Safety Assessment of Pharmaceutical Distribution in a Hospital Environment

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Abstract

Many of the catastrophic errors in health care are related to inadequate procedures. Robust preventative actions are therefore required to minimize the risks inherent to the prescribing, dispensing and administration of medicines. The redesigning of subsystem processes is a goal that should be undertaken to improve the overall safety of hospitals. Many organizations are beginning to apply traditional aerospace engineering methodologies to the study of patient safety. In a hospital setting, the pharmacy department is responsible for the procurement, distribution, and control of all medicines used within the organization. Pharmacists should ensure that medicines are delivered to patient care areas in a safe and secure manner and that they are available to the administration within a time frame that meets the essential needs of patients. A Failure mode analysis applied to pharmaceutical distribution has been carried out in the S.G.Battista Hospital in Turin (Italy), from the receiving of the goods stage to the delivery to the departments. Two main high risk activities have been identified from risk matrices and risk priority number analysis. The first activity concerns the picking and packing phases and the second one is due to the low efficiency of the random controls of pharmacists. The analysis has also pointed out some medium risk activities in the refill request control, storage temperature control and consignment to delivery service departments. The present analysis has offered the opportunity of quantifying safety within a specific hospital environment and of designing feasible corrective actions. The real effectiveness of the proposed actions will be verified during a subsequent experimental phase.

Keywords: Healthcare; Pharmaceutical distribution; FMECA, Risk management; Patient safety

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1. Introduction

A key characteristic of high-reliability industries, such as that of nuclear power, aviation, automobile manufacturing and chemical processing, is the acceptance of the fact that errors can occur, that the impact of errors can be devastating and that efforts should be made to discover any weaknesses in the system before harm occurs. Patient safety and medical errors have become a major international issue over the past few years. Adverse events in US health care appear to be responsible for 44,000 to 98,000 accidental deaths each year (Harvey et al., 2003; Kohn et al., 2000). This means there is one death in every 343 to 764 admissions. In comparison, the aviation field averages one death every 8 million flights (Harvey et al., 2003). These shocking numbers are an indication that health care should be considered a high hazard industry. One main conclusion is that the majority of medical errors do not result from individual recklessness or the actions of a particular group. Errors are commonly caused by faulty systems, processes and conditions that lead people to make mistakes or fail to prevent them. For example, stocking patient-care units in hospitals with certain full-strength drugs, even though they are toxic unless diluted, has resulted in deadly mistakes. Robust preventative actions are therefore required to minimise the risks inherent to the prescribing, dispensing and administration of medicines (Marx et al., 2003; Burgmeier, 2002; Hulbert et al., 2008). The redesigning of subsystem processes is a goal that should be undertaken to improve the overall safety of hospitals. The manufacturing and the use of a pharmaceutical product necessarily entail some degrees of risk, as can be seen in the case studies presented in (Hulbert et al., 2008), and a wide variety of specific approaches can be adopted to appropriately assess, reduce and manage these risks. The use of risk assessment tools in hospital environments was formally introduced in the USA on 1st July 2001, when the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) required each accredited hospital to conduct at least one proactive risk assessment annually. Failure modes and effects analysis (FMEA) was recommended as a tool to conduct this task. The Agency for Healthcare Research and Quality (AHRQ) is the federal agency that has been designated to conduct research efforts in the area of medical error and patient safety, in a similar way to NASA (National Aeronautics and Space Administration), which is responsibility for research in aviation and space safety management. AHRQ has identified proactive risk assessment as an appropriate patient safety research methodology and has encouraged health care organizations to set up partnerships with experts outside health care to conduct comprehensive risk assessment research activities. (Adachi and Lodolce, 2005) used FMEA to identify dosing and administration errors associated with intravenous medications, and to develop interventions to change the process. As a result, one year later, medication errors related to intravenous fusion pumps were reduced. (Burgmeier, 2002) found FMEA a valuable tool in reducing the risks and problems inherent to the blood transfusion process. (Gowdy and Godfrey, 2003) used FMEA to assess and prevent the falls of patients within a geriatric psychiatric unit. Once the FMEA action plan was implemented, the rate of patients falls decreased. In 2003, the Italian Healthcare Minister published a technical note on Health Care Risk Management and indicated FMEA analysis as a useful tool for risk identification and injury prevention (Ministero della Salute, 2004). Numerous authors have questioned the difference between reactive (Incident Reporting, Root Cause Analysis) and proactive (Failure Mode and Effect Analysis, Socio-Technical Probabilistic Risk Assessment) tools as the methods of choice in risk management (Burgmeier, 2002; Hulbert et al., 2008; Chiozza et al., 2009). Proactive methods are more readily accepted, because they exploit professional competences through a positive approach to problems by focusing on the examination of the entire process, while reactive tools focus on events rather than processes.
The first formal FMEAs (Failure Modes and Effects Analysis) were conducted in the aerospace industry after the introduction of the USA Military Standard N.1629 (MIL-STD 1629A, 1980). Used for Aerospace rocket development, FMEA, and the more detailed Failure Modes and Effects Criticality Analysis (FMECA), have proved helpful in avoiding errors in small sized samples of costly rocket technology components. An example of this is the Apollo Space program. The first efforts in failure prevention were observed in the 1960's during the development of the technology to place a man on the moon. Ford Motor Company introduced FMEA to the automotive industry in the late 1970's, for safety and regulatory reasons, after the disastrous "Pinto" affair. Ford Motor Company also used FMEA effectively to improve not only production but also design processes. FMEA, soon became a key tool in the improvement of safety, especially in chemical process industries. The goal of FMEAs was, and still is, to prevent accidents and incidents from occurring.

