PATIENT SAFETY IN CHEMOTHERAPY ADMINISTRATION

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1. Introduction

In 1995, the classic prospective cohort study of Leape et al. warned of medication errors that can occur in the circuit of drug use in hospitals. In the article is reported that 39% of errors are during the prescription phase, 12% during transcription, 11% during dispensing and 38% in administration. Over than half of errors that occurred during the prescription were intercepted before they reached the patient, but only 2% of the errors occurred during the administration were intercepted. (1)

The Institute Of Medicine in EEUU estimates that on average, an admitted patient is subject to a medication error a day, and provides that safety in medication administration must become a primary goal of health institutions.

Many times, the way of drug management in hospitals and its successive and interrelated processes has been described. But nothing like the example of handling of chemotherapy to understand the numerous improvement opportunities facing us and the fatal consequences that may occur when there is a fault in it.

Our goal is not only to describe the risks and get alarmed at his result; we aim to challenge them, and to take advantage of our ability of leading this interdisciplinary process, to find solutions that succeed in improving patient safety.

It should be recognized that most medication errors are caused by human error, and nothing better to take advantage of new technologies, available to us in other areas around us, to fit them into the healthcare environment and specifically in the cycle of continuous improvement of care quality.

This is already reported in 1999 in the report commissioned by President Clinton to the Institute Of Medicine as a result of a media error caused precisely by an overdose of chemotherapy. The title reflects the content of the report: "To err is human. Building a safer health system. "That is: it is our duty to build a safer health system. (2)
Patient safety has been widely studied from the point of view of the epidemiology of errors and adverse events, rather than on practices that reduce such events. “Making Health Care Safer” represents the first effort to bring the area of patient safety through the evidence-based medicine theory. New approaches must take into account not only the errors that cause adverse effects but process avoid the errors.

GEDEFO group (Spanish Group for the Development of Oncology Pharmacy) establishes the main reasons for an institution to take action on limiting errors: (3)

- Ethical responsibility not to harm the patient (non-maleficence).
- Ethical Responsibility to produce the expected benefit to the patient (beneficence).
- Economic cost associated with iatrogenic effects or expenses related to lawsuits and criminal proceedings against professionals.
- Social impact of chemotherapy errors.

The safe handling of cancer treatments is a shared, multidisciplinary process, and although the responsibility for its administration, as with other drugs, lies with the nursing staff, that is the main actor in this process, it is important the collaboration of the pharmacy to facilitate this work and teamwork.

The pharmacist, both by training and by their position in the circuit, can play a coordinating role in the process. Their responsibility is not limited to ensuring that preparation is carried out in conditions of good practice and take a comprehensive review of medical orders in the validation process, but must go beyond establishing barriers to prevent the occurrence of system failures and therefore achieve the common goal of patient safety is in the process of administration of cytostatics.

2. Errors in the administration of cytostatics. Factors involved.

GEDEFO group (Spanish Group for the Development of Oncology Pharmacy) describes the chemotherapy medication error as "any actual or potential fault, in which adjuvant chemotherapy or medication is prescribed, transcribed, prepared, dispensed or administered to a different than the appropriate for that patient, an incorrect date, incorrect and / or improper administration technique, including the vehicle, duration, speed, concentration, consistency and stability in solution via dose order management, or self-management technique. Inadvertent omission of any medication on prescription or transcription are also included. (3)

Nurses that carry out the chemotherapy, should consider that this stage is the last chance to avoid potential error, and that along with the development process, errors that occur are considered "silent errors ", because they are very difficult to detect.
The main aspects to be taken into account in the administration process are:

1. The patient is correct.

2. Medication dispensed by pharmacy corresponds exactly to the prescription.

3. Administration be carried out following the procedures adopted by the institution, to prevent occupational risk and the possibility of extravasation of the drug in the patient.

4. The order or sequence of administration is appropriate, taking into account the approved protocols at the center.

5. The timing and duration of administration is established.

6. It takes into account the patient's history regarding the possibility of allergies or previous infusion reactions that need extra care.

3. Application of new technologies to improve safety in medication administration.

The development of information and communication technologies tools provide a high value on pharmacotherapeutic processes.

Various international and national organizations provide in their recommendations that health systems are committed to the application of new technologies in the process of using drugs in order to increase both the safety and efficiency of the process.

In this sense, the U.S. Agency for Healthcare Research and Quality Healthcare (Agency for Healthcare Research and Quality, AHQR) promotes the use of information technology in health as a strategy to improve patient care. Since 2004, AHRQ has invested more than 300 million dollars in contracts and grants to more than 150 communities, hospitals, providers and systems of health care in 48 states to develop knowledge and encourage the adoption of practices of information technology in the health to improve the quality and safety. (4)

In Spain, the Agency for Quality Health Ministry and social policy establishes annually the Quality Plan for the National Health System and within the security strategies of patients attending health centers of the national health system. To facilitate compliance establishes the specific agreements between the Autonomous Communities and the Ministry of Health and Social Policy, which will include funding for system development and evaluation of compliance projects.

