

*Model Formulation* ■

# A Risk Analysis Method to Evaluate the Impact of a Computerized Provider Order Entry System on Patient Safety

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**Abstract Objectives:** Quantitative evaluation of safety after the implementation of a computerized provider order entry (CPOE) system, stratification of residual risks to drive future developments.

**Design:** Comparative risk analysis of the drug prescription process before and after the implementation of CPOE system, according to the Failure Modes, Effects and Criticality Analysis (FMECA) method.

**Measurements:** The failure modes were defined and their criticality indices calculated on the basis of the likelihood of occurrence, potential severity for patients, and detection probability. Criticality indices of handwritten and electronic prescriptions were compared, the acceptability of residual risks was discussed. Further developments were proposed and their potential impact on the safety was estimated.

**Results:** The sum of criticality indices of 27 identified failure modes was 3813 for the handwritten prescription, 2930 (−23%) for CPOE system, and 1658 (−57%) with 14 enhancements. The major safety improvements were observed for errors due to ambiguous, incomplete or illegible orders (−245 points), wrong dose determination (−217) and interactions (−196). Implementation of targeted pop-ups to remind treatment adaptation (−189), vital signs (−140), and automatic edition of documents needed for the dispensation (−126) were the most promising proposed improvements.

**Conclusion:** The impact of a CPOE system on patient safety strongly depends on the implemented functions and their ergonomics. The use of risk analysis helps to quantitatively evaluate the relationship between a system and patient safety and to build a strategy for continuous quality improvement, by selecting the most appropriate improvements to the system.

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## Introduction

In the last few years, patient safety issues have become a major concern in healthcare and an important target for the use of information technologies. Preventable fatal medical errors of all types have been estimated to cause between 44,000 and 98,000 deaths per year in the USA<sup>1,2</sup> and as many as 7,000 of that total are estimated to occur due to medication-related errors.<sup>3,4</sup> A well-designed study prospectively measured a rate of 6.5 adverse drug events per 100 admissions, of which 28% were preventable, with errors occurring at the stage of ordering (49%), transcription (11%), dispensing (14%) and administration (26%).<sup>5</sup>

Health care processes are complex, and they rely primarily on the performance of humans in difficult environments with high cognitive loads. In medication prescribing, the performance of highly trained operators has been shown to be

associated with error rates in the range of 1% for dispensation<sup>6,7</sup> and 10% for dose calculation.<sup>7,8</sup> Significant efforts are underway to prevent human errors and improve patient safety. Many hospitals are investing in information technologies (IT), with the hope of improving patient safety.<sup>9</sup> Information technologies may simplify manual or cognitive steps leading to high error rates, and they target systems rather than individuals, a strategy that has been shown to be effective in reducing errors in other fields such as aviation industry.<sup>10</sup>

For these reasons, the use of information technologies in drug prescription and administration has received considerable attention in recent years. Computerised provider order entry (CPOE) system refers to a variety of computer-based systems that share the common features of supporting the drug ordering process and to improve standardised, legible, and complete orders.<sup>11</sup> Clinical decision support systems (CDSS) are built into most CPOE systems with varying degrees of sophistication, from providing basic computerised advice limited to drug databases such as doses, routes, frequencies and interactions up to complete integration within a computerized patient record along pathways with drug allergy, drug-laboratory checking and complete workflow management.

Numerous publications have described the positive impact of CPOE systems and CDSS on medication safety (see

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Kaushal et al.<sup>12</sup> for review). The two most significant studies have demonstrated an important decrease of 55 to 81% in the rate of serious medication errors after the implementation of CPOE systems.<sup>13,14</sup> When the results are analyzed according to steps in the process from ordering to administration, it is interesting to note that CPOE system diminished ordering errors by only 19%, whereas transcription (−84%), dispensing (−68%) and administration (−59%) errors were more markedly reduced.<sup>13</sup> The reduction in ordering errors is strongly dependent of the exhaustiveness of the CDSS integrated with the prescription tool.