While the first aim of FMEA is to promote a systematic approach to ensuring the safety of patient care processes, a total cost reduction should also be achieved simultaneously when considering the entire patient care process. Both goals, increased patient safety and cost reduction, have recently been achieved after FMEA was introduced and applied to the entire health care system of the Aosta Valley, a small region in Italy (Chiozza et al., 2009). This experience has pointed out that, after one-year, a dramatic reduction in the risk of error has been obtained both in hospital and non-hospital health care institutions, including clinical laboratories and blood banks. However, it should be underlined that the advantages derived from risk analysis, using tools such as FMEA, will be short-lived if clinical laboratory management fails to support continuous safety improvements.

Another important Italian experience was obtained by the Istituto Ortopedico Galeazzi (IRCCS) in Milan (Morelli et al., 2007). The institution implemented a clinical risk management program in order to study the epidemiology of adverse events and to improve new pathways to prevent clinical errors: a risk management FMECA-FMEA pro-active analysis was applied to both an existing clinical support pathway and to a new process before its implementation. The application of FMEA-FMECA allowed the clinical risk unit of the hospital to undertake corrective actions in order to reduce the adverse events and errors of the high-risk procedures used inside the hospital. In a hospital setting, the pharmacy department is responsible for the procurement, distribution and control of all medicines used within the organisation. Pharmacists should ensure that medicines are delivered to patient care areas in a safe and secure manner and that they are available for administration within a time frame that meets the essential needs of patients. Methods adopted to dispense medicines within European hospitals differ. In some hospitals, patient packs are supplied, while in other hospitals unit dose drug packages are supplied. The authors have studied the application of the Failure Modes and Effects Analysis during pharmaceutical distribution in the S.G.Battista Hospital in Turin (Italy), from the receiving goods stage to the delivery to the departments. Some criticalities have been detected and the suggested corrective actions are here described in detail.

2. FMECA System analysis

The aforementioned procedure, has been used to investigate the criticalities of a system according to a phased approach that includes: 1) identification of the safety needs, 2) application of methods and tools, 3) development of interventions and 4) validation of possible improvements.
The primary goal of the research presented in this paper is to understand and mitigate any potential high risk error causes in a hospital pharmaceutical distribution environment. This is the main safety requirement that was identified by the organization for analysis.

A proper application of the methodology has required the setting up of a team of experts who are able to analyze the process and identify the potential critical sources of errors. The minimum number of people was dictated by the number of areas that would be affected by the FMECA. In the present study, the Hospital level was represented by the Risk Management Dept., while the subsystem level was represented by pharmaceutical Warehouse pharmacists and technicians. The team also included two aerospace engineers in order take advantage of their familiarity with the FMECA analysis. The figures who were more familiar with the process could offer valuable insights, but could overlook some of the most obvious potential problems. The figures who were less familiar with the process or product could offer unbiased, objective ideas to the FMECA process.

When the potential failures of the process were understood and the causes identified, particular solutions were introduced and specific interventions were developed to eliminate or reduce the risk of critical failures. The analysis finished with a validation of the possible improvements, comparing the initial safety level with the final one. Three types of process improvement strategies were proposed and are evaluated hereafter. The first strategy was designed to eliminate the chance of failure, the second makes it easier for people to do the right thing and the third has the aim of identifying failures quickly and of taking appropriate corrective action. The FMECA team members may be asked to review performance data periodically in order to establish how much safer the process has become since the action has been implemented (Fig. 1).

