Healthcare improvement based on learning from adverse outcomes

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Chapter 1

Introduction and outline of the thesis

INTRODUCTION AND OUTLINE OF THE THESIS

The patient safety movement

Healthcare is a high-risk industry in which patients may experience harm that is associated with the care process itself rather than their underlying diseases. This type of harm is commonly referred to as iatrogenic or healthcare-associated harm, with events described as complications or adverse events.[1] Research indicates that nearly 1 out of every 10 patients are affected by adverse events, most of which are related to surgical procedures or medications.[2]

Systematic efforts to prevent adverse events and improve the safety and quality of healthcare can be traced back to pioneers such as nurse Florence Nightingale in the late 1800s, and surgeon Ernest Codman in the early 1900s, who monitored mortality and morbidity rates in their institutions.[3,4] The modern 'patient safety movement', however, is considered to have been launched by the report *To Err is Human* from the US Institute of Medicine, published in November 1999.[5] This report called attention to large national studies in the preceding years, such as the Harvard Malpractice Study,[6,7] which estimated that over half of all fatal adverse events in hospitalized patients resulted from medical errors that could have been prevented. This publication underlined the reality that healthcare was not as safe as it should or could be, and increased public and institutional awareness of the need to improve patient safety.

Similar developments occurred in the Netherlands, where, since 1996, the Quality Law for Healthcare Institutions has required hospitals to systematically monitor, control and improve the quality of their care; a process of self-regulation that was monitored by the Dutch Healthcare Inspectorate.[8] Evaluation of this law in 2001 revealed that little progress had been made towards implementation of formalized systems to improve quality.[9] In response, the Dutch government consulted captains of industry, such as the President of Royal Dutch Shell, for strategies to facilitate improvement in healthcare. In a report in 2004, Shell recommended that hospitals should implement more robust safety management systems.[10] Subsequently, a dedicated task force formulated the basic requirements for such systems in a national stakeholders agreement in 2007.[11] These requirements included practices such as a hospital-wide incident reporting system and form the basis for external hospital audits. In 2015, the Dutch government enacted a new law on healthcare quality ('WKKGZ'), requiring all hospitals to have an incident reporting system as well as an officer for patient complaints.[12]

The increased focus on quality and safety in healthcare resulted in the implementation of various systems to gather information on patient outcomes. The report *To Err is Human* encouraged hospitals to develop and participate in adverse event reporting systems.[5] In fact, roughly 20% of the report dealt with some aspect of reporting.[13] Equally so, national governments have encouraged and enforced reporting of adverse events and serious incidents in healthcare institutions. In the late 1990s, the Dutch surgical society developed a national, standardized system for routine doctor-driven reporting of adverse events.[14,15] The presence of an adverse event reporting system has been included in the list of 'quality indicators' for

hospitals of the Dutch Healthcare Inspectorate since 2004.[16] In that year, at least 75% of the Dutch hospitals had adverse event registries for interventional specialties, such as surgery, gynecology and orthopedics.[16] It remained unclear, however, whether all this information was actually useful in helping to improve the quality and safety of healthcare.

Learning from adverse events: morbidity and mortality conferences

By 2007, more than 80% of all Dutch hospitals reported routinely discussing data from adverse event registries with their teams.[17] The traditional format for periodic discussions of cases with adverse events is commonly known as the 'morbidity and mortality conference' (M&M). At M&M, physicians review past cases to find opportunities to improve care for future patients. This practice emerged in the early 20th century, when the first medical specialties, particularly anesthesiology and surgery, started to openly discuss cases with substandard outcomes as these were expected to reflect substandard care.[4] Currently, M&M is standard practice for most medical specialties around the world and mandated by many residency programs as part of specialty training.[18,19] While it is one of the oldest practices for learning from adverse events in healthcare, there is no definitive evidence that M&M conferences are effective in improving the quality and safety of care.[20,21] Despite the widespread use of these conferences, the format used for M&M varies greatly between departments and hospitals,[21–23] and a gold standard or best practice for M&M is lacking.

