Implementation of a new health information technology for the management of cancer chemotherapies

Olivier Vosters,¹ Youssef Jaadar,¹ Laure-Anne Vidts,¹ Anne Demols,² Sophie Lorent,¹ Viviane Liévin,¹ Marc Demoulin¹

¹Department of Pharmacy, Erasme Hospital, 808 Route de Lennik, Brussels, Belgium
²Department of Gastroenterology, Erasme Hospital, 808 Route de Lennik, Brussels, Belgium

Correspondence to

Youssef Jaadar, Department of Pharmacy, Erasme Hospital, 808 Route de Lennik, B-1070 Brussels, Belgium; youssef.jaadar@erasme.ulb.ac.be

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ABSTRACT

Background Cancer chemotherapy drugs are classified as high-risk molecules. Safety of the cancer chemotherapy process is often achieved with the implementation of a health information technology to each step or to the entire process. However, computerisation could lead to the emergence of new unintended medication errors. The aim of the study was to evaluate the impact of new software designed for the management of anticancer chemotherapies.

Method The cartography of the process and the failure modes, effects and criticality analysis were performed by a multidisciplinary team. Criticality indexes were calculated considering or not the implementation of the commercial software (CytoWeb). Quality and satisfactory indicators were measured before the implementation and during the use of the software.

Results Our results demonstrated the complexity of the cancer chemotherapy process in the hospital. Risk analysis highlighted the positive impact of CytoWeb on the process safety but pointed out some steps that were not positively influenced by the software. Although a decrease of 38.6% of error rate was observed with the electronic system, new unintended medication errors emerged. These errors were due to inadequate use of the software (encoding of the wrong drug, the wrong dose, the wrong patient parameters or lab results and lack of prescriber adherence). Our satisfaction survey showed that the hospital pharmacists and doctors were less satisfied by the software than the nurses, mostly in terms of task achievement and time saving. Survey's results highlighted some weaknesses in the user training and in the collaboration between the medical staff.

Conclusions Our work showed the emergence of unintended medication errors linked to computerisation that were due to an inadequate use of the software. Other issues were highlighted such as the lack of collaboration between the medical staff, the lack of prescriber implication and weaknesses in the user training or in the information related to CytoWeb.

INTRODUCTION

Cancer chemotherapy drugs are classified as high-risk molecules considering their high toxicity profile and the potential secondary effects. Moreover, these drugs are administered to weakened patients because of their pathology. Chemotherapy is given usually intravenously according to complex protocols and for repeated cycles. The dosage is usually adapted to the patient's parameters. In this context, multiple errors can occur

during prescribing, transmission of documents and drug delivery, potentially leading to serious consequences.¹ Furthermore, these drugs have to be prepared and conditioned by experimented manipulators in a secured area to avoid further accidental exposure of hospital staff and patients to chemotherapy drugs.²

The hospital pharmacist is in charge of the delivery of the right drug to the right patient, at the right dose, by the right route, at the right timing, with the right information and the right documentation. Several studies published in the last decade showed the occurrence of medication errors implying various steps of the medication process in a hospital. Drug prescription and administration are the main steps implicated in medication errors.^{3–6} A recent study published by Jaadar *et al*⁷ concerning the monoclonal antibodies-based chemotherapies confirmed that medication errors can arise at all steps and that the hospital pharmacist is playing a central role in detecting such errors. Indeed, among the 13 233 prescriptions, 577 events have been identified from which 94% were detected by the hospital pharmacist. The most frequent errors concerned the prescription process and more particularly errors related to the dosage, the therapeutic schema and patient parameters.

