Evidence-Based Quality Improvement: A recipe for improving medication safety and handover of care
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CHAPTER 10

Summary and future perspectives
SUMMARY

Our healthcare system is complex, the care for a patient is usually divided among several disciplines and healthcare professionals that all have to work together as a team to provide high quality and safe care. Due to the complexity of the system, opportunities for error are always present. In the introduction of this thesis (chapter 1) we explained that the underlying causes for errors can be found in the design of the system of care. Therefore, we hypothesized that effective improvement of quality and safety contains the following ingredients: 1) analysis and insight into factors that contribute to the causes of errors. 2) the acknowledgement of local circumstances and involvement of clinical leaders and end-users for the development of tailored local interventions. 3) evidence of effectiveness of interventions, and 4) indicators to continuously measure performance and improve quality and safety. The aim of the research in this thesis was to gain further knowledge and understanding of the required ingredients for evidence-based quality improvement (EBQI) of two processes with high potential for errors: the medication process and handover of care.

PART I Medication safety

Chapter 2 presents the results of a qualitative study of nurses’ experiences with and perspectives on preventing medication errors. Besides safe preparation and administration, nurses have a role in the continuous assessment of a patient’s condition in relation to the medications prescribed. However, to perform this role nurses need to have sufficient knowledge of medication safety issues, consensus on which medications are high risk and/or which patients in certain clinical situations require additional safety practices. Further education and increased knowledge on medication safety is also important for the uptake and implementation of safety practices because the perceived advantage or benefit of a safety practice is an important incentive to adopt and apply a practice. However, from the interviews it is also clear that even if education on a certain safety practice (e.g. double checking) is given and the benefit is evident, the application of the practice sometimes is not feasible in daily practice. Work pressure, the practice environment with frequent interruptions and the dependency of others, influence nurses’ ability to adequately perform their role. These circumstances, in combination with the perceived risk, appear to determine whether nurses adhere to safety practices. From this study we conclude that nurses’ experiences coincide with the assumption that they are in a
pre-eminent position to enable safe medication management; however, their ability to adequately perform this role depends on sufficient knowledge to assess the risks of medication administration and on the circumstances they work in.

From research in high risk industries it is known that interruptions are conditions that contribute to errors. Therefore, we carried out an observational study to obtain further insight in the number and duration of verbal and non-verbal interruptions during medication preparation and administration (chapter 3). Through unobtrusive structured observations on 32 medication administration rounds on five surgical and five non-surgical departments we found that interruptions occurred often (6.9 times per nurse each hour). The most frequent interruptions were caused by nursing colleagues (43%) and non-verbal interruptions from the ward environment (25%), such as noises from pagers, conversations in the vicinity of the nurse, the work of cleaners, or stock management by pharmacy staff. The longest durations of interruptions were from nursing colleagues’ verbal interruptions, more and longer interruptions were observed during the morning rounds than those at noon and interruptions occurred more often and lasted longer in non-surgical units than those in surgical units. Our observations confirmed that interruptions during medication administration rounds are frequent and originate from different human and environmental sources.

The use of drug round tabards is a cheap and widespread intervention that is advised to reduce the number of interruptions and medication administration errors (MAEs) by nurses. However, evidence for their effectiveness is scarce. In chapter 4 we describe the results of the introduction of drug round tabards on three nursing units. In a mixed methods before-after study we evaluated the effect of drug round tabards on the frequency and type of interruptions, MAEs and the linearity between interruptions and MAEs. We also explored the nurses’ experiences with the use of the tabards in order to obtain insight in the feasibility and acceptability of the tabards. A total of 313 medication administrations were observed. Significant reductions in both interruptions and MAEs were found after implementation of the tabards. In the third period, a decrease of 75% in interruptions and 66% in MAEs was found. Linear regression analysis revealed a model $R^2$ of 10.4%. However, the reduction in MAEs cannot be fully explained by the decrease in interruptions alone; other factors may have also influenced the effect on MAEs. The drug round tabard may have made the nurses more aware of
their task and the involved risks, which may have resulted in them working with more attention and concentration. Also, the visible leadership of the ward managers during the drug rounds may have contributed to the effect. From the exploration of experiences it became clear that nurses have mixed emotions about wearing the tabard as well as on its perceived effectiveness. They feel awkward and uncomfortable in the tabard and sometimes have feelings of unprofessionalism, but they are prepared to wear the tabard if its effectiveness can be demonstrated. This study indicates that wearing drug round tabards contributes to a reduction in interruptions and MAEs. However, the reduction in MAEs cannot be fully explained by the decrease in interruptions alone; other factors may have also influenced the effect on MAEs.