It is clear that more research is warranted to understand the key elements required to maximize the value of M&M, and to inform the development of best practices.[24] One benefit of the current practice variation in M&M practice is that it allows a comparison of the relative strengths and weaknesses of different formats. However, while this practice has been frequently studied, few studies provide a comprehensive description of the conference's goals, structure (e.g. audience, timing), and process or content (e.g. case selection, presentation).[22] Additionally, M&M is usually viewed as an educational conference where the objective of improving quality is realized through education about how something *should have* been done differently. However, with the rise of the 'patient safety movement', there was a growing belief that this conference should be used not only to teach but also to collectively seek ways to improve the system in general. Thus, identifying system-level improvements became an additional objective of M&M. It remains unclear, however, to what extent the M&M conference has actually evolved to meet this contemporary expectation. Moreover, there is a paucity of qualitative research on the actual learning process that occurs at M&M and the mechanisms by which this learning leads to positive changes in clinical practice. This is a missed opportunity as qualitative methods may provide rich and nuanced information[25] that quantitative methods cannot reveal. For example, while learning and change theories stipulate that learning is affected by individual and team factors, little is known about the role of these factors in M&M practice.

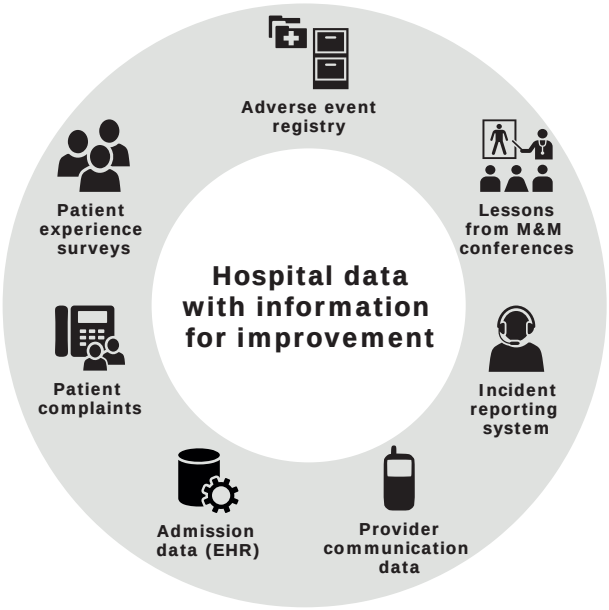
Even though the literature commonly highlights the need for an atmosphere that is free of 'shame and blame' to support open discussions at M&M, the key components of such an atmosphere, and how to support them, remain poorly understood. One theory that offers suggestions on how to harness a culture of learning and trust is 'Just Culture', which has received increased attention in healthcare in recent years.[26–29] Just Culture is based on the principle that professionals should not be punished for unintended adverse outcomes.[30] This theory stipulates that when learning is the objective, such as in M&M or further study of cases with adverse outcomes, blame or culpability should be avoided because these pose a serious threat to the learning process. While most hospitals aim to achieve a blame-free culture that promotes learning, research indicates that crucial aspects of Just Culture may not be fully understood, may be difficult to implement or are perhaps lost in translation from theory to healthcare practice.[31]

In general, research into M&M practice is hampered by a variety of factors, including the fundamental problem that there is currently no adequate agreed measure of success. The conference aims to improve healthcare quality and safety through learning from past cases, therefore the apparent measure of success should be improvements in these domains, such as a decrease in adverse event rates. However, it would be unrealistic to use these rates as a measure of M&M output, because the impact of M&M on these outcomes cannot be isolated from other, simultaneous, advancements in clinical practice. Instead, the lessons and plans for improvement that are derived from M&M may serve as an initial measure of its success.[24] Most M&Ms, however, do not routinely document these plans or lessons learned, which makes it difficult to use these data for research or monitoring purposes.[32] While some studies have been able to investigate the improvement plans that derived from M&Ms, they had only limited amounts of data and provided few details on what was actually learned or targeted for improvement.[33–35]