Safety of the medication process and, especially the cancer chemotherapy process, can be achieved by using new technologies such as the computerised physician order entry, the clinical decision support system, the e-prescribing system or other systems enabling the management of drug administration. Indeed, numerous publications described the positive impact of health information technology (HIT) on medication safety.^{5 6 8–10} Nevertheless, more recently, these technologies were shown to facilitate the emergence of new medication errors.^{11–15} These new errors were due to multifactorial conditions and can be categorised in four main types including computer, human or both factors and organisational factors.¹⁵

The aim of this study was to evaluate the impact of the new software implemented in the Erasme Hospital for managing the anticancer chemotherapies and to identify residual risks or critical points that have to be addressed in the future before implementation of any new HIT by using a risk analysis method and by the measurement of quality and satisfactory indices.

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Figure 1 Criticality indexes for the 7 steps of the medication process calculated by the working group considering (CYTOWEB) or not (Initial) implementation of CYTOWEB.

MATERIAL AND METHOD

Settings and system description

The project was conducted in a 986-bed academic hospital with an ambulatory facility. Around 14 000 chemotherapy treatments per year have been prepared in a centralised production area (class A horizontal or vertical laminar airflow cabinet placed in a class B room) from the Department of Pharmacy. Handwritten prescriptions containing patient's identification and location, chemotherapy protocol, treatment scheme, dose, date and conditions of administration were completed by physicians (specialists in oncology). The patient parameters (weight, height and body surface area) were measured and calculated by the nurses. All prescriptions were specific and individualised and were then transmitted to the pharmacy by fax or by the medical staff. The prescriptions were validated by the pharmacist using an in-house database programme in which all prescriptions were registered, allowing the pharmacist to check patient data, previous treatment and adjustment or deviation from the therapeutic protocol. Labels for perfusions were edited by the database programme and given with the prescription to the pharmacy technician for preparation. Prior to dispensing, all preparations were checked and validated by the pharmacists. Administration to the patient was performed by the nursing staff.

The software CytoWeb V.3.0 (Knoware, Nivelles, Belgium) was implemented since November 2015 in the hospital for inpatients and outpatients and for few medical disciplines including gastro-enterology, pneumology, urology, gynaecology and other medical oncology disciplines. The software is a comprehensive tool solution for safe chemotherapy treatment management and is marked as CE medical device. The software can be interconnected with other software packages in the hospital, including the electronic patient records, the pharmacy stock management

tool, the invoicing and pricing tools and the laboratory parameters. CytoWeb software provides complete closed loop integration, supports prescribing and secures the complete flow. Indeed, chemotherapy treatments were allowed to be selected by the physicians among preselected and validated protocols or products. The doses were automatically calculated based on the latest patient's parameters such as age, size and weight or creatinine clearance. A complete overview of the validated preparations to come is available for the pharmacists who were also guided through the complete preparation process. At any moment, a complete overview of the situation for all planned, active and finished administrations is available for the staff.

Failure modes, effects and criticality analysis (FMECA) procedure

A prospective risk analysis was performed according to the methodology previously described^{16–18} by a multidisciplinary working group composed by hospital pharmacists, oncologists, nurses and quality assurance specialists. They were required to meet as many times as was necessary to complete the analysis. The main steps of the medication process were identified by the working group, and a brainstorming session was organised to define the potential failure modes. For each failure mode, a score for the occurrence, the severity of the potential effect and the detectability was determined according to a scale between 1 and 5. The criticality index (CI) was calculated by multiplying occurrence, severity and detectability scores and ranged between 1 and 125. The results were analysed by the working group, and each failure mode was thereafter classified according to their CI score in three risk categories: insignificant (CI 1–12), acceptable (CI 13–24) or not acceptable (CI 25–125). A similar analysis was performed by the working group considering the implementation of the CytoWeb software, and a new CI score was assigned to each failure modes. The risk was considered as eliminated (CI ≤4), controlled (CI 5–12), prevented (CI 13–24) or not controlled (CI 25–125). The CI scores were then compared in order to quantify the safety improvement and to identify remaining risks that may be the target of further actions.