CPOE systems can also have negative effects, and some recent papers have emphasized the problems that can ensue after introduction of computerized prescriptions. In one study, a CPOE system was shown to have increased 22 types of medication risks.<sup>15</sup> This publication led to an intense debate, because the system used was considered to be obsolete.<sup>16</sup> In a second study, an increased mortality from 2.8 to 6.6% was observed in a paediatric referral centre after the implementation of a commercially sold CPOE system.<sup>17</sup> This unexpected result was only partially attributable to the new prescribing tool itself, and the induced major changes in the process organization and the communication channels seemed to play a key role.

These results highlight the difficulty of ensuring a successful implementation, which is influenced not only by the quality and the exhaustiveness of the system itself, but also by numerous external technical, organisational, cultural and human factors. Owing to the complexity of each institution and their heterogeneity, a success-story with a system in a specific hospital cannot be considered to be a sufficient guarantee for a safe implementation in another one. Moreover, many different commercial and home-made systems are available, and each of them needs to be carefully evaluated. To increase the chance of successful implementation, the development of evaluation and certification methods is highly desirable,<sup>18,19</sup> and mechanisms for feedback and continuous improvements should be in place.<sup>20</sup>

Medication error reporting systems have been used to assess the impact of CPOE systems, but these methods have inherent biases due to voluntary reporting and retrospective analysis.<sup>21,22,23</sup> The Leapfrog group adopted general quality standards for evaluating the safety of CPOE systems. The evaluation methodology simulates different clinical scenarios using a wide variety of test patients to determine how a CPOE system responds to unsafe medication ordering and clinical situations. The results assist hospitals in identifying needed improvements in their current CPOE systems.<sup>24</sup>

In order to improve the reliability of CPOE systems but also to assess their effects on safety, there has been a growing in employing prospective risk analysis approaches used in a number of other high hazard industries, such as nuclear power or aviation.<sup>25</sup> In the United States, the Joint Commission on Accreditation of Health Organizations (JCAHO) has, since July 1, 2001 required each accredited hospital to conduct at least one proactive risk assessment annually.<sup>26</sup>

Among these methods, Failure Modes, Effects and Criticality Analysis (FMECA) is a well described tool that was recommended both by the VA National Center for Patient Safety<sup>27</sup> and the Institute for Healthcare Improvement

(IHI).<sup>28</sup> It identifies possible or likely errors (“failure mode”) and gauges what their effect will be, even before they take place. Unlike FMEA (Failure Modes and Effects Analysis) which is only qualitative, FMECA includes a quantitative evaluation of the criticality of each failure mode. The criticality indices are calculated by multiplying three components—likelihood of occurrence, severity and detection—on the basis of known or estimated data. FMECA compares the top critical events in different process organisations, allowing a simple measurement of the potential impact of new solutions on patient safety. The method was originally developed to assess risk in major projects, especially in the aerospace industry. By providing a structured analysis of a process based on the combined experience of several professionals having different point of views, FMECA helps to decide whether a risk is acceptable or not and to estimate the potential impact of different improvement scenarios, prior to their implementation. A drawback is the relative subjectivity of the analysis which produces results that are not appropriate for statistical analysis. As the main goal is to reflect the perception of risk by the participants and to be a decision tool, this disadvantage does not limit the potential utility of the method.

We started to apply FMECA in our hospital when reengineering the paediatric parenteral nutrition production<sup>29</sup> and the anticancer chemotherapy process,<sup>30</sup> with significant reductions in the estimated criticality. The method has proven to be a useful tool, and we decided to apply it to other high-risk processes.

The objective of the current study was to perform a comparative risk analysis of drug prescribing before and after the implementation of a computerized patient record including a CPOE system, to compare the risks to patient safety in the manual and computerized systems, and to identify any major residual risks in the computerized system that should be the target of additional action.

## Methods

### Setting and System Description

The setting for the study was the Geneva university hospitals, a consortium of hospitals on four campuses and more than 30 ambulatory facilities, comprising 2,200 beds, 5,000 care providers, over 45,000 admissions and 750,000 outpatients' visits each year. It covers the whole range of in- and outpatient care, from primary to tertiary facilities. A computerized patient record (CPR) mostly developed in-house is used in all facilities and runs on more than 4,500 PCs.

The CPR is based on a component-based architecture and a message oriented middleware. It is written using Java. The CPR includes a CPOE system, called “Presco”. It is a global order entry platform for all orders, including drugs, radiology, laboratory, nursing care among other. When the risk analysis was performed (summer 2006), the system was running in inpatient facilities with a total of 1,200 beds. The deployment is in progress for the rest of inpatients and for outpatient clinics. Decision support includes all basic information on drug, including all specific rules for paediatrics orders; it supports orders sets, various kinds of alerts and reminders. It is tightly linked with the CPR allowing rules based on laboratory or other clinical information.

As it is the case in almost all Swiss hospitals, drug dispensing is performed by nurses, from a ward stock, without systematic review by a hospital pharmacist. The “last mile” is not yet computerized, that is the nurses do still have to manage by hand the preparation and administration. The stock is refilled by global orders to the central pharmacy.

### FMECA Risk Analysis

This analysis was performed in the service of general internal medicine according to the methodology previously described.<sup>30,31</sup>

#### Team Definition

For the analysis, a team was created consisting of two physicians and two nurses using the CPOE system, two representatives of the medical informatics department (a physician and a developer), a pharmacist and a psychologist with a masters degree in informatics and ergonomics. Physicians and nurses were selected by the head of service, on the basis of their daily use of the CPOE system and their interest in the improvement approach. They were also asked to represent their colleagues' opinions and to consult them if necessary during the analysis. The medical informatics representatives were the most involved people in daily development and implementation of the CPOE system.

#### Failure Modes Definition

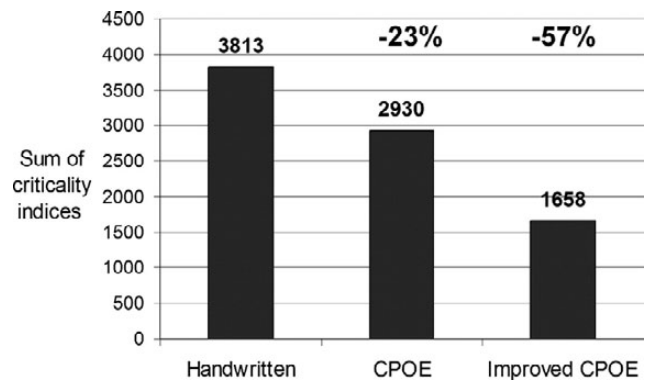
The analysis was limited to drug management, including all direct decision support such as drug-drug interactions, laboratory checks and order sets for example (i.e., Laboratory analysis). The process considered extended from prescription by physicians up to administration of the drug to patients by nurses and further review by physicians. The decomposition of the whole process into steps characterized with specific failure modes was made by the team, driven by a specialist in the FMECA approach. This was the major initial task performed by the team.

A brainstorming session was organised to determine the ways the process could fail at each step. The team had to answer to the following question “What could possibly go wrong within this process step? Each participant first worked individually and a Delphi discussion method was then used to analyze all propositions, to aggregate similar topics, and to finalize the list of failure modes.

#### Criticality Analysis

The likelihood of occurrence (incidence) for each failure mode was classified from 1 to 10, the severity of the potential effect for the patient from 1 to 9, and the chance of detecting the failure before it affected patient safety from 1 to 9. Estimates were obtained by team consensus for all failure modes, taking into account the local context and workload. Most of the time, no quantitative data were available and the scoring was based on the practical experience of the participants. The evaluation was carried out on the basis of explicit criteria, published elsewhere<sup>30</sup> and was as consistent as possible with published information of similar events. The criteria were applied to all items.

For each failure mode, the criticality index was simply calculated by multiplying the determined frequency, effect and detection scores (minimum: 1, maximum: 810). Results were summarized in figures comparing the criticality indices for each mode of failure before and after CPOE system implementation.



**Figure 1.** Evolution of the total criticality indices in the three studied process organizations.

The criticality indices were analysed by the team to measure the evolution of risks from the handwritten to the electronic process. The sum of all individual criticality indices was calculated for each process and then compared to determine the global impact in the safety and the potential impact on patient outcome.

#### Acceptability and further Improvements

For each mode of failure, the change in criticality was discussed and the acceptability of the residual risk was evaluated. When it was not considered to be appropriate, additional improvements to the system were proposed. Their potential impact was estimated by a consensual view of their effect on the previously determined frequency and/or detection. The reduction in criticality that could potentially be obtained by implementing all proposed improvements was calculated (“improved CPOE system”). Development priorities were defined based on the criticality of the failure mode, the estimated impact of each proposed improvement and its feasibility.

## Results

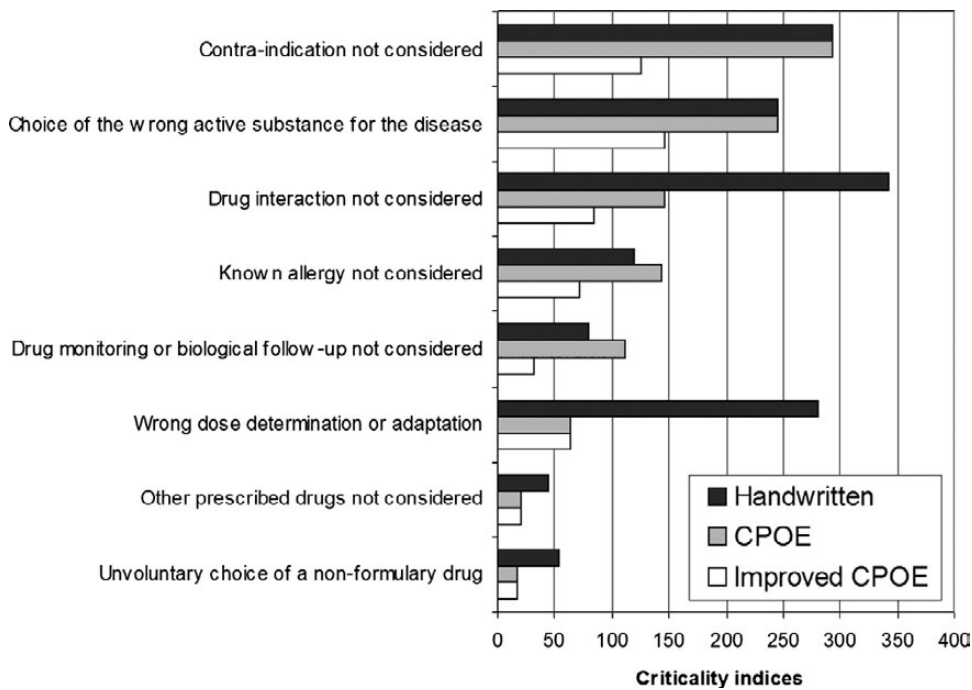
### Failure Modes Definition

The process was split into four major steps: therapy selection and prescription modalities, formal prescription, order management by nurses and treatment follow-up and adaptation. Twenty seven failure modes were determined during the brainstorming.

### Criticality Analysis

The sum of criticality indices was 3,813 for the handwritten prescription and 2,930 for the actual CPOE system, which represents a 23 % reduction in total criticality (Figure 1). The criticality indices calculated from the defined frequency, severity and detection scores for each of the failure modes are illustrated in Figures 2 to 5, for the four major steps of the process.

For 12 out of 27 failure modes, the criticality index was smaller with the CPOE system than handwritten orders. The reduction of individual indices varied from 7 to 245, with a mean reduction of 103. The larger reductions of the criticality were observed for errors due to ambiguous, incomplete or illegible orders (−245), wrong dose determination or adaptation (−217) and drug interactions not considered (−196). For 6 failure modes, the risk remained unchanged, and an increase was calculated for the re-



**Figure 2.** Therapy selection and prescription modalities: failure modes and criticality indices.

maining 9. The increase of individual indices varied from 4 to 140, with a mean increase of 39. The larger increases of the criticality were observed for vital signs not considered during treatment adaptation (+140) and prescription to a wrong patient (+84).

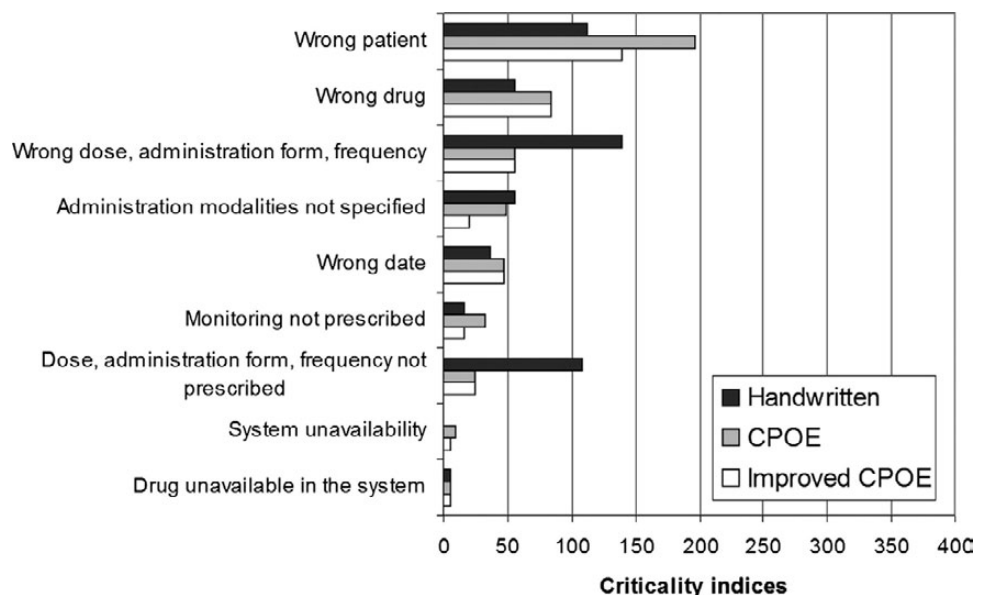
The highest risks in the handwritten process were computed for errors due to ambiguous, incomplete or illegible orders (CI = 392), drug interaction not considered (343), contra-indications not considered (294), treatment adaptation forgotten (280), and wrong dose determination or adaptation (280). With the actual CPOE system, the most critical steps were contra-indications not considered (294), treatment adaptation forgotten (294), and choice of the wrong active substance for the disease (245), three critical failure modes

that were not improved by the CPOE system, as well as vital signs not considered (245).

**Acceptability and Further Improvements**

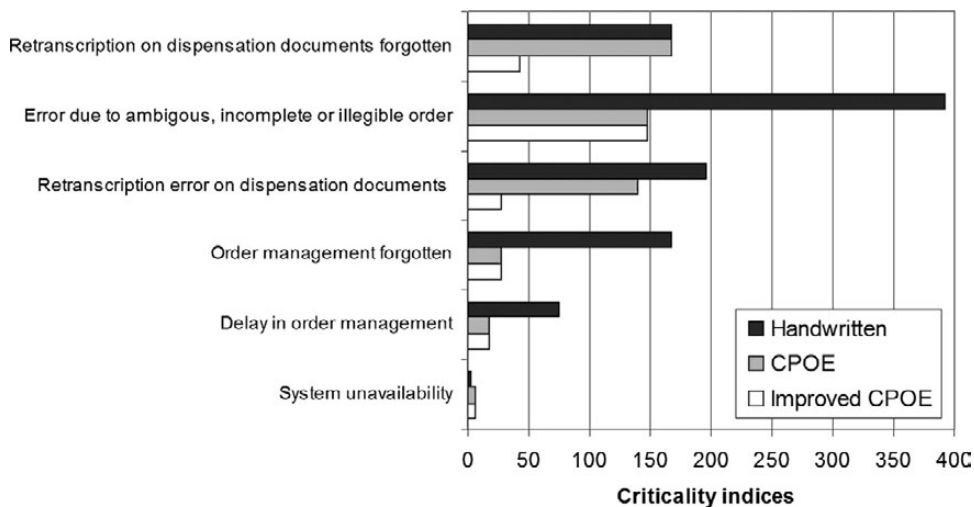
The criticalities calculated for the actual CPOE system were examined to evaluate their acceptability. For fourteen mode of failures (11 of them having a criticality index over 100), the risk was considered to be unacceptable and further developments were then proposed to lead to an improved CPOE system, bringing these modes into acceptable ranges. Their impact on criticality was evaluated (Figures 2–5) and the reduction of individual indices varied from 4 to 189, with a mean reduction of 91 points. The larger reductions of the criticality were calculated for treatment adaptation forgotten (–189), contra-indications not considered (–168), vital signs

**Figure 3.** Formal prescription: failure modes and criticality indices.





**Figure 4.** Order management by nurses: failure modes and criticality indices.



not considered (-140), and retranscription on dispensation documents forgotten (-126). In the case of an implementation of all the proposed improvements, the sum of the criticality indices for the new CPOE system would be 1658. This would correspond to an additional 43% reduction of the criticality in comparison with the actual CPOE system and a total 57% reduction in comparison with the handwritten process (Figure 1).

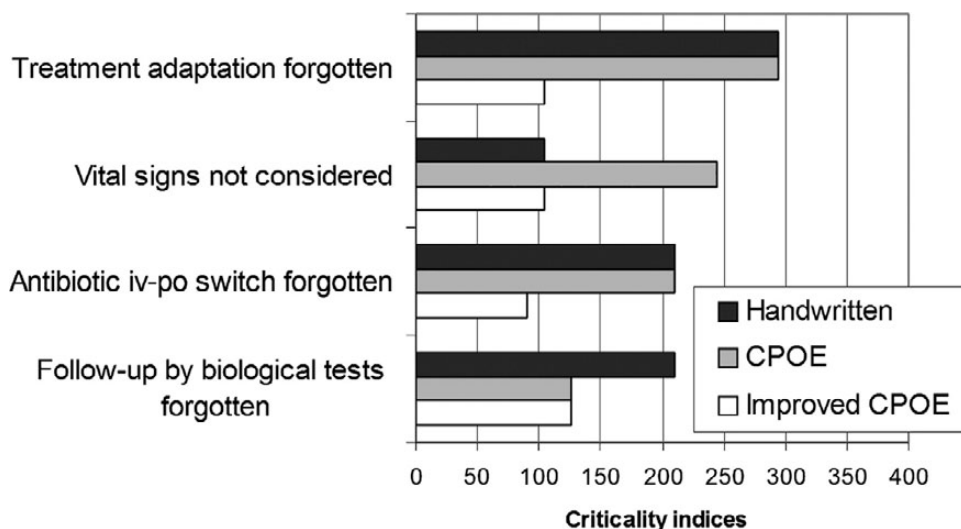
As all the improvements couldn't be developed simultaneously, a classification was established by considering the value of the criticality index in the actual CPOE system, the extent of the expected reduction in criticality and the volume of work needed to develop the proposal (Table 1). Five developments impacting six failure modes were prioritized and their implementation expected to reduce the total criticality from 2930 to 2171 (-759), a 26% and 43% reduction in comparison with the actual CPOE system and the handwritten process, respectively.

**Discussion**

The FMECA method confirmed a significant safety improvement consecutive to the implementation of CPOE system.

More important, it helped to have quantitative measurements of several steps in this complex process as well as to improve understanding of system changes and their potential impacts on safety. An important outcome of this work is to establish the link between specific functionalities of a CPOE system and patient safety, taking into account the local context. For example, as our system already included drug-interactions checks, this tool was estimated to significantly reduce this specific risk. In contrast, as the CPOE system wasn't able to take into account previously documented allergies, this aspect of the system was perceived as having a negative impact on safety. These findings are consistent with the conclusions of Gandhi et al, who addressed the need for advanced CDSSs to significantly prevent potentially harmful errors.<sup>32</sup> Although CDSSs are expected to improve the quality of drug prescription by providing useful information to the physician, our study also confirmed that CPOE systems first improve safety by making the orders unequivocal, complete and legible, as the greatest reduction in criticalities was computed for this failure mode. This safety gain can be obtained by every CPOE system.

The implementation of information technologies can also introduce new risks. In our case, the criticality of 9 out of 27



**Figure 5.** Treatment follow-up and adaptation: failure modes and criticality indices.

Table 1 ■ Priority Table for Further CPOE System Improvements

Failure Mode	CI CPOE	Improvement	CI		Feasibility	Priority
			Improved	↓ CI		
Treatment adaptation forgotten	294	Targeted pop-up alerts (avoid systematic alerts)	105	189	2	X
Contra-indication not considered	294	Link between a patient contra-indication list and drugs contra-indications	126	168	3	
Vital signs not considered	245	Integration of vital signs in the electronic patient record	105	140	1	X
Choice of the wrong active substance for the disease	245	Link between the diagnosis and the therapeutic indication of the drug	147	98	3	
Antibiotic iv-po switch forgotten	210	Pop-up alerts to propose a switch according to predefine criteria's	90	120	2	X
Wrong patient	196	Improve the readability of the patient name	140	56	1	
Retranscription on dispensation documents forgotten	168	Automatic edition of documents needed for the dispensation	42	126	2	X
Drug interaction not considered	147	Keep the same alerts, but showing them before prescription validation	84	63	2	
Known allergy not considered	144	Structured alerts during the prescription	72	72	1	X
Retranscription error on dispensation documents	140	Automatic edition of documents needed for the dispensation	28	112	2	X
Drug monitoring or biological follow-up not considered	112	Automatic proposal of important controls related to the prescription	32	80	2	
Administration modalities not specified	49	Include reconstitution and administration modalities in the drug database	21	28	2	
Monitoring not prescribed	32	New homepage with the monitoring	16	16	1	
System unavailability	10	Improve the reliability of WIFI connexion	6	4	2	

CI= criticality index, Feasibility: 1= actually under development, 2=medium-term, 3= long-term Priority: X = high priority.

failure modes was increased by the CPOE system, although we estimated that the safety improvements were quantitatively higher than the reductions. The analysis provided support for the identification and prioritization of additional developments targeted to failure modes for which the criticality was judged to be unacceptable.

Modification of processes to accommodate the CPOE system can have a negative impact on safety, as exemplified by the consideration of vital signs during ordering. In the handwritten process, the physicians used to check vital signs easily, as they were available in the same file as the prescription sheet, but this was not the case in the CPOE system. Physicians therefore consulted them less frequently, inducing a higher risk of establishing a prescription without taking into consideration some important parameters. The evaluation of the impact of vital signs integration on risk reduction led to the assignment of a high priority to the implementation of this new function.

Our study confirms the importance of a systematic evaluation of the impact of CPOE system implementation on patient safety. One single method cannot consider all the different aspects of this very complex process change. A combination of several techniques, both reactive and proactive, is strongly recommended to promote continuous improvement in efficiency and safety. The major benefits of using FMECA as proactive risk analysis method are its simplicity and the quantitative evaluation it allows by combining three complementary factors. The evaluation can be easily performed by the users and developers themselves, with the help of a moderator, and the time required is limited. In our case, the team's work required 4 pizza

lunches of 2 hours each, plus 3–4 hours for the moderator to summarize the results. The analysis identifies the top critical events and quantifies the potential impact of process modifications, even before they have been implemented, which is very helpful for assigning priorities actions to be taken. Moreover, the active discussions necessary to find consensus estimates contribute to the development of a very clear and shared vision of the process organisation, taking into account all the different perspectives. In our case, the users and the developers of our CPOE system met together, and the structured analysis method allowed for very constructive, objective and respectful discussions. At the end, all the team members mentioned that they appreciated the opportunity to participate and gained a much better understanding of each other's constraints.

The FMECA method has begun to be used in the field of medicine, and several publications have specifically focused on paediatric chemotherapy electronic prescription.<sup>33,34,35</sup> Process reengineering allowed for risk reductions, and all authors underlined the usefulness of the FMECA analysis helping them to improve their processes.

The major limitation of FMECA is unavoidable subjectivity in the selection of failure modes and the determination of the criticality indices. The team involved should be large and multidisciplinary to buffer this bias. In our study, we obtained consensus agreement from all the members of the team, helping to improve objectivity. The frequency, the severity and the ability to detect a failure mode were determined on the basis of explicit criteria, which also limits subjective variability. The main objective of FMECA is to stratify risks and to determine orders of magnitude, so some imprecision is acceptable. Our

results are applicable to our situation and the conclusions are not generalizable, although the process we used can easily be generalized. Moreover, most of the failure modes we defined are also applicable to other institutions, and our data can be a foundation for the repetition of the same evaluation with different systems.

## Conclusion

We used a well known, simple and cost-efficient methodology to quantitatively evaluate safety of various processes around implementing information technologies in healthcare. This approach confirmed a significant risk reduction by the implementation of CPOE system and helped in identifying additional system improvements that would have a strong impact on safety. With the implementation of the identified improvements, the final potential reduction in criticality is 50%, in comparison with handwritten prescriptions. Our work demonstrated the usefulness of risk analysis methods in healthcare processes. A more systematic use of these tools in the future may guide and help prioritise continuous safety improvement in high-risk medical activities.

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