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Quality Improvement Report

Searching for possibilities to reduce harm to patients in medical treatment - a Six Sigma driven analysis of Adverse Drug Events at the Hospital Group of Skaraborg in Sweden

by

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Medical Error, Adverse Drug Event, Six Sigma, health care, electronic prescription

Background
The Hospital Group of Skaraborg (SkaS) is situated in the Western Region of Sweden and
serves a population of 260 000. The group consists of four hospitals – the hospitals of
Lidköping, Skövde, Mariestad and Falköping. The services offered by SkaS include acute
and planned care in a large number of specialties. In total there are more than 700 beds and
around 4700 employees at SkaS. SkaS shares its responsibility together with the local
authorities and the primary care units for the entire health care chain of integrated care.
The Skaraborg Hospital Group has recently started a wave of systematic quality initiatives of
which this study is one. Others include i.e. the safety of the warfarin treatment process and
other topics which are mostly driven by industry evolved Six Sigma techniques.

The first signs of the significant role of medical errors emerged with the Harvard Medical
Practice Study in 1991 [1]. The number of unnecessary deaths owing to iatrogenic injury in
the United States was estimated to be equivalent to 3 jumbo jet crashes every 2 days.[2]. In
the report "Error in medicine" (1994) Lucian Leape, a pediatric surgeon and patient safety
pioneer came to the conclusion that there are significant parallels between human error
science and medical errors: medical errors were seldom caused by irresponsible or
unprepared individuals, but rather intrinsic to the system we work in. He stated, "All humans
err frequently. Systems that rely on error-free performance are doomed to fail" [3]. In 1998
the Institute of Medicine (IOM) [4] published its 1998 report, "To Err is Human." which

concluded that between 44,000 and 98,000 Americans die annually from medical mistakes. The report estimated the cost of injury to be between $17 and $29 billion annually, over half of which was the direct cost of treating injury [4]. The response was the creation of both voluntary and mandatory error reporting systems. Hospitals started to form patient safety agendas. In 2001 the IOM published a second medical error analysis, "Crossing the Quality Chasm," thus the conclusion was that big improvements were not seen yet and it suggested that "environments have to be created that foster and reward improvement by (1) creating an infrastructure to support evidence-based practice, (2) facilitating the use of information technology, (3) aligning payment incentives, and (4) preparing the workforce to better serve patients in a world of expanding knowledge and rapid change". [5]

In Sweden the National Board of Health and Welfare [6] estimated a number 150 of such cases in 2003 and a number of preventable non-fatal adverse events of around 30.500 per year. Unintended and severe medical errors are common in the complex area of pharmaceutical treatment.[6] The Swedish National Board of Health and Welfare estimates that about 10% of all treatment time for hospitalized patients in internal medicine clinics are due to wrong pharmaceutical treatment [8]. These so called adverse drug events (ADE) are in many cases preventable and have the potential to be reduced significantly. [6;7]. Studies show that serious ADEs are likely to prevent with information technology in certain key processes i.e. ordering by checking known information about the patient (allergies, bi-diagnosis, etc.) against known information about the drugs intended for treatment, which often is a very complex process and prone to errors. [6;7]. In order to reward improvement, it is necessary to focus further research on medical errors in interaction with human behavior, error reporting systems and how close they are to reality. Quality measurement of overall service is needed in order to discover the right relations between these three fields and to leave the grounds of assumptions. This study is a step towards that aim.

In order to reach measurable improvements in service, the Six Sigma initiative, which first launched by Motorola 20 years ago and is today used by companies such as ABB, Kodak, General Electric, Siemens, Toshiba, NEC, Motorola, Ericsson and Samsung, gives us the tools required. The main goal of Six Sigma is to optimize the performance of processes [9]. Putting the focus on error reduction in medical treatment processes, Six Sigma delivers possibilities to eliminate defects in process outcome through identification and control of variation in processes. The aim is to identify factors and root causes of hazardous processes and to redesign the processes in to order to gain safe, stable and predictable results. Six Sigma defines ultra high-quality manufacturing systems, in which only 3.4 defects occur per 1 million opportunities, a nearly perfect production rate of 99.9997%. Today most of businesses reach the level of three or two Sigma, meaning a defect rate between 65,807 and 308,530 defects per 1 million opportunities. It has been estimated that healthcare is unlikely to become better than three Sigma. Six Sigma has two key methodologies:[10] DMAIC and DMADV. DMAIC (Define - Measure - Analyze - Improve - Control) is used to improve an existing business process. DMADV(Define - Measure - Analyze - Design - Verify) is used to create new product designs or process designs in such a way that it results in a more predictable, mature and defect free performance.

Purpose / Aim

The aim of the analysis of the error reports is to identify and assess related risk factors and root causes for adverse drug events. In a second more theoretical step effectiveness of different IT interventions for error reduction are rated and further possible development steps are named. This analysis delivers more transparency in risk factors and root causes for

adverse drug events and produces hypotheses, which are of value for intervention studies that are aimed to reduce adverse drug events by applying information technologies.

