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Elaboration and validation of a drug administration checklist for patients in research protocols

Elaboração e validação de checklist para administração de medicamentos para pacientes em protocolos de pesquisa

Elaboración y validación de checklist para la administración de medicamentos para pacientes en protocolos de investigación

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ABSTRACT

Objective: To describe the elaboration and validation of a checklist as a strategy for safe drug administration.

Method: It is a Validation study by consensus of experts conducted from January to June 2018, in a Clinical Research Center of a university hospital. The checklist was validated by three nurses, two nursing technicians, a pharmacist, two nurse teachers and one medical teacher, all with extensive experience in drug administration and in clinical research. For the final version of the checklist, a consensus of 100% was considered.

Results: A guide was prepared consisting of six items to be checked by the care team before, during and after administration of Clinical Research drugs.

Conclusion: The validation of the checklist provided guiding elements for the prevention of behaviors that could lead to the risk of adverse events and also allowed the care teams to seek safe strategies of care in drug administration.

Keywords: Checklist. Nursing assessment. Validation studies.

RESUMO

Objetivo: Descrever a elaboração e validação de um checklist como estratégia de administração segura de medicamentos.

Método: Estudo de validação por consenso de especialistas conduzido de janeiro a junho de 2018 em um Centro de Pesquisa Clínica de um hospital universitário. O checklist foi validado por três enfermeiros assistenciais, dois técnicos de enfermagem, um farmacêutico, dois enfermeiros professores e um médico professor, todos com ampla experiência na administração de medicamentos e em pesquisa clínica. Para a lista final foi considerado consenso de 100% entre os especialistas.

Resultados: Elaborou-se um guia composto por seis itens a serem checados pela equipe assistencial antes, durante e após a administração de medicamentos de Pesquisa Clínica.

Conclusão: A validação do checklist forneceu elementos norteadores para a prevenção de comportamentos que podem levar ao risco de eventos adversos e também permitiu que as equipes assistenciais buscassem estratégias seguras de cuidado na administração de medicamentos.

Palavras-chave: Lista de checagem. Avaliação em enfermagem. Estudos de validação.

RESUMEN

Objetivo: Describir la elaboración y validación de un checklist como estrategia de administración segura de medicamentos.

Método: Estudio de validación por consenso de especialistas conducido de enero a junio/2018 en Centro de Investigación Clínica de un hospital universitario. El checklist fue validado por tres enfermeros asistenciales, dos técnicos de enfermería, un farmacéutico, dos enfermeros profesores y un médico profesor todos con amplia experiencia en administración y supervisión de medicamentos y investigación clínica. Para la lista final se consideró consenso del 100% entre los expertos.

Resultados: Elaboró un guía compuesto por seis ítems a ser chequeados por el equipo asistencial antes, durante y después de la administración de medicamentos de Investigación Clínica.

Conclusión: La validación del checklist proporcionó elementos orientadores para la prevención de comportamientos que pueden llevar al riesgo de eventos adversos y también permitió a los equipos asistenciales buscar estrategias seguras de cuidado en la administración de medicamentos.

Palabras clave: Lista de verificación. Evaluación en enfermeria. Estudios de validación.

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INTRODUCTION

Patient safety gained even more prominence in health care organizations around the world. The increase in rates of infection, complications in the clinical framework of the patients and prolongation of the period of hospitalization are consequences intimately related to the occurrence of adverse events in health care[1]. An international study points out that, annually, from 44,000 to 98,000 patients die as a consequence of drug administration errors, generating high costs for health services[2].

The preparation and administration of drugs require extreme concentration and skills that include knowledge about the drugs, their mechanism of action, route, adverse effects and benefits[3]. In addition, changes in the demand for care and in the complexity of patients' demands have constantly required restructuring the processes of attention in health care organizations, seeking to ensure safety[4].

For participants in clinical research, a setting which is already more risky due to the infusion of new medicines, it is essential for the team involved with the preparation and administration of medications to have a behavior pattern. Inherent to this process of work, the commitment from all team members is necessary to avoid the occurrence of unsafe incidents with patients[4].

As a fundamental part in the process of care, the nursing staff may consider the use of instruments that help to ensure a safer care, based on the best practices. A checklist consists of a structured work tool that considers a set of behaviors, names, items, or tasks that need to be considered and/or followed, aiming to carry out a systematic observation[5]. In this context, the development of the checklist is a measure that promotes the improvement of communication and decreases the number of failures by omission[6], acting as an intervention tool for the achievement of a good and safe assistance.

In this setting, aiming to standardize the nursing care with drug administration and preventing the occurrence of adverse events, a motivation emerged to develop and validate a checklist to be used as a security strategy for the participant in clinical research. In this perspective, the aim of this study is to describe the development and validation of a checklist as a strategy for the safe administration of drugs.

This study is relevant as it will ensure the safety of the assistance provided by the care team in the administration of drugs, in a systematic way, through a tool that is widely used as a measure of security.

METHOD

This is a study of validation by consensus of experts of a checklist for the safe administration of drugs in clinical research. This method allows the access to a collective opinion or agreement among experts regarding a specific phenomenon and has been used in nursing in order to define standards of practice[7-8].

The research was conducted in a Clinical Research Center, reference of a university hospital in the South of Brazil, from January to June 2018. This center has six beds and 10 chairs for the care of patients participating in researches, and performs an average of 185 infusions/month of different specialties.

From a situational diagnosis performed by the nursing team of the unit in relation to security in the administration of drugs, a review of the literature was conducted, in the databases US National Library of medicine (Pubmed) and Cumulative Index to Nursing and Allied Health Literature (CINAHL), including publications from January 2013 to June 2018, with the terms "chemotherap" [MeSH] or "antineoplastic" [MeSH] or "medication therapy management" [MeSH] or "immunotherapy" [MeSH] and "clinicalresearch/quality assurance" [MeSH] or "patient safety" [MeSH] were considered. Based on the literature and on the experience of the professionals, a working group for the elaboration of the checklist was organized. This group held periodic meetings with the aim of discussing each step of the process of drug administration, seeking to clarify doubts, in the light of examples from daily life assistance and from scientific evidence. Considering these discussions, the safety items to be contemplated in the construction of the checklist were elaborated.

After its construction, a group of experts was intentionally selected to validate the checklist. It was composed of three nurses, two nursing technicians, two nursing teachers, a pharmacist and a medical professor who coordinates the Clinical Research Center. For its elaboration, the consensus of 100% between the experts was required.

The project was approved by the ethics committee under the CAAE 95847518.1.0000.5327. The authors signed a Term of Commitment in Data Use to have access to the minutes of the meetings between experts, and committed themselves to preserve the privacy and anonymity of those involved.

RESULT

The result of this study was the development of a checklist for administration of intravenous and subcutaneous drugs, composed of six steps. This tool covers from the admission of the research participant in the room of infusions to the record of the procedure done, and aims to qualify, with safety, every step of the process of drug administra-

tion. It is worth noting that, in the elaboration of the checklist, the International Goals of Patient Safety were taken into account. As an example, Goal 1 is the correct identification of the patient, with verification of the full name and chart number before drug administration. The use of standard precautions and Personal Protective Equipment (PPE) was also included as suggested in the specific regulations[9], aiming not only at patient safety but also at that of the professional. The "nine" rights related to the administration of drug were also considered[10].

Image 1 presents the checklist with the validated items by this study.

CHECK LIST – ADMINISTRATION OF RESEARCH DRUG Date:

1. Admission in the Infusion Room
a) Identification:
□ Name
□ Medical record
□ Confirm with bracelet
Known allergy:
□ Yes Which?_____
□ No
□ Vital signs control
□ Explain the procedure to the participant
b) Venous access
□ Prepare Saline 0.9% and infusion set, installing the number of threeway depending on the number of chemotherapy (QT) or immune medications prescribed
□ Hand hygiene and disinfection of the work table
□ Peripheral access Location:_____ no. of attempts: ___ □ Central ____
c) Blood Collection □ Not applicable
□ Identification of the tubes
□ Pre-infusion. Time:_____
□ During infusion Time:_____
□ Post infusion: Time:_____
d) Standard Precaution/ Use of PPE
□ Hand hygiene
□ Put The Apron □ Mask □ Goggles □ Gloves
□ Install the plastic bag to dispose of QT

2. Installing the drug
a) Check the Label/Prescription/Participant
□ Check the appearance of the solution (inspect precipitation and foreign bodies) and the presence of leaks
□ Confirm the identification of the label with the bracelet of the participant
□ Confirm in the prescription the time to be installed
Confirm the label with the prescription: □ Drug
□ Dosage
Dilution:
□ Saline □ Dextrose □ Expiration of the dilution
□ Volume to be diluted □ Expiration of the diluent
□ The total Volume (final)

b) Type of access
□ Test the permeability of venous access
c) Connection verification
□ Confirm the adjustment of the caps and threeway
□ Connect the infusion set of the drug in the access of the participant, and keep the threeway closed
d) Programming of infusion pump:
Program: □ Total Volume
□ Infusion time
□ Rate/flow
□ Confirm volume/time/rate programmed
□ Put the drop sensor
□ Open the threeway in the direction of the catheter
□ Confirm the opening of the threeway in the direction of the catheter
□ Open the dripper of the drug
□ Start the infusion □ Pause
□ Explain to the participant about the beginning of the medication and possible local and systemic reactions □ Identify the infusion sets

3. Drug withdrawal
□ Hand Hygiene/disinfection of the work table
□ PPE use (goggles, gloves, mask, apron)
□ Gather supplies in the tray
□ Inject 20ml Saline 0,9% or Dextrose 5% on the lateral connector or clef (safety device) of the bag at the end of the infusion to wash the infusion set
□ At the end, open the saline to flush the venous access
□ Close the central catheter and heparinize
□ If peripheral catheter, withdraw
□ Put the infusion set and empty bags in the transparent bag specific to chemotherapeutic drugs
□ Close, without removing the surplus air, and throw away the bag in the garbage of chemotherapeutic drugs

Signature:
_____

4. Bolus Medications □ Not applicable
□ Check the appearance of the solution (inspect precipitation and foreign bodies) and the presence of leaks
□ Confirm with the identification of the participant
Confirm: □ Time
□ Drug
□ Dosage
Dilution: □ Saline □ Dextrose
□ Volume
□ Expiration of the dilution

□ Connect the syringe in the threeway
□ Open in the direction of the catheter
□ Administer the drug
□ Monitor participant for adverse events and report if symptoms occur during infusion
□ Observe the access during the drug administration
□ Keep the syringe connected to the threeway at the end of the infusion
□ Open serum bag for washing the access
□ Throw way in the transparent bag for QT and discard the bag in the specific garbage for chemotherapy

5. □ Perform registration

Observations:
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

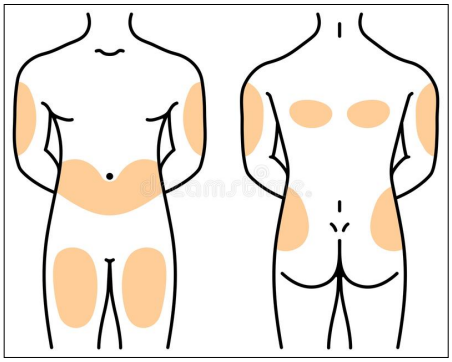
Identification bracelet

Clinical Research Center-CPC
Project GPPG

6. SC drug □ Not applicable
□ Check the appearance of the solution (inspect precipitation and foreign bodies) and the presence of leaks
□ Confirm the identification of the label with the participant identification bracelet
Confirm with the prescription:
□ Time to be administered
Confirm the label with the prescription
□ Drug
□ Dosage
Dilution: □ total Volume (final)
□ Expiration of the dilution

□ Assess the location to be applied and perform asepsis
□ Administer the drug
□ Observe the application area during and after the administration of the drug
□ Bandage
□ Discard in transparent bag specific to QT
□ Discard the bag in the specific bin for QT
□ Mark on the figure the location of the application

a) Mark "X" in the location(s) of subcutaneous (SC) drug application(s)



b) Volume given in ml:
application 1. _____
application 2. _____
application 3. _____
application 4. _____

Image 1 - Checklist for the verification of security items for the administration of drugs in a clinical research center.

DISCUSSION

The increasing complexity of protocols for clinical research increases the possibility of errors in the various steps of the process that includes the administration of drug being studied here. Thus, ensuring the maintenance of the safety of the participant and of the professionals involved, is an increasingly important responsibility of the institutions.

A study[11] pointed out that the development and implementation of a checklist, in order to standardize procedures and conducts, in addition to facilitating the work of professionals, promotes a reduction of failures in each step of the process, acting as an effective strategy to detect possible errors related to the administration of drugs.

The use of checklists has been encouraged by international organizations to provide information and develop guidance that can be adapted to the reality of health care, minimizing, in this way, the possibility of adverse events[12]. In this context, other authors[13-14] emphasize that the elaboration of mechanisms aimed to preemptively analyze the possibility of failures in the processes amplifies the means to provide a safe administration of drugs and, consequently, a better quality in health assistance.

The construction of the checklist made it possible, for nurses and nursing technicians of the unit, to come into contact with knowledge about how to assess each item of safety. The details of the drug administration process are critical because they are the last step for the prevention of incidents involving the patient.

Literature shows that the use of guides can add benefits, since they can serve as clear, objective and accessible references to the interpretation of the guidelines. However, an educational guide does not eliminate the need for verbal direction[15]. This justifies the constant need to create strategies for the training of professionals in health institutions, in order to meet the specificities of each research protocol involving drugs.

The collective construction of a checklist led to the development of material that provides subsidies to a safer care for the daily practice of the professionals of the institution, enabling it to be widely used, even in other realities. The application of this tool requires the nursing to reflect about and pay attention to the integral evaluation of the patient during the process of care.

The items of the checklist may facilitate the understanding of the care needed to ensure the safety of the participant in a clinical research. However, scientific knowledge is constantly renewed, new protocols are instituted, and thus, it is necessary to continuously update the guides so that they fulfill their function of qualifying the safety of research participants and the care team.

FINAL CONSIDERATIONS

The checklist was developed and validated through a process of consensus among experts. This material qualifies and standardizes care through safety items to be checked before, during, and after the administration of drugs.

The material produced is being used in a systematic way and presented good acceptance by the nursing team, which now has greater attention to the care provided, regarding the administration of drugs.

The results of this study contribute to the management of care, the training of the professionals, and to increasing the safety of the patients and of the institution. However, only the application of a checklist does not ensure the absence of complications. The need for the creation of a culture tuned to the co-responsibility and involvement of all members of the team must not be understated.

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