Medication safety in pediatric care
Maaskant, Jolanda

Link to publication

Citation for published version (APA):
Maaskant, J. M. (2016). Medication safety in pediatric care
Chapter 1

Introduction
PATIENT SAFETY

Patient safety has been high on the international agenda since the Institute of Medicine report “To err is human” [1]. The risks for patients described in this report are confirmed in many studies from various countries, that show incidence rates of preventable adverse events ranging from 1% to 9% of all admissions in hospitals [2-7]. Although most of preventable adverse events do not result in patient harm, still 1% to 9% causes significant harm and 1% to 3% contributes to death [3-7]. Since the extent of the safety problem became visible, many countries formed institutes to support and monitor patient safety improvements. Examples are the National Patient Safety Foundation (NPSF) in the United States of America, the National Patient Safety Agency (NPSA) in the United Kingdom and the Australian Patient Safety Foundation (APSF). Large scale patient safety initiatives have started, such as the “100,000 Live Campaign” and the “Safer Patient Initiative” [8,9]. Patient safety has become an important issue in the Netherlands as well. Based on an advice report about risk management in Dutch hospitals, a patient safety management system (VMS, Veiligheidsmanagement systeem) has been developed [10]. Since 2007 all Dutch hospitals have started to implement this system [11,12].

MEDICATION SAFETY

Within the field of patient safety the medication process is identified as a key area of risk. This is based on research that shows that 8% to 27% of the preventable adverse events are related to medication [2,3,6,13]. Patient harm as a result of medication is called an Adverse Drug Event (ADE). ADEs include adverse drug reactions (ADRs) and medication errors (MEs). An ADR is defined as “any response to a drug which is noxious, unintended and which occurs at doses normally used for prophylaxis, diagnosis or therapy of the disease” [14]. A ME is defined as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer” (NCC MERP) [15]. The difference between ADEs, ADRs and MEs is visualized in Figure 1. It is estimated that 30% to 40% of the ADEs that affects hospitalized patients are preventable and must be considered MEs [16-18]. Studies have shown that 3% to 10% of such errors result in significant harm [18-21]. MEs are also associated with outcomes such as additional length of stay, readmissions and increased costs [18,19,21-24].
THEORETICAL FRAMEWORK

Patient safety in healthcare is strongly influenced by several pioneers, such as Walter Shewhart, Joseph Juran and Edwards Deming. Shewhart, Juran and Deming were colleagues at the Hawthorne factory of the Western Electric Company and their work on improvement science has been widely applied in industry as well as in healthcare. Shewhart emphasized using statistics in controlling processes in an organization. Juran is best known for his contribution to Total Quality Management, that apart from process control also includes cultural issues, leadership and customers’ satisfaction. Deming emphasized quality development as a continuous cycle of improvement. Inspired by the work of these pioneers the DMAIC improvement framework was developed. This model includes five steps: Define, Measure, Analyze, Improve and Control. By applying each of these steps in the right order, data and analyses of the context form the base of effective interventions in complex situations. The DMAIC framework also represents the continuous character of quality improvement (Figure 2).

Define

In the field of medication safety the pediatric population is particularly vulnerable. It is suggested that specific characteristics of the pediatric medication process increase the risk of MEs and related harm [25,26]. Firstly, pharmacological factors such as age-based variability in absorption, metabolism and excretion of medications create special risks of overdosing in children as compared to adults. Secondly, dosage calculations in children are much more prone to human error because of the constant need for weight- and
surface area-based dosing and unit conversion to get the small doses required. Thirdly, the absence of medications in dosages appropriate for children makes it necessary to manipulate the medications before administration is possible. Finally, children cannot identify MEs, are less likely to communicate side effects and are much more dependent on the observations of their caregivers. In addition, it is estimated that the potential harm as a result from a ME is three times greater in children than in adults [27]. Taking into account the specific features of the medication process, research on medication safety in pediatrics is essential, as the types of pediatric MEs and the interventions necessary to prevent them might be different from those involving adults. Until now, medication safety in pediatric hospitalized patients is still not fully explored.

**Figure 2.** The DMAIC framework

**Measure and analyze**

Up to date, research has reported a wide variation in the prevalence of MEs in pediatric care, ranging from 0.15 to 55 per 100 admissions [23,25,28,29]. Omission, dosing error and wrong time of administration are reported most frequently [27,29,30-33]. Less is known about patient harm as a result of MEs, but a prevalence of between 0.52 and 11.4 harmful incidents per 100 admissions has been reported [17,27,30,32]. This variety in results seems to depend on definitions, choice of denominator, differences in study population, study design and error detection method [33-37]. Besides the actual size of the problem, the factors contributing to MEs must be understood. Known factors that contribute to MEs are slips and lapses, inadequate communication, high workload and lack of knowledge [38-40]. Despite the extensive research the actual size of the problem...
stays unclear and an in-depth understanding of the various contributory factors, taking into account the interdisciplinary character of the medication process, is lacking.

