ORIGINAL

TRACEABILITY IN THE PREPARATION AND ADMINISTRATION OF CYTOSTATIC AGENTS AT THE HOSPITAL DE BARCELONA

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ABSTRACT

Introduction: Oncology patients are especially vulnerable to medication errors. Cytostatic agents are «high risk» drugs; they may cause great damage if used inappropriately and may even be lethal.

Methods: A gravimetry-based, technology-assisted workflow was implemented that allows traceability of preparations until their administration to patients in the day hospital, with bar code readings and gravimetric controls during compounding.

Results: Eighty per cent of the preparations were compounded with gravimetry but only 20-40% were administered using the traceability system. Around 8% of the preparations did not pass gravimetric controls, and so validation by the pharmacist was required.

Conclusions: The system detects errors during preparation and administration and keeps a record of all the products used. It requires a substantial investment in equipment, a good Wi-Fi network and informatics support.

Bar Code – Cytostatic – Gravimetry – Oncology –Traceability

RESUMEN

Introducción: Los pacientes con cáncer son especialmente sensibles a los errores de medicación ya que se les administra fármacos denominados de «alto riesgo». Se denominan así porque, no usados correctamente, tienen una alta posibilidad de causar daño incluso la muerte. Para controlar esta medicación numerosos estudios proponen sistemas de lectura de códigos de barras en la preparación y/o administración y gravimetría durante su elaboración.

Métodos: Se implantó un programa informático que permitiera por un lado la trazabilidad de los preparados hasta su administración al paciente en Hospital de Día con lecturas de códigos de barras y por otro controles gravimétricos durante la elaboración.

Resultados: Se prepararon con gravimetría en torno al 80% de los preparados pero solo se administraron con trazabilidad en torno a un 20-40%. No pasaron el control de peso quedando pendientes de validación farmacéutica alrededor de un 8%.

Conclusiones: El sistema detecta errores que puedan producirse durante la preparación y administración y a su vez mantiene un registro de todos los productos usados. Requiere una inversión importante en equipos y un buen funcionamiento de la informática y redes WiFi.

Código de barras – Citostáticos – Gravimetría – Oncología – Trazabilidad

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INTRODUCTION

The definition of medication error (ME) of the National Coordinating Council for Medical Error Reporting and Prevention) is «any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer».[1]

Patients with cancer are especially vulnerable to ME due to the high toxicity of their drugs, the multiple dose adjustments requiring precise monitoring of laboratory parameters, and the nature of the disease itself, which affects vital organs, immune function and functional status. Cytostatic drugs are also considered «high risk»; they may cause great damage if used inappropriately and may even be lethal. Via both parenteral and oral routes, cytostatic drugs are included in the «high risk» list published by the Institute for Safe Use of Medications (ISMP).[2-4]

It has been estimated that when adverse drug events occur in the hospital setting, the patient's length of stay increases by an average of 4.6 days.[5] According to ISMP-Spain, ME are responsible for between 4.7 and 5.3% of hospital admissions with an average cost of nearly 3,000 euros.[6]

Chemotherapy errors occur at a rate of one to four per 1,000 orders. They affect at least 1-3% of adult and pediatric oncology patients and may occur at any stage of the medication process.[4] In a 2015 survey of 206 nurses in Turkey, 83.4% had experienced at least one undesirable error while preparing or administering chemotherapeutics during their professional life.[7] Bar code (BC) medication administration reduces medication errors by electronically verifying the «five rights» of medication administration: right patient, right dose, right drug, right time and right route.[5] The American Society of Health System Pharmacists (ASHP) encourages health systems to adopt bar-code-enabled medication administration technology so as to improve patient safety and the accuracy of medication administration and documentation. It also advocates the involvement of pharmacists in the interdisciplinary planning, development, implementation and management of these systems and urges the Food and Drug Administration (FDA) to mandate pharmaceutical manufacturers to use symbols that can be deciphered by scanning equipment, such as the National Drug Code, lot number and expiration date. Along the same lines, the ISMP believes that both BC and gravimetry should be used during preparation.[8] The involvement of nursing staff is also essential to successful system implementation and use. A 2005 ASHP survey estimated that only 13.2% of hospitals used a BC system, but by 2013 this figure had risen to 80%.[9, 10]

According to standard practices at our hospital, when compounding cytostatic agents for the DH, pharmacy technicians follow a guide to select the components and quantities required, using a volumetric method which requires visual inspection of the syringe and the vials by the pharmacist to ensure that the appropriate volume of drug is prepared.

The new technology includes BC identification for the preparation and the patient in the DH, and BC identification and gravimetric evaluation in the Pharmacy Service for the components and preparations. Several studies have evaluated this gravimetry-based technology-assisted workflow.[2, 11-13]

The processing in the Pharmacy Service and DH includes prescription and pharmaceutical validation, preparation of the chemotherapy, and patient admission, administration and discharge.[11]

In order to detect (and prevent) medication errors and to trace the preparations from their validation to their administration to the patient, the Hospital de Barcelona (HB) has introduced a traceability program (Lugh Technologies®), using BC and gravimetric evaluation. In this study the results of introducing a traceability program in our hospital are reported.

METHOD

In this study we collected data form 2016 to 2019. The program was tested first in the Pharmacy Service during the preparation process and later in the DH. Electronic prescriptions were integrated in the DH system and patients were identified with their own bar codes on admission.

At the Pharmacy Service a new database was created with information on reconstitution, dilution, conservation, stability, density and EAN-13 (the BC of each drug, which does not contain information on lot number or expiry date) of all the cytostatic agents and also on the intravenous solutions used when compounding. The database also specifies the margin of error accepted (5-10%). The goal is to transform the volume of the preparation into weight taking account the density of each component. At each stage of the preparation measured solutions were weighed on an electronic balance and the density of the components was checked, so that the system was able to determine the dose of the cytostatic by comparing the difference in weight of the final container before and after adding the drug. The lot number of each component was also recorded.

