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Artículo Original

MEDICATION ADMINISTRATION DISTRACTION OBSERVATION SHEET CHECKLIST: CULTURAL ADAPTATION AND VALIDATION INTO SPANISH

Lista de chequeo: "hoja de observación de distracciones en la administración de medicamentos.": adaptación cultural validación al español

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PALABRAS CLAVE:
Distracción; Interrupción; Enfermería; Medicamentos; Estudios de validación.

RESUMEN

Introducción: Las distracciones son aferencias sensoriales que superan el umbral de atención del individuo razón por la cual se han asociado con las fallas procedimentales y errores clínicos en la práctica asistencial. **Objetivo.** Adaptar y validar al contexto colombiano la lista de chequeo "Hoja de Observación de Distracciones en la Administración de Medicamentos." **Materiales y Métodos.** Estudio de enfoque cuantitativo, transversal, metodológico que comprendió la adaptación cultural y validación de apariencia y, contenido de un instrumento que mide dos atributos del concepto distracciones (origen y frecuencia) con la participación de cinco expertos en la temática. Se determino la confiabilidad inter observador a través del coeficiente Kappa y la consistencia interna con el coeficiente alfa de Cronbach en el paquete estadístico SPSS v22. Resultados. La lista de chequeo adaptada y validada al español colombiano conservo todos los ítems originales del instrumento, queda con una razón e índice de validez de contenido de 1, una confiabilidad inter-investigador entre 0,82-1,00 (concordancia substancial) y un alfa de Cronbach de 0,54 (aceptable). **Conclusiones.** Pocas investigaciones reconocen utilizar el instrumento tal cual el autor lo propone, algunos se inspiran en él para crear sus propios instrumentos, mientras que otros lo usan, pero no reportan su validación. Solo tres estudios entre ellos el presente reportan análisis psicométricos realizados al instrumento con cambios menores posterior a su ejecución. El instrumento puede aplicarse a la práctica clínica de enfermería en Colombia y se recomienda a futuro incluir nuevos atributos del concepto.

KEYWORDS:
Distraction; Interruption; Nursing; Medication; Validation studies.

ABSTRACT

Introduction: Distractions are sensory inputs that exceed the individual's attention threshold, which is why they have been associated with procedural failures and clinical errors in care practice. Objective. To adapt and validate the "Observation Sheet for Distractions in the Administration of Medication" to the Colombian context. Materials and methods. The study followed a quantitative, cross-sectional, and methodological approach that included the cultural adaptation and validation of both the appearance and the content of an instrument measuring two attributes of the concept of distractions—namely, origin and frequency—with the input of five experts on the topic. Inter-observer reliability was determined through the kappa coefficient, and internal consistency with Cronbach's alpha coefficient in the statistical package SPSS v22. Results. Once adapted and validated to Colombian Spanish, the checklist kept all of the original items of the instrument, with a content validity ratio and index of 1, an inter-observer reliability between 0.82 and 1.00 (substantial agreement), and a Cronbach's alpha of 0.54 (acceptable). Conclusions. Few studies admit to using the instrument as the author proposes; some draw inspiration from it to create their own instruments, while others use it but do not report its validation. Only three studies, including this one, report psychometric analyses performed on the instrument with minor changes after its execution. The instrument can be applied to clinical nursing practice in Colombia; in the future, it is recommended to include new attributes of the concept.

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MEDICATION ADMINISTRATION DISTRACTION OBSERVATION SHEET CHECKLIST: CULTURAL ADAPTATION AND VALIDATION INTO SPANISH

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INTRODUCCIÓN

Distractions (DS) during nursing work are common and idiosyncratic to work environments, with an average of 9.9 interruptions per hour (interval 6.3 – 20)[1,2]; the medication process is the most susceptible to distraction (preparation 73% - 95% and administration 26% - 48%), with 5.8 interruptions per medication round[3,4]. A study conducted in intensive therapy showed that each distraction increased the risk of procedural failure and clinical error by 12.7%, and a higher frequency of distraction and changes in the nurse's physical position meant higher risk and time to resume the activity[5].

Therefore, distractions have as their first victim the patient, who suffers the consequences, but as their second victim the nursing staff, given that they are the receptors of these. The DS are sensory afferences that surpass the person's care threshold, forcing them to decide whether to accept or reject the interruption by changing the mental process in course to make way for the secondary activity (the distraction). This is why a DS alters, prolongs, changes, or cancels one task in favor of another, not planned, being deleterious in essence for professional performance[6].

