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Standards for the safe administration of chemotherapy in oncological patients 2015 – 2020: A systematic review

[Estándares para la administración segura de quimioterapia en pacientes oncológicos 2015 – 2020: Revisión Sistemática]

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Resumen

En la actualidad el cáncer es un problema de salud pública. Cabe señalar que los pacientes en su mayoría requieren tratamiento con quimioterapia y radioterapia entre otros procedimientos para recuperar la salud. El presente estudio tuvo como objetivo: Analizar el desarrollo de las evidencias científicas sobre estándares para la administración segura de quimioterapia en pacientes oncológicos. Metodología: se realizó una revisión sistemática descriptiva con la búsqueda de las bases de datos en Pub Med y Scopus se seleccionó artículos del 2015 – 2020 en idiomas de inglés y español. Los resultados indican que la administración segura de quimioterapia en pacientes oncológicos se requiere que enfermera utilice los protocolos y guías de atención estandarizadas actualizadas con entrenamiento continuo, así como también realizar acciones preventivas de monitoreo, control y seguimiento para el cumplimiento de los protocolos. Se concluye que los eventos adversos deben ser socializados entre los enfermeros para asumir planes de mejoras y estrategias para elevar la calidad de los servicios que presta el profesional de enfermería, así como también evitar errores y complicaciones de mala praxis en la administración de quimioterapia.

Palabras clave: Estándares para la administración segura, quimioterapia, pacientes oncológicos, revisión sistemática.

Abstract

Cancer is currently a public health problem. It should be noted that most patients require treatment with chemotherapy and radiotherapy among other procedures to recover their health. The aim of this study was to analyze the development of scientific evidence on standards for the safe administration of chemotherapy in cancer patients. Methodology: a descriptive systematic review was performed with the search of databases in Pub Med and Scopus selected articles from 2015 - 2020 in English and Spanish languages. The results indicate that the safe administration of chemotherapy in oncology patients requires nurses to use updated standardized protocols and care guidelines with continuous training, as well as to carry out preventive actions of monitoring, control and follow-up for compliance with the protocols. It is concluded that adverse events should be socialized among nurses to assume improvement plans and strategies to raise the quality of the services provided by the nursing professional, as well as to avoid errors and complications of malpractice in the administration of chemotherapy.

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Keywords: Standards for safe administration, chemotherapy, oncology patients, systematic review.

1. Introduction

The World Health Organization indicates that every 7 to 10 cases are attributed to non-communicable diseases among them is cancer (WHO, 2019). In this sense, it is reported that each of the various types of cancers that are detected require oncological therapy, surgical treatment chemotherapy, radiotherapy, palliative care and bone marrow transplantation (WHO, 2021). It should be noted that chemotherapy treatment, are chemical agents used to inhibit cell growth these in turn cause side effects such as myelosuppression, nausea, vomiting, stomatitis, alopecia, oncological therapy generates damage of mechanical barriers, blood disorders, alterations of flora, organic alterations which constitutes to the multidisciplinary team to have a complex management (Liu et al., 2014).

Despite the fact that this treatment is very complex, there are currently no exact figures on the prevalence of errors associated with the administration of chemotherapy, however, there is evidence that the presence of a designated nurse verifier in a health institution helps to identify prescription errors which prevent chemotherapy administration errors, thus improving patient safety (Lima, et al., 2016). Undoubtedly, errors in the administration of chemotherapy can have serious consequences due to the fact that the therapeutic margin of antineoplastic drugs is very narrow for patients, since the therapeutic dose is often dictated by the limit of acceptable toxicity, so that even small increases in the dose can have serious toxic consequences (Carreño-Dueñas, et al., 2014).

In this sense, to err is human determined that there are many factors that cause the occurrence of errors during the patient's hospital stay among them, the lack of systematization of information, the increased complexity of treatments and the lack of training in staff (Otero et al., 2018), consequently patient safety tries to reduce the incidence of adverse events ranging between 4% and 17%, of which 50% of these cases are avoidable. Likewise, Peru has been making great efforts to address cancer, whose main objective is to increase survival to at least 60% by 2030, with 4 pillars: early diagnosis, reducing treatment abandonment, creating a national cancer registry, as well as the enactment of the Law on medical urgency and comprehensive cancer care (PAHO/WHO, 2019).

Likewise, organizations leading oncology issues, focus on structuring standards influenced in safety during the administration of chemotherapy schemes in adults but upon determining that there is also a high population demand, implementing 4 domains: creation of a safety system, treatment planning , ordering, dispensing, preparation and administration of drugs and follow-up after chemotherapy administration it is relevant to consider that errors caused by chemotherapy administration such as therapeutic index can cause toxicity problems therefore such errors should be prevented (Ramos and De La Cruz-Vargas,2020). (Leiva et al., 2020).

In this same line, maintaining high quality standards to improve patient safety is to maintain and safeguard the integrity, ensuring the identification of the stages of the process, from prescription to follow-up at the end of treatment, adding to this also the safety of health personnel (Otero et al., 2018). In the same way, international studies such as Sharp, et al. (2019) express that there are differences in the perception of patient safety culture in oncology nurses, taking into account teamwork and staffing as dimensions with higher and lower percentage respectively, concluded that patient safety varies in European countries and contextual factors, being the Oncology Nurse, key to the promotion of this.

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For Sheldon (2016) argues that the creation of a safe environment is a multidisciplinary task that includes caregivers. This would contribute in decreasing adverse events in the patient and health personnel, creating the reporting culture to identify quality improvements. On the other hand, Sullivan, et al., (2020) that predictors of non-compliance with quality standards decrease the possibility of achieving high quality at the international level.

It is unquestionable to offer quality services through the implementation of standards that favor the possibility of safe administration in the oncology patient, taking into account strategies that should be aimed at preventing or minimizing the damage caused by the health system. Likewise, the standards for the safe administration of chemotherapy in oncology patients provides knowledge about the importance of these standards, the economic and social burden generated by unsafe health care, as well as the medical expenses due to complications that could have been avoided, in the social aspect, safe care favors health care workers and patients, as well as the institutions, generating standardization in the processes to avoid adverse events (Lima, et al. 2014).

With regard to safe patient management, Vincent and Amalberti (2016) argue that all failures are not necessarily related to the human factor, but have a lot to do with the system, taking into account Reason's model, they identified seven factors: patient, work, individual, team, workplace, management and institution. They also mention that the safety culture has to do with how committed the patients and their families are: and on the part of the healthcare personnel, transparency regarding their errors. It also refers to international safety goals which are important to be able to talk about quality in health, these international goals are six: a) correct patient, b) timely communication, c) optimize the management of high-risk medications, d) safe surgery, e) control the risk of infection, f) minimize the risk of falling (Schleisman and Mahon, 2015).

Finally, quality standards are indicators that allow to ensure a safe environment to the patient avoiding practice errors and performing monitoring, follow-up and control of the health system process to optimize patient care actions. Based on the above, the following question arises: What is the development of scientific evidence on standards for the safe administration of chemotherapy in oncology patients?

2. Materials and methods

The study is a systematic review which was performed the exploration and selection of various articles in reliable databases such as Pubmed and Scopus being these a free search system, characterized by its constant updating and specialization in health sciences taking into account articles published during the years 2015 - 2020 for being in English and Spanish, to perform the search the commands Administration AND chemotherapy Standards were used, resulting in 1385 articles related to the topic that after being evaluated selected and eliminated 17 articles remained. For the evaluation and selection, the CONSORT flowchart was used, which was developed to achieve improved reports in the field of Health.

The procedure consisted of 4 phases, taking as a reference the consort diagram, the sequence followed was as follows:
a) the need for review on standards for the safe administration of chemotherapy in oncology patients was identified, then the search for information from the Scopus and Pubmed databases was performed, giving a total of 1385 articles, which were similar to the topic to be investigated in the study, it was verified that they are not duplicated and that they have full text,
b) Pre-selection phase, in this stage the screening of the identified articles was carried out, finding 300 articles,

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c) selection phase, here the total number of articles was identified, finally a total of 17 articles remained which met the selection criteria, indicating that the articles eliminated during the process were due to the fact that they were duplicated or did not have full text. According to the above, to pose the research question, the instrument PICO is used.

Table 1: Question approach Using the PICO instrument

P=Participants/Population	I=Intervention	C=Comparison	O=Outcomes (Results)
Oncology patient	Standards	Scientific articles related to the variables	Safe administration of chemotherapy

The proposed research problem was: What evidence exists on the standards for the safe administration of chemotherapy in oncology patients? Also to answer the question: What are the standards for the safe administration of chemotherapy in oncology patients? What are the adverse events that are attributable to the lack of standards for the safe administration of chemotherapy in oncology patients?

To analyze the scientific evidence on standards for the safe administration of chemotherapy in oncology patients and as specific objectives: To describe the standards for the safe administration of chemotherapy in oncology patients, To describe the adverse events that are attributable to the lack of standardization in the safe administration of chemotherapy in oncology patients

3. Results

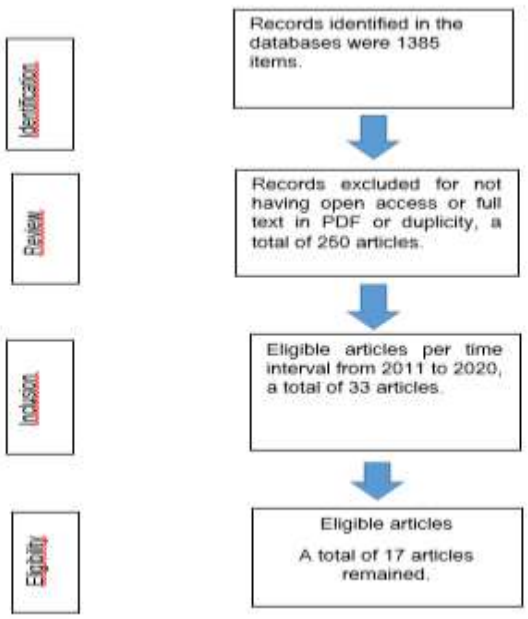

Figure 1. Database and phases developed for the collection of information.

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Table 2. Number of articles according to database.

Database	N°	%
Pubmed	14	83%
Scopus	3	17%
Total	17	100%

Table 3. Countries of origin of the articles

Country	N°	%
USA	10	58.8%
India	1	5.9%
Brazil	1	5.9%
Spain	5	29.4%
Total	17	100%

Table 4. Predominant language of the articles found

Language	N°	%
English	14	82.4%
Spanish	3	17.6
Total	17	100%

Table 5. Designs used in the systematic review articles

Design	N°	%
Qualitative	1	5.8%
Systematic review	4	23.8%
Quantitative	9	52.8%
Case study	2	11.50
Literature review	1	6.1%
Total	17	100%

Table 6. Database of the systematic review articles

Author	Title	Year	Methodology	Population/ Sample	Results	Conclusions
Baldwin A. y Rodríguez E	Improving patient safety with error identification in chemotherapy orders by	2016	Qualitative	4,282 adverse events related to unsafe administration of	A total of 4,282 chemotherapy-related events were entered into the Safety and Quality Improvement Reporting system. Most events were	The role of the nurse verifier contributes to improving the safety of chemotherapy administration and decreases the

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	verification nurses.			chemotherapy	classified as near miss events or those that, due to chance, did not result in injury to the patient and were identified at the time of prescription	occurrence of adverse events.
Bernabeu-Martínez M., Merino M., Santos J., Alvarez L., Wanden-Berghe C, Sanz-Valero J.	Guidelines for the safe handling of hazardous drugs: a systematic review.	2018	Systematic review	41 articles	Only one guideline addressed all stages of the HD management process (including stages with and without risk of exposure). The most described stages were drug preparation (41 guidelines, 67.2%), staff training and/or patient education (38 guidelines, 62.3%) and administration (37 guidelines, 60.7%). No standardized computerized system was found to ensure quality management.	Most of the guidelines analyzed limit their recommendations to the handling of antineoplastic agents. The activities most frequently described were preparation, training and administration. It would be convenient to apply ICT (Information and Communication Technologies) to implement in a more complete and simple way the processes involving HDs.
Colvin C., Karius D, Albert N.	Nurses' adherence to safe handling practices: observation versus self-assessment.	2016	Quantitative	twenty-two cases of chemotherapy management with 12 of 33 nurses completing self-assessments.	Objective and subjective behavioral adherence, three behaviors were found to be performed more frequently than nurses perceived in the questionnaires (double gloving and gowning when disconnecting chemotherapy and properly discarding chemotherapy). Two behaviors were performed less frequently than nurses provided in the questionnaires (double gloving and protecting	There is actual and subjective adherence of ambulatory oncology nurses to the recommendations of safe chemotherapy management guidelines preventing chemotherapy exposure.

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					work surfaces during administration).	
Coyne E, Northfield S, Ash K, Brown-West L.	Current evidence on education and safety requirements for chemotherapy administration in nursing: an integrative review.	2019	Systematic review	17 studies	The content analysis identified five themes: governance, process safeguards, communication, interdisciplinary collaboration, and education. Key strategies or interventions that increased patient and/or nurse safety identified were computer-generated standardized chemotherapy orders, barcoding, medication safety procedures, education, and simulated learning.	There is a need to select evidence-based educational and safety strategies and provide appropriately resourced work environments to support the safe administration of chemotherapy by nurses and provide the best possible outcomes for patients.
Day S., Sullivan CE, Morrissey L, Abramovitz L, Segovia L, Punjwani R, et al.	Development and content validation of an instrument to measure benchmark standards for pediatric oncology nursing in low- and middle-income countries.	2020	Quantitative	Assessment questionnaire instrument to measure benchmark standards for pediatric oncology nursing in low- and middle-income countries.	10 experts validated and analyzed the evaluation questionnaire within 2 weeks. However, two questionnaires were incomplete and therefore were not included in the analysis. Details of the country, WHO region, position, and work experience of the eight experts who completed the questionnaire	Oncology nurses have limited access to specialized education and clinical training. Decreasing toxicity and treatment dropout rates in low- and middle-income countries, thus improving survival rates, requires the resources and support to provide quality nursing care.
Fisher C., Kim A., Elder J.	Impact of a pharmacist-led chemotherapy education program on the knowledge of pediatric hematology/oncology nurses.	2017	Quantitative	30 licenciadas en enfermería	Los puntajes posteriores a la prueba después de la implementación del programa muestran un aumento significativo en el conocimiento básico. Las puntuaciones aumentaron un 14,1%	Un programa educativo dirigido por un farmacéutico mejora significativamente el conocimiento de la administración y el seguimiento de la quimioterapia en las enfermeras de

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					(p <0,001) en general; aumentaron 6% (p = 0,266), 22% (p = <0,001) y 16,5% (p = <0,001) después de las sesiones 1, 2 y 3, respectivamente. Todos los encuestados solicitaron clases adicionales para orientación o educación continua.	oncología pediátrica y fue bien recibido por los participantes como una oportunidad de capacitación adicional.
Gallegos R, Kogelman A, Wagner M, Cloud A, Olson M, Robideau K, et al.	Chemotherapy education: an interprofessional approach to standardize processes and improve nurse and patient satisfaction	2019	Quantitative	Nurses and patients	Patient satisfaction scores were high in the pre- and post-implementation phases (mean overall score of 4.3 and 4.1, respectively).	standardization of chemotherapy education practices improved nurse and patient satisfaction.
Kalo K, Karius D, Bena J., Morrison S., Albert N	Chemotherapy safety: reducing errors with a nurse-directed time-out process.	2019	Quantitative	Pharmacy administration records and chemotherapy safety events.	The overall error rate in chemotherapy administration was initially low (before the intervention) and similar to published reports of error rates after interventions to reduce error rates were implemented. The error rate remained low in the two post-intervention evaluation periods.	The safety of chemotherapy administration by nursing staff was high while the error rate remained low.
Koyama A., Sheridan C., Li L, Bucknall T, Westbrook J.	Effectiveness of double-checking to reduce medication administration errors: a systematic review.	2019	Systematic review	thirteen studies, including ten studies using an observational study design, two randomized controlled trials and one	No studies investigated changes in medication-related harms associated with dual monitoring. Reported double-check adherence rates ranged from 52% to 97% of administrations. Only three studies reported whether and how independent and	There is insufficient evidence that dual or single control of drug administration is associated with lower rates of MAE or reduced harm.

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				randomized trial in a simulated setting.	prepared double checks differed.	
LeFebvre K., Felice T.	Nursing application of oral chemotherapy safety standards: an informal survey.	2016	Quantitative	50 nurses	Initial survey data reflect inconsistent application of safety standards in practice.	Interprofessional team collaboration is essential to establish safe procedures in the ordering and administration of oral anticancer therapy.
Lennes I., Bohlen N, Park E., Mort E, Burke D, Ryan D.	Chemotherapy errors: a call for a standardized approach to measurement and reporting.	2016	Quantitative	149,929 chemotherapy orders and 330 reported chemotherapy safety events	Although all 10 events were determined to have the potential for serious harm, none resulted in serious harm. Trends in the number of safety events, the types of safety events, and where in the process the event occurs (documentation, prescribing, order review, medication preparation/dispensing, or medication administration)	There are many methods for identifying safety events: safety reporting systems, direct observation, chart audits, review of patient complaints, malpractice data, etc. Each method has limitations and advantages. Safety reporting systems are endorsed by the Institute of Medicine and employed by most hospitals. Safety event reporting is the best available indicator for oncology practices.
Looper K, Winchester K, Robinson D, Price A, Langley R, Martin G, et al.	Best practices for chemotherapy delivery in pediatric oncology: improvements in quality and safety processes.	2016	Quantitative	40 nurses 186 infusions	Start and end times were now integrated into the electronic documentation system and were available for the nurse to accurately record. Reactions related to chemotherapy infusions were only linked to the drug itself and were integrated	Quality improvement in healthcare is an important focus for all organizations. Best practices for pediatric chemotherapy administration also include the safety of healthcare personnel, so they

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					into the nurse record application. All documentation can now be retrieved from the medical record, and the information technology team continues to create reports for clinical research associates to access information needed for both clinical trial audits and internal audits.	must have appropriate equipment such as gloves, hats, filter masks, face shields, etc., in place.
Morgan J, Deyo J, Cox J, Fasipe F, Mohamed A, Russo C.	Quality improvement interventions in a network of pediatric hematology and oncology clinics.	2019	Case studies	60 oncology patients	Across the network of affiliated clinics, the timing of antibiotic administration improved from the pre-intervention period (23% of patients received antibiotics within 60 minutes of registration) to 53% and 73% in successive post-intervention periods. Implementation of a central line bundle for implanted catheters was associated with increased compliance and a trend toward longer time between CLABSI.	The implementation of a quality improvement approach using a monitoring system with annual clinical audits, development of joint quality improvement initiatives, continuing education, and focused staff training to bring about changes that improve patient care at multiple institutions.
Oliveira P., De Santos V., Bezerril M., Andrade F., De Paiva R., Silveira E.	Patient safety in the administration of antineoplastic chemotherapy and immunotherapy for oncology treatment	2019	Systematic review	47 studies	The following data emerged from the results: Safety standards for the administration of antineoplastic drugs for parenteral chemotherapy; Good practices for patient safety in the use of oral antineoplastic therapy; Safe administration and handling of	Safety during oncology patient care in the administration of chemotherapy is achieved by standardizing protocols based on safety, constant education of nurses, as well as the implementation of standards and

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					immunotherapeutic drugs; Prevention and management of errors related to the administration of antineoplastic chemotherapeutics and immunotherapeutics for chemotherapy.	processes that contemplate safety as a pillar to prevent errors during the administration of drugs.
Otero M., Vera R, González-Pérez C, Ayala de la Peña F, Peñuelas Á, Quer N.	Oncology patient safety Recommendations of the Spanish Society of Hospital Pharmacy, the Spanish Society of Oncology Nursing and the Spanish Society of Medical Oncology for the safe management of antineoplastic medication in oncology patients.	2018	Systematic review	23 studies	A total of 68 recommendations were defined, organized into 5 sections. They include aspects related to the training of health professionals, the necessary technological requirements, adequate treatment planning, the education given to patients and their families, the processes of prescription, preparation, dispensing and administration of chemotherapy, whether oral, endovenous or intrathecal, assessing adherence to treatment and reducing toxicity.	It is essential that healthcare establishments implement specific measures aimed at preventing medication errors, in order to ensure safe oncological treatment for the patient.
Patil V., Chakraborty S, Bhattacharjee A, Dessai S.	Survey on the status of implementation of the American Society of Clinical Oncology/Oncology Nursing Society safety standards for chemotherapy	2018	Literature review	23 studies	Adequate treatment planning, patient and family education, the processes of prescription, preparation, dispensing and administration of chemotherapy, whether oral, endovenous or intrathecal, assessing	It is essential that healthcare establishments implement specific measures aimed at preventing medication errors, in order to ensure safe oncological treatment for the patient.

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	administration in India.				adherence to treatment and reducing toxicity.	
Schleisman A., Mahon S.	Preventing chemotherapy errors with comprehensive medication assessment	2015	Case studies	Case control	Failure to comply with the 10 principles of drug administration contributes to chemotherapy errors. Electronic safeguards may not prevent chemotherapy errors.	Chemotherapy errors can occur if the American Society of Clinical Oncology and Oncology Nursing Society chemotherapy administration guidelines are not consistently applied.

4. Discusions

The systematic review made it possible to visualize that the criteria of the standards of safe administration of chemotherapy in oncology patients are attributed as quality indicators and preventive actions to reduce the complications derived from health care.

In this sense, the standardization of care actions in safe administration is to prevent errors in the administration of chemotherapy in patient. Therefore, nursing professionals should reinforce knowledge on safety criteria for the administration of chemotherapy for which continuing education is required. These strategies provide a safe work environment and require adequate material and human resources to support the execution of safe chemotherapy administration by nurses and provide the best possible outcomes for patients.

According to, Fisher et. al., (2017), refers that the educational program significantly improves the knowledge of chemotherapy administration and follow-up in oncology nurses. For Baldwin and Rodriguez (2016), expresses that the nurse plays an important role in improving safety, avoiding errors and reduction of adverse events during hospitalization (Patil et. al.,2018; Mousavi et.al., 2020).

On the other hand, Day et. al. (2020), indicates that oncology nurses have limited access to specialized education and clinical training, therefore, improving survival rates requires resources and support to provide quality nursing care. In this sense, Bernabeu-Martínez et. al., (2018) refer that preventive activities to avoid medication errors specialists agree that training and training of protocols and guidelines for the safe administration of chemotherapy treatment in patients are efficient. Likewise, Colvin, Karius, Albert (2016), state that there is real and subjective adherence of oncology specialist nurses suggests the use of safe chemotherapy management guidelines that prevent exposure to chemotherapy for safe handling (Belderson & Billett, 2017).

For Oliveira et. al., (2019) states that the safety of the oncology patient during the administration of chemotherapy, is realized when evidence-based protocols, continuing education of nursing professionals and the implementation of safety standards and processes are put in place, as a pillar to prevent errors in the administration of medications.

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For Schleisman A., Mahon S. (2015), indicates that chemotherapy errors can occur if chemotherapy administration guidelines are not consistently applied. These statements state that the nurse is aware of the need for monitoring, control and follow-up on the application of safety measures in the administration of chemotherapy by nursing staff when there is greater preventive actions the error rate remains low levels (Coyne, et. al.,2019).

According to Gallegos et. al., (2019), highlights that the standardization of chemotherapy education practices improved nurse satisfaction in daily practice and reduces errors. It is so that the safety in the administration of chemotherapy by nursing staff responds when there is higher level of control the error rate remained low (Kalo et. al.,2019). These statements agree with the expressed by Koyama et. al., (2019) who state that there is insufficient evidence that double or single control of drug administration is associated with lower rates of MAE or reduced harm.

There are many methods for identifying security events: security reporting systems, direct observation, chart audits, patient complaint review, negligence data, etc. Each method has limitations and advantages. The notification of safety events is the best indicator available for oncology practices (Lennes et. Al., 2016).

Undoubtedly, according to LeFebvre et. al., (2016), indicates that the collaboration of the interprofessional team is essential to establish safe procedures in the request and administration of anticancer therapy. According to, Looper et al., (2016) point out that improving the quality of care and practices for the administration of pediatric chemotherapy are also the safety of health personnel is so they must have adequate implementation such as gloves, caps masks with filter, facials. Also, Morgan et al., (2019) state that the approach to quality improvement using is using a monitoring system with annual clinical audits.

Finally, patient safety in the administration of chemotherapy is important to prevent errors and provide quality care, therefore, it is important that the nurse is in constant training and must comply with the guidelines and protocols established by the institution

5. Conclusions

The present systematic review addresses the topic of Standards for the safe administration of chemotherapy in oncology patients, but no sustainable evidence was found at the local level, so it is recommended that research on this topic be encouraged. Among the categories of the standards is the correct identification of the patient, which helps to reduce adverse events in health care, being a necessity the placement of bracelets and the timely communication by the staff avoids errors of omission. The most frequent adverse events are high toxicity, wrong treatment and dosage, due to work overload and lack of a nurse verifier.

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