We also needed to adapt the Biological Safety Cabinets with the BC reader, screen, scale, label printer and speech recognition system with headphones and microphone for the voice-controlled preparation. At the DH, BC readers, computer, label printer and a personal digital assistant (PDA) with Wi-Fi were required.

Description of the process

Pharmacy. The pharmacist records the medical order and the technician introduces into the system the cytostatic agents to be used during the day.

In the Biological Safety Cabinet and with an interactive voice system the technician follows the instructions. Throughout the process gravimetric controls are needed to ensure that the dose is within the given specifications. Each final container (syringe or parenteral infusion solution) is labeled from the beginning with data of the preparation including the expiry date, conservation conditions and a BC.

TABLE 1. Reports of traceability.

	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Total cytostatics	7,250	6,656	5,696	6,115
Prepared with the system	6,629 (91)	5,795 (87)	5,224 (92)	4,489 (79)
Administered with the system	2,150 (32)	2,767 (48)	2,280 (44)	671 (15)
Incorrect weight	548 (8)	374 (6)	376 (7)	392 (8)
Released by the pharmacist	465 (85)	312 (83)	309 (82)	NA

NA: Not Available.

TABLE 2. Errors reported by Day Hospital (DH).

	2015	2016	2017	2018	2019*
Errors reported by DH	27	6	5	7	49

*: Change In The Hospital's Notification System.

Day Hospital. The process begins with the identification of the nurse and the preparation. Once these BCs are read the system gives instructions for the preparation of the premedication (antiemetics, hydration and others). After this, using the PDA the nurse checks the BC wristband of the patient, the ward and the infusion pump, and the administration begins. The screen also indicates the order of the administration and the nurse must check each BC before administration. Once the process is finished the system releases the ward and the pump for use with the next patient.

Any discordance in gravimetry at the Pharmacy Service or in the BC at either the Day Hospital or the Pharmacy Service stops the process. As the whole process is recorded the drugs and lots used for a patient can be tracked. The system also optimizes storage since it is possible to read the BC of the drugs without re-labeling them. It also handles the lots, expiry date and partially used vials.

RESULTS

This system was introduced in late 2015. Between 80 and 92% of the cytostatic agents are compounded with this program at the DH although only between 15 and 44% are administered using the program (Table 1). One of the reasons is that the program uses Wi-Fi for administration in DH and any malfunction in the WiFi slows down the process considerably. In view of the continuous flow of patients in the DH, this problem may restrict the program's use.

The system also detects incorrect weight in between 7 and 8% of preparations. When this occurs the system notifies the technician and the pharmacist decides whether to validate or to repeat the preparation.

In 2015, prior to implementation, 27 errors were reported by the DH. This number fell to six after the implementation of the system (Table 2). The system informs the nurse when an error is detected but does not record it (it records only errors in preparation), so this information must be provided by the nursing staff.

DISCUSSION

At the HB, between 80 and 92% of the cytostatic agents are compounded with this program although only between 15 and 44% are administered using it. The system detected incorrect weight in between 7 and 8% of preparations during this period.

Technological advances allow the administration of treatments in the Day Hospital (DH), increasing patient comfort and convenience. However, in the outpatient setting the estimation of ME in patients with cancer ranges from 2 to 7%.[14, 15]

In a 2017 study in Spain a questionnaire designed to investigate the application of new technologies in preparation and administration was sent out to 50 hospitals in the area of Madrid. Regarding the preparation process, 11 centers of the 31 that responded reported recording the components used through BC reading, and six more had implemented a trial period. The voice-controlled technique for assistance in preparation was not implemented, although it was under trial in two centers. The final examination through gravimetric control was performed at two centers and was in trial phase at three.[16]

Many published studies have presented data on the incidence of errors in chemotherapy. However, due to the variety in design and methods, the data are difficult to compare. A retrospective analysis performed in 2016 of medication errors identified during preparation at 10 centers detected error levels outside the accepted tolerance range in 7.89% of the 759,060 doses prepared between July 2011 and October 2015. The study concluded that the system is useful for preventing dosing errors, because it identifies errors that would have gone unnoticed using conventional methods and could have resulted in toxicity or suboptimal therapeutic outcomes.[12] At the HB

the system only records differences in gravimetry; any other errors (wrong container, wrong patient or wrong sequence, etc.) stop the process but are not recorded. White and col [15] reported five steps during the mixing process that might induce errors: staging (preparing all the materials required), reconstitution, mixing, verification and label application. In a 2017 study [6] no errors were reported in the administration stage prior to the introduction of measures; however, with the BC administration device, 29.5% were detected and prevented. Besides the detection of errors, the system is also useful because it records lot numbers and controls the expiration dates of the preparations.

Error tolerance levels set by centers vary from 25 to 6%. However, extended tolerances of up to 30% were found for medication such as bortezomib, vincristine, methotrexate and cytarabine whose formulations are difficult to maintain within normal limits for preparation.[12] In our setting we found that the same drugs (plus azacitidine) failed to stay within our center's preset tolerance limits of 10% and so we extended this limit up to 15%.

Administration rates by the nursing staff were low, mainly due to Wi-Fi issues. It is very important to ensure a correct Wi-Fi signal for the PDA in all DH wards. Another limitation for the implementation of these technologies is the economic investment required for their setup.

The system is useful since it avoids medication errors and also guides the technician during compounding, and the nurse during administration. CP

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