Medication errors reporting system

The study was conducted in the centralised cytotoxic production unit in which chemotherapy treatments were prepared for outpatients and hospitalised patients. The reporting system consisted in the analysis of chemotherapy, monoclonal antibody and concomitant-related medication error observed, in parallel, in handwritten and electronic medical prescriptions during a 7-month study period. A medication error was defined as any deviation of what should have been done in the therapeutic drug management of the patient. The medication errors were reported to the hospital pharmacist in charge of the project, as previously described.⁷ Briefly, all prescriptions were checked for the patient's identification, administrative information and parameters; for chemotherapy protocol, drug selection, formulation and frequency, dose calculation or adaptation; and for concomitant therapy. Data were collected, stored and registered anonymously. Data were classified according to the WHO taxonomy.¹⁹ Medication errors observed in the handwritten medical prescriptions and in the electronic prescriptions were statistically compared using χ^2 test.

Satisfaction survey

A structured questionnaire was sent to CytoWeb users including hospital pharmacists (n=8), physicians (n=7) and nurses (n=9).

Table 1 Initial risk category and risk management evaluated by the working group considering the implementation of CytoWeb

Initial risk category	n	Risk management with CytoWeb			
		Not controlled	Prevented	Controlled	Eliminated
Not acceptable	21	0	8	13	0
Acceptable	8	0	0	6	2
Insignificant	9	0	0	0	9
Total	38	0	8	19	11

Table 2 Classification of notified medication errors according to the WHO taxonomy, in both prescription systems

WHO taxonomy	Handwritten	CytoWeb
Wrong patient	5	0
Wrong drug	2	0
Wrong dose/strength or frequency	31	12
Wrong formulation or presentation	1	0
Omitted medicine or dose	3	2
Others	10	11
Total	52	25

Queries (n=24) about the user satisfaction were evaluated according to a 5-point Likert scale (from 1=very unsatisfied to 5=very satisfied). Queries were divided in three groups: 7 queries concerning the implementation phase of the software, 14 queries concerning the use of the software and 3 queries concerning the expectations of the users. The questionnaires were sent 7 months after the implementation of the software CytoWeb and were collected 15 days after their diffusion. Mean satisfaction scores for each query and the global satisfaction mean taking into account the 24 queries were calculated. Data for each group of users were analysed and statistically compared using analysis of variance (ANOVA) test.

Statistical analysis

Statistical analyses were performed using χ^2 test or a one-way ANOVA test and a multiple Bonferroni test using the statistical software GraphPad Prism V.5 (GraphPad Software, La Jolla, California, USA).

RESULTS

FMECA and risk analysis

The medication process was split into seven major steps: prescription, transmission, validation, preparation, delivery, pricing and administration. According to FMECA results, the working group found 38 potential failure modes: 12 for the prescription step, 6 for the transmission step, 5 for the validation step, 6 for the preparation step, 3 for the delivery step, 2 for the pricing step and 4 for the administration step. The CI calculated from the defined occurrence, severity and detectability scores were examined for each failure mode. The sum of the CI for each of the seven steps was 404, 236, 92, 192, 20, 62 and 190, respectively (figure 1), for a total of 1196. For each failure mode along the process, the risk was then evaluated for acceptability. For 21 out of 38 failure modes, the calculated CI were ≥ 25 , and the risk was considered as not acceptable (table 1). Six out of 21 were found in the prescription step, four were found in the transmission step, five were found in the preparation step, two were found in the pricing step and four were found in the administration step. For 8 out of 38 failure modes, the calculated CI were between 13 and 24, and the risk was considered as acceptable (table 1). Three out of 8 were found in the prescription step, one was found in the transmission step and four were found in the validation step. Finally, for 9 out of 38 failure modes, the calculated CI were below 12, and the risk was considered as insignificant (table 1). Three out of nine were found in the prescription step, one was found in the transmission step, one was found in the validation step, one was found in the preparation step and three were found in the delivery step. A similar analysis was performed by the working group considering the implementation of the CytoWeb software, and a new CI score was assigned to each failure mode. In this case, the sum of the