The literature reports numerous empirical indicators to address the DS concept; one of them, and perhaps the model for the rest, corresponds to the "Medication Administration Distraction Observation Sheet (MADOS)," an instrument that objectively evaluates DS[7]. This was designed by Dr. Theresa Pape in 2002 after a careful review of the literature and a rigorous validation process using the Content Validity Index (CVI), with a CVI of 7.0 indicating a highly valid instrument[8,9]. Since its development, the instrument has been used successfully in multiple clinical scenarios globally without priori or subsequent reports of a validation process[10,11]. Given the high degree of usefulness of the instrument to measure the concept and become the standard for future empirical indicators on the topic, the objective of this study was to adapt and validate the MADOS checklist to be used in Spanish in the Colombian population.

MATERIALS AND METHODS

Type of study: this was a quantitative, cross-sectional, and methodological study of cultural adaptation and face and content validation into Spanish in the Colombian context of an instrument to evaluate the distractions of nurses during the medication process[12-14].

Instrument: the checklist, entitled "Medication Administration Distraction Observation Sheet (MADOS) v.20167-9" is made up of ten items designed to list the distractions during the administration of medication. These items are categories that include the origin or potential source of the DS (medical staff, other staff members, telephone calls, problems with the medications, emergency situations, conversations, noise, problems with equipment, and others), along with an open statement for comments. The researcher (observer) must fill out the list by making a vertical mark for each DS in the corresponding category as these are presented; at the end, the marks are added up, generating a number that corresponds to the amount of DS in that category. The checklist also permits characterizing the context of the observation with data such as date of observation, observation number, the number of patients assigned, number of medications each patient, scheduled medication time, start time, stop time, and elapsed time.

Study period: this research was conducted between June 2018 and January 2019. The face validation and content validation phases were executed through communication via email with the panelist. The inter-researcher reliability phase was carried out in a tier IV health institution (adult hospitalization) and the phase internal consistency was developed in two scenarios (hospitalization and adult intensive therapy in two tier III and IV institutions from the Colombian southwest).

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Sample size: the sample size was determined by considering the modification of the Lawshe model for the quantitative opinion of the content validity, which calls for at least five experts[15,16]. In this case, the panelists were five nurses with an average of 12 years of mixed clinical experience (hospitalization and adult intensive care unit), with academic training in areas related to the study topic (Master's and/or PhD in Public Health, Epidemiology, Critical Care and/or Pharmacology), all aware of the concept, with experience in evidence-based decision making, and with motivation and availability to participate in the study.

Information collection format: the study used a format composed of tables in Microsoft Word®, which had a heading with the panelists' general information, in addition to another table with multiple-choice closed-ended questions. Two aspects from the MADOS checklist were evaluated: a) face validity, which assessed understanding of the approach, accuracy of the statement, and language clarity; b) content validity, with single-answer closed-ended questions to assess if the items were "essential" (indispensable to measure the concept), "useful but not essential" (important but not indispensable), or "not necessary" (not important for measuring the concept) (Table 1 and Table 2). The aforementioned was considered bearing in mind the peculiarities of the Spanish language for Colombia and the area of health. Upon finishing each table, an observations column was included that permitted the experts to broaden their comments in that respect, as well as an explanation booklet with information on filling out the instrument, the purpose of the instrument, the conceptual definition, the components, and the characteristics to measure.

Table 1. Evaluation format of face validity of the MADOS checklist

No. / Question and answer options	Clarity		Accuracy		Understanding		Suggestions and Recommendations
	YES	NO	YES	NO	YES	NO	
Item #1 ...							

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Item #1 ...							

Procedure and data collection. **First step:** request permission from Dr. Theresa Pape, author of the instrument, to reprint it, subject it to the cultural adaptation process, and therefore modify it[16].

Second step: direct translation (English to Spanish) by a team of three translators certified by the Colombian Ministry of Foreign Relations, skilled in both languages (English and Spanish), knowledgeable of health literature, and experienced in translating instruments, who worked independently. The final product by each was revised by a fourth translator who elaborated the final version in Spanish. The purpose of this "process is not the textual or literal translation, but the translation of the conceptual sense that each item seeks"[12,16].

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Third step: the evaluation format was sent by email to the panelists, who had to fill it out according to the criteria of face validity—clarity, accuracy, and comprehension—and criteria of content validity to determine if these should or should not belong to the instrument (essential); this step was repeated twice until obtaining unanimity among the evaluators[15,16].

Fourth step: this phase consisted of the re-translation into the original language (English) of the instruments from their translated version (Spanish) after the face and content validation, which was carried out by a team of official translators different from the first group, independent of the project and previously ignoring the objectives or concepts of the study (the process was exactly the same previously described). This was done to diminish the probability of bias and expectations towards their own work. Production of the official version in English was carried out by following the same steps of the direct translation and sent to the author for recognition and approval[12,16].

Fifth step: the instrument was applied within the framework of a larger study titled "Relationship of Distractions, Socio-Demographic and Contextual Characteristics with Safe Injection Practices During Nurses' Clinical Practice" by the Faculty of Nursing at the Universidad Nacional de Colombia, intended to obtain data related to the instrument's psychometric behavior in clinical scenarios, among which inter-rater reliability between researchers in the pre-pilot phase (three weeks) executed in three different opportunities along this stage (at the start, middle, and end of the phase) for a total of 18 medication processes observed. This phase includes the observation at the same time by two researchers of an injection practice and the recording of the distractions that occurred in that period of time. Internal consistency was calculated after the operational phase of the study (two months) observing 448 medication processes[12,16]. This last phase occurred withing the framework of the large study.

Quantitative data analysis: data obtained in the face validation were analyzed with descriptive statistics (proportions), accepting items with positive scores ≥ 70% among the panelists. Items not obtaining said score were subjected to a language adjustment with the subsequent notification and authorization by the author. The content validation also carried out descriptive statistics (proportions) in the "essential" category for each item, conserving those reaching consensus ≥ 58%. The content validity rate (CVR) was estimated for each item, and the content validity index (CVI) for the entire test15; inter-rater reliability was obtained through the Kappa coefficient by using the scale proposed by Landis & Koch to evaluate the degree of agreement (0: Poor; 0.01 – 0.2: Slight; 0.21 – 0.4: Regular; 0.41 – 0.6: Moderate; 0.61 – 0.8: Substantial; 0.81 – 1: Almost Perfect)[17,18]. Lastly, internal consistency was calculated with Cronbach's alpha coefficient[19]. All data were processed in the statistical package for the social sciences SPSS v22.

Ethical considerations: the research to which this study belongs was approved by the ethics committee of the Faculty of Nursing at the Universidad Nacional de Colombia (AVAL 050 – 2018) and by the ethics committees of the health institutions. The present investigation was considered without risk because it does not intervene physical or psychological variables in human being according to Resolution 8430 of 1993 of Colombia[20]. Similarly, the ethical recommendations for nursing research proposed by Garzon Alarcon 2008 were followed. The previous ones were truthfulness of the results, faithfulness to the methodological protocol, confidentiality and privacy of the data, reciprocity with the participants, respect for the autonomy of the panelist and nurses observed during the medication process, use of the results for the benefit of participants, and discipline, justice, and respect for intellectual property[21].

RESULTS

MADOS - face validation: in the first round with the panelists, 7 of the 10 items obtained scores between 60% and 70% in one of the three criteria (clarity, accuracy, and/or comprehension). These items corresponded to the following distraction categories: medical staff, other staff members, calls, problems with the medication, emergency situations, conversations, and equipment; these required revision of each item, bearing in mind the recommendations by the panelists, the original document, and advice from a linguist, including the following changes:

Following panelists' recommendations, acronyms not used in medical charges in Colombia were removed ("MD", "PA", "NP") and replaced with the term "medical staff," which encompasses all medical specialties.

•Also following panelists' recommendations, all the definitions modified the verbal tense to the present indicative because the instrument is filled out while the distraction takes place; for example, "The medical staff distracts or interrupts the nurse who administers the medications."

•In the category "Equipment," the panelists recommended providing examples in the definition that made it easier for the researchers to understand what the statement means, for example, "Problems with equipment (e.g. monitors, computers, infusion pumps) that interrupt the process," rather than "Problems with equipment that interrupt the process."

•After the suggested changes were implemented, a second face-validation round was conducted with the panelists, obtaining 100% clarity, accuracy, and comprehension within each item.

MADOS – content validation: the 10 statements were evaluated by the panelists as essential for the instrument in the first round; the content validity rate (CVR) for each item was 1, while the content validity index (CVI) for the entire test was also 1.

MADOS – inter-researcher reliability: agreement among observers on the distractions experienced by the nurses during the medication process is shown in Table 3. The Kappa coefficient ranged between 0.82 and 1.00 for a level of agreement between substantial and almost perfect.

Table 3. Inter-rater reliability of two independent observers of the distractions experienced by the nurses during the medication process

Distractions / MADOS	MEASUREMENT 1: start of pre-pilot phase (n observations = 9)		
	Agreement observed	Kappa	p-value
Source	100%	0.873	0.00
Frequency of the distraction	80%	0.82	0.035
Conclusion: the first measurement identified differences in understanding some items, aspects discussed and feedback to improve agreement and registry among observers.			

Distractions / ITEM	MEASUREMENT 2: at the midpoint of the pre-pilot phase (n observations = 4))		
	Agreement observed	Kappa	p-value
Source	100%	1.000	0.045
Frequency of the distraction	100%	1.000	0.001
Conclusion: the second measurement showed substantial improvement in agreement among observers.			

Distractions / ITEM	MEASUREMENT 3: at the end of the pre-pilot phase (n observations = 5)		
	Agreement observed	Kappa	p-value
Source	100%	1.000	0.002
Frequency of the distraction	100%	1.000	0.000
Conclusion: the third measurement showed very good agreement among observers in all items.			

*Significance of 0.05 bilateral. Kappa hypothesis test: null hypothesis (Ho): $\kappa = 0$ and alternative (H1) $\kappa \neq 0$. Elaborated by the authors.

MADOS – internal consistency: internal consistency of the whole checklist was 0.54 with nine items and n = 305 distractions in 448 medication processes (Appendix A).

DISCUSSION

The adaptation and validation process of the checklist "Medication Administration Distraction Observation Sheet (MADOS) v.2016" developed in the present study provides an empirical indicator for the Colombian context. This is an internationally recognized instrument due to its contribution to research on the concept of distractions during the medication process. The nurse experts provided recommendations in aspects of form, such as not using English acronyms, maintaining a consistent grammatical structure throughout the document, using inclusive (gender-neutral) language, and providing examples that further clarify the messages of the items; these are measures that facilitate understanding the questions within the Colombian intra-hospital environment.

The first version of MADOS checklist (v2003) underwent a process of translation and validation onto the Colombian context in 2011 in which improvements were included, such as adding to the definition of the source "physician" the words "medical rounds," to the source "other staff members" the word "students," and to the source "visitors" the word "relative". (Family member). After the aforementioned modifications, the instrument was left with 10 items approved with 100% clarity, accuracy, and comprehension. With respect to the CVR from each item, it ranged between 0.75 and 1, with a CVI of 0.90 for the entire test[22]. The changes made to improve the writing and clarity of the items, as well as the values obtained in the CVR and CVI, are similar to those evidenced in this study.

Comparison of the results with other validation processes is complicated, given that few studies recognize using the instrument as proposed by the author. Many others are inspired by it as the gold standard to create their own checklists[10,11]. Two of these studies took place in English-speaking countries (the United States and the United Kingdom) and did not carry out any cultural adaptation process[23,24]; another two were conducted in Switzerland and Italy. Only the Italian study reports a direct and back-translation into Italian and accompaniment by a group of experts to eliminate and introduce new items related to pediatric units (for example, of the items reviewed: other nurses, another patient, parent/visitor, noise/doorbell), but, even so, these do not report any statistical analysis related to the process[25,26]. This is surprising because the literature recommends transcultural validation and measurement of the internal consistency every time the instruments are used in a geographic zone and dialect different from the original13. The same occurs with information related to the panelists' socioeconomic and labor data, which are also not available; hence, it is not possible to discuss their pros and cons[25,26].

With respect to inter-observer reliability, only the original study, which validated the instrument for the first time, reports this analysis, but it is carried out differently during the pilot test, given that the Kappa value or the agreement observed are not used. Said study calculated the total number of distractions per category and divided it according to the number of agreements over the number of agreements plus the number of disagreements, then compared the results between the principal researcher and the research assistant. Reliability in that study was > 0.90, similar to that reported in the present research[7-9]. However, the same does not occur with respect to the internal consistency tests, which are not reported in the publications that have used the instrument, with this being the first time it has been carried out[7,9,21,25,26].

Regarding the low results in the Cronbach's alpha estimation, we consider that these do not reflect the real internal consistency of the instrument, but rather the poor variability of the data gathered in the study. The low amount of distractions was observed during a selected time margin (medication process through injection practice) which was tight and ranged from 30 s to a maximum of 3 min 40s (results obtained from the operational phase), a reduced time frame to capture a considerable amount of distractions that would allow us to run the test with greater ease. This is why future research should provide this instrument with a greater time period and include different members of the health staff (technicians, technologists, odontologists, physicians, anesthesiologists, etc.) to capture the phenomenon with the greatest possible diversity, increasing variability and therefore permitting the execution of more complex statistical tests; if this is not done, the combination of few items, a shorter time period, and a reduced sample may lead to mistaken estimations and wrong interpretations of the analyses[27,28].

Furthermore, it is necessary for future investigations using this instrument to divulge the results corresponding to internal consistency, which are valuable data in that they reveal how the test behaves in repeated measurements to compare results. Likewise, it is worth exploring how the instrument behaves in other phases of the medication process, such as prescription, documentation, and monitoring. Lastly, it is important to examine if the same checklist structure and attributes of the concept can be studied within the framework of other care practices.

It is evident from the literature that the MADOS was the first empirical indicator in the nursing discipline to address the concept and start with the only two attributes described to date (origin – source of the distraction and frequency of appearance). Thereafter, researchers further expanded the frontier of knowledge of the concept by adding new attributes to inquire about, bearing in mind the reality of the phenomenon in the clinical scenarios, the methodological approaches selected, and technological progress, which is why numerous formats of structured observation and software-type instruments are available, such as the Work Observation Method by Activity Timing (WOMBAT)[29,30] and the Remote Analysis of Team Environments (RATE)[31,32]. Neither of these has been validated and used in research in Latin America; these instruments would allow future execution of the validity of concurrent criteria.

In recent years, other attributes have emerged as parts of the anatomy of distraction: duration in time, relevance of the distraction to the task being conducted (negative when it is disruptive, not related to the task in process, and does not seek a therapeutic objective; positive when the distraction provides significant information to the activity underway and benefits the patient's direct and immediate care), the nurse's handling of the distraction (immediate, negotiation, mediation, reprogramming, and multitasking), the task interrupted (better known as the secondary task), effectiveness in the nurse's return to the primary task after the distraction (not effective when the nurse has difficulty returning to the task due to forgetting, omission, or the compounding effect of another distraction), the context or place in which the distraction takes place and the results for the patient, the nurse's productivity, and the health institution6,[33-37]; all of the above are characteristics that the literature demands of new empirical indicators in the concept and which must be kept in mind by the authors of previously elaborated instruments to be updated[38].

The creation and update of empirical indicators in the concept present as their principal limitation a poorly developed conceptual and/or theoretical base, requiring most researchers to generate instruments from the literature review; in these aspects, the MADOS is no exception. Nevertheless, the author positions the concept in a macro vision of safe medication administration, where the DS is a "restrictive" environmental factor, which, when diminished—or, ideally, removed—leads the system to a higher level of efficiency, guaranteeing greater quality in care and in professional performance[8,9]. However, this vision excludes a microscopic view of the characteristics of the distractions and how these take place in reality, demanding a formulation of the scientific evidence into a theory and robust empirical indicators.

It is imperative in the future to consider that distractions are not only external; fatigue/tiredness, hunger/thirst, concerns related to the family, physiological needs (for example, going to the restroom), signs and symptoms of disease (for example, pain), and behaviors for self-care during a shift (for example, rest by sitting for a few minutes) are considered by the literature as "internal distractions," self-initiated, underestimated, poorly studied, and not included in the empirical indicators reviewed, leading to a vicious cycle in which no information is available due to a lack of studies addressing the theoretical development of the concept—which, in turn, does not permit generating new empirical indicators nor updating traditional ones. This can be seen as an opportunity to expand the frontier of knowledge of the phenomenon within the framework of the discipline.

CONCLUSIONS

The MADOS, adapted and validated into Colombian Spanish, maintained all the original items measuring two attributes of the concept (origin and frequency), with small linguistic modifications, a CVR and CVI of 1, and acceptable internal consistency, which is why it is possible to apply it in clinical practice. However, subsequent investigations should use it with diverse members of the health staff and for longer periods of time to corroborate internal consistency.

In nursing, it is fundamental to have tools validated and adapted to the context that can be implemented in the clinical practice and research; in this case, the MADOS checklist permits identifying the frequency and source of distractions, permitting the promotion of improvement actions in the nursing practice during the medication process. However, future research needs to include and evaluate new attributes of the concept of distractions. Moreover, as a reflection from this study, some considerations are posed to consider in methodological studies:

• It is essential for researchers to contemplate the validity of the empirical indicators prior to their selection and the start of the research, and, in the event that they do not have it, that they take the pertinent measures (carrying out the process of translation and cultural adaptation of the instrument); this will diminish instrument bias and increase the credibility of the results.

• Researchers have a responsibility for the research phenomenon, the method selected, and the information collection instruments. Each study must provide feedback to these three pillars; otherwise efforts will be repeated in investigations with inefficient instruments and plain methods. The aforementioned points will allow the instruments to evolve with the advance of scientific evidence and not join the list of instruments which have fallen into disuse and are no longer updated.

• Reporting the findings of validation processes every time an instrument is used will provide points of comparison not only of the quality of the test over time, but also of the research phenomenon per se.

• Finally, one of the consequences of these finding is to enable the use of the MADOS checklist in Spanish-speaking countries with the corresponding cultural adaptation.

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Conflict of interests: the authors declare that they have no conflict of interest.

APENDICE

Instrumento MADOS

La Hoja de Observación de Distracciones en la Administración de Medicamentos (Medication Administration Observation Sheet – MADOS) sera utilizada por el investigador teniendo en cuenta las definiciones dadas a cada categoría de distracciones o interrupciones durante la administración de los medicamentos. El investigador no debe mostrar esta hoja a nadie, ni divulgar detalles específicos de lo que se está observando, sino únicamente que se está estudiando el proceso de medicación. Mantenga una discreta distancia del participante durante las observaciones (usualmente 1 metro). Haga una marca en el área de la categoría que causó cada interrupción o distracción.

Fecha de la observación	Observación N.	N. de pacientes asignados:	N. de medicamentos para cada paciente:
Tiempo de medicación programado	Hora de inicio	Hora de detención	Tiempo transcurrido

Número de DISTRACCIONES / INTERRUPCIONES								
Personal médico	Otros miembros del personal	Llamadas	Problema con el medicamento	Conversación	Ruido	Equipo	Emergencia	Otro

Definiciones: una interrupción es una situación que llama la atención y cambia el curso de la tarea (alguien interrumpe, hace falta un medicamento). Una distracción es un evento que aleja la atención de la persona o interrumpe los procesos de pensamiento (ruidos, pensamientos, conversación). las categorías se definen a continuación.

Personal médico	El personal médico distrae o interrumpe al enfermero que administra los medicamentos.
Otros miembros del personal	Otros miembros del personal distraen o interrumpen al enfermero durante la administración de los medicamentos.
Llamadas	El enfermero que administra los medicamentos es interrumpido por una llamada telefónica o un mensaje, o hace una llamada telefónica o envía un mensaje.
Problema con el medicamento	Encuentra un problema con el medicamento (por ausencia, pérdida o se encuentran incompletos los insumos) lo cual causa que el enfermero tome alguna acción para recuperar el medicamento.
Situación de emergencia	Cualquier situación de emergencia como un código o un cambio en la salud de un paciente que necesite una acción inmediata del enfermero.
Conversación	Conversación no relacionada con la administración del medicamento en la que el enfermero se involucra. Conversación fuerte que tienen lugar en el área y distrae al enfermero.
Ruido	Ruidos fuertes (música) audibles para el enfermero, que lo distraen.
Equipo	Problemas con los equipos (eje: monitores, computadores, bombas de infusion etc) que interrumpen el proceso.
Otro	Interrupciones o distracciones que no encajan en ninguna otra categoría (comentario a continuación).
Comentarios:	

REFERENCIAS

1. Sasangohar F, Donmez B, Easty A, Storey H, Trbovich P. Interruptions experienced by cardiovascular intensive care unit nurses: An observational study. J Crit Care [Internet] 2014 [Consulted: August 15 2021];29(5):848–53. DOI: http://dx.doi.org/10.1016/j.jcrc.2014.05.007

2. Spooner AJ, Corley A, Chaboyer W, Hammond NE, Fraser JF. Measurement of the frequency and source of interruptions occurring during bedside nursing handover in the intensive care unit: An observational study. Aust Crit Care [Internet] 2015 [Consulted: August 15 2021];28(1):19–23. DOI: http://dx.doi.org/10.1016/j.aucc.2014.04.002

3. Duruk N, Zencir G, Eşer I. Interruption of the medication preparation process and an examination of factors causing interruptions. J Nurs Manag. [Internet] 2016 [Consulted: August 15 2021];24(3):376–83. DOI: http://dx.doi.org/10.1111/jonm.12331

4. Reed CC, Minnick AF, Dietrich MS. Nurses' responses to interruptions during medication tasks: A time and motion study. Int J Nurs Stud. [Internet] 2018 [Consulted: August 15 2021];82(March):113–20. DOI: https://doi.org/10.1016/j.ijnurstu.2018.03.017

5. Westbrook JI, Woods Amanda Rob, Marilyb Dunsmuir W, O. Day R. Association of interruptions with an increased risk and severity of medication administration errors. Arch Intern Med. [Internet] 2010 [Consulted: August 15 2021];170(8):690–2. DOI: https://doi.org/ 10.1001/archinternmed.2010.58

6. Brixey J, Robinson D, Johnson G, Johnson T, Turkey J, Zhang J. A Concept Analysis of the Phenomenon of Interruption. Adv Nurs Sci. [Internet] 2007 [Consulted: August 15 2021];30(1):26–42. DOI: http://dx.doi.org/10.4172/2167-1168.1000353

7. Pape T. Applying airline safatey practices to medication administration. MEDSURG Nurs. [Internet] 2003 [Consulted: August 15 2021];12(2):77–93. Available from: https://bit.ly/30ofbcH

8. Pape TM, Guerra DM, Muzquiz M, Bryant JB, Ingram M, Schranner B, et al. Innovative approaches to reducing nurses' distractions during medication administration. J Contin Educ Nurs. [Internet] 2005 [Consulted: August 15 2021];36(3):108–16. DOI: http://dx.doi.org/10.3928/0022-0124-20050501-08

9. Pape TM, Dingman SK. Interruptions and distractions during anesthesia induction: A pilot study. Plast Surg Nurs. [Internet] 2011 [Consulted: August 15 2021];31(2):49–56. DOI: http://dx.doi.org/10.1097/PSN.0b013e31821b5b84

10. Colligan L, Guerlain S, Steck SE, Hoke TR. Designing for distractions: A human factors approach to decreasing interruptions at a centralised medication station. BMJ Qual Saf. [Internet] 2012 [Consulted: August 15 2021];21(11):939–47. DOI: http://dx.doi.org/10.1136/bmjqs-2011-000289

11. Tomietto M, Sartor A, Mazzocoli E, Palese A. Paradoxical effects of a hospital-based, multi-intervention programme aimed at reducing medication round interruptions. J Nurs Manag. [Internet] 2012 [Consulted: August 15 2021];20(3):335–43. DOI: http://dx.doi.org/10.1111/j.1365-2834.2012.01329.x

12. Muñiz J, Elosua P, Hambleton RK. Directrices para la traducción y adaptación de los tests: Segunda edición. Psicothema. [Internet] 2013 [Consulted: August 15 2021];25(2):151–7. DOI: http://dx.doi.org/10.7334/psicothema2013.24

13. Consejo General de la Psicología, El uso de los test y otros instrumentos de evaluación en investigación. Comision Internacional de Tests. [Internet] 2014 [Consulted: August 15 2021]. Available in: https://bit.ly/3i7cthZ

14. Muñiz J, Hernández A, Ponsoda V. Nuevas directrices sobre el uso de los test: investigacion, control de calidad y seguridad. Papeles del Psicol. [Internet] 2015 [Consulted: August 15 2021];36(3):161–73. Available in: https://bit.ly/3kVPif7

15. Tristán-López A. Modificación al modelo de Lawshe para el dictamen cuantitativo de la validez de contenido de un instrumento objetivo. Av en medición. [Internet] 2008 [Consulted: August 15 2021];6:37–48. Available in: https://bit.ly/3i3Ziyd

16. Sánchez R, Echeverry J. Validación de escalas de medicion en salud. Rev Salud Pública. [Internet] 2004 [Consulted: August 15 2021];6(3):302–18. DOI: http://dx.doi.org/10.1590/S0124-00642004000300006

17. Mandeville PB. Tema 9: El coeficiente de correlación intraclase (ICC). Ciencia Uanl. [Internet] 2005 [Consulted: August 15 2021];8(3):414–416. Available in: https://bit.ly/3i9vAHV

18. López A, Galparsoro DU, Fernández P. Medidas de concordancia : el índice de Kappa. Atención Primaria en la Red. [Internet] 2001 [Consulted: August 15 2021]. p. 2–5. Available in: https://bit.ly/39V1cOK

19. Campo-Arias A, Oviedo HC. Propiedades psicométricas de una escala: la consistencia interna. Rev Salud Pública. [Internet] 2008 [Consulted: August 15 2021];10(5):831–9. DOI: http://dx.doi.org/10.1590/S0124-00642008000500015

20. Ministerio de Salud de Colombia. Resolución 8430 de 1993. [Internet] [Consulted: February 23 2022]. Available in: https://bit.ly/3M2opB6

21. Garzón-Alarcón N et all. Recomendaciones éticas para las investigaciones en la facultad de enfermería de la Universidad Nacional de Colombia. Bogotá D.C.: Universidad Nacional de Colombia. [Internet] 2008 [Consulted: February 23 2022]. Available in: https://bit.ly/3JSzYsV

22. Ramos DY, Soto VI, Identificar distracciones en el proceso de administración de medicamentos garantiza una práctica segura. Av enferm. [Internet] 2014 [Consulted: August 22 2021];32(1):44-52. DOI: http://dx.doi.org/10.15446/av.enferm.v32n1.46034

23. Yoder M, Schadewald D, Dietrich K. The Effect of a Safe Zone on Nurse Interruptions, Distractions, and Medication Administration Errors. J Infus Nurs. [Internet] 2015 [Consulted: August 22 2021];38(2):140–51. DOI: http://dx.doi.org/10.1097/NAN.0000000000000095

24. Relihan E, O'Brien V, O'Hara S, Silke B. The impact of a set of interventions to reduce interruptions and distractions to nurses during medication administration. Qual Saf Heal Care. [Internet] 2010 [Consulted: August 22 2021];19(5). http://dx.doi.org/10.1136/qshc.2009.036871

25. Dall'Oglio I, Fiori M, Di Ciommo V, Tiozzo E, Mascolo R, Bianchi N, et al. Effectiveness of an improvement programme to prevent interruptions during medication administration in a paediatric hospital: A preintervention-postintervention study. BMJ Open. [Internet] 2017 [Consulted: August 22 2021];7(1):1–8. DOI: http://dx.doi.org/10.1136/bmjopen-2016-013285

26. Huckels-Baumgart S, Niederberger M, Manser T, Meier CR, Meyer-Massetti C. A combined intervention to reduce interruptions during medication preparation and double-checking: a pilot-study evaluating the impact of staff training and safety vests. J Nurs Manag. [Internet] 2017 [Consulted: August 22 2021];25(7):539–48. http://dx.doi.org/10.1111/jonm.12491

27. Ursachi G, Horodnic IA, Zait A. How Reliable are Measurement Scales? External Factors with Indirect Influence on Reliability Estimators. Procedia Econ Financ. [Internet] 2015 [Consulted: August 22 2021];20(15):679–86. DOI: http://dx.doi.org/10.1016/S2212-5671(15)00123-9

28. Streiner DL. Starting at the beginning: An introduction to coefficient alpha and internal consistency. J Pers Assess. [Internet] 2003 [Consulted: August 22 2021]80(1):99–103. DOI: http://dx.doi.org/ 10.1207/S15327752JPA8001_18

29. Reed CC, Minnick AF, Dietrich MS. Nurses' responses to interruptions during medication tasks: A time and motion study. Int J Nurs Stud. [Internet] 2018 [Consulted: August 22 2021];82(March):113–20. DOI: https://doi.org/10.1016/j.ijnurstu.2018.03.017

30. Westbrook JI, Ampt A. Design, application and testing of the Work Observation Method by Activity Timing (WOMBAT) to measure clinicians' patterns of work and communication. Int J Med Inf [Internet]. 2009 [Consulted: August 22 2021];78(Suppl 1):S25-33. DOI: https://doi.org/10.1016/j.ijmedinf.2008.09.003.

31. Trbovich P, Prakash V, Stewart J, Trip K, Savage P. Interruptions during the delivery of high-risk medications. J Nurs Adm. [Internet] 2010 [Consulted: August 22 2021];40(5):211–8. DOI: http://dx.doi.org/ 10.1097/NNA.0b013e3181da4047

32. Sasangohar F, Donmez B, Easty AC, Trbovich PL. Mitigating nonurgent interruptions during high-severity intensive care unit tasks using a task-severity awareness tool: A quasi-controlled observational study. J Crit Care. [Internet] 2015 [Consulted: August 22 2021];30(5):1150.e1-1150.e6. DOI: http://dx.doi.org/10.1016/j.jcrc.2015.05.001

33. Cohen J, Larue C, Cohen HH. Attention interrupted. Cognitive distraction & Workplace Safety. Proffesional Safety. [Internet] 2017 [Consulted: August 22 2021];62(11):28-34. Available in: https://bit.ly/3i6Rr2U

34. (34) McCurdie T, Sanderson P, Aitken LM. Traditions of into interruptions in healthcare: A conceptual review. Int J Nurs Stud. [Internet] 2017 [Consulted: August 22 2021];66:23–36. DOI: http://dx.doi.org/10.1016/j.ijnurstu.2016.11.005

35. Wirzberger M, Esmaeili Bijarsari S, Rey GD. Embedded interruptions and task complexity influence schema-related cognitive load progression in an abstract learning task. Acta Psychol (Amst). [Internet] 2017 [Consulted: August 22 2021];179(December 2016):30–41. DOI: http://dx.doi.org/10.1016/j.actpsy.2017.07.001

36. Hayes C, Jackson D, Davidson PM, Power T. Medication errors in hospitals : a literature review of disruptions to nursing practice during medication administration. J Clin Nurs. [Internet] 2015 [Consulted: August 22 2021];24:3063–76. http://dx.doi.org/10.1111/jocn.12944

37. Thomas L, Donohue-Porter P, Stein Fishbein J. Impact of Interruptions, Distractions, and Cognitive Load on Procedure Failures and Medication Administration Errors. J Nurs Care Qual. [Internet] 2017 [Consulted: August 22 2021];32(4):309–17. DOI: http://dx.doi.org/10.1097/NCQ.0000000000000256

38. Gaitán-Gómez OL, Aristizabal P, Bueno-Robles LS. Distracciones durante la práctica clínica de enfermería : revisión integrativa. Cienc y Cuid. [Internet] 2020 [Consulted: August 22 2021];17(2):129–42. DOI: http://dx.doi.org/10.22463/17949831.1576