In order to monitor and improve the safety of the medication process feasible performance measurement is required. Chapter 5 explores the use of quality indicators for performance measurement. Through a systematic literature review we searched for evidence-based quality indicators (structure, process and outcome) for safe in-hospital medication preparation and administration. A total of five studies used an evidence-based approach for quality indicator development and were included. The clinical implications and feasibility of the quality indicators were poorly studied or described. These are important aspects to consider, because if data collection for the indicator is difficult, this might result in poor or insufficient data and an unreliable indicator. From the five studies a total of 21 partly overlapping quality indicators were identified: 5 structure indicators (e.g. safety management and high alert medication), 11 process indicators (e.g. verification and protocols) and 5 outcome indicators (e.g. harm and death). These quality indicators mainly address the “right drug” and “right dose” rights of the 7 rights of safe medication preparation and administration. On the “right patient”, “right route”, “right time” and “right documentation” there is room for future development of indicators. To enable the use of outcome indicators such as MEs to measure the safety of the medication process, it is important to develop generally accepted definition(s) of MEs that define both scope and content. Despite the relatively small number of included studies, the identified quality indicators can serve as an excellent starting point for further development of nursing specific quality indicators for medication safety.

A potential effective and time-saving strategy for measuring the safety of the medication process is through the detection of MEs from registered
patient information. In a cross-sectional study, we looked at the diagnostic accuracy of an existing pediatric medication-focused trigger tool in detecting harmful MEs compared to a multifaceted method of clinical record review combined with voluntary incident reports as reference comparison (chapter 6). All patients admitted during two months were screened using the trigger tool as well as the reference standard to obtain full verification. The reference standard identified 33 harmful MEs, but none were identified by the trigger tool. The trigger tool revealed only false-positive scores and left harmful MEs undiscovered. When two symptoms “pain” and “nausea/vomiting” were added to the trigger tool, 19 harmful MEs were identified. This extended trigger tool resulted in a sensitivity of 21.2 and a positive predictive value of 36.8. The inability of the trigger tool to detect (harmful) MEs in our study deviates from the results of other studies. Possible explanations for the differences between our results and that of other studies may be: 1) hospital and patient characteristics may influence the specific triggers needed to identify the specific harmful MEs, 2) a higher prevalence of MEs as a consequence of differences in definitions and reference values used, 3) a relatively small sample size, 4) a more narrow scope for the main outcome of the study, and 5) ignoring adverse events that are identified “spontaneous” while reviewing records but without an association with a specific trigger. The multifaceted method of record review combined with incident reports remains the preferred method to detect harmful MEs. The additional value of the trigger tool stays unclear and the results of our study suggest that exchange of trigger tools between organizations may be limited.

**PART II Safe handover of care**

The second part of this thesis is about another process with high potential for error: handover of care. Communication failures threaten patient safety, especially at moments when care is handed over from one healthcare professional to another. If clinically relevant information is shared accurately and in a timely manner, it may prevent adverse events, inappropriate treatment and delay and omission of care. Global initiatives on handover, as well as accreditation bodies, promote standardization of the handover process to enhance continuity of care and patient safety. During the past decade many organizations responded to this call and initiated quality improvement (QI) projects to standardize the handover process.
In chapter 7 we present the results of a Cochrane systematic literature review to determine the effectiveness of interventions designed to improve hospital nursing handover. We systematically searched the literature to identify which nursing handover style(s) are associated with improved outcomes for patients in the hospital setting and which nursing handover style(s) are associated with improved nursing process outcomes. Unfortunately, we found no eligible studies for inclusion in the review, due to the absence of studies with a randomized controlled study design. As a consequence, uncertainty about the most effective practice remained and one can only rely the best available evidence from systematic reviews of studies with simple before-and-after designs.

To ensure continuity and safety of care, standardization of the handover process is deemed necessary. However, recently it also became clear that the handover process is heavily influenced by cultural and environmental issues that are not measurable and easy to standardize. This local context is considered of equal importance to improve the handover process. Chapter 8 describes the results of the development of a local standard for nursing shift handover in the AMC. In an evidence-based formal consensus procedure we combined evidence from four systematic literature reviews with the local context of the nurses of the AMC. We composed 15 provisional recommendations on ‘how’, ‘what’, ‘where’ and the ‘preconditions’ of shift handover. In an iterative three round process the nurses reached consensus on a final set of 18 recommendations for handover: one recommendation on how to handover (e.g. structured), 12 recommendations on what to handover (a minimal dataset and a bedside safety check), three recommendations on where to handover (e.g. quiet location) and two recommendations on the preconditions for an effective handover (e.g. communication verification and training). The recommendations were bundled in a ‘nursing shift handover blueprint’ and the minimal dataset was structured with the mnemonic NURSEPASS. The nurses assessed the method as a feasible and effective approach to develop a local standard.

Chapter 9 presents the results of a mixed methods pilot implementation of the nursing shift handover blueprint on two nursing departments of the AMC. In an interrupted time series (ITS) design with three pre and three post intervention periods, we evaluated the effect of the introduction of the handover blueprint on the quality of the handover. We also examined the ability of the bedside safety check to detect discrepancies in expected
and actual clinical situation of the patient. The pilot was concluded with focus groups to elicit the nurses’ experiences with the handover blueprint. The pre intervention period showed an increase in high scores by 7.1% and an increase of low scores by 0.1%. After implementation of the handover blueprint the high scores continued to improve, however the positive trend was preceded by a decrease immediately after the implementation (-12.7% (p=0.05)). The low scores decreased after the implementation (-4.38% (p=0.09)). For both the high and low scores there was no significant change in post intervention slopes. The two topics that were specifically targeted with the handover blueprint (organization/efficiency and contents of handover) showed a significant decrease of post intervention slope -6.35% (p=0.03) and -3.75% (p=0.02) respectively. The introduction of the bedside safety check was highly appreciated and mainly intercepted discrepancies with drains and intravenous medications. The visual check of the patient’s clinical situation as well as the checking of IV medications, equipment, drains and bandages gave the nurses a more complete clinical picture and a well prepared feeling at the start of their shift. Since this was a pilot study our pre and post measurement periods were too short to assess conclusive results on the effectiveness of the nursing handover blueprint, but a time series analysis can be used to analyze quality of handover. Such a design is recommended for a larger scale evaluation because it produces more reliable results and enables monitoring of the sustainment of the intervention. A major success factor on implementation was the involvement of leading senior nurses for informing and reinforcing the team on the new practice.

**FUTURE PERSPECTIVES**

The path towards safe, effective, patient centered, timely, efficient, and equitable care remains the ultimate goal for healthcare organizations. A challenging goal, especially with the increasing need for cost containment and the demands from government bodies, insurers and accreditation bodies to implement practice standards and provide transparency on performance as well.\textsuperscript{12} Too often, healthcare professionals are required to change their practice based on these external pressures, causing organizations to move directly into action, instead of carefully researching a topic first. This may result in changes in the system of care, but it may not always be improvements.\textsuperscript{3} As a consequence, the changes are not naturally embraced by healthcare professionals and it may even result in resistance, frustration and waste of valuable resources. The challenge is to create a
situation where QI is inspired by the intrinsic motivation of the healthcare professionals, thus creating a practice environment where EBQI is a natural element of everyday care.\(^3,4\) The research in this thesis has contributed to the requirements for such a situation, which are:

- Careful research into the complex problems that underpin QI with sufficient attention for local context.
- Practice based iterative design and small scale evaluation of QI interventions that build up towards rigorous research designs and long term measurement of effectiveness as well as implementation.
- Information from Electronic Patient Records (EPRs) that supports high quality care through the incorporation of clinical decision support as well as performance management through use of indicators.
- Further professionalization in quality improvement, through continuous education and a safety culture with adequate leadership.

**Complexity**

The starting point for all QI initiatives is careful research into the causes of the targeted problem. This may seem an obvious statement, but QI problems are usually complex with multiple combined causes and interdependencies that need to be targeted together (chapter 2 and 3).\(^5\) As a consequence the interventions become complex as well, with various interacting components, required behaviors of those delivering or receiving the intervention as well as a variability of outcomes (chapter 9). If we examine the reasons why things go wrong, we assume that we can design our systems to ensure ‘as few things as possible go wrong’.\(^6\) However, it appears that we may need to shift from this pure technical approach that assumes processes are predictable and ‘simple’, towards a more socio-technical approach that acknowledges that varying conditions and variability in healthcare processes are inevitable and necessary.\(^7\) We should move towards an approach that ensures ‘as many things as possible go right’ and acknowledge that the human factor is a necessary resource for system flexibility and resilience, thus ensuring that things go right.\(^7,8\) Therefore, we should also research how things usually go right, since that is the basis for explaining how things occasionally go wrong. Before deciding on a or (a bundle of) interventions it is of vital importance to include healthcare professionals as well as leadership in an early stage of the analysis and subsequent development of interventions. They are the experts in pointing us to the root causes of things that go ‘wrong’, the conditions that ensure processes go ‘right’ as well as the potential barriers and facilitators for the implementation of an intervention.
Last but not least, another important aspect for QI is the local context. Context is about the characteristics of the organization and its environment, such as safety culture, available resources and the way processes are organized. Interventions need to be adapted to the local context of the organization. What may fit very well in one organization, may be a bridge to far in another organization. This way we ensure that interventions are tailored to the local situation, and that the views of healthcare professionals are incorporated. Next, if a small scale pilot can demonstrate the benefit of the intervention, the intrinsic motivation for the intervention will increase and the intervention is more likely to be implemented and sustained.

Practice based iterative development and evaluation

When a potential effective (bundle of) intervention(s) has been developed, we need to evaluate its effectiveness. The appropriate research design and extent of the evaluation are dependent on the stage of maturity of the intervention. If a potential effective intervention is not yet well defined and the ingredients for successful implementation are not clear yet, it may be a waste of resources to commence a large scale evaluation. Through an iterative approach of field testing and small scale pilot implementations, information can be gathered on barriers and facilitators, potential modifications to the intervention as well as the most optimal implementation strategy. This way iterative refinement of the intervention and the implementation strategy is ensured before commencing a large scale evaluation. This approach of incremental development and measurement requires different research designs in different stages. In our studies we have gained experience with BA and ITS designs. In the early stages of development of an intervention, small scale BA designs can be appropriate because they give a sense of feasibility of measurement of the outcomes and give some indications of the potential effectiveness of the intervention. If successful, further larger scale evaluations with controlled BA designs or preferably ITS designs are appropriate. Especially the ITS design has the potential to measure effectiveness on a longer period of time, it provides the opportunity to determine the effectiveness of different implementation strategies at different moments and it corrects for seasonal influences and other confounders. On a national level a research infrastructure needs to be established that enables larger scale evaluations among hospitals. The confederated university medical centers (NFU) can jointly decide on a prioritized research agenda for EBQI
and thus enable larger scale multicenter evaluations of interventions. ZonMw as the largest research funder for healthcare can support this with the finances needed.16

Information

Documentation of information of the required and delivered care for a patient is indispensable for everyday care. The EPR is a valuable tool for registration and sharing of this information, thus supporting everyday care processes. Also, the EPR increasingly provides functionality for reminders and decision support. Through the incorporation of, for example, reminders for timely administration of medications, closed loop medication administration with barcode scanning, identification of patients at risk (chapter 6), and the incorporation of clinical rules from guidelines, the possibilities of the electronic patient record will further advance QI.17-19 The EPR is also an invaluable resource for QI: the information can be used to derive quality indicators for performance management (e.g., % of timely administered medications or % of patient receiving appropriate antibiotic prophylaxis). However, the development of quality indicators should rely on an evidence-based approach (chapter 5), with clear definitions.20 The resulting performance on the quality indicators subsequently can be used for further QI, for instance through prospective risk analyses or engagement in activities to improve implementation and/or adaptation of the indicators themselves. However, the described opportunities of the EPR require well designed and adaptable EPR systems that make use of uniform language.21 When thinking about the organization of the EPR the needs for supporting everyday care as well as the needs for ongoing performance measurement and QI should be considered in advance.

Professionalization in QI

Currently EBQI is not yet a self-evident element of everyday practice. To achieve this, we need to look at the characteristics of so-called ‘high-performance organizations’.22 Such organizations have shown positive effects on patient-related outcomes, such as medication errors, infections, falls, and patient satisfaction.23 They are characterized by strong clinical leadership and prospects for professional development.22 However, such an environment takes time to develop and is not achieved overnight. First, clinical leadership is vital for quality of care and team-based working. However, there is evidence that, at present, front-line leaders are ill equipped to lead effectively and lack confidence in their ability to do so.24 Therefore, educa-
tional programs are needed to train clinical leaders and equip them with the right competencies. Second, leading role models that disseminate EBQI are needed as well. These role models need to be clinical academic champions; they are considered opinion leaders by their colleagues, still work in daily practice and have a good understanding and knowledge of the requirements for research as well as implementation (chapter 9). Last but not least, we need team based thinking and working to enable inter-professional collaboration and provide opportunities for case-based teaching and knowledge sharing and thus lifelong learning. This way we can develop towards 'high-performance organizations' that are eager and willing to participate in every day EBQI.

Conclusion

The abundance of opportunities for error from the clinical scenario in the introduction of this thesis will remain existent. However, to enable safe processes we need team based collaborative care that puts the patient and its safety at center of every healthcare process. This requires that all healthcare professionals are equipped with the competencies and intrinsic motivation to practice EBQI in such a way that each opportunity for error is prevented from actually becoming an error.

“If you try to impose a new practice by simply telling the front line ‘Do this,’ it will fail. To get people to embrace a practice, it has to be easy to use, adaptable to a variety of settings, and of obvious benefit. The other crucial thing is having senior people who practice what they preach.”

(Atul Gawande)
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Summary and future perspectives