Healthcare improvement based on learning from adverse outcomes

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Chapter 11

General discussion

GENERAL DISCUSSION

This PhD thesis examined current practices and sources for learning from adverse outcomes that aim to contribute to healthcare improvement, focusing on three approaches (Figure 1):

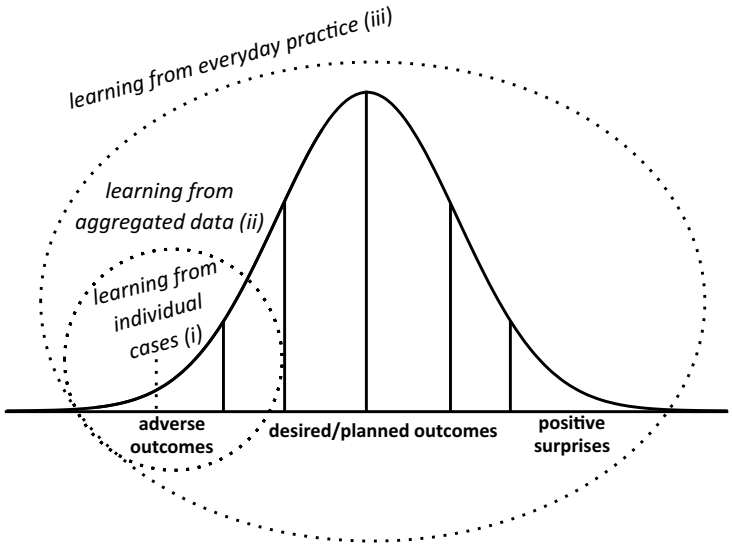
(i) Learning from discussions of individual cases at M&M conferences;

(ii) Learning from adverse outcomes in the context of other information sources, such as incidents, complaints and patient experiences.

(iii) Learning from processes in everyday practice

These approaches for learning are affected by various challenges embedded in healthcare practice and improvement, which will be considered in relation to the results of the research in this thesis and the wider literature. This will not be a comprehensive overview, but a reflection on some of the pertinent challenges and issues that we are facing in this field.

Figure 1. The normal distribution of the outcomes of everyday practice and the different approaches for learning from these outcomes (adapted from figure 1, chapter 1)



The depicted approaches are focused on: i) individual cases with adverse outcomes (e.g. at M&M conferences), ii) aggregated data on adverse outcomes (e.g. incident reports or patient complaints); iii) everyday practice with adverse as well as desired outcomes.

LEARNING FROM CASE EVALUATIONS

Although the M&M conference is the traditional forum for case-based learning, the research presented in this thesis indicates that it does not meet current expectations of serving as a means for continuous and system-wide improvement **(chapters 2-4)**. It is clearly a significant challenge to remain sensitive to the opportunities for learning, to subsequently apply these

lessons in clinical practice, and to then sustain the lessons learned in the collective memory of the department or wider organization. Issues that may particularly hamper the effectiveness of learning from individual case discussions are related to a narrow focus of learning, and challenges posed by cultural factors and the multidisciplinary nature of healthcare.

Persistent focus on individual-based rather than systems-based lessons

It has long been acknowledged that a simplistic focus on 'human error' is not an effective strategy. Nearly twenty years ago, the landmark publication *To Err is Human* declared that "The problem is not bad people; the problem is that the system needs to be made safer".[1] This 'systems approach' has been widely embraced as a more effective approach to achieve sustainable improvement in healthcare.[2,3] However, it seems that these principles have not yet been successfully implemented in practices for learning from adverse outcomes. **Chapter 4** provides empirical evidence that lessons drawn from M&M are often person-based rather than systems-based: lessons often concerned reminders to adhere to protocols or to pay more attention despite the fact that similar issues recurred over time. Others have described a similar focus in root cause analyses in healthcare, where the investigation may identify a deviation from prescribed practice as 'human error' without delving deeper into the underlying drivers of the behavior.[4,5] Often the subsequent corrective actions are limited to education and reinforcement of local policies but do not address the systemic problems that led to the behavior and therefore place others at risk in the future. A focus on correcting individual behavior will also not be effective in preventing 'organizational forgetting',[6] as seen in the case example in Box 1. Although systems-based strategies, such as environment (re-)design or forcing functions, require more effort, they ultimately have greater and longer-lasting effects than person-based lessons.[4]

It has been demonstrated that in everyday clinical practice, obstacles that hinder expected work processes, such as missing resources, greatly outnumber human mistakes (86% vs. 14%).[7] Therefore, in many cases, mere training will not suffice, because it cannot compensate for poor system design.[8] System problems are not only a hazard for patient harm and a source of frustration, but also waste valuable, well-paid professionals' time. It has been estimated that nurses spent about 33 minutes per eight-hour shift (or 15% of the time of 26 nurses) coping with system failures.[7,9] A better strategy would be to evaluate and address the conditions that allowed a problem to occur, famously described as "draining the swamp, not swatting at mosquitoes."[4,10] However, it seems that our initial responses to cases discussed at M&M or to complaints received from patients (**chapter 6**), are often regarded as end products rather than the beginning of a longer process of investigation, implementation, follow-up and adaptation. Such an approach only scratches the surface of the system, failing to dig deeper into underlying issues. In medical terms, we are often still treating symptoms rather than diagnosing and curing the disease when it comes to learning and improvement.