Improve
Based on the sense of urgency that was created on medication safety, healthcare professionals have, from their own perspectives, developed and implemented various interventions to improve the medication process. These interventions can be categorized as delivery arrangements and implementation strategies [41]. In the first category, most publications describe the effectiveness of Computerized Physician Order Systems with or without Clinical Decision Support to prevent prescribing errors [42,43]. Furthermore a wide range of interventions in this category are proposed, i.e. storage facilities, dosage calculation sheets and smart pumps technology [44,45]. Implementation strategies include interventions targeted at healthcare professionals, like the supportive tasks of a pharmacist on clinical wards, interdisciplinary teamwork, education and the involvement of families [44-46]. Most interventions are a reaction on incidents or success stories from other hospitals and their effectiveness is disputable as little evidence exists regarding whether these interventions reduce MEs [47,48]. A recent example is Tall Man lettering to prevent “look-alike sound-alike” errors. This technique a widespread implemented despite the incomplete and conflicting evidence [49,50].

Control
After an intervention has proven to be effective, an iterative process of evaluation is necessary to achieve evidence of its effectiveness in a specific context [51,52]. Therefore, in the fifth step of the DMAIC cycle, it is crucial to be able to measure medication safety with tools that are valid and reliable. In addition, the measurement tools must be accurate for measuring MEs in the context of the unique pediatric hospital care. However, measuring MEs is difficult and time-consuming and the various methods seem to influence the results [34,36,37]. Also establishing medication-related harm is challenging in children, particularly in the pre-verbal age. For example, suboptimal medication might result in discomfort, that in pre-verbal children can only be established with the help of an observational tool, that must be valid and reliable. Up to date the performance of the existing measurement tools to establish MEs and related patient harm is unclear.
AIM AND OUTLINE OF THIS THESIS

With the research presented in this thesis, we aimed to contribute to the knowledge, ultimately to improve medication safety and prevent medication related harm in pediatric patients in hospital. Specific objectives were:

1. to gain knowledge on the prevalence, nature and impact of medication errors, and factors that contribute to medication errors;
2. to attribute to the existing evidence on interventions to improve medication safety;
3. to explore measurement tools to monitor medication safety.

We take the first steps of the DMAIC cyclus in chapter 2 and 3 of this thesis. In chapter 2, we describe a cross-sectional study that explored the prevalence, type and the severity of patient harm due to MEs in an academic pediatric population. In chapter 3 we present a qualitative study that contributes further to an understanding of the contributory factors that may lead to MEs as experienced by the key professionals: doctors, nurses and pharmacists. To move forward to improvements, we conducted three studies to help clinical practice to increase medication safety. The first study describes the development of a list of high-alert medication. Therefore, we conducted an international modified Delphi study and validated the results with reports on medication incidents in children based on national data. Because children are particularly vulnerable to MEs, such a list particularly for children might help to develop focused strategies to prevent harm. This study is described in chapter 4. The second study in the “improvement step” is a systematic review of the existing evidence to determine the effectiveness of interventions to reduce MEs in hospitalized children: chapter 5. Although all hospitalized pediatric patients are vulnerable, children admitted to the Pediatric Intensive Care Unit (PICU) are even more exposed to harm. In that setting, MEs can be fatal, especially when high-alert medications are involved. In chapter 6 we describe the results of an interrupted time series study that examined the effectiveness of a multi-faceted intervention by a clinical pharmacist on a PICU. The fifth step of the DMAIC cycle emphasizes monitoring patient safety with measurement tools that are valid and reliable. It is suggested that a trigger tool may be an effective and time-saving strategy to measure MEs, but its measurement performance is unclear. Therefore, we studied the diagnostic accuracy of an existing pediatric medication-focused trigger tool in detecting harmful MEs. This study is described in chapter 7. It is also important to be able to establish patient harm and discomfort. The COMFORT scale is a well-known measurement tool, that describes distress and pain in children of different ages, with different health conditions and in different clinical contexts. However, formal assessment of the methodological quality of these studies has not been undertaken. Therefore, we performed a systematic review to study the clinimetric properties of the
COMFORT scale: chapter 8. In chapter 9 we describe a longitudinal study in which we investigated whether the safety culture changed during a five years period of active safety management in our pediatric hospital. This thesis closes with a summary of the findings and a general discussion in chapter 10.
REFERENCES