Assisted electronic medication administration, is a new technology that allows the nurse to check and record the medications that the patient is administered using an available electronic device that has an electronic data capture
software. For the record of the administration must be directly connected to the prescription and previously validated by the pharmacist.

Within the new technologies applied to drug administration process include mainly two:

1) - The radio frequency control
2) - Control by bar-code scanning.

These two technologies should be complemented by a third, which is the use of smart infusion pumps for the administration of cytostatics. These should be connected to software that manages these drugs in the hospital, helping to ensure the safety of the cancer patient.

The most widespread method is the bar code, due to problems that arise with the use of radio frequency signals in the healthcare environment, coupled with the high costs due to the use individually in each dose of medication.

The administration by bar-code scanning has developed as a barrier between the nurse and the patient and his most basic level helps achieve the rule of "five Rights".

Specifically helps to reduce the following types of errors:

- Identification of the patient.
- Correct Drug.
- Administration sequence.
- The route of administration.
- The timing and duration of administration if IV infusion.

The following table describes the criteria to be considered for the choice of an administration system by barcode scanning: Hospital Pharmacy vol 43, nº12 (directors forum) (5)

<table>
<thead>
<tr>
<th>CRITERIA TO BE CONSIDERED FOR THE ELECTION OF A BARCODE SYSTEM</th>
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<tbody>
<tr>
<td>Manageability by nurses</td>
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<tr>
<td>Manageability by the Pharmacy Service</td>
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<tr>
<td>Ease of integration with existing computer systems</td>
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<tr>
<td>Possible connection with smart infusion pumps</td>
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<tr>
<td>Portable wireless systems</td>
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<tr>
<td>System utility that emits alerts</td>
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<tr>
<td>Ability to include alarms and problems during administration.</td>
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<tr>
<td>Export records generated databases and reporting</td>
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<tr>
<td>Ability to extract data for quality indicators</td>
</tr>
<tr>
<td>Cost of process</td>
</tr>
<tr>
<td>Maintenance and Support System. Technical service</td>
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</table>
The degree of implementation of these technology is highly variable and unknown, and the results obtained from its use, due to the variety of terms used and the lack of uniformity on the methodologies used in the form of measurement. It would therefore be necessary to have validated methods for the analysis results.

In this sense, Michael Cohen, director of the U.S. ISMP recommends no rates of medication errors obtained as comparators with other organizations or as quality indicators should be used. Recommended as medication safety systems self-assessment, ie, measuring incidents or potential incidents, analyze their causes, to avoid setting changes and measure the results of their implementation, all within the same organization and the same methodology.

To assess the degree of implementation is difficult and it had been found very different numbers. In the U.S., a survey conducted by the ASHP in 2005 showed that 17.2% of hospitals with more than 400 beds had developed technology barcode for administration.

In Spain the survey conducted in 2007 on the implementation of new technologies to the hospital pharmacy, shows that only 1.4% of respondents possessed barcode system for identifying the medication before administering it to the patient. Also, only four hospitals were going to implement some technology in the administration shortly. (6)

Technological innovation should be linked to results obtained from its application and these should be of three main types: results on efficacy, safety results and results in cost savings avoided.

We have published numerous studies that demonstrate the utility of this technology, one of the most recent and comprehensive is that of researchers at Brigham and Women's Hospital Boston compared 6,723 administrations of drugs in hospital units before the implementation of a code system bars and eMAR (Electronic medication administration record) with 7,318 medication administrations after using the system. Using technology with barcode eMAR was linked to reductions in errors associated with drug administration schedule of 41.4% and 50.8% of errors not related to the schedule. (NEJM 2010, May 6 (7)

Although there are numerous international publications describing the decrease in the error rate is obtained in the process of administering medication after implantation technology barcode administration, there are also data that indicate that technology by itself does not ensure system error-free and that the process of change can lead to other new sources of error.