CI for each of the seven steps was 96, 66, 39, 67, 10, 24 and 52, respectively (figure 1), for a total of 354. As shown in table 1, 8 out of the 21 risks classified as not acceptable were considered as prevented and 13 as controlled, considering the implementation of the CytoWeb software. Six out of the eight risks classified as acceptable were considered as controlled and 2 as eliminated. Finally, the totality of the nine risks classified as insignificant were considered as eliminated. Among the eight risks considered as prevented but not controlled or eliminated following the implementation of CytoWeb, two concerned drug errors in the prescription step, two concerned patient's identification and parameters in the transmission step, two concerned errors regarding drug preparation and identification in the preparation step and two concerned wrong administration or supervision in the administration step.

Medication errors

During the 7-month study period, 52 medication errors have been notified with the handwritten medical prescriptions, while 25 medication errors have been observed with the electronic prescription system CytoWeb. The number of prescription lines encoded was 6946 and 5397, respectively. The error rate, consisting in the ratio between medication errors and prescription lines, was 7.5‰ for the handwritten system and 4.6‰ for the electronic system. The difference was considered as statistically significant (p value=0.0457). This result demonstrated a decrease in error rate of 38.6% with the electronic system. Medication errors were thereafter classified according to the WHO taxonomy as represented in table 2.

As shown in table 2, errors related to wrong patient, wrong drug or wrong formulation were completely eliminated with the use of the software, whereas errors concerning wrong dose or frequency were reduced by 61.3% (from 31 to 12). Medication errors that did not fit with the WHO taxonomy were classified as 'Others' and concerned wrong patient parameters, wrong administrative information, wrong prescription date or format and omitted adaptation of the selected concomitant therapy. Among other medication errors, errors concerning the patient parameters were drastically reduced by 87.5% (from 8 to 1) with the electronic prescription, whereas the increase of new error types was observed with the use of the electronic system CytoWeb, such as omitted adaptation of the concomitant therapy in a validated anticancer chemotherapy (from 1 to 6).

Satisfaction survey

In our study, 100% of the questionnaires (n=24) were received back and were all taken into account. The global satisfaction mean ($\pm$ SE of the mean) calculated on a 5-point Likert scale for hospital pharmacists, physicians and nurses was 3.81 ($\pm$ 0.07), 3.97 ($\pm$ 0.07) and 4.18 ($\pm$ 0.06), respectively. Therefore, these findings showed that the CytoWeb software was associated with satisfaction (score >4) for nurses, whereas the system was associated with mild satisfaction (score between 3 and 4) for hospital pharmacists and physicians. Only the difference between the global satisfaction mean for hospital pharmacists and for nurses was considered as statistically highly significant (p value <0.01). The results for each query were then compared between the three groups of users, and no statistically significant difference was found. Nevertheless, for the query concerning the impact of the CytoWeb system on the duration of the daily work, the satisfaction score on a 5-point Likert scale expressed as the mean ($\pm$ SD) was 3.38 ($\pm$ 0.92), 3.71 ($\pm$ 0.76) and 4.33 ($\pm$ 0.50) for hospital pharmacists, physicians and nurses, respectively. The

difference between the satisfaction score for the hospital pharmacists and the nurses was shown as statistically significant (p value=0.0432).

DISCUSSION

The medication process in a hospital is very complex and involves many health professionals that have to interact and cooperate. In this context, the implementation of a new health technology may have a positive impact on the patient care quality and safety as observed in many previous studies.^{2 6 16–18 20 21}

