

System-based risk analysis in healthcare

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ABSTRACT

In this paper, we describe the use of Root Cause Analysis and Failure Mode and Effect Analysis in a large University Medical Center in the Netherlands. Both methods were successfully piloted and then implemented into the hospital-wide patient safety program. Systematic risk and hazard analysis can be used in healthcare. The effect on patient safety still has to be proven.

Keywords

RCA, HFMEA, incident analysis, process analysis, patient safety

INTRODUCTION

Patient safety is an increasingly important subject in healthcare all over the world. Different studies in different countries have shown that a substantial portion of patients suffer adverse events due to healthcare management and delivery. Many of these adverse events are considered preventable. Adverse events in healthcare are often of a complex nature. The structures and systems with which these incidents were dealt with are no longer considered satisfactory. Analysis of reported incidents is seldom systematic or reproducible. Mostly just the incidents with a dramatic outcome are analysed and the focus is often on human factors (e.g. disfunctioning personnel) instead of on organisational factors. Well structured pro-active risk analysis of healthcare processes, finding out what can go wrong before it goes wrong, nearly never takes place. Since a couple of years healthcare has started to look at industry and has adapted some methods for risk management to the healthcare situation, like RCA and FMEA. Root Cause Analysis (RCA) is a structured and process-focused way to analyze incidents and has proven its use in the engineering industry. Healthcare Failure Mode and Effect Analysis (HFMEA) is based upon the same principles as RCA but is used for proactive risk and hazard analysis. The University Medical Center Utrecht has implemented both methods in 2004.

INCIDENT ANALYSIS

Background

It is widely acknowledged that there is an underreporting of incidents in health care, even though the means for reporting are well-known and easily accessible. Two primary reasons for not reporting are the perception that reporting does not lead to improvements and the fear for negative consequences for the reporter.

Assessments of incidents are usually limited to those that have had serious consequences. There is no reproducible method of assessment that has proven useful and assessment is nearly always limited to the collection of data without structural analysis of all factors contributing to the incident. Only on very rare occasions personnel concerned are thoroughly questioned or brought together to discuss the incident. This deprives personnel from learning from each other's mistakes and gaining insight in the strong points and the limits of their collective collaboration. It also makes it very difficult to discover less obvious contributing factors like organizational failure. Thus, conclusions are based on insufficient information and subsequently many of the changes proposed to prevent reoccurrence of similar incidents will have limited effect. Furthermore, involved personnel can feel threatened by incident analysis because of fear that the goal of the analysis is finding someone to fix the blame on. This has often been the case in the past, and the blame was most easily fixed on personnel on the "sharp end", the ones at the end of the chain of events. By reprimanding or firing the involved nurse or physician, the organization gave themselves and the outside world the illusion that the problem had been solved.

Experience in high-risk organizations as nuclear power plants and aviation has learned that this mode of reacting to incidents does not improve safety. On the contrary. It fosters a culture in which personnel are afraid to address mistakes or unsafe situations and so prevents organizations from using the experience from these situations to their advantage. These high-risk organizations have accepted that humans will always

make mistakes. Reporting a mistake or unsafe situation is seen as positive behaviour because it creates the opportunity to continuously redesigned the systems in such a way that mistakes are detected and intercepted before they lead to unsafe situations.

Incident reporting and analysis in health care is in its infancy. We look towards other high-risk industry to learn how we can change this situation for the better. One way is to introduce a systematic and reproducible method to analyse incidents multidisciplinary in a blame-free environment. Root Cause Analysis (RCA) is such a method.

Root Cause Analysis

RCA is a structured and process-focused way to analyse incidents without relapsing to “blaming and shaming”. Organizational factors can be identified, acknowledged and addressed, giving personnel the chance to suggest improvements of these factors. This way the personnel get a chance to learn from the adverse event and the organization can make effective changes to reduce the likelihood of future incidents. Thorough analysis of an adverse event also makes it easier to explain the chain of events to the involved patient or his/her family.

Experience in hospitals in the United States and Denmark (verbal communication) gave reason to believe that using RCA not only produces significant results in understanding the cause of adverse events, but also contributes to a culture in which the emphasis rests on improvement of patient safety instead of on blame.

Implementation

Training

Two trainers from the Training Center of the UMC Utrecht and the patient safety coordinator attended a RCA training in England. Using this experience, together with the literature on RCA and experience from international contacts, they created a Dutch version of RCA. This was piloted during several months. The Training Center then set up a two day Dutch RCA training.

The UMC Utrecht is divided into 12 divisions (surgery, internal medicine etc). The hospital management asked all divisions to send at least two people to the training. From each division two to four nurses and physicians were chosen by the division management. The training started with an introduction to patient safety and human factors engineering. Each participant was asked to bring along an incident which he or she had heard of or been part of. The different steps of RCA were explained and the trainees practiced each step using role playing based upon one of their own incidents. Eventhough most trainees had no idea what they had been sent to and some were outright sceptic at the start, at the end all attendees were enthusiastic about RCA and gave very high marks in the evaluation form.

Organisation

The UMC Utrecht, as all hospitals in the Netherlands, has a Central Incident Reporting Committee (CIRC). All incidents that are reported go to the CIRC for evaluation and filing. Before introduction of RCA, serious incidents would be evaluated by a member of CIRC without using any particular format of inquiry. This changed after RCA was introduced. Now, when an incident is reported, the CIRC still decides if the incident should be analysed, but to help them decide, they use a hazard matrix in which the frequency of similar incidents is related to the severity of the outcome. When an incident scores high on the hazard matrix, or if the CIRC feels that the incident merits further analysis for any other reason, the decision is made to do a RCA. The CIRC no longer executes the analysis itself, but requests two RCA-trained personnel from the division in which the incident occurred to carry out the investigation. When they have completed the RCA, it is discussed with the patient safety coordinator for a final check. This is to ensure a constant quality of all RCAs and the reports, because many personnel will only do one or two RCAs a year. The CIRC then judges the report and, if it agrees, sends it to the division or hospital management. Management is requested to give a reaction to the conclusion of the report and to specify if and when the suggested improvements will be implemented.

Method

The Dutch version of RCA consists of seven steps.

Step 1: collecting information. The goal is to collect as much information as possible relevant to the incident. Typically, the patient chart is read and personnel involved in the incident or personnel well known with the process in which the incident took place are interviewed. In some instances the location where the incident took place is visited or extra information is gathered from outside the hospital (e.g. from a supplier).

Step 2: sorting information. The goal is to get an overall picture of the incident and specifically the situation that the involved personnel were in just before and whilst the incident took place. The RCA investigator should be able to envision the incident as if it were a movie.

Step 3: define the subject of the investigation. The goal is to state the borders that the investigation is limited to, so as to keep the RCA manageable. Incidents often consist of a main incident and one or more sub-incidents, things that also go wrong around the same time. The deeper the search, the more elements are found to be suboptimal. An enthusiastic investigator will want to fix all these problems at once. But it is important to prevent the RCA process from taking too much time and diluting, because that will not only have a negative influence on the RCA itself, but also on the enthusiasm and acceptance of the method amongst personnel. It is impossible to change the whole hospital

in one session, so the focus must remain on the incident at hand.

Step 4: identify the causes of the incident. The goal of this step is to identify the root causes of the incident and the other factors that have made the incident possible. In this step the investigator also pays attention to the things that did go according to plan, so as not to just focus on the negative elements. This not only reduces the intimidating effect RCA might have on personnel, but also yields productive information on the strong points of the organisation. This information can be a valuable asset for the next step.

Step 5: devise safety and quality improvements. The goal of this step is to devise useful and pragmatic suggestions on how to prevent similar incidents from occurring in the future. For this step, the RCA investigator preferably draws ideas from the professionals that work in the process in which the incident took place and the middle management. If an incident took place in a patientward, the head nurse and attending physician would be consulted, before a suggestion were to be included in the report.

Step 6: write a report. The goal is to produce a concise report that lets management take considered decisions on how to act in response to the incident. This means that the report should be understandable for a layman and stick to the facts. Suggestions should preferably be written SMART (Specific, Measurable, Achievable, Realistic, Timely).

Step 7: Follow-up. The goal is to make sure that everybody who was involved in the RCA knows what happened with the suggestions made in report. If for example hospital management changes a policy due to the report, this is communicated to them. In this way personnel gets feedback on the effect that their collaboration with the RCA process has had.

Results

The time-span of the project is still too small to give results. Preliminary findings show that RCA takes 10 to 24 hours per investigator. Because most RCAs are done by two people, that means that an RCA costs 20 to 48 staff-hours. This constitutes a practical problem, especially for physicians. Personnel involved in RCA seem to find it a positive experience. Six months after the training a meeting was organized to share experiences. Nearly all 30 of the trained personnel attended, even those who had not done a RCA since. Halfway 2005 fifteen other Dutch hospitals have sent a total of 60 people to the UMC Utrecht RCA training and the Dutch Institute for Quality in Healthcare has incorporated the UMC Utrecht RCA training in their patient safety program.

PRO-ACTIVE RISK ASSESSMENT

Background

Except for specialised work environments (e.g. pharmacy, lab) pro-active risk assessment is seldomly used in healthcare. Even highly specific treatment processes like chemotherapy are not proactively and systematically assessed for potential hazards. Safety is considered adequate when a protocol exists and the personnel are well trained. Personnel are trained in the background of the disease and in their part of the process. Commonly, a member of a care team will have no knowledge of the parts the process in which they are not involved. Therefore, they lack insight into the effect that errors or changes can have on those parts the process that are beyond their scope.

Healthcare Failure Mode and Effect Analysis

Failure Mode and Effect Analysis (FMEA) is a well known and widely used method in industry to carry out pro-active risk assessment. In 2001 the National Center for Patient Safety of the United States' Department of Veterans' Affairs (www.patientsafety.gov) adapted FMEA to the healthcare situation. Healthcare Failure Mode and Effect Analysis (HFMEA) has since then been used in their hospitals and clinics.

Pilot

In 2004 the UMC Utrecht did a pilot using HFMEA to analyse the use of one type of chemotherapeutic agent in one of the childrens' wards. A multidisciplinary team was assembled including physicians, nurses, a pharmacist and the mother of a patient. The team met seven times with two week intervals, the first two times for 60 minutes and afterwards for 90 minutes. This change was made because usually the first half hour was needed to get everybody on track. Between meetings some team members made "homework", for example a literature search. It was also expected that the team members would discuss the preliminary findings with their colleagues between the meetings, so as to get feedback.

Method

HFMEA consists of 5 steps.

Step 1: Define the topic. The topic should be a manageable process with a clear beginning and end. "The medication process" would not be suitable because this is far too large a process. Better would be "the transition of medication care from the neurology ward to the primary care doctor".

Step 2: Assemble the team. The team should consist of a member from each speciality that plays a role in the process which is investigated. If possible, a patient who has experienced the process should be included. Patients can play an invaluable role because they have seen or

experienced risks during care that personnel are not aware of.

Step 3: graphically describe the process. A flow diagram is made of the process and subprocesses. Each process step is numbered.

Step 4: conduct a hazard analysis. For each process step, the team considers all possible failure modes (ways in which parts of the process can go wrong). For each failure mode, the severity and the probability are determined. After this, a decision tree is used to determine the criticality and detectability of the failure mode. Only then does the team brainstorm about all possible causes for that failure mode. The causes are then evaluated in the same way as the failure modes. If a cause is judged to be significant, the team goes to the next step.

Step 5: action and outcome measures. The decision is made to “eliminate”, “control” or “accept” the failure mode cause. The team then decides what action should be taken, who should be responsible and what outcome measure can be used to check if the action is executed and if it serves its purpose.

Results

At the end of the pilot, the team found the process to consist of 32 steps. 60 failure modes were identified. 14 had a high score on the hazard matrix, meaning they could either occur frequently, have a major impact on the patient or both. Of these 14 failure modes, 10 had already been adequately foreseen and dealt with (e.g. the pharmacy never dispensed more than 2 mg for one patient). For the remaining 4 failure modes, 9 recommendations were made, of which 8 were implemented. Six months after the recommendations had been implemented, 6 were still in place and 2 partly. Although the HFMEA placed a time burden on all team members, they responded positively in the evaluation form. The mother remarked that it would have been better if her son had completed his therapy before she was involved in the HFMEA, because this had not made it easy for her. Asked what she would remember most

she responded: the honesty with which the process had been discussed in the presence of a parent.

Implementation

Hospital management has included HFMEA in the hospital-wide patient safety program and has made it mandatory for each division to do one HFMEA of a self-picked high risk healthcare process annually.

CONCLUSION

RCA and HFMEA can be used in a large Dutch University Medical Center. For both methods however, it remains to be investigated what the cost-effectiveness and effects on the overall patient safety are.

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