Also described are workarounds used in routine practice, mainly nurses, either to avoid using them or to solve common problems that arise with their use. Workarounds are a method of carrying out an activity when the usual process is not working well, and although the problem is a temporary solution, it is also an indicator that the technology needs to improve.
Koppel et al. observed that nurses prevented the system in 4.2% of patients and 10.3% of the medications. Also up to 15 workarounds were described classifying them as skipped steps, step out of sequence, unauthorized steps and they identified up to 31 different causes thereof. These include: barcode that can not be read (crumpled, blotted, crooked, covered by another label, etc), malfunctioning scanners, patient wristbands that are unreadable or missing, loss of connectivity wifi network. (8)

Sakowski et al. describe the errors intercepted after administration by barcode scanning are mostly mild and there remains the possibility of occurrence of serious errors that are not detected by this technology. (9)

A review of the errors associated with technology barcode sent to USP-MEDMARX in 2006, shows that most of them (51%) is due to labeling and the primary cause is manual tagging, which identifies the wrong drug. (10)

The introduction of any new technology presents barriers to it, mainly include:

- Lack of leadership, there must be a leader in its implementation.
- High short-term economic cost.
- Complexity when it affects different professionals and the organization of the system, requiring coordination.
- Need for training and learning different professionals.

Also, the introduction of a new technology, you should be aware Hype cycle, shown in Figure 1, and we already have experience with the implementation of electronic prescribing in hospitals. However, it is reported that the implementation of barcode technology means less time and difficulties than the electronic prescription.

Figure 1. The Technology Hype Cycle (Gartner, Inc.)
New technologies have a predictable course that is important to learn to anticipate the next phase. The initial optimism of its launch, followed by a phase of disappointment when the problems begin its operation, but if you firmly believe in the potential benefits and the technology is good, more enthusiastic professionals will continue to work to correct the same problems and improve until proven value. The problems are corrected only by those who use it, so the feedback to the user is the key to success.

The Pharmacy Department must assume leadership in the process of implementing technologies that will improve patient safety in the pharmacotherapeutic process, and has been recognized by organizations such as NQF (National Quality Forum): "Leadership of Pharmacy Services is the key to the success of a program of medication safety element. The pharmacist leadership structures and systems secure an interdisciplinary and integrated approach to ensure the safety of the use of drugs in the center. "(11)

4. Change Management: Application in clinical practice

In our own hospital environment, the key points of change management in the process of administration of cytostatics, have materialized in the following decisions, taking into account the Oncofarm® software that was already available in the Pharmacy:

- Installation of WiFi in the oncology day hospital for data transmission to electronic devices.
- Control of the dispensing pharmacy barcode.
- Double patient identification wristband to placing you.
- Control of the administration to the patient by reading wristband barcode.
- Registration process results. Observational study.
- Design changes and improvements.

4.1 Interdisciplinary communication. Stakeholders.

The drug treatment process of cancer treatments is usually defined based on terms of safety including prescribing, preparation, dispensing and administering the right drug to the right patient. But this process involves successive and interrelated activities of different health professionals and even the patient himself and all have a key role in it.

In this regard, it is important to develop technologies that facilitate communication throughout the process, and even to establish traceability of treatments with a single purpose: the process is interdisciplinary and everyone involved must verify part of their due process. A premise of the interdisciplinary
model is interdependence. With this, we ensure that its failure does not cross all barriers and even that can be replicated in subsequent administrations.

Carers involved in the process and its main role in the circuit are as follows:

- Doctor: Prescription. You must be precise and unambiguous, adjusted to protocols and appropriate for the particular patient based on their condition and health.

- Pharmacist: Validation of the prescription. Ensure that the patient receives the correct medication and appropriate to their condition.

- Nurse / Technician qualified in Pharmacy Service: Preparation of chemotherapy according to the orders of preparation and appropriate techniques to facilitate proper processing. It is a critical point in the process. Prepared according to established procedures.

- Pharmacy Assistant / Technician qualified: preparation and dispensing.

- Assistant: The cytostatic must be transported to the administration point safely for both the drug and the environment.

- Nurse: Ensure that the correct patient receives the correct medication in an appropriate manner.

- Patient: It is important to assume that the patient may be an essential part in preventing errors in their own treatment, and in that sense we encourage to enter them an active role in the prevention system thereof. Professionals should be sensitized to consider patient involvement as an additional guarantee of security and not as intrusive.

The Oncofarm ® software we use, is designed to facilitate this horizontal networked communication between the various "players" in the process, so that everyone knows at the same time the state of a patient and their treatments through a program screen where, depending on the situation, it changes the color of the same. Access restricted to professionals based on their user profile allows this horizontal communication without interference of other steps, while allowing monitoring the process in real time each patient. Thus, each professional has full information on those aspects of patients they deserve, and can act only where they are within its jurisdiction.

All staff involved are responsible for part of their process and therefore their actions are necessary and essential for the next one that could be carried out smoothly.
4.2 Administration of cytostatics by barcode.

The barcode systems allow identifying all products that are part of the protocol of a patient and are dispensed from the pharmacy service in a single package identified by patient name. It thus ensures that all drugs have to be administered on this day.