Design / methodology / approach
The Hospital Group of Skaraborg (SkaS) has installed a semi-structured electronic error reporting system since 2004 and has collected around 400 drug related error reports. All patient related staff has had an introduction into the system and has the possibility to report 24/7 in an online form after a personal login. Reporting can be done with or without naming the patients personal data and leads to an automated reporting routine to the responsible staff leaders who decide if an investigation (i.e. in case of a sentinel event - for example operation on wrong body part) needs to be triggered. Due to the variation in formal aspects and quality of the reports, all reports had been reviewed and classified one by one before using statistical tools for analysis. Reports of insufficient quality for evaluation have not been added to the analysis.
In the analysis the error reports of 223 adverse drug events were grouped into 4 different severity codes: (1) minor, (2) moderate, (3) major, (4) catastrophic. The basis for the classification is the risk and action plan of the the Swedish National Board of Health and Welfare [11] which itself is based on the United States´ VA National Center for Patient Safety's Prospective Risk Analysis System [12]. A list of attributes describes in which group an event should be classified. In order to address adequate awareness to the topic all so called "close calls" or near misses, those events that could have resulted in an adverse event but were prevented through timely invention were classified as if they were adverse events. All error reports were systematically screened for risk factors and root causes that were related to the adverse event. During this screening process, new risk factors and root causes emerged successively. In addition the adverse events were also traced in which step of the pharmaceutical treatment process they appeared. These risk factors and root causes can be grouped, but they are partially overlapping and often represent different views on an event. Authors like Zhang [13] suggest models how to classify different types of errors through a cognitive perspective on the medical error. The identified risk factors and root causes were assessed through the severity codes and the frequency they appeared and subjected to a ranking. In this assessment process the different severity codes where rated with logarithmic values (1, 4, 16, 64) in order to represent the grade of the differentiation between a minor and a catastrophic event. This rating is of course rather arbitrary and should be regarded as a help tool. An absolute realistic rating seems to be impracticable due to ethical reasons. Patients and their relatives who had been victims of adverse events can evaluate the same event completely different due to different coping mechanisms. The would be understandably irritated if their cases would be made directly comparable to others. A relative ranking in a form that i.e. a catastrophic event always weights more that any number of major events is also thinkable but less practical in this study´s case. In a second step all events were theoretically tested against information technology solutions that are available as well as others that are technically thinkable in order to produce hypothetical rankings of effective solutions.

Findings
The grouping of the events revealed that most reports matched minor (38,1%, 85 reports) and moderate (37,7 %, 84 reports) ADEs. Major ADEs were described in 19,7% (43 reports) and catastrophic ADEs were described in 4,5% (10 reports) of all cases. It is difficult to estimate if this distribution reflects the quantity and distribution of real incidents, but studies of Cullen et al. [14] let us assume that there are a vast number of real incidents that do not appear in error reporting systems yet. Furthermore it can be assumed that minor ADEs are obviously

underreported due to the disproportion of time for reporting and the actual risk in the incident. The regression analysis and ranking (maximum 100 points) showed that documentation errors (46 points), the involvement of intravenous medication (41 points), mistakes in the actual application process (36 points) and communication errors between to persons or two departments (34 points) were the most common risk factors and root causes for severe adverse drug events in the Hospital Group of Skaraborg. They were followed by confusion and mixing-up of patient, dose, drug, administration time (32 points), omission (31 points) and inaccessible information (18 points). Most of the severe adverse events do have their origin in process step of ordination and the administration of the drug. The more theoretical testing of the events against possible solutions showed that 80% of the events were likely capable of being positively influenced though interventions. 17% of the events were less likely capable for positive change and 3% of the events were probably resistant to change. 62% of the events were capable of being positively influenced through IT interventions and 35% had the potential of being eliminated through IT interventions. However, already 4% of the events had IT as a risk factor even if there was only sparse IT deployment in the pharmaceutical treatment process. The hypothetical ranking (maximum 100 points) showed that a boundary-less electronic prescription system (19,4 points), an automated control of substance interaction and dose rate ranges (13,9 points), an electronic prescription with certain constrained fields (13,9 points) and the integration of the whole warfarin prescription process into a boundary-less electronic prescription system (12,2 points) were the most effective interventions to reduce severe adverse drug events. These possible interventions were followed by integration of the Swedish pharmacy dose packing order entry system (APODOS) (9,1 points), integration of laboratory results into a alert system (8,9 points), templates for standard operating procedures (8,7 points) and an integrated dose/amount calculator for intravenous medications.

Research limitations
It is known that error reporting represents only a small amount of the actual events and the collected error reports are of different quality and lead inevitably to variations in interpretation, which can distort the picture of the events behind them. Both are issues that ought to be improved by further research and development. Negative effects of IT interventions cannot be foreseen at this stage, but must be considered carefully with every change in the process. This is critical because IT interventions can distract and destabilize processes in larger scales when not applied appropriately and by this way threaten the overall outcome of the intervention [15]. A reliable quality measurement system with quick response in the organization is necessary to meet this challenge. The research presented in this article is confined to SkaS. Consequently, the results and findings of this research are SkaS specific. However, the authors believe that the solutions presented in this article can, with certain modifications, be replicated at other similar hospitals.

Practical Implications
In addition to the results of this analysis, a learning process of the importance of error reporting and process redesign has evolved throughout the organization. The results of this analysis are used in the strategic management decision process for the deployment of an electronic prescription system.

Originality / value
The very complex process of pharmaceutical treatment of unequal patients with the involvement of many actors, a network of hardly manageable substance interactions and a countless number of vulnerable factors have often been the reason for personal imputation

when things went wrong neglecting the underlying structural causes for errors. The described analysis tries to identify risk factors and root causes for adverse drug events in a blame-free environment and aims to make them more transparent to the actors in order to help them to understand why they appear. Thereby awareness for weak processes can be improved and actors in healthcare organizations can convert their processes towards safer and more reliable and better predictable ones.

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