Improving patient safety for the critically ill
The challenges of implementation
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SUMMARY AND FUTURE PERSPECTIVES
SUMMARY

Actually integrating new research findings into daily practice is challenging, especially if they require changes to behaviour, clinical practices, the organization, or the way professionals collaborate. In many cases patients come to harm because evidence-based recommendations or guidelines are not followed consistently. Multiple studies have shown that patients receive only half of the recommended care. In health care, there is a slow uptake of new research findings in guidelines and daily care. This thesis focuses on the implementation of strategies for improving patient safety and quality of care of critically ill patients. Part I focuses on improving patient safety for critically ill patients on nursing wards by implementing a rapid response system (RRS). Part II focuses on improving patient safety for critically ill patients in the intensive care unit (ICU) by implementing evidence-based care bundles.

Part I. Improving patient safety of critically ill patients on nursing wards.

In part I, we focus on the implementation of the RRS on nursing wards. RRSs are developed to improve the care for deteriorating patients in hospitals. Previous studies have shown that most patients who suffer from serious adverse events, such as an unplanned ICU admission, cardiac arrest and unexpected death, have vital sign abnormalities prior to these adverse events. However, these signs are not always recognized in time by nurses or are not adequately and timely acted upon. RRS involves the recognition of patients’ conditions prior to deterioration by using a ‘track-and-trigger system’, such as the modified early warning score (MEWS). The rapid response team (RRT) should be called in case the patient’s condition deteriorates beyond a certain MEWS threshold. Chapter 2 describes the implementation of the MEWS on nursing wards of the Academic Medical Center in Amsterdam. In this quasi-experiment, we studied the effects of protocolized measurement (i.e. three times daily) of the MEWS versus measurement when clinically indicated. The study was conducted between September and November 2011. All patients admitted to the hospital for at least one overnight stay were included. Nursing wards were randomized to measure the MEWS three times daily or on indication. In total, 902 patients were included in this study, and a set of 6598 vital sign measurements were registered in the patient files during the three study weeks. The results showed that in the protocolized randomization arm, the MEWS was calculated in 70%. On wards where the MEWS was measured on indication the MEWS was measured in only 2%, difference 67.9%, 95% confidence interval 66.3 to 77.0, P-value < 0.001. Furthermore, there were 90 calls to the primary physician on the ward in the protocolized arm versus nine calls on the wards randomized on indication. The results indicate that measuring the MEWS three times daily results in improved compliance to
the protocol and better detection of physiological abnormalities, compared to leaving the frequency of measurement up to nurses themselves. In Chapter 3 we analysed the so called ‘false arrests’ in order to determine the ‘level of urgency’. False arrests were defined as activations of the cardiac arrest team while patients do not actually suffer from it.10-13 This study was conducted in order to find a scope for improvement in efficiency within the emergency care, thereby saving time and money. Cardiac arrest team activations for false arrests from September 2009 to 2012 were retrospectively analysed. These calls were classified as urgent or less-urgent. The results showed that a large part of the activations of cardiac arrest teams for false arrests were classified as less urgent. In these cases activation of a RRT might be more appropriate and efficient. It may be suggested that to minimize the activations of cardiac arrest teams for false arrests, nurses need to early recognize patients who clinically deteriorate. In order to do so, the MEWS screening tool should be used correctly.

Part II. Improving patient safety of critically ill patients in the ICU.

In part II, we describe the development and implementation of evidence-based care bundles. The concept of care bundles was developed by the Institute for Healthcare Improvement (IHI).14-16 Care bundles were developed in order to enhance the reliability of care and to improve the quality of care.14-17 They consist of a small set of three to a maximum of five evidence-based interventions for clinical processes or patient populations. The strength of bundling a small set of interventions together is that evidence-based care will be uniformly applied to every eligible patient, which may result in better patient outcomes than when the interventions were implemented individually.15,16