![Diagram of FMECA process](image)

**Fig 1.** FMECA to improve the safety of the system
The application of the “failure modes and effects analysis” tool follows a stepwise approach:

**Step 1: Process and Team selection**
The system included in the analysis is identified by: 1) Definition of the system boundaries 2) Collection of the available information that describes the system, including drawings, used procedures, functional descriptions and operational and environmental conditions 3) Interviews with personnel. A Collection of information should be made about previous and similar designs from internal and external sources. The San Giovanni Battista University Hospital is the oldest hospital in the city of Turin, is the largest hospital in Piedmont, and is the third largest National Hospital with 12 health departments, 116 wards, 1,076 beds and 32,825 dismissed patients in a year (Cestino et al, 2010). It is a multi-specialistic, teaching Hospital and its main functions are health care, nursing, teaching and research. The principal goal of the Hospital Pharmacy is to ensure the safe, appropriate and cost-effective use of medicines. Hospital pharmacists use their specific knowledge to dispense drugs and advise patients about the medicines they have been prescribed. They work together with other health care professionals to devise the most appropriate drug treatment for each patient. Some pharmacists are also involved in manufacturing the required drugs. The Hospital pharmacists are also engaged in some of the main aspects of other activities, such as the logistics and distribution of drugs, medical devices and diagnostics, the compounding of drugs and clinical pharmacy. As far as logistics and distribution are concerned, the hospital pharmacists are responsible for ensuring medicinal products are stored appropriately and safely in order to guarantee freshness and potency so that they reach the patient in the correct form and dose. They are also responsible for the accurate dispensing and timely distribution of drugs and medicines for inpatients and outpatients, and for the supervising and checking of work of less experienced and less qualified staff, and therefore make an important contribution to the therapeutic quality and drug safety of the hospital.

The best size of an FMECA Team is from six to ten people, the members being selected carefully on the basis of the contribution they can make to the specific FMECA. In the present analysis, the FMECA Team was composed of ten people: one Risk management expert, three pharmacist supervisors involved in the entire process, two engineering experts in safety assessment techniques, one logistic coordinator and two technicians involved directly in the process.

**Step 2: System structure analysis**
The team’s first task was to identify and make a diagram of the high-level steps in the process under review in flow-chart format. An example of the high-level steps pertaining to the studied case is shown in Fig. 2. The presented study is restricted to the second phase of the pharmacy distribution chain and in particular to the Standard delivery to the department subsystem.

Once the high-level process steps had been identified, each one was then further broken down into “sub-process” steps. The team broke the analysis into manageable units. The most logical breakdown was into the key components of the pharmaceutical distribution from the pharmaceutical warehouse to the departments: 1) Receipt of goods 2) Product control 3) Product management system of the uploading or warehouse storage 3) Delivery to departments. The analysis was performed for a standard delivery case because it showed a lower safety level than an emergency situation. The system has been illustrated using the functional block diagram shown in Fig. 3.

Fig 2. High level description of the Pharmaceutical system and warehouse subsystem

Fig 3. Sub-level description of the analyzed system
Step 3: Brainstorming Potential Failure Modes

Once everyone on the team had an understanding of the pharmaceutical process, obtained through an examination of the actual procedures, the team members began to consider the potential failure modes that could affect the safety of the distribution system. Some brainstorming meetings were organized and lists of ideas were produced.

The team then examined all the potential failures of each of the identified components. All the available material (procedures and previous incident reports) was analysed and discussed during the sessions. The most likely probable type of errors were pointed from an analysis of the internal procedures and of the “unconformity reports”, as shown in Fig 4. The previously detected unconformities (N.C.) were divided into nine categories: 1) The delivered product did not correspond to the requested one 2) The delivered product did not correspond to the invoiced one 3) The delivered quantity was not correct 4) The invoiced indicated quantity was not correct 5) The storage conditions were not correct 6) The product was delivered close to the expiry date 7) The Department number was not correct 8) Delivery to the department was not correct 9) Others.