The FMECA method is often used to evaluate the potential risks linked to complex processes in a hospital pharmacy. Indeed, this method is proactive, intuitive and prospective, and consists in the identification of the potential failure modes of a complex process and their causes and includes a quantitative evaluation of the criticality for each failure mode.^{16–18 22 23} In our study, the FMECA demonstrated that the majority (21 out of 38) of the failure modes were judged by the working group as not acceptable. Furthermore, the working group confirmed the reduction of the potential risks by the implementation of new software for the management of anticancer chemotherapies. These observations were in line with other comparable studies.^{16–18 22 23} Indeed, the sum of all CIs was reduced by about 70% (from 1196 to 354). Nevertheless, 8 out of 21 failure modes that were initially judged as not acceptable were poorly influenced by the new HIT as the risk was evaluated as prevented but not controlled or eliminated after the implementation of CytoWeb. These findings showed that additional actions should be taken in order to achieve the optimal safety of the process. As discussed by others,^{16–18 22 23} the major limitation of the FMECA is the subjectivity in the selection of failure modes and the determination of CIs, making these results only applicable to one institution although the tool can be generalised to other healthcare activities and other institutions.

Recently, Jaadar *et al* illustrated the central role of the hospital pharmacist in the medication process and mainly in the management of patient safety related to anticancer chemotherapies.⁷ Although the error rate detected in the handwritten prescription was smaller in our study than in the Jaadar's study, we confirmed that detected medication errors were mostly related to wrong dose or frequency, wrong drug, wrong patient or wrong patient parameters. As expected, our study confirmed the reduction of medication errors by using an electronic prescription system (CytoWeb). Indeed, in the last decades, most studies concluded in the decrease of medication errors after implementation of a new HIT, although other contradictory results were also published.^{21 24} In fact, an increasing number of papers related the emergence of new unintended errors after the implementation of HIT.^{11 13 25–27} As proposed in a recent review paper,¹⁵ unintended errors could find their origin in four categories of factors: human factors, computer factors or both factors and organisational factors. In our study, new medication errors observed after the implementation of the CytoWeb system could be explained by the inadequate use of the software (encoding the wrong drug, the wrong dose, the wrong patient parameters or lab results and lack of prescriber adherence). In our study, the inappropriate use of the software could be explained by many factors such as lack of training for the medical staff or lack of experience or lack of information regarding the software, technical difficulties with the software or layout problems.²⁸ These critical points have been pointed out according to the results of the satisfactory survey. Furthermore, the survey showed that the global satisfactory score was lower for hospital pharmacists and prescribers than for nurses, although all CytoWeb users were in agreement

with the improvement of patient safety. Nevertheless, the use of CytoWeb was judged to be time consuming according to hospital pharmacists and physicians as also observed in another study.²⁹ This is in contrast to the conclusions of a recent study showing that prescribing using an electronic system took less time than the physicians thought it would take.³⁰ Altogether, the results of our satisfaction survey did not show the same pattern of satisfaction among HIT users than previously described.^{29 30} The discrepancies could be explained by the specifications of the various commercially available HIT that were evaluated. We also observed that the implementation of the new system changed the way pharmacists, physicians and nurses interact. In our case, hospital pharmacists were deeply involved in the implementation of CytoWeb. This could also explain their lower satisfaction regarding their high expectations. This point may represent a limitation of our satisfaction survey.

In conclusion, implementation of new HIT requires a careful approach. In this context, recommendations can emerge from our study: (1) to perform a risk analysis by a multidisciplinary working group before the implementation, (2) to involve all potential users in successive steps of the implementation, (3) to dispense extended information concerning the new system and practical formation for all users, (4) to consider adaptation of the software layout according to the user's remarks, (5) to consider interconnectivity with existing software (ie, the electronic patient records, the pharmacy stock management tool, the invoicing and pricing tools and the laboratory parameters) and (6) to regularly assess system quality, performance and user's satisfaction by following predefined indicators.

What this paper adds

What is already known on this subject

- Safety of the cancer chemotherapy process can be achieved by new technologies.
- New technologies are also associated with the emergence of unintended medication errors.

What this study adds

- Implementation of new technology requires a careful approach and the implication of all potential users.
- Risk analysis method and measurement of quality and satisfactory indices should be performed before implementation of a new technology.

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