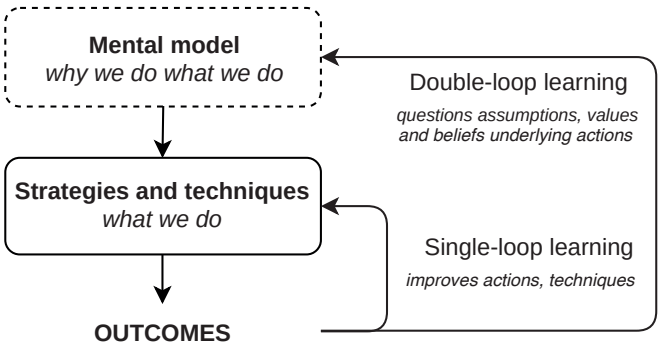
Box 1. Real case example of 'organizational forgetting'

In a large acute care hospital, the wrong lens was inserted during an elective eye surgery led by an experienced eye surgeon. The error was detected and the patient was safely reoperated. A subsequent root cause analysis of the case identified that there had been two lenses in the operating room: the surgeon had brought the correct lens, but a wrong lens had been brought in by an operating department assistant. The investigation concluded that the incident had been caused by having more than one lens in the room and a failure in the double-checking process. Plans for improvement included a training program, improved documentation, a protocol emphasizing the responsibility of the surgeon to select the appropriate lens, and a poster emphasizing the importance of double-checking. One year later, a different patient with a different surgeon had the same procedure in the same hospital. Once again, the wrong lens was implanted. In this case, the staff member who chose the wrong lens was the surgeon.

Example modified from Peerally et al. BMJ Qual Saf 2017;26:417-422

In the organizational learning literature, the distinction between fixing the problem at hand versus actually understanding and addressing underlying conditions is referred to as 'first-order vs. second-order problem solving' or 'single-loop vs. double-loop learning'.[7,11,12] Single-loop learning seeks to find an explanation for an outcome (i.e. what did we do to get this result), which focuses on "making techniques more efficient."[13] This corresponds to the observed focus of learning at M&M in **chapter 4**. Double-loop learning is more reflective and questioning, confronting basic assumptions and values by asking why we do what we do (Figure 2).[12,14] This way, individuals are encouraged to reflect on the 'mental maps' they use to take action, of which few are usually aware.[14] Put differently, single-loop learning is about "doing things right", whereas double-loop learning focuses on "doing the right things". To illustrate, the many recurring lessons in **chapter 4** stipulated that attention and techniques for patient positioning should be improved, whereas an example of second-loop learning would have been to consider why positioning may have been given lower priority in these cases (e.g. unclear task division or trade-offs across goals), and how this should be balanced in future cases. The scientists who developed the theory of double-loop learning assert that this is an important mechanism to support professionals in making informed decisions in rapidly changing, often uncertain contexts,[11,14,15] such as in healthcare.

Figure 2. Single-loop learning and double-loop learning



Effects of culture and psychological safety

While most research on M&M has focused on organizational aspects (e.g. presentation formats, moderators), learning and change theories underline that these processes are also affected by psychological and cultural factors. How culture may hamper learning, e.g. by focusing on blame, is discussed by the 'Just Culture' theory central to **chapter 10.** It is clear that more work is required to establish such a culture, as illustrated by the results of the study in **chapter 2**. Although most respondents expected that M&M should be free of shame and blame, 3 out of 10 respondents at both sites reported that this was their experience only sometimes or rarely in practice.

The findings of the studies in **chapters 3 and 4** indicate that it requires more than just organizational efforts, such as how the meeting is set up, to promote a learning environment with open discussions. This is captured in the renowned quote "culture eats strategy for breakfast", which has been attributed to management expert Peter Drücker. Based on interviews with clinicians, feelings of ownership and control (or: 'motivation' and 'realization') were identified as factors of influence on learning at M&M. The qualitative study in **chapter 3,** unique in the field of M&M research, reveals how audience composition and team dynamics additionally affect discussions at M&M. Certain unwritten rules exist that may be potential barriers to speaking up, such as the high value placed on 'team spirit' and the subsequent unwillingness to be perceived as 'back-stabbing'.

The organizational learning literature highlights how 'psychological safety' is essential to fostering a learning environment, described as one in which people feel comfortable with speaking up with questions, observations, insights and concerns, even if those are perhaps difficult or perceived as bad news.[9] The construct of psychological safety describes an individual's "perceptions of the consequences of taking interpersonal risks,"[16] such as acknowledging lack of competence, asking for help or trying something new. Psychological safety is a critical factor in understanding phenomena such as voice, teamwork, team learning and dealing with uncertainty.[16] The relationship between psychological safety and learning is evident: if people feel safe to voice concerns, admit mistakes, offer suggestions or provide feedback, they will be more likely to do so. Psychological safety also affects everyday performance: perceived consequences of taking risks will determine how one will respond to situations with uncertainty, or a need for creativity, assistance or collaboration – all of which are common in healthcare.