Step 4: Preparation of the FMECA Worksheet

The analyst had to consider all the functions and all the operational modes of each unit, and to decide whether any failure of the function could result in an unacceptable system effect. If the answer was negative, then no further analysis of that function was necessary. If the answer was positive, then the function had to be examined in more detail. The various columns in the used FMECA worksheet shown in Table 1 are now deals with. A reference number and the name of the subsystem are indicated in the first two columns. The third column lists the functions of the unit. It is important to list all the functions. A checklist may be useful to ensure that all the functions are covered. The potential failure modes for each function and operational mode of a single unit have to be identified and listed. It should be noted that a failure mode should be defined as non fulfillment of the functional requirements of the functions specified in the previous column. The effects that

![Fig 4. Past unconformity reports analysis](image-url)
each failure mode can have on the system (global effects) are listed in the fourth column. An extra column was added in order to describe the type of compensation action that has actually been introduced.

**Step 5: Prioritization of the failure modes**

The relative risk of failure and its effects are determined by three factors:

- **Severity (S)**, which indicates the degree of impact on a system due to the failure of an individual component or an operational procedure. Severity is divided into 5 levels, and the rating definitions and scoring criteria are given in Table 2.

- **Occurrence (O)**, which indicates the degree of frequency with which an individual component failure or an operation process failure can occur. Occurrence is divided into 5 levels, and the rating definitions and scoring criteria are given in Table 3.

- **Detection (D)**, which indicates the degree of impact caused by the failure of an individual component or operational process that cannot be detected. Detection is divided into 5 levels, and the rating definitions and scoring criteria are given in Table 4.

**Table 1** FMECA Worksheet example

<table>
<thead>
<tr>
<th>N</th>
<th>Unit</th>
<th>Function</th>
<th>Failure mode</th>
<th>Global effects</th>
<th>Compensation actions</th>
<th>S</th>
<th>O</th>
<th>D</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dept. Refill request</td>
<td>1A: Product qualitative assessment</td>
<td>Undetected demand for products that require different supply modes than the normal one</td>
<td>Absence of the product which results in delays in procurement</td>
<td>Ability to whole the company to access by web to the PTO. PTO Monthly update on the web. Eliminate the possibility of the normal demand for products being requested by other prescriptive profile modes</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1B: Product quantitative assessment</td>
<td>Confirmation of excessive amounts</td>
<td>Organizational failure (excess inventory)</td>
<td>Calculating average consumption of the departments</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>9</td>
</tr>
</tbody>
</table>

**Table 2** FMECA Severity evaluation criteria

<table>
<thead>
<tr>
<th>Effect</th>
<th>Description</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absence of consequences</td>
<td>A failure not serious enough to cause temporary disability</td>
<td>1</td>
</tr>
<tr>
<td>Minor</td>
<td>A failure which may cause a temporary low risk disability</td>
<td>2</td>
</tr>
<tr>
<td>Major</td>
<td>A failure which may cause a high risk temporary disability or hospitalization or prolongation of existing hospitalization</td>
<td>3</td>
</tr>
<tr>
<td>Critical</td>
<td>A failure which may cause persistent or significant disability/incapacity or life threatening</td>
<td>4</td>
</tr>
<tr>
<td>Catastrophic</td>
<td>A failure which may cause patient death</td>
<td>5</td>
</tr>
</tbody>
</table>
Using the data and knowledge of the process, each potential failure mode and effect can be rated for these three factors on a scale ranging from 1 to 5 (low to high), as indicated in the new LD.5.2 JCAHO patient safety standard. The severity of a failure mode is the worst potential (but realistic) effect of the failure considered at the system level (the global effects). The Severity, Occurrence and Detection classes indicated in Tables 2, 3 and 4 have been adopted for the present analysis.

### Step 6: Calculating the Risk Priority Number

The impact of failure on a patient or system is evaluated by multiplying the rankings of the three factors (severity × occurrence × detection); a risk priority number (RPN) is thus determined for each potential failure mode and effect. The risk priority number (which ranges from 1 to 125 for each failure mode) is used to rank the need for corrective actions in order to eliminate or reduce the potential failure modes. The failure modes with the highest RPNs should be attended to first, although special attention should always be given when the severity ranking is high (4 or 5), regardless of the RPN.

### Step 7: Redesigning the process

The main objective of this step is to apply strategies to decrease the severity and occurrence of the event or to increase detection. Once corrective action has been taken, a new RPN of the failure is determined by re-evaluating the severity, occurrence, and detection rankings. This new RPN is called the “resulting RPN.” The improvement and corrective actions must be continued until the resulting RPN is at an acceptable level for all potential failure modes.