Learning from other hospital data

Hospitals routinely collect various types of information on the quality and safety of their care, and specifically, data on various types of adverse outcomes, such as adverse events and incidents (Figure 1). Adverse events concern patient harm, regardless of whether this has been the result of suboptimal care. Incidents refer to suboptimal processes, regardless of whether these have inflicted patient harm. Incidents can be reportable circumstances, near misses (e.g., medication error that was prevented), no harm incidents (e.g., medication error that did not cause harm) or harmful incidents (i.e., causing adverse events).[36] A harmful incident that causes a severe adverse event is considered a 'sentinel event'. Dutch hospitals are required to report sentinel events, as well as a subsequent investigation report, to the Healthcare Inspectorate. Adverse events and incidents are for local review only, with adverse events usually reported by clinicians[15] or identified through retrospective record review,[37] and incidents mostly reported by nurses.[38,39]

Figure 1. Hospital data that can serve as a source of information for improvement used in the research presented in this thesis.



Other information sources are available that reflect the patient perspective on quality and safety. Patients have long been able to file a complaint or claim against hospitals, but this remained a primarily a concern of legal departments rather than hospital quality departments. The problems raised in complaint letters are often complementary to those identified by other systems of monitoring, such as incident reporting or record review.[39,40] Patient experience has become increasingly recognized as a central pillar of quality in healthcare, which led to a more systematic collection of patient-reported experience and satisfaction data.[41–43] National patient experience surveys emerged around the world, particularly between 2002 and 2006.[44–46] It is intuitive that patient experience would be affected by adverse outcomes, and although there is evidence in this direction,[47] relationships between patient experience and patient safety remain poorly understood.[48] Patients may not always be in the position to identify specific adverse events,[49] but they may be able to report on underlying problems that have contributed, such as the quality of doctor-patient communication.[50] Greater insight into the relation between patient experience and adverse outcomes could be used to identify signals that forewarn a negative patient experience so that providers could intervene earlier and, on a more general level, improve our responses to patients' needs to ensure a positive experience.

The described systems to collect quality and safety data (Figure 1) have been instituted at different times and for different purposes. As a result, their data are mostly stored and used in isolation from each other. Connecting patient experience data in closer connection to other data sources is further hindered by the fact that these data are usually anonymized,[51]

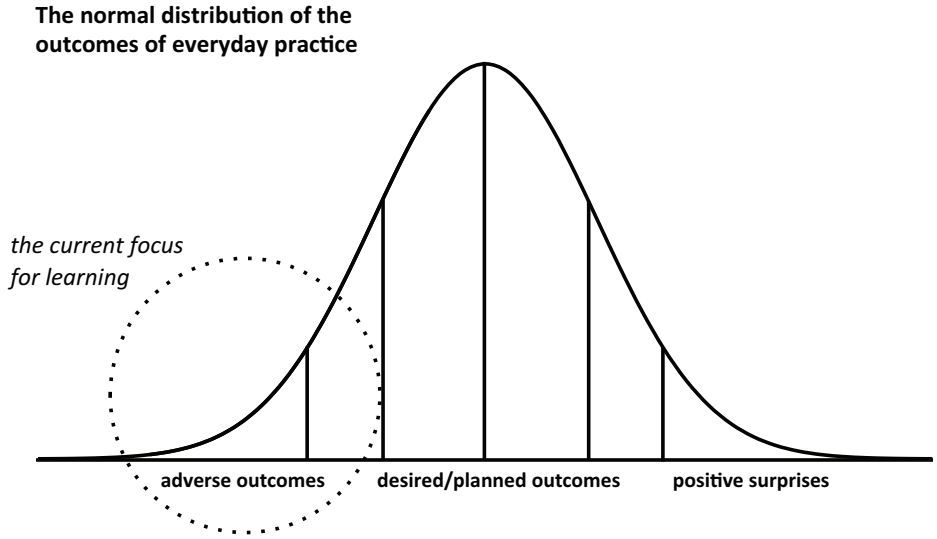
preventing linkage with admission or safety data. Prior studies have demonstrated that each of these data systems reveal different types of safety issues,[39,52,40,53] and recommend that hospitals use more than one method. However, while these systems collect different signals from the same 'patient journey', they are likely to be related at the patient level as events may trigger each other and potentially lead to a cascade of events (e.g., incident → adverse event → negative patient experience → complaint). These relations remain obscured by the currently isolated data sources, but in a research setting, these data could be linked to each other to study potential clustering of these events, and to explore whether data linkage could reveal additional information for improvement that use of individual sources may not provide.

Another potential source of valuable information is the hospital communication data, which could be used to investigate clinicians' workload, work flow interruptions, and inefficiencies in hospital communication,[54] all of which are relevant for safety and quality of care. A method that is widely used for communication within hospitals, particularly in the United States, is text paging.[55–57] Text paging generates large volumes of free-text data, as a single physician may receive approximately 60 messages per shift.[54] While not commonly used for this purpose, assessment of the frequency and timing as well as the content of these pages may reveal recurring issues and bottlenecks in care processes.

Learning from everyday practice

The traditional approach to safety alerts us to the *absence* of safety by signaling and assessing situations where things go wrong, but this tells us little about the *presence* of safety when things go right (Figure 2).[58,59] A focus on situations where there was an absence of safety is a logical and seemingly efficient approach, because these situations are thought to most likely contain opportunities for improvement. However, this strategy has various limitations, which may render some of the conclusions invalid. Identifying 'errors' is biased by retrospection (hindsight bias), knowledge of the outcome (outcome bias) and by the fact that reviewers always have a different perspective than those making decisions in the face of complexity and uncertainty (outsider bias). Moreover, such a 'find and fix' approach assumes that a specific bad component can be identified and changed for the better. In reality, however, healthcare is a complex adaptive system in which many human and technological actors interact in various ways.[60] Therefore, individual components cannot be assessed in isolation but rather must be seen as part of an interdependent whole. Likewise, a component cannot be changed in isolation without affecting other parts of the system. Changes that are based on a single undesired exceptional case could even, inadvertently, hamper the system's ability to succeed (e.g., additional checks may increase complexity and inefficiency). A sole focus on cases with adverse outcomes (Figure 2) thus fails to consider that most of the time, the same staff and care processes and perhaps very similar situations, have led to desired outcomes. Ironically, because desired outcomes are seen as 'normal', these are often referred to as situations where 'nothing happens'.[60]

Figure 2. The normal distribution of outcomes of everyday work and the current focus for learning.



Adapted from Hollnagel E (2015).[76]

The notion that we should not change the whole system in reaction to a non-representative event bears some similarity to the concept of 'common vs. special cause variation' in statistical process control theory, a scientific method developed in the 1920s.[61] The method cautions to not react to special cause variation as if it were common. If a severe adverse outcome may be considered a form of special cause variation, this would also imply that it should not serve as the basis for systemic changes. This theory furthermore stipulates that processes with this type of variation are unstable and unpredictable,[62] which is a characterization that can be made for healthcare settings in general.[59] Moreover, it is questionable whether we have an accurate and complete view of how the particular work is actually carried out. The renowned W. Edwards Deming remarked: *"If you can't describe what you're doing as a process, you don't know what you are doing*".[63] Nevertheless, many descriptions may still be inaccurate, because how a process works in theory can be quite different from how it is actually carried out in the imperfect and messy reality of everyday practice in healthcare.

Understanding everyday practice, and how it usually leads to desired outcomes, is a key element of proactive approaches to safety that emerged in the wider field of safety science,[60,64] and found their way to healthcare between 2012 and 2015.[59,65–67] These new approached aim to proactively learn from *everyday* practice, and seek to understand how things mostly "go right" as an explanation for how things sometimes "go wrong".[59,60,68] After all, regardless of the outcomes, all performance ultimately flows from the same underlying processes, with the same behaviors and practices.[59] Therefore, if we want to support and enhance the capacity for safe performance, we must first increase our understanding of everyday practice (work-

as-done), and how this relates to concepts of how work is done held by those removed from the sharp end (work-as-imagined).[60] Currently there is only limited research on how this approach could best be used to enhance healthcare improvement and questions remain about how exactly we can learn from everyday practice rather than specifically defined cases as well as what should we study, how and when. One method that has been developed to study everyday practice is the Functional Resonance Analysis Method (FRAM), which visualizes essential activities of a work process, including their interactions and variability.[69] Renowned safety experts, such as James Reason, have endorsed this method and the underlying theory as a way forward to improve safety in complex systems, such as healthcare.[70] While FRAM has been used in other industries, such as aviation and air traffic management,[71–73] uptake is still limited in the medical field.[74,75]

Aims and outline of this thesis

The objective of this PhD thesis was to study how processes for learning from adverse outcomes could be optimally used, both individually and collectively, to continuously improve healthcare. Specific research questions included:

How can we learn most effectively from adverse outcomes:

(i) based on case discussions at morbidity and mortality conferences;

(ii) by integrating available aggregate-level data (eg, incidents, patient experiences);

(iii) in context of everyday practice that produces adverse as well as desired outcomes; in order to continuously improve healthcare?

The first three chapters of this thesis present quantitative and qualitative studies with the aim of identifying factors for successful learning from adverse events discussed at morbidity and mortality conferences, healthcare's oldest practice for learning and improvement.

In **chapter 2,** the study objective was to identify strengths and challenges of different formats for M&M, comparing surgical M&M practices of an American and Dutch teaching hospital, as well as their participants' expectations and experiences.

Chapter 3 assesses factors that may hamper or facilitate success of M&M (i.e., whether learning and improvement occurs), through qualitative analysis of semi-structured interviews with the conference's participants.

In **chapter 4**, the frequency and type of lessons for patient care identified during eight years of surgical M&M were studied to assess the focus and sustainability of learning at this conference.

The following chapters examine how integration with other types of routinely collected data could further enhance learning and improvement processes in hospitals.

In **chapter 5,** independent data collection systems for patient complaints, incidents and adverse events, were linked at the patient level to assess the complex relationship between

events co-occurring in admissions, which may reveal valuable information for improvement efforts.

The value of information from the patient perspective is more closely examined in **chapter 6** and **chapter 7,** which examine the use of patient complaint letters and the use of patient experience survey data for improvement respectively.

Chapter 8 aims to study how hospital communication data, obtained from text paging between clinicians, may help to identify domains for improvement of patient care. The technique of natural language processing is used to examine this information source with large volumes of free-text data.

The potential value of learning from everyday practice was examined in the next two chapters. Well-known problem areas may best serve as targets for these types of studies that seek to understand how a process usually ensures safe and high-quality care. Therefore, in **Chapter 9,** the process of preoperative anticoagulation management was studied in an Australian and Dutch teaching hospital using FRAM. The aim of this study was to examine the usability and value of FRAM for safety improvement in healthcare. **Chapter 10** presents a perspective on how principles of the Safety-II and Just Culture theories on learning from everyday practice in a culture of trust, learning and accountability, could be applied to learning from sentinel events in healthcare.

Chapter 11 provides a general discussion with future perspectives, and a summary is enclosed in **chapter 12**.

GLOSSARY OF TERMS

Adverse outcomes	Term used in this thesis to refer to adverse events, incidents, sentinel events, patient complaints and negative patient experiences.
Adverse event[1]	An undesired patient outcome that may or may not be the result of an error; sometimes referred to as a 'complication'.
Incident[2]	An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.
Medical error[3]	An adverse event or near miss that is preventable with the current state of medical knowledge.
M&M[4]	The morbidity and mortality conference, a traditional forum that provides clinicians with an opportunity to discuss medical error and adverse events.
Patient safety[5]	The avoidance, prevention and amelioration of adverse outcomes or injuries associated stemming from the processes of healthcare.
Second victims[6]	Healthcare professionals who have been involved in a patient safety incident, medical error or adverse event, for which they feel personally responsible and experience emotional distress.
Sentinel event	Harmful incident that causes a severe adverse event. In the Netherlands, these cases need to be reported to the Dutch Healthcare Inspectorate.

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