In Chapter 4 we conducted a systematic review to identify what methods were available that could support the development of new care bundles for the ICU besides the approach of the IHI. The IHI described the methods used on how to develop care bundles.15,16 However, these methods may not always be applicable to all ICUs and in every situation. In the literature, other useful methods to design care bundles were published as well. Electronic databases were searched for eligible studies from January 2001 to August 2014. We identified useful methods for designing evidence-based care bundles. The results were used to build a comprehensive flowchart to provide an overview of the methods used to design care bundles so that others could choose their own applicable method. It guides through all necessary steps in the process of designing care bundles.
The delivery of care, such as the delivery of enteral nutrition (EN), consist of a complex series of interactions between physicians, nurses, patients and medical interventions. Monitoring and systematically analysing these interactions can be helpful in identifying those areas where optimal care is potentially at risk. The identification of those risks is important in finding opportunities in improving the quality of care. And thus, an area were care bundles could be effective. Malnutrition is a serious problem in critically ill patients. We do, however, not exactly know to what extent patients are at risk in receiving adequate EN therapy. In Chapter 5 we conducted a retrospective cohort study, in which we identified patients who were at risk for malnutrition in order to find ways of improving the quality of care. Patients admitted to the ICU from January 2012 to December 2014 were included. Ideal calorie intake was calculated as 25 Kcal/kg/day. Ideal protein intake as 1.2 to 1.5 g/kg/day. Multilinear regression was used to describe the factors of success of EN intake. The results showed that, the delivery of EN in critically ill patients was moderate to high in the majority of the patients. However, a substantial part of the EN delivery was still suboptimal during admission and need to be improved. This implies a strong argument to support ICU staff in the adequate delivery of EN. This could be facilitated by a nutritional care bundle to support guideline uptake and thereby improve the delivery of EN. In Chapter 6 a systematic review was performed to determine the strategies used to implement care bundles in adult ICUs. Furthermore, we assessed the effect of these strategies when implementing bundles. The electronic databases, PubMed, Ovid Embase, CINAHL and CENTRAL, were searched for eligible studies. The most frequently used strategies were education (86%), reminders (71%) and audit and feedback (A&F) (63%). Our results showed that compliance was influenced by multiple factors, i.e. types and numbers of elements varied and different compliance measurements were reported. Furthermore, compliance was calculated within different time frames. Also detailed information about compliance, such as numerators and denominators, was not reported. Therefore, recalculation of consistent monthly compliance levels was not possible. We concluded that the heterogeneity among the included studies was high, caused by the variety in study designs, number and types of elements and types of compliance measurements. Due to the heterogeneity of the data and the poor quality of the studies, conclusions could not be determined about which strategy results in the highest levels of bundle compliance. Therefore, it is recommended that studies in quality improvement should be reported in a formalised way in order to be able to compare research findings.

In Chapter 7 we developed and implemented a transfusion care bundle for the delivery of red blood cells (RBCs). In this implementation study, with a quasi-experimental study design, we investigated the difference in effect on transfusion bundle compliance between monthly team level A&F versus monthly team level A&F with the addition of
timely individual A&F. The results showed that monthly A&F on team level with timely individual A&F significantly improved bundle compliance during implementation compared to monthly A&F on team level alone. The overall effect of compliance during the study period was significantly higher with an OR of 4.05 (95% confidence interval: 1.62 to 10.08), \( P < 0.001 \). This indicates that when using the combined A&F strategy nurses are more likely to be compliant to the bundle than when monthly A&F was used alone. Providing timely individual A&F plus monthly A&F on team level might also be effective for the implementation of other bundles in healthcare. Future research could elaborate on longer duration of the intervention, the use of information and computer technology to lower costs of the intervention and to enhance sustainability.

In Chapter 8 we investigated whether the application of the transfusion bundle would reduce the number of inappropriate RBC transfusions in an ICU setting. Restrictive RBC transfusion has been widely described in transfusion guidelines.\(^{21}\) However, compliance to these guidelines is often poor.\(^{22,23}\) In this before and after study, we quantified the true effect of the transfusion bundle by assessing, per transfusion, whether the decision to transfuse was based on a lower pre-transfusion haemoglobin (Hb) level than the patients’ individual preset Hb threshold. The primary outcome was the percentage of appropriate transfusions, referring to those transfusions that were in accordance to the patients’ individual preset Hb threshold. The results showed that the introduction of the transfusion bundle has resulted in a significant reduction of the percentage of inappropriate transfusions. The number of inappropriate transfusions decreased from 25% (111/439) during baseline to 15% (42/280) during implementation, a difference of 10%; 95% CI: -0.164 to -0.042, \( P < 0.001 \). This further decreased to 12% (45/370) in the post-implementation phase. Effectively, using the transfusion bundle helps to improve compliance with transfusion guidelines in daily practice. We have not assessed whether the preset Hb threshold was considered adequate for each individual patient according to the transfusion guideline. Interestingly, our results show that in most cases, restrictive Hb thresholds were used as stated in the transfusion guideline.\(^{21}\)
FUTURE PERSPECTIVE

A hospital is a highly complex system. This complexity is due to the many interactions between humans (patients, family, health care professionals), the organization (teams, wards, hospital) and the financial and political environment. Dynamic systems such as ICUs are particularly complex, given the multitude of technologies, treatments, medications, severity of the illnesses of patients, and the fact that professionals work in multidisciplinary teams. Errors are very likely to occur in dynamic and complex systems. In hospitals patient safety is an important issue that is also complex. Patient safety is broad-based, and operates at various levels of the system. It applies to various patient categories that employ multiple techniques and interventions, and can be influenced by cultural, technical, clinical, psychological, and financial aspects.

We conducted the studies included in this thesis within these complex contexts.

One of the most challenging aspects of increasing patient safety in a hospital setting is the successful implementation of new evidence-based practices (Chapters 2 and 7). For each new implementation activity, there are a large number of factors that hamper implementation. Cabana et al. conducted a systematic review in which they identified barriers to physicians’ compliance with clinical guidelines. These were barriers related to professionals’ knowledge and attitudes as well as to external barriers such as patient-, guideline-, or environment-related factors. Successful implementation depends on considering these various barriers and searching for adequate implementation strategies to overcome them. To achieve effective implementation, a systematic approach and a well-designed implementation plan are imperative. The plan should include an analysis of the target group, the setting, and the existing barriers. This information is necessary to tailor the implementation strategy to a specific situation. Although audit and feedback (A&F) is a widely used implementation strategy for improving patient safety and quality of care, it appears to be only moderately effective. A&F is more likely to be successful when the source is a senior colleague or supervisor, when it is provided in both written and verbal formats, when the goals are measurable, or when it is provided in a timely fashion (i.e. at least once a month). However, given the heterogeneity in outcome measures and methodology in the available studies, no strong conclusions can be drawn about A&F.

A wide variety of implementation strategies can be used, including reminders, A&F, and educational activities. These implementation strategies show varying effects and the most effective strategy or combination of strategies for successful implementation remains elusive. According to current thinking on this subject, to increase the chances of success, a tailored and often multifaceted approach is required.
to overcome existing barriers. The implementation strategies should be evidence-based and have a theoretical foundation. However, given the uncertainty of the outcome of each implementation activity, cost and time investment should be taken into account. The additional costs of multifaceted implementation strategies should be weighed against the realistic chance of (regularly) achieving only small improvements.

As described in the Introduction section, we should realize that errors inevitably occur in hospitals. Human errors are hardly ever caused in isolation by one person, but can occur due to underlying flaws within the organizational system. To protect patients against these human errors, the working environment, or so called ‘system,’ needs to be redesigned. This can, for instance, be achieved by the simplification and standardization of processes, automation, standardization of equipment and functions, or by decreasing simple reliance on memory (Chapters 2 and 7). With these methods, care processes can be optimized to improve the reliability of care. Improving reliability means that clinical procedures need to be applied reliably, such as compliance with hand hygiene or timely administration of antibiotics for septic patients. The use of care bundles or early warning score systems to detect clinical deterioration, are also useful strategies to improve the reliability of care processes (Chapters 2 and 7). Such quality improvement strategies are necessary and widely applied on hospital wards. However, they are never the complete solution for achieving improvements. These interventions could for instance be complemented by strategies to enhance the safety culture itself.

The concept of a ‘safety culture’ has become an important one for hospitals striving to improve patient safety. Safety culture reflects the attitude, values, perceptions and beliefs of leaders and health care providers towards taking risks, following rules, speaking up about safety and the values of risk management and safety. Safety culture can vary significantly between different wards and different groups, and each group or discipline has its own culture and habits. What are known as ‘high safety cultures’ are more willing to change behaviour and are associated with improved reliability of care. Pronovost et al. showed that promoting the safety culture, in combination with the implementation of a central line bundle, resulted in large improvements in infection reductions. But, improving the safety culture is a real challenge at every organizational level. This can only be achieved when leaders are visibly willing to change and when they encourage health care providers to openly talk about and share safety issues. If such a safety culture is not achieved, it can lead to an unwillingness to report adverse or other unsafe events. Professionals may fear disciplinary measures, or believe that reporting will not result in change. A safety culture needs to be present at all levels of the organization in order to improve quality of care.
Risk management in hospitals is crucial to improving quality and increasing patient safety. Care processes should be systematically monitored and analysed to identify potential risks. This provides valuable information about the variability that occurs within care processes, and the results can then be used to find opportunities for managing and reducing risks. Care bundles are frequently used as tools to continuously monitor care processes. They monitor the performance of professionals over time for a single process, which can be helpful in tracking progress towards outcomes and in making adjustments to performance if necessary (Chapter 7). They can be used to monitor predefined outcome measures (i.e. quality indicators). The quality indicator reflects a change that result from the implementation of the intervention. Thus, continuously monitoring the effect the care bundle has on the predefined quality indicator detects changes in a professional’s performance (Chapter 8). The use of quality indicators together with quality improvement interventions has proven to be effective in improving quality of care. However, general safety in hospitals cannot be improved by just one indicator for a single process. Multiple indicators should be used in combination with other approaches for monitoring safety on both hospital wards and across the organization, such as safety walks, monitoring safety at handovers, incident reporting, complaints procedure, complication registries and clinical audits. Because health care practice and scientific evidence changes over time, it is important to periodically evaluate and revise the set of quality indicators used. One realistic aspect of monitoring indicators that needs to be addressed is that it implies an administrative burden for health care providers. Even though automated electronic data extraction can help to reduce the registration workload, the decision to monitor indicators should be worth the effort.

Improving patient safety also involves being fully committed to the quality and safety of the entire organization. The concept of high reliability is often mentioned as facilitating risk management in hospitals and changing hospital systems and processes to achieve high quality of care. It is designed for those organizations that deal with dynamic, variable and unexpected circumstances, and has been adapted from industries outside of health care such as commercial aviation and nuclear power. In organizations in these industries, humans work under hazardous and complex conditions, and safety has an extremely high priority, which results in exceptionally high levels of reliability. These high reliability organizations (HROs) are constantly searching for methods to reduce errors and harm, and are urged to cope with errors and quickly recover when things do go wrong. Even though hospitals differ from the aviation and nuclear power industries, they can learn from how they think. High reliability is a way of thinking about quality and safety, and a concept that helps hospitals achieve their quality and safety goals. Striving to become an HRO can be achieved by creating a safety culture and by optimizing processes that are effective at reducing system errors, and can effectively
anticipate when errors will occur. Transforming hospitals into HROs is impossible unless leaders at all organizational levels are fully committed to achieving safe and high-quality patient care. There are five principles that guide HRO thinking, and help to focus on emergent risks and select the right set of interventions for addressing them: 1) preoccupation with failure; 2) reluctance to simplify interpretations; 3) sensitivity to operations; 4) deference to expertise; and 5) commitment to resilience. Embracing the HRO approach might be challenging in hospitals, where there are cost restraints and a high turnover of team members. It will be interesting to see whether hospitals can achieve this state of high reliability, how they achieved this, and, most importantly, how they sustain this state.

Healthcare is rapidly changing in many different ways. More people live with one or more chronic disease such as kidney disease, diabetes, cardiovascular disease or cancer. Diseases that were once fatal have become more and more chronic conditions. In the near future, hospitals will be focussing more on treatments and procedures requiring high levels of expertise using innovative techniques. More innovative medications, procedures, techniques, therapies have been developed and introduced leading to much shorter hospital stays. Patients will be discharged from the hospital sooner and care will be delivered in the patients homes or in centres outside the hospital. The changes in healthcare has implications for professionals as well. One interesting change is the role and tasks of physicians and nurses. This is rapidly changing since more care can be provided by specialized nurses instead of by physicians. Physicians will have a greater role in supervising and in making complex decisions. These are only a few examples that indicates that healthcare is rapidly changing. Due to these changes new risks will be created. Like Vincent argues, we must expand our view on patient safety. An interesting development is the approach of resilient healthcare. This approach is often called the ‘Safety II’ approach. Safety II is not meant as a replacement of the current approach on safety rather to use complimentary. From this point of view healthcare is resilient and the daily care is more often successful than that it fails. Thus, instead of focussing on the errors and the things that go wrong, the focus should be the other way around, i.e. focussing on the positive things and learn from it. This forms the basis of understanding why errors sometimes do occur in healthcare. Errors do not occur because healthcare providers react as they are told to, but they adjust to the varying circumstances to do the right thing for the patient. In the future, methods for such analyses should be more explored and investigated in different contexts.
Conclusion
Over the past decades, improving patient safety in hospitals has become an extremely important issue worldwide. However, there are still significant challenges to the uptake and implementation of quality improvement interventions. To encourage this and to increase the chances of successful interventions, a tailored and often multifaceted implementation strategy is required to overcome existing barriers. Throughout the implementation process it is essential to continuously monitor and analyse data to track progress towards outcomes, and adjust the chosen strategy if necessary. As patient safety evolves over time within the context of the ongoing development of innovative techniques and increasingly complex hospital care, it will continue to receive considerable attention in the decades to come.
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