### 3. Results and corrective actions

The FMECA team studied the FMECA worksheets and the risk matrices for the subsystem indicated in Figure 3 as well as the risk priority numbers (RPN). The main objectives were:

1. To decide whether or not the system was acceptable
2. To identify feasible improvements of the system in order to reduce risks. This may be achieved by:
   (a) Reducing the likelihood of occurrence of the failure
   (b) Reducing the effects of the failure
   (c) Increasing the likelihood of the failure being detected before the system reaches the end-user.

Two main high risk activities were identified, the first one pertained to the picking and packing phase “quali/quantitative conformity between request and product delivery (High Risk N.1)” and the second one to a low efficiency of random pharmacist (High risk N.2) controls. The analysis also pointed out some medium/high risk activities in the refill requests control (substitution of similar products), in the Picking and packing (product storage temperature control) and consignment to delivery service (storage temperature not correct during delivery). The last activity is on the border of the high risk domain and has been labeled as High Risk N.3. Improvement measures were identified considering the sub-processes with the highest RPN.

The possible improvements that can be introduced to the system in order to reduce the RPN of the identified risk activities are: 1) The introduction of a barcode-system in the picking and packing phase 2) Increasing the number and quality of the random controls 3) The introduction of TempTale. The FMECA worksheets were revised and compared with the original case, after the introduction of the proposed improvements. The current system at the S.G.Battista Hospital employs electronic ordering of medicines. This system is effective in preventing errors at the start (ordering) of the medication use system. However, electronic prescribing only offers a weak control over the subsequent stages of dispensing, distributing and administration of the medicines, although the information technology applied to the prescription stage has a positive effect on the overall use of the medication system.

![Fig 5. RPN diagram for the considered functions](image-url)
The barcode based scanning of medicines offers an important advantage in the identification of medicines during medicine procurement, inventory, storage, preparation, dispensing and administration. Medication safety is increased because the above technology leads to an important reduction in Occurrence and an increase in the detectability of errors. On the basis of our conclusions, occurrence and detectability change, as can be seen in Table 5. In the current organization, the random controls of the pharmacists are carried out without considering statistically significant amounts compared to the entire volume of distributed drugs. The definition of a significant sample on which to perform the qualitative/quantitative check between the required drugs and drugs delivered to the department could be an effective way of increasing error detection in the drug dispensing phase and would lead to an increase in the safety of the entire process. Moreover, this activity can also provide valuable information for the risk review. On the basis of our conclusions, detectability is the main parameter that has changed in Table 5. The efficacy and safety of pharmaceuticals, which require low controlled temperature storage, depend on the temperatures being maintained within the manufacturers’ recommended ranges. The use of a temperature monitoring device to verify the correct storage temperature conditions leads to a greater detection of unsuitable storage conditions on arrival in the department. This could reduce the possibility of administering a drug that has become harmful to the patient. On the basis of our conclusions, detectability changes, as can be seen in Table 4. As illustrated in Table 5, the difference in the estimated risk index before and after modifications indicates a significant decrease in the three main identified high risk activities. In a subsequent phase, an experimental activity will be conducted in order to demonstrate the real long-term effectiveness of the proposed corrective actions.

### Table 5 Risk activities after corrective actions

<table>
<thead>
<tr>
<th>Corrective action HR N.1: Barcodes</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Value</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>60</td>
</tr>
<tr>
<td>Revised Value</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>% RPN Reduction</td>
<td></td>
<td></td>
<td></td>
<td>92%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Corrective action HR N.2: Random Controls</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Value</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>48</td>
</tr>
<tr>
<td>Revised Value</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>% RPN Reduction</td>
<td></td>
<td></td>
<td></td>
<td>75%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Corrective action HR N.3: Temptale</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Value</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>36</td>
</tr>
<tr>
<td>Revised Value</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>% RPN Reduction</td>
<td></td>
<td></td>
<td></td>
<td>75%</td>
</tr>
</tbody>
</table>

### 4. Conclusions

The application of FMECA could play a specific role in the safety assessment of pharmaceutical distributions in a hospital environment and could allow the effectiveness of the adopted procedures to be evaluated and the processes themselves to be redesigned. The FMEA analysis applied to the pharmaceutical distribution in the S.G.Battista Hospital in Turin (Italy) has pointed out two main high risk activities. The first one concerns the picking and packing phase and the second one is due to a low efficiency of the pharmacists’ controls. A redesigning of the process has been proposed with the introduction of barcodes and machine readable codes. This has led to the accurate
quali/quantitative identification and introduction of significant statistically-based pharmacist controls.

References