The process steps are:

1 - Dispensing medication labeled with its barcode from the Pharmacy unit.

2 - The nurse before administering the medication to the patient, puts him an identification wristband with barcode that contains information about the medication that the patient should receive. Double patient identification is made, following the security objectives of the Joint Commission: oral evidence by verbal confirmation with the patient name and visual scanning of the barcode.

3 - Before administration, nurse scans the patient's wristband and medication and waits to check the suitability notice to be issued by the PDA screen. If an alarm is issued, it is checked and proceed to act accordingly.

4 - Recording of incidences on the PDA during administration.

4.3 Observational study for assessment process:

Errors that occur in this stage are rarely reported and sometimes carry a bad practice to work hard to assess. Therefore, observational studies of medication administration process are the best way to extract data to afford valid and reliable results.

The methodologies of observational studies have been criticized because they can sometimes change the behavior of people that feel watched. In this case it could lead to a correct use of the technology and the omission of workarounds that can be performed on usual conditions.

To evaluate the results of the application of this technology in our healthcare environment, we have proposed conducting an observational study.

The goal is not to evaluate the reduction of errors after application of this technology, as we believe that if used properly, it is needless to prove its utility, because as previously mentioned, a large number of national and international agencies recommend as a strategy to improve patient safety in the administration process. We also have a large number of publications that demonstrate their validity in preventing errors during the administration process.

We intend when implemented the new technology, assess whether their use is appropriate and what kind of new errors we can find to demonstrate the need to
improve it to exploit its full potential. It is also important to assess the degree of
user satisfaction with the technology. It is necessary to implement the
circuit of evaluation and quality improvement.

- Study Objectives: To evaluate the use of technology in the
administration barcode system, based on some predefined items of good
practice. Establish improvement actions.
- Study Design: Study design for a prospective observation.
- Scope: Oncology Day Care Unit
- Study population: Oncology Nurses during the administration of
cytostatics. It is considered as one observation each administration that is made
- Variables of the study:
  - Variables on utilization procedure: According to data collection
    sheet, discrepancies between the methodology followed and the
    omitted steps, unauthorized or out of sequence are determined
    and considered process errors
  - Variables or failures relating to technology.
- Method: An expert in safety and quality pharmacist and two pharmacy
  students in 5th year, make direct observation of the administrations in the
  Oncology Day Care Unit
- Ethical issues: It was agreed with the nursing supervisor conducting the
  study and the nursing staff of the unit. Oral approval was obtained. Data were
  anonymous upon the identity of the study population. As the observation was
  conducted on nurses and not on patients, it did not need informed consent.
- Limitations: those of an open-label observational study, where influence
  the behavior of staff can be influenced
- Results:

Observaciones sin incidencia
Observations without incidence
Observaciones con una incidencia
Observations with one incidence
Observaciones con más de una
Observations with more than one
incidence

Observations with one incidence
Observations with more than one incidence

26%
4%
70%
### Variables related to procedure

<table>
<thead>
<tr>
<th>Indicator: Fulfillment</th>
<th>% Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verifying patient identity by verbal confirmation, medical order and barcode scanning of the wristband</td>
<td>100</td>
</tr>
<tr>
<td>Right Start (scan wristband and medication)</td>
<td>97,3</td>
</tr>
<tr>
<td>Right end (scan wristband and medication)</td>
<td>93,7</td>
</tr>
<tr>
<td>PDA notice: read and confirmed</td>
<td>99,1</td>
</tr>
<tr>
<td>Pharmacy failure for not dispensing in the program</td>
<td>95,5</td>
</tr>
</tbody>
</table>

### Variables related to technology

<table>
<thead>
<tr>
<th>% Failures</th>
</tr>
</thead>
<tbody>
<tr>
<td>False error messages</td>
</tr>
<tr>
<td>Lock of PDAs during process</td>
</tr>
<tr>
<td>Failure wristband printer</td>
</tr>
<tr>
<td>Fault scanning barcode of wristband the 1st time</td>
</tr>
<tr>
<td>Fault scanning barcode of mixture the 1st time</td>
</tr>
<tr>
<td>Failure wifi network</td>
</tr>
<tr>
<td>Bag label wrong pasted</td>
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</table>
4.4. Satisfaction Survey

A satisfaction survey to the nursing staff on issues related to the safe use of this technology was performed. Their results are shown in the following Figure:

![Nursing Satisfaction Survey](image)

5. Conclusion

To implement an effective and safe drug administration in hospitals, promotes patient safety and helps to strengthen the leadership of the pharmacist in medication safety processes.

6. References


4. Effect of bar-code technology on the safety of medication administration. NEJM 2010, MAY 6, 362 (18):1698-707