A psychologically safe environment is not created from the top down but from the bottom up, and thus greatly dependent on the behavior of *local* leadership.[9] A critical aspect is that leaders need to be clear about what constitutes unacceptable behavior, which is where the literature on 'psychological safety' overlaps with that on 'Just Culture' (**chapter 10**). Since learning in teams involves personal effort, this process must be inspired, organized, supported and led by frontline leaders.[9] This aligns with **chapter 3** that describes how 'motivation' and 'realization' serve as mediating pathways for successful M&M, as well as with the findings

of **chapters 2 and 3** that point to the important role of strong leadership (e.g. moderator, dedicated committee).

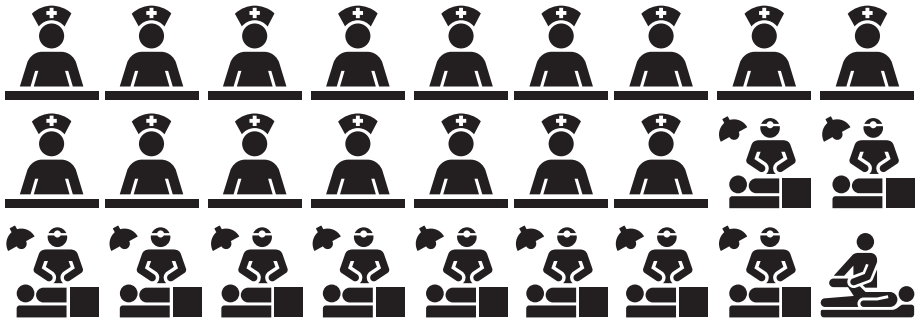
The influence of culture has also been discussed in relation to what seems to be the best example of a successful large-scale patient safety intervention: the Michigan Keystone project to decrease catheter-related bloodstream infections.[17] Experts attribute the project's success to the fact that it not only included technical interventions, such as a checklist, but was also designed to improve culture, teamwork and communication.[18–22] Checklists were just one component in a wider program that influenced the culture of the teams (e.g., shifting power relations, empowering nurses).[18] Moreover, local teams customized the checklist to fit their specific context. When another group implemented this program without the socioadaptive components, improvements slowed down until these were added.[23] In essence, this project abandoned a 'command and control' regime, where instructions (e.g., checklists) are simply dictated to professionals, instead creating "social networks with a shared sense of mission".[18] While instructions may seem effective in theory, professionals will seek workarounds in practice if they do not believe in their value. To illustrate this, that a similar project in England was less successful and this was partially attributed to a misalignment of the goals, interests and priorities with those of staff at the sharp-end.[21] Again, culture may "eat strategy for breakfast."

Challenges posed by multidisciplinarity

Although healthcare professionals have a high turnover rate, particularly in teaching hospitals, underlying system conditions are likely to affect new employees who start to work in that environment. This also explains why systems-based improvements are more effective than person-based improvements. Moreover, as found in **chapters 3 and 4**, a lack of continuity of clinicians (e.g., rotating residents) can make it particularly difficult to implement and sustain lessons that are focused on people rather than environments. For example, it has been estimated that a mean total of 26.6 (range 2-75) healthcare professionals are involved in a surgical patient's stay (Figure 3).[24] These numbers reaffirm that it is unrealistic to attribute negative patient experiences or complaints to individual providers (**chapter 6**).

The presented research also illustrated that the multidisciplinary nature of healthcare plays a role in learning and implementation processes: lessons that involved other disciplines were infrequent overall, but recurred frequently over time (**chapter 4**). Although many studies, including **chapter 4**, propose multidisciplinary participation as a way forward for M&M,[25–28] the qualitative study in **chapter 3** adds nuance to these studies by showing that participants may feel inhibited to speak freely when other disciplines or specialties attend the conference. Yet, it would be unrealistic to try to improve a process in isolation from others involved, since many problems have their origin in other parts of the system.[7] This was also illustrated by the workflow interruptions in **chapter 8** that seemed to stem from problems encountered by other providers, such as nurses, creating the need to communicate via text paging. Similarly, the models in **chapter 9** revealed how activities of multiple disciplines and specialties are tightly

Figure 3. Average number of healthcare professionals involved in a surgical inpatient's stay (i.e. 15.9 nurses, 10.0 doctors, 0.8 allied health professionals).



Estimates based on: Whitt et al. N Z Med J 2007;120(1253):1-8.

coupled, which helped to understand (and show providers during reflection meetings) how a problem early on in the process might propagate through the system, affecting the activities of other team members. Overall, it seems that, although modern healthcare is increasingly multidisciplinary, our practices for learning and improvement lag behind in readiness to cross traditional boundaries between departments and disciplines.

LEARNING FROM AGGREGATED DATA

Over the years, hospitals have implemented various systems to collect data, reflecting the quality, safety and patient experience of the delivered care (Table 1). Previous studies have examined various data sources and revealed that each collect different types of information, supporting hospitals' use of various methods to detect safety issues and targets for improvement.[29–33] The research in this thesis (**chapters 5-7**), however, adds that although each system collects different signals from the same patient journey, these data have complex relations at the patient level. Therefore, a specific opportunity that is yet to be seized is making better use of available data sources in relation to each other.

The need to connect the silos of information

There is not only a practical objective to make effective use of the collected data to improve care, but it would also be unethical to ask patients and providers to report information if this is not used to its full potential. **Chapter 5** illustrates how data triangulation can reveal complex relations between events that would remain obscured when these data are used in isolation. Individually, these data only allow for uni-directional assessments (i.e., incident → adverse event[AE]) of one-on-one relations between events; namely, whether an incident caused AEs (incident reporting) or whether AEs were preceded by suboptimal care (record review). At the admission-level, these data may have many-to-many relationships, potentially in the opposite direction when initial AEs trigger incidents due to increased complexity or vulnerability.

Table 1. Features of hospital data sources for learning and improvement studied in this thesis.

Source	*Features*[1]	*Source*	*Features*[1]
n=total per year for one department		*n=total per year for one department*	
 **Admission data (EHR)**	- Automatically collected - Contains patient identifiers and patient characteristics - Numerator for other sources	 **Patient complaints**	- 'Stories' from patients - Reveals issues often not captured elsewhere - Difficult to use aggregated form: unstructured data of low and unreliable volume
n=3678 (100%) pts		*n=9 (for inpatients)*	
 **Adverse event registry**	- Collected by providers (underreporting risk) or record review (labour intensive) - Useful for benchmarking and to inform patients on risks	 **Patient experience surveys**	- Voluntary reports of patients - Combination of open text and validated survey items - Affected by response bias - Can be used for monitoring
n=759 / 647 (18%) pts		*n=921*	
 **Lessons from M&M conferences**	- Documented by providers - Useful for tracking progress and M&M output, e.g. using recurrence of lessons	 **Provider communication data**	- Text pages ca. 193.000/year, but not used by all hospitals - Useful to study frequency, content and distribution of interprovider communication
n=38		*differs per source*	
 **Incident reporting system**	- 'Stories' from providers - Cannot be used for monitoring (unreliable reporting rates) - Unique in revealing hazards before harm is inflicted		
n=552 / 339 (9%) pts			

Pts, inpatient admissions.

[1]Admission, adverse event, incident, patient complaints and experience survey numbers represent total numbers from the LUMC surgical department in 2015 (chapter 7). Number of M&M lessons and text paging volume represent mean annual total from chapters 3 and 8.

Similarly, **chapter 7** shows how linkage of safety and patient experience data allows a more comprehensive approach to make sense of this information for improvement. Although adverse outcomes were not independently associated with risk of a suboptimal experience, they did increase this risk when patients also reported problems with 'respect' and 'continuity and transition' (interaction effect). Patient experience data, however, are typically presented in aggregated, provider-level reports, and data linkage is complicated by surveys being anonymous.[34] Even though regulatory and ethical standards control anonymity of patient surveys,[34] patients themselves may be willing to participate in this sort of data linkage,[35] especially when checks and balances are in place (e.g. a trusted third party to link and then anonymize the

data). Complaints data represent another source of information from the patient perspective, but these also typically remain isolated from improvement or clinical staff, as highlighted in **chapter 6**. In addition, while not commonly used for this purpose, hospital communication data, such as text paging data, can be used to examine bottlenecks in care processes, but the large volume of these free text data requires more specific techniques to analyze this wealth of information (**chapter 8**).

Cultural factors affecting data collection

A paradox is present in the relation between local culture and reporting data: the less psychologically safe, blame-free and 'just' the culture of a department, the better their metrics will seem because reporting will be discouraged. Even in departments with a blame-free and safe environment, important events may go unreported as clinicians have a tendency to fix problems on the spot, without tracking them to their source or informing others involved either in the department or across the hospital.[7,36,37] Although high levels of reporting may suggest a strong culture of reporting and thus safety, this could also reflect a poor culture of learning that resulted in repeated reports of the same type[38] – akin to the recurring lessons in **chapter 4**. Another difficult aspect of reporting systems is that they may be misused as a means to delegate the problem to others or to avoid difficult conversations with colleagues. While not discussed in the study itself, many of the incident reports examined in **chapter 5** reflected frustrations with colleagues that did not seem to have a place in incident reporting systems (e.g., "physician did not listen or respond to my concerns as a nurse"). Another example was observed during a team meeting in which a physician ordered a nurse to file an incident report on another nurse who had made more than three unsuccessful attempts to draw blood from a patient. The physician stated that "this is not the way we do things around here" and chose to turn to the incident reporting system instead of talking to the nurse or team about this issue.

Safety bureaucracy

The current state of the patient safety field has been described as a one of 'confusing complexity,'[39,40] referring to the theory that knowledge moves in three phases (i.e. superficial simplicity → confusing complexity → profound simplicity).[41] 'Superficial simplicity' is reflected in the initial notion that specific methods, such as incident reporting, could simply be adapted from other safety-critical industries.[38,39] It has become increasingly clear, however, that fundamental aspects of these methods were misunderstood, misapplied or left out,[38] and safety issues in healthcare appeared to be far more complex and omnipresent than initially expected.[39] The report that describes the 'confusing complexity' in patient safety argues that this is illustrated by the large variety of specific improvement targets with interventions for each, such as surgery checklists, infection prevention programs, and barcoding.[39] In light of the research in this thesis (**chapters 5-7**), one may argue that the wealth of information produced by the separate data collection systems also adds to this 'confusing complexity'.

Now that methods are in place and staff have been encouraged to report all potentially relevant information, it has become a challenge to process and prioritize all this data. Incident reporting alone can generate more than 5000 reports per hospital per year.[42,43] As a result, important signals in this data may be swamped with noise, and analytical and attentional resources may be overburdened.[38,42,44,45] In itself, quality and safety management generates additional work and bureaucratic means.[46] A recent study, part of a national initiative to reduce the overall administrative burden for clinicians, revealed that Dutch medical specialists spend an average of 15 hours per week on administrative tasks.[47] Another study estimated that residents spend an average 38% of their 10-hour workdays on administrative tasks, and an additional 51 minutes from home.[48] This raises the question of whether administrative tasks related to quality and safety management, such as reporting systems or administration for M&M, further contribute to the overall burden of administrative work for unclear or potentially limited gains. In any case, the study in **chapter 2** indicates that clinicians do not perceive adequate gains from M&M, as it does not meet their expectations for improvement and changes in clinical practice.

LEARNING FROM EVERYDAY PRACTICE

By design, current practices for learning have a focus on reacting to events where there is a lack of safety (e.g., incidents, complaints, case reviews) and pay little attnetion to how the system usually works and performs. As a result, many of these practices are focused on individual cases and the solutions are likewise aimed at preventing specific, and often rare, failures.[6] However, even the aggregated data discussed above only represent a small subset of outcomes of everyday practice, namely, only the adverse ones, and therefore provide little information on how 'safety' is achieved and ensured. An analogy would be to study how a successful marriage is built and maintained, but only including divorced couples as study subjects. A more proactive proactive approach to safety, labelled Safety-II, focuses on how work succeeds in everyday practice and how to enhance this successful performance of the system.

Understanding work-as-done in everyday practice

Healthcare can be characterized as a complex adaptive, socio-technical system, in which human activities and technology are tightly coupled. One of the features of complex dynamic systems is that accidents are often preceded by *normal work*, which may contain the daily frustrations, improvisations and workarounds that are 'everyday circumstances' for professionals.[46,49,50] As a result, these circumstances do not typically exceed the threshold of a problem worthy of reporting for clinicians, and hence do not surface in the team discussions or reporting systems described above. Yet, these are e

"precisely the kinds of things that do show up in big accidents."[46] In many cases, outcomes of complex systems are *emergent* rather than resultant, because variability may combine in unexpected ways, producing disproportionate, non-linear effects (i.e., more than just the sum

of the parts).[51,52] This explains why properties of complex systems cannot be directly predicted from its elements.

Although a single, simple or one-size solution does not exist for problems in complex systems with multiple interdependent elements, these elements can potentially be reshaped to increase likelihood of success.[53] **Chapter 9** presents how the Functional Resonance Analysis Method (FRAM) can be used to increase understanding of a process in everyday practice. A central idea in the underlying theory is that understanding of the everyday functioning of a complex system provides a more useful basis for understanding a specific development within that system, such as a sentinel event.[51,54,55] However, the ability to support things to go right in everyday practice requires an understanding of how things are actually done in practice, not just 'in theory', as well as an understanding of the underlying conditions. Simply reminding clinicians to adhere to the 'paper version' of local policies (i.e. single-loop learning) will not solve underlying problems such as impracticalities or conflicting expectations in these policies (i.e. double-loop learning). For case investigations, this approach would add a different type of questions than we normally use, to provide insight into the context of clinicians' work, such as: Why did professionals believe they were doing the right thing considering the circumstances? Why did it seem acceptable and make sense at the time? Were there any trade-offs involved, for example, in attention allocation or between efficiency and thoroughness, and are these common?[12,56]

Lack of compliance could be viewed as a gap between work-as-imagined and work-as-done, and bridging this gap requires understanding *both sides*.[57,58] Clinicians rarely intentionally violate policies and likely have various reasons for doing something in a certain way.[6] Broader consideration of the rest of the system and the 'messy reality' of clinical practice, provides valuable insights into, for example, the underlying reasons for workarounds by clinicians.[6,59] **Chapter 9** demonstrated how work-as-done may deviate from what could be expected based on guidelines or policies (work-as-imagined), and points at pragmatic reasons that may explain this. These findings may have been interpreted as 'protocol deviations' that produce adverse outcomes if identified in a sentinel event investigation, while they appear to be part of the everyday work that commonly produces desired outcomes.

Ultimately, plans for improvement need to help to make the right thing to do, the easy thing to do for those at the frontline.[4] In practice, this may not yet be the case and there remains an ongoing reliance on clinicians' flexibility and compensatory mechanisms. This was illustrated by a Danish study filming nurses at work during regular medication dispensation, revealing that nurses had to compensate for inconsistencies between the lay-out of the prescription software and the medication tray.[60] Moreover, both the software and tray had little relation to the physical layout of the patient beds in the rooms, which nurses used as a 'mental picture' of reference while dispensing medications for these patients. This serves as a good example of how everyday practice with successful rather than adverse outcomes, can serve as a meaningful study object to enhance safe performance. A large advantage of this proactive approach

to safety is that it does not require a harmful or negative event, and thus does not require interviews with potentially traumatized patients and providers (**chapter 10**).

Actions are not a priori acceptable or unacceptable

A focus on the wider system does not mean to imply that clinicians are not responsible for their actions, but honors the notion that their actions are affected by the context in which they occur.[2] While the Just Culture philosophy is sometimes misused a means to determine the culpability of 'unsafe acts' (e.g., with a flow chart), this philosophy actually underlines that professionals' actions cannot be viewed as a priori 'acceptable' or 'unacceptable', but that this greatly depends on the context (**chapter 10**).[6,61,62] The systems approach should neither be misunderstood as attempts to reduce professionals' autonomy through, for example, standardization, or to seek explanations for failure outside of individuals, simply blaming the system.[2] In contrast, it strives to design the system in such a way that it supports individual autonomy and competence in creating desired outcomes.[2] Because procedures, protocols and checklists do not guarantee success or safety in itself, professionals' autonomy and resilience are key factors for success in practice.[2,54]

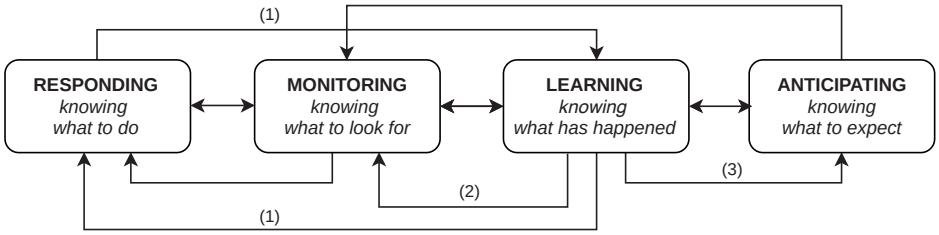
Resilient performance

To a great extent, hospitals rely on dedicated and adaptable clinicians to compensate for problems and to cope with uncertainty and complexity in everyday practice. This resilience allows achieving success despite conditions that could easily lead to failure (e.g. unusual demands, disruptions, goal conflicts, inaccurate or incomplete information), and allows quick recovery after failure.[63] This is why we should refrain from seeing humans as merely a hazard in (e.g. of error) our systems but instead appreciate their essential role in enabling success under varying circumstances. In other words, "People are solutions, not problems."[64] The field of resilience engineering focuses on enhancing 'resilient performance', defined as *the ability to sustain required operations under both expected and unexpected conditions by adjusting functioning prior to, during, or following events (changes, disturbances and opportunities)*.[65] Although often unnoticed, safe and high-quality care regularly depends on resilience (e.g. responding to a high influx of patients).[63] Lack of insight can easily lead to misjudging contributors to resilience as 'waste' and eliminating them (e.g. slack resources that improve reliability and agility).[63] Therefore, it is a critical need for patient safety to find ways to identify and enhance resilience.[63] Resilience engineering proposes four abilities necessary for resilient performance[65] (Figure 4):

- *the ability to respond* to (ir)regular changes, disturbances and opportunities;
- *the ability to monitor* components that could seriously affect system's performance;
- *the ability to learn* from experience (representative events, not only catastrophes);
- *the ability to anticipate* potential disruptions, demands, constraints or conditions.

The ability to learn from experience is central to this thesis, with an additional focus on monitoring in the studies on aggregated data (**chapters 5-8**). More specifically, **chapters 5 and 7** discuss how triangulation of available data can be used to assess the ability to respond, by examining how further problems, such as other AEs/incidents or a negative patient experience, were prevented in cases with initial AEs. **Chapter 9** illustrates how FRAM can be used to examine the current state of the system, including essential functions, interdependencies and variability (ability to monitor). FRAM can also be used to study something that has happened (ability to learn),[12] or to assess potential problems with implementation of a new protocol or process design (ability to anticipate).[66]

Figure 4. Potentials for resilient performance.



Adapted from Hollnagel (2015).[65]
(1) Learning from previous responses may improve our ability to respond in future cases;
(2) Lessons learned may affect our monitoring strategies;
(3) Lessons learned may inform us about what to expect and anticipate.

PRACTICAL IMPLICATIONS AND FUTURE PERSPECTIVES

Despite the increased attention and information on patient safety, research indicates that widespread improvements have not occurred.[67–69] One potential implication from the above discussions is that this may be due to the mismatch between the interventions we use and the real nature of the system to which they are applied. The challenge is therefore about how to successfully shift the focus from person-based, technical solutions towards greater appreciation for the system, its complex-adaptive nature, cultural factors, and the crucial role of humans to ensure success under varying circumstances.

Reflective discussions

Team meetings for learning and improvement (e.g. M&M) need to be more reflective and contemplative, striving to achieve double-loop rather than only single-loop learning. In this respect, focusing discussions on the underlying processes in everyday practice rather than specific cases may help to bring discussions to a higher level. Feedback to staff on progress and effects of formulated plans needs to improve greatly to encourage a longer process of investigation, implementation and follow-up (e.g. using rapid-cycle improvement strategies). Additional time for follow-up and feedback may mean that fewer cases can be investigated

within the available time, but a more thorough approach will be more meaningful than superficially studying large volumes of data.[70] Although multidisciplinary participation may negatively affect openness, it is important to plan (additional) meetings with "the whole system in the room" (a concept from 'appreciative inquiry'[71]) to gather information and create engagement for change. Schools and training programs for physicians and nurses play an important role in harnessing an open, cooperative culture among professionals from diverse disciplines and specialties; yet, it is just as important that senior clinicians reinforce and model these behaviors.

Combining existing and novel resources and methods

Currently available data in hospitals (Table 1) should be linked to allow triangulation between information sources and more comprehensive analyses. Furthermore, these data can be integrated into current practices, for example, by discussing AEs at M&M in the context of patients' experience and incidents. Linkage of admission data to the various sources of quality and safety data would allow identifying cases *without* adverse outcomes, perhaps despite challenging circumstances (e.g., high-risk patient profile or procedure), which can be targeted for further study to understand how safety was achieved (e.g., resilience). Future research should explore how to reduce the overall burden of data collection and administration, while still being informed about quality and safety of care in a way that we can report to others (e.g., board of directors, inspectorate). Traditional methods should be combined with complex systems approaches to safety. For example, the commonly used 'lean' method can be used to identify potential resources of waste, after which FRAM can be employed to study which resources are required to manage unexpected variability, referred to as 'slack resources'.[72] Another example is that statistical process control can be used in combination with FRAM models to measure relevant outputs of functions.[73]

Culture and team dynamics

For many aspects of clinical practice, we need more than technical solutions if we are to achieve safer care, as these cannot solve problems that are primarily social and cultural.[18] The described difficulties with multidisciplinary discussions touch upon a more deep-rooted problem in healthcare, namely the barriers that exist between medical disciplines and specialties, which is a promising avenue for further study in relation to (effects on) patient safety. Many studies in patient safety, however, focus on clinical rather than cultural interventions, resulting in a paucity of evidence on how to achieve, for example, better teamwork.[22] There is thus a great need for more research on team dynamics, culture, and resilience in healthcare. A specific challenge for research on these phenomena is that they are not easily converted to numbers.[63] More qualitative (e.g. interviews, direct observation,[74] video ethnography) and mixed-methods designs are thus required, including funding for such 'non-traditional' studies in medicine. Although the science behind patient safety and improvement are not tra-

ditionally part of medicine, they have become integral components of good medical practice and required competencies for clinicians. Moreover, it is important that those who examine and work to improve a process are familiar with it in practice.[46] Yet, there remains a need for experts from other fields (e.g. safety science, human factors, organizational change),[8] and we should call upon their expertise, as we commonly do with epidemiologists or statisticians.

Resilience and system complexity

Patient safety is on the verge of moving from a focus on human error and linear models, to one that embraces complexity, systems thinking and resilient performance. Complexity science and complex adaptive systems theory offer an alternative theoretical framework.[53,75] In addition to studies that describe or model parts of systems (e.g., using FRAM), further studies with complex systems approaches are needed to examine how to implement improvements in these systems.[76] More research is also warranted to identify resilient performance and how it could be enhanced, so that professionals can be equipped for adequate responses to challenging situations. An increased focus on compliance with protocols may inadvertently lead to risk aversion and a constraint on initiative, thus creating an unpreparedness for situations that do not fit those anticipated by the protocols.[46] Further study should address how an increased focus on safety and efficiency can be balanced with the flexibility and resilience required for success, including how to prevent that plans for increased reliability (e.g. double-checking procedures) create 'organized distractions', unnecessary interruptions and increased workload.

CONCLUSIONS

While healthcare has invested in the foundations to gather and learn from data on adverse outcomes, the research presented in this thesis pointed at various challenges that remain. M&M meetings to learn from individual cases exhibit a tendency to focus on individual behavior and technical performance, and thus may benefit from greater reflectivity that triggers learning with greater appreciation of underlying system-level issues. In addition, cultural factors, such as dynamics in teams and among disciplines, were found to affect learning at M&M, which underlines the need for more qualitative research on these domains. Currently available aggregated data remain encased in separate silos, but should be used in closer connection to each other to allow more comprehensive analyses. Proactive and complex systems approaches to safety are promising to further enhance understanding of how everyday practice usually goes right and to support this capacity so that patients' safety can be ensured.

REFERENCES

1. Kohn LT, Corrigan JM, Donaldson M. *To Err Is Human: Building a Safer Health System*. Washington DC, USA: National Academy Press; 1999.
2. Dekker SWA, Leveson NG. The systems approach to medicine: controversy and misconceptions. *BMJ Qual Saf*. 2015;24:7-9.
3. Wachter R, Shojania K. *Internal Bleeding*. New York, NY: Rugged Land; 2004.
4. Trbovich P, Shojania KG. Root-cause analysis: swatting at mosquitoes versus draining the swamp. *BMJ Qual Saf*. 2017;26:350-353.
5. Kellogg KM, Hettinger Z, Shah M, et al. Our current approach to root cause analysis: is it contributing to our failure to improve patient safety? *BMJ Qual Saf*. 2017;26:381-3787. doi: 10.1136/bmjqs-2016-005991
6. Peerally MF, Carr S, Waring J, et al. The problem with root cause analysis. *BMJ Qual Saf Saf*. 2017;26:417-422. doi:10.1136/bmjqs-2016-005511
7. Tucker AL, Edmondson AC, Hall M, et al. Why hospitals don't learn from failures: *Calif Manag Rev*. 2003;45:55-72.
8. Russ AL, Fairbanks RJ, Karsh B-T, et al. The science of human factors: separating fact from fiction. *BMJ Qual Saf*. 2013;22:802-808. doi:10.1136/bmjqs-2012-001450
9. Edmondson AC. Learning from failure in health care: frequent opportunities, pervasive barriers. *Qual Saf Heal Care*. 2004;13:ii3-ii9.
10. Reason J. Human error: models and management. *BMJ*. 2000;320:768-770.
11. Argyris C, Shön D. *Organizational Learning: A Theory of Action Perspective*. Reading, MA, USA: Addison-Wesley Publishing Company; 1978.
12. Hounsgaard J. Patient safety in everyday work. Learning from what goes right [MSc thesis]. University of Southern Denmark; 2016. http://functionalresonance.com/onewebmedia/Hounsgaard%20(2016).pdf (Accessed 20 April 2018).
13. Usher R, Bryant I. *Adult Education as Theory, Practice and Research*. London, UK: Routledge; 1989.
14. Argyris C, Shön D. *Theory in Practice: Increasing Professional Effectiveness*. San Francisco: Jossey Bass; 1974.
15. Argyris C. *Overcoming Organizational Defenses: Facilitating Organizational Learning*. Boston: Allyn and Bacon; 1990.
16. Edmondson AC, Lei Z. Psychological Safety: The History, Renaissance, and Future of an Interpersonal Construct. *Annu Rev Organ Psychol Organ Behav*. 2014;1:23-43.
17. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med*. 2006;355:2725–2732.
18. Bosk CL, Dixon-Woods M, Goeschel CA, Pronovost PJ. Reality check for checklists. *Lancet*. 2009;374:444-445.
19. Shojania KG, Dixon-Woods M. "Bad apples": time to redefine as a type of systems problem? *BMJ Qual Saf*. 2013;22:528-531. doi: 10.1136/bmjqs-2013-002138
20. Pronovost PJ, Cleeman JI, Wright D, et al. Fifteen years after *To Err is Human* : a success story to learn from. *BMJ Qual Saf*. 2016;25:396-399. doi: 10.1136/bmjqs-2015-004720
21. Dixon-Woods M, Leslie M, Tarrant C, et al. Explaining Matching Michigan: an ethnographic study of a patient safety program. *Implement Sci*. 2013;8:70. doi: 10.1186/1748-5908-8-70
22. Shojania KG, Thomas EJ. Trends in adverse events over time: why are we not improving? *BMJ Qual Saf*. 2013;22:273-277. doi:10.1136/bmjqs-2013-001935

23. Palomar M, Álvarez-Lerma F, Riera A, et al. Impact of a national multimodal intervention to prevent catheter-related bloodstream infection in the ICU: the Spanish experience. *Crit Care Med*. 2013;41:2364–72.
24. Whitt N, Harvey R, McLeod G, Child C. How many health professionals does a patient see during an average hospital stay? *NZ Med J*. 2007;120:1-8. http://www.nzma.org.nz/__data/assets/pdf_file/0006/17835/Vol-120-No-1253-04-May-2007.pdf (Accessed 20 April 2018).
25. Kwok ESH, Calder LA, Barlow-Krelina E, et al. Implementation of a structured hospital-wide morbidity and mortality rounds model. *BMJ Qual Saf*. 2017;26:439-448. doi:10.1136/bmjqs-2016-005459
26. Kauffmann RM, Landman MP, Shelton J, et al. The Use of a Multidisciplinary Morbidity and Mortality Conference to Incorporate ACGME General Competencies. *J Surg Educ*. 2011;68:303-308.
27. Deis JN, Smith KM, Warren MD, et al. Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement. Agency for Healthcare Research and Quality (US); 2008.
28. Bal G, Sellier E, Tchouda SD, François P. Improving quality of care and patient safety through morbidity and mortality conferences. *J Healthc Qual*. 2014;36:29-36.
29. Levtzion-Korach O, Frankel A, Alcalai H, et al. Integrating Incident Data from Five Reporting Systems to Assess Patient Safety: Making Sense of the Elephant. *Jt Comm J Qual Patient Saf*. 2010;36:402-410.
30. Sari A, Sheldon T, Cracknell A, Turnbull A. