, as described above. Although the Fleiss Kappa test was not statistically significant among the observers, the CVI presented excellent agreement values, as shown in Charts 1 and 2. Chart 1 shows the results of this evaluation according to the items created from the TPB elements.

Chart 1 – Agreement among the experts regarding comprehensibility and relevance of each item and the scope of the Beliefs dimensions of the *5R-MEDSAFE* Questionnaire, according to CVI-Item and CVI-Total – Santa Maria, 2023.

Items	*P	E1	E2	E3	E4	E5	CVI-I	CVI-Total	Consensus version
1. Intention									
1.1 I intend to adhere to safe drug administration behaviors (doing all 5 "rights") over the next two weeks.	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
1.2 I plan to adhere to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
1.3 I intend to adhere to safe drug administration behaviors...	†C	4	4	4	3	4	1.0	-	Unchanged
	‡R	4	4	4	3	4	1.0	-	
1.4 I want to adhere to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0		
1.5 I will strive to adhere to safe drug administration behaviors	†C	4	4	4	4	3	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
1.6 The probability of me adhering to safe drug administration behaviors (doing all 5 "rights") over the next two weeks is...	†C	4	4	4	4	3	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
Items – Intention	§S	4	4	4	4	4	1.0	1.0	
2. Attitude									
For me, adhering to safe drug administration behaviors (doing all 5 "rights") over the next two weeks is: 2.1 Very bad; bad; no opinion or neutral; good; very good	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
2.2 Very unnecessary; unnecessary; no opinion or neutral; necessary; very necessary	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
2.3 Very useless; useless; no opinion or neutral; useful; very useful	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
2.4 Very relevant; relevant; no opinion or neutral; irrelevant; very irrelevant	†C	4	4	4	4	2	0.8	-	Very irrelevant; irrelevant; no opinion or neutral; relevant; very relevant
	‡R	4	4	4	4	4	1.0		

Chart 1 – Cont.

Items	*P	E1	E2	E3	E4	E5	CVI-I	CVI-Total	Consensus version
2.5 Very disadvantageous; disadvantageous; no opinion or neutral; advantageous; very advantageous	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
2.6 Very difficult; difficult; no opinion or neutral; easy; very easy	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	3	4	1.0	-	
2.7 Very time-consuming; time-consuming; no opinion or neutral; fast; very fast.	†C	4	4	4	2	4	0.8	-	Unchanged
	‡R	4	4	4	2	4	0.8	-	
2.8 Very repetitive; repetitive; no opinion or neutral; not very repetitive; not repetitive at all	†C	4	4	4	3	4	1.0	-	Unchanged
	‡R	4	4	3	3	4	1.0	-	
Items – Attitude	§S	4	3	4	4	4	1.0	1.0	
3. Perceived Norm									
3.1 People whose opinions are important to me would approve of me adhering to safe drug administration behaviors... (doing all 5 “rights”) over the next two weeks.	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
3.2 People whose opinions are important to me want me to adhere to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
3.3 Most of my coworkers who are important to me will adhere to safe drug administration behaviors (doing all 5 “rights”) over the next two weeks.	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
3.4 Among the coworkers I know: ( ) None of them ( ) Less than half ( ) Half ( ) More than half ( ) All of them ...adhere(s) to safe drug administration behaviors...	†C	4	4	4	4	3	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
3.5 As a Nursing worker, I am expected to adhere to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
Items – Perceived Norm	§S	4	3	4	4	4	1.0	1.0	Unchanged
4. Perceived Behavior Control									
4.1 It is only up to me to adhere to safe drug administration behaviors (doing all 5 “rights”) over the next two weeks.	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
4.2 It is within my control to adhere to safe drug administration behaviors (doing all 5 “rights”) over the next two weeks.	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
4.3 I am sure that I can adhere to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	

Chart 1 – Cont.

Items	*P	E1	E2	E3	E4	E5	CVI-I	CVI-Total	Consensus version
4.4 I am confident about my ability to adhere to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
4.5 I am able to adhere to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
4.6 It is only up to me to adhere to safe drug administration behaviors (doing all 5 “rights”) over the next two weeks.	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
4.7 It is within my control to adhere to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
4.8 I am sure that I can adhere to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
4.9 I am confident about my ability to adhere to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Unchanged
	‡R	4	4	4	4	4	1.0	-	
Items – Perceived Behavior Control	§S	4	4	4	4	4	1.0	1.0	

*P: Property; †C = Comprehension; ‡R = Relevance; §S = Scope.

The results corresponding to the experts’ assessment of the items measuring beliefs in adherence to the safe drug administration 5Rs are shown in Chart 2.

Chart 2 – Agreement among the experts regarding comprehensibility and relevance of each item and the scope of the Beliefs dimensions of the *5R-MEDSAFE* Questionnaire, according to CVI-Item and CVI-Total – Santa Maria, 2023.

Items	*P	E1	E2	E3	E4	E5	CVI-Item	CVI-Total	Consensus version
5 Behavioral Beliefs									
Adhering to safe drug administration behaviors (doing all 5 “rights”) over the next two weeks: 5.1 would prevent me from making mistakes when administering medications.	†C	4	4	4	4	4	1.0	-	...would help me avoid making mistakes when administering medications.
	‡R	4	4	4	4	4	1.0	-	
5.2 would contribute to patient safety.	†C	4	4	4	4	4	1.0	-	...would contribute to patient safety.
	‡R	4	4	4	4	4	1.0	-	
5.3 would enable me to act in accordance with Nursing professionals’ ethics	†C	4	4	4	4	4	1.0	-	...would increase the time I need to administer medications.
	‡R	4	4	4	4	4	1.0	-	
5.4 would increase the time I need to administer medications.	†C	4	4	4	4	4	1.0	-	Excluded
	‡R	4	4	4	4	4	1.0	-	

Chart 2 – Cont.

Items	*P	E1	E2	E3	E4	E5	CVI-Item	CVI-Total	Consensus version
5.5 would give me a sense of accomplishment.	†C	4	4	4	4	3	1.0	-	...would give me a sense of accomplishment.
	‡R	4	4	4	4	4	1.0	-	
Items – Behavioral Beliefs	§S	4	4	3	4	4	1.0	1.0	
6 Control Beliefs									
6.1 Having knowledge would make it easier for me to adhere to safe drug administration behaviors...	†C	4	4	4	4	3	1.0	-	Over the next two weeks, the following factors would ease my adherence to safe drug administration behaviors (doing all 5 “rights”): My knowledge level
	‡R	4	4	4	4	4	1.0	-	
6.2 Attending regular training sessions would make it easier for me to adhere to safe drug administration behaviors.	†C	4	4	4	4	4	1.0	-	My participation in previous periodic training sessions
	‡R	4	4	4	4	4	1.0	-	
6.3 Having professional experience would make it easier for me to adhere to safe drug administration behaviors (doing all 5 “rights”) over the next two weeks.	†C	4	4	4	4	3	1.0	-	My level of professional experience
	‡R	4	4	4	4	4	1.0	-	
6.4 Supporting the safety culture in the workplace would make it easier for me to adhere to safe drug administration behaviors...	†C	4	2	2	4	3	0.6	-	The institution’s support for the safety culture in my work environment
	‡R	4	4	4	4	4	1.0	-	
6.5 Insufficient Nursing staffing would hinder my adherence to safe drug administration behaviors...	†C	4	4	4	4	3	1.0	-	Appropriate Nursing staffing in my work environment
	‡R	4	4	4	4	4	1.0	-	
6.6 Resistance to changes in the work routine would hinder my adherence to safe drug administration behaviors...	†C	2	2	4	4	2	0.4	-	Being open to changes in the work routine
	‡R	4	3	4	4	3	1.0	-	
6.7 Noise in the medication preparation room would hinder my adherence to safe drug administration behaviors (doing all 5 “rights”) over the next two weeks.	†C	4	4	4	4	2	0.8	-	Over the next two weeks, the following factors would hinder my adherence to safe drug administration behaviors (doing all 5 “rights”): Noise in the medication preparation environment
	‡R	4	4	4	4	3	1.0	-	

Chart 2 – Cont.

Items	*P	E1	E2	E3	E4	E5	CVI-Item	CVI-Total	Consensus version
6.8 Absence of an exclusive place for preparing medications would hinder my adherence to safe drug administration behaviors...	†C	4	4	4	4	2	0.8	-	Absence of an exclusive area for preparing medications.
	‡R	4	4	4	4	3	1.0	-	
6.9 Work overload would hinder my adherence to safe drug administration behaviors...	†C	4	4	4	4	4	1.0	-	Work overload
	‡R	4	4	4	4	4	1.0	-	
6.10 Performing too many activities at the same time would hinder my adherence to adhere to safe drug administration behaviors...	†C	4	3	4	4	3	1.0	-	Performing several activities at the same time
	‡R	4	3	4	4	4	1	-	
Items – Control Beliefs	§S	4	3	4	4	4	1	1.0	
7 Normative Beliefs									
7.1 Most of the patients think that I should adhere to safe drug administration behaviors...	†C	4	3	4	4	4	1.0	-	Unchanged
	‡R	4	3	4	4	4	1.0	-	
7.2 Most of the patients' relatives would expect me to adhere to safe drug administration behaviors...	†C	4	3	4	4	4	1.0	-	Unchanged
	‡R	4	3	4	4	4	1.0	-	
7.3 My immediate manager and/or supervisors would expect me to adhere to safe drug administration behaviors...	†C	4	3	4	4	4	1.0	-	Unchanged
	‡R	4	3	4	4	4	1.0	-	
7.4 All Nursing professionals think that I should adhere to safe drug administration behaviors...	†C	4	3	4	4	4	1.0	-	Unchanged
	‡R	4	3	4	4	4	1.0	-	
7.5 Adhering to safe drug administration behaviors (doing all 5 "rights") over the next two weeks would mean doing the right thing.	†C	4	4	4	4	3	1.0	-	Excluded
	‡R	2	4	4	4	4	0.8	-	
7.6 Adhering to safe drug administration behaviors (doing all 5 "rights") over the next two weeks would mean acting in accordance with professional ethics.	†C	4	4	4	4	4	1.0	-	Adhering to safe drug administration behaviors (doing all 5 "rights") over the next two weeks: 8.1...would mean acting in accordance with professional ethics
	‡R	2	4	4	4	3	0.8	-	
7.7 Adhering to the safe drug administration behaviors (doing all 5 "rights") over the next two weeks is Nursing professionals' duty.	†C	4	4	4	4	4	1.0	-	8.2 ...is Nursing professionals' duty.
	‡R	2	4	4	4	3	0.8	-	
7.8 Adhering to safe drug administration behaviors (doing all 5 "rights") over the next two weeks is Nursing professionals' responsibility.	†C	4	4	4	4	4	1.0	-	8.3 ...is Nursing professionals' responsibility.
	‡R	4	4	4	2	3	0.8	-	
Items – Normative Beliefs	§S	4	3	4	2	4	0.8	1.0	

*P: Property; †C = Comprehension; ‡R = Relevance; §S = Scope.

After the evaluation stage by the experts' committee, the preliminary version of *5R-MEDSAFE* consisted of 46 items, distributed as follows: Behavior (items 1 and 2); Intention (3,4,5,6, 7 and 8) – 6 items; Attitude (9.1 to 9.7) – 7 items; Perceived Norm (10,11,12, 13 and 14) – 5 items; Perceived Behavior Control (15,16,17, 18 and 19) – 5 items; Behavioral Beliefs (20. 1 to 20.4) – 4 items, with item 20.3 having a reverse score; Control Beliefs (21.1 to 22.4) – 10 items; Normative Beliefs (23,24, 25 and 26) – 4 items; and Moral Norm Beliefs (27.1 to 27.5) -– 5 items.

5R-MEDSAFE pre-test results: cognitive interviews

Fourteen Nursing professionals took part in the instrument pre-test stage by means of cognitive interviews, nine of them nurses and five nursing technicians, who made a few suggestions about the wording of some items, which were incorporated into the final version of the instrument.

Although the subjective measurement of behaviors and the answer scale reached CVI=1.0 in the pre-test, the cognitive interviews showed that most of the interviewees felt that using percentage bands hindered their answers. It was therefore decided to change the answer scale to: "Rarely or never; Less than half of the times; Half of the times; More than half of the times; Frequently or always".

DISCUSSION

The creation and content validation of the instrument proposed in this article reveal the complexity of carrying out the stages that make up a methodological study. This complexity is reflected in the stages that are conducted, which cohere as they are performed. Creation and validation processes complement each other in terms of what they aim at achieving and of what they measure[18–19]. The content validity of this instrument indicates that it measures what is intended to, considering the study objective[20].

It was possible to list the salient modal beliefs for creating the instrument from renowned experts in the field, which conferred security and rigor both to the interview script and to the instrument itself. This possibility of a rapprochement between experts from different realities (Brazil and Canada) indicates that it is possible that the beliefs surveyed are similar in both realities.

The CVI calculated in both stages evidenced good balance among the experts, which allowed for minor adjustments and consensus between the researchers. The CVI is a safe and reliable quantitative analysis, even though it is measured based on a subjective analysis by a specialist with expertise in the area under study and remarkable knowledge about the topic[14].

As for the items assessing the direct psychosocial factors of behaviors, the experts made suggestions for the wording and reorganization of the Moral Norm items, which were incorporated into the group of items in the Professional Norm domain. As behavior involves the work context, it was decided to keep the items grouped under Professional Norm, which includes the values and principles of the profession[10]. Another study also observed that subjective norms, personal norms or norm beliefs are important factors in determining nurses' intention to adhere to universal venipuncture precautions[21]. In view of this, it is possible that the values of the profession are the most important determinants for the performance of health behaviors by workers.

The beliefs were grouped according to the TPB constructs. In the Behavioral beliefs group, the participants' perception regarding patient safety as a reason for adhering to the behaviors stands out. Some studies evidence that people have greater intention or adhere to a given behavior when they believe that there will be positive consequences if they adopt it[21,22,23]. This can also justify the belief in doing the right thing.

In relation to the control beliefs, it is verified that items related to infrastructure and staffing adequate to the job demands, as well as space for training sessions, support from the institution and professional experience, emerged as important elements for adherence to the behaviors. These aspects are also similar to a study that assessed adherence to hand hygiene, in which the participants also indicated organizational culture, structure and supervision as important variables for carrying out the behaviors[24]. These results indicate the importance of the institution's support in relation to the feeling of control over a given behavior. Thus, initiatives that seek the participation of supervisors, bosses or managers in the discussion of improvements in the work environment and the engagement of all those involved are fundamental to adherence to safe drug administration behaviors[21]. One study identified that improvements in the work environment are also positive for the notification of incidents[25] which can also be positive for improving adherence to safety protocols, especially for safe drug administration

Concern about the evaluation of patients and their families, supervisors and managers, as well as coworkers, was a belief that prevailed in the Normative beliefs group. Some authors assert that, by themselves, behaviors related to adherence to care protocols already carry along a strong appeal from subjective norms[26]. This may explain the appeal experienced by Nursing professionals in complying with standardized routines.

In relation to the items in the instrument for assessing beliefs in a global way, it was observed that there were no differences among the participants in the pre-test. Therefore, the beliefs listed in the instrument are present at both institutions in different Brazilian regions. Although the beliefs were not assessed in this article, this pre-test result suggests that the instrument may be used in other regions of the country. Although there may be differences in the training and work panorama between the South and Southeast regions, as indicated by a document that outlined the profile of Brazilian Nursing[27], the beliefs related to the behaviors under study seem to be similar in these contexts.

This initial finding from the pre-test allows reflecting on how positive the instrument might be in assessing the direct and indirect psychosocial factors of workers' behaviors associated with adherence to the safe drug administration protocol in terms of the 5Rs. Thus, if the items listed in *5R-MEDSAFE* are common and present in different realities, it is possible that the proposals for improving safe care by preventing incidents in drug administration can also be shared. This aspect reinforces the need and importance of studying these behaviors among Nursing workers.

The study limitations include the fact that it was carried out during the COVID-19 pandemic, which made it difficult to sensitize workers to take part in the research. This resulted in a small sample. However, other studies can be carried out with larger samples and, consequently, other analyses using *5R-MEDSAFE* can be conducted.

CONCLUSION

The results obtained in this creation and content validation study of the *5R-MEDSAFE* instrument indicated that the tool presented diverse content validity evidence. Its application can be useful in different contexts as a way of assessing adherence to these behaviors among Nursing workers. This will make it possible to identify which elements of the behaviors are amenable to intervention, as well as to implement the most appropriate intervention, according to the TPB constructs.

REFERENCES

1. Rohde E, Domm E. Nurses' clinical reasoning practices that support safe medication administration: An integrative review of the literature. J Clin Nurs [Internet]. 2018 [cited 2023 Jun 5];27(3-4):402-11. Available from: https://doi.org/10.1111/jocn.14077
2. Martyn JA, Paliadelis P, Perry C. The safe administration of medication: Nursing behaviours beyond the five-rights. Nurse Educ Pract [Internet]. 2019 [cited 2023 Aug 5];37:109-14. Available from: https://doi.org/10.1016/j.nepr.2019.05.006
3. Paulino GME, Matsuda LM, Matta ACG, Ferreira AMD, Dias A de O, Silva LF. Costs and root causes of medication errors and falls in a teaching hospital: Cross-sectional study. Texto Contexto Enferm [Internet]. 2021 [cited 2023 Apr 15];30:e20200045. Available from: https://doi.org/10.1590/1980-265X-TCE-2020-0045
4. Camargos RGF, Azevedo C, Moura CC, Manzo BF, Salgado PO, Mata LRF. Protocolo de segurança na prescrição, uso e administração de medicamentos: Mapeamento de intervenções de enfermagem. Texto Contexto Enferm [Internet]. 2021 [cited 2023 Oct 22];30:e20200511. Available from: https://doi.org/10.1590/1980-265X-TCE-2020-0511
5. World Health Organization. Global patient safety action plan 2021–2030: Towards eliminating avoidable harm in health care [Internet]. Geneva, (CH): World Health Organization; 2021 [cited 2023 Jun 5]. Available from: https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan
6. Brás CP da C, Figueiredo M do CAB de, Ferreira MMC. Safety culture in obstetric nurses' clinical practice. Texto Contexto Enferm [Internet]. 2023 [cited 2023 Nov 10];32:e20220330. Available from: https://doi.org/10.1590/1980-265X-TCE-2022-0330en
7. Ministério da Saúde (BR). Portaria nº.529, de 1 de abril de 2013. Institui o Programa Nacional de Segurança do Paciente (PNSP) [Internet]. Brasília, DF(BR): Diário Oficial da União República Federativa do Brasil; 2013 [cited 2020 Jan 10]. Available from: https://www20.anvisa.gov.br/segurancadopaciente/index.php/legislacao/item/portaria-529
8. Hanson A, Haddad LM. Nursing rights of medication administration. In: StatPearls [Internet]. Treasure Island, (FL): Stat Pearls Publishing; 2023 [cited 2020 Jan 10]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560654/
9. Ajzen I. From intentions to action: A theory of planned behavior. In: Kuhl J, Beckman J, editors. Action control: From cognition to behavior. Heidelberg: Springer; 1985. p. 11-39.
10. Nickell GS, Hinsz VB. Applying the theory of planned behavior to understand workers' production of safe food. The JWOP [Internet]. 2023 [cited 2019 Nov 15];39(2):89-100. Available from: https://doi.org/10.5093/jwop2023a10
11. Jannuzzi FF, Cornélio ME, São-João TM, Gallani M-C, Godin G, Rodrigues RCM. Psychosocial determinants of adherence to oral antidiabetic medication among people with type 2 diabetes. J Clin Nurs [Internet]. 2020 [cited 2019 Nov 15];29(5-6):909-21. Available from: https://doi.org/10.1111/jocn.15149

12. Ajzen I. Theory of planned behavior diagram [Internet]. 2019 [cited 2022 Jan 5]. Available from: http://people.umass.edu/aizen/tpb.diag.html

13. Campanelli P. Testing survey questions. In: De Lleuw ED, Hox J, Dillman DA, editors. International handbook of survey methodolgy. New York, NY(US): Lawrence Erlbaum Associates; 2008. p. 176-200.

14. Polit DF. Assessing measurement in health: Beyond reliability and validity. Int J Nurs Stud [Internet]. 2015 [cited 2022 Jan 5];52(11):1746-53. Available from: https://doi.org/10.1016/j.ijnurstu.2015.07.002

15. Fleiss JL. Measuring nominal scale agreement among many raters. Psychol Bull [Internet]. 1971 [cited 2022 Jan 5];76(5):378-82. Available from: https://doi.org/10.1037/h0031619

16. Polit DF, Yang FM. Measurement and measurement of change: A primer for the health professions. Philadelphia, PA(US): Wolters Klumer; 2016.

17. Gagné C, Godin G. Mensuração das variáveis teóricas e dos comportamentos. In: Godin G. Os comportamentos da área da saúde: Compreender para melhor intervir. Campinas, SP(BR): Editora da Unicamp; 2019. p. 237-96.

18. Ramos FRS, Barlem EL, Brito MJM, Vargas MAO, Schneider DG, Brehmer LCF. Construção da escala brasileira de distresse moral em enfermeiros – Um estudo metodológico. Texto Contexto Enferm [Internet]. 2017 [cited 2022 Jan 5];26(4):e0990017. Available from: https://doi.org/10.1590/0104-07072017000990017

19. Souza AC, Alexandre NMC, Guirardello EB. Propriedades psicométricas na avaliação de instrumentos: Avaliação da confiabilidade e da validade. Epidemiol Serv Saúde [Internet]. 2017 [cited 2022 Jan 5];26(3):649-59. Available from: https://doi.org/10.5123/s1679-49742017000300022

20. Cicchetti DV, Feinstein AR. High agreement but low kappa: II. Resolving the paradoxes. J Clin Epidemiol [Internet]. 1990 [cited 2022 Jan 5];43(6):551-8. Available from: https://doi.org/10.1016/0895-4356(90)90159-m

21. Ganon MP, Legaré F, Godin G. Aplicação das teorias de predição no caso dos comportamentos associados às práticas clínicas de trabalhadores da saúde. In: Godin G. Os comportamentos da área da saúde: Compreender para melhor intervir. Campinas, SP(BR): Editora da Unicamp; 2019. p. 217-34.

22. Sousa S, Correia E, Viseu C, Larguinho M. Analysing the Influence of Companies' Green Communication in College Students' Green Purchase Behavior: An application of the extended theory of planned behavior model. Adm Sci [Internet]. 2022 [cited 2023 Nov 15];12(3):80. Available from: https://doi.org/10.3390/admsci12030080

23. Cui H, Sun R, Wang Y, Lin L, Duo R, Li Y, et al. Investigation and influencing factors of the behavioral intention of nurses voluntarily participating in the care of older adults with disabilities. Int J Nurs Sci [Internet]. 2023 [cited 2023 Nov 15];10(1):64-71. Available from: https://doi.org/10.1016/j.ijnss.2022.12.008

24. Ghaffari M, Rakhshanderou S, Safari-Moradabadi A, Barkati H. Exploring determinants of hand hygiene among hospital nurses: a qualitative study. BMC Nurs [Internet]. 2020 [cited 2023 Nov 15];19(1):109 Available from: https://doi.org/10.1186/s12912-020-00505-y

25. Rogers JW, Fleming M, Tipton J, Ward A, Garey KW, Pitman EP. Investigating inpatient medication administration using the theory of planned behavior. Am J Health Syst Pharm [Internet]. 2017 [cited 2020 Jan 22];74(24):2065-70. Available from: https://doi.org/10.2146/ajhp160502

26. Borges AR, Magalhães AMM, Lima GO, Silva T, Dornfeld D, Quadros DV, et al. Incidentes de segurança do paciente pediátrico antes e durante a COVID-19: Estudo de métodos mistos. Texto Contexto Enferm [Internet]. 2022 [cited 2023 Oct 22];32:e20220179. Available from: https://doi.org/10.1590/1980-265X-TCE-2022-0179pt

27. Machado MH, coord. Perfil da enfermagem no Brasil: Relatório final [Internet]. Rio de Janeiro, RJ(BR): NERHUS, DAPS, ENSP, Fiocruz; 2017 [cited 2023 Jun 5]. 750 p. Available from: https://www.cofen.gov.br/perfilenfermagem/pdfs/relatoriofinal.pdf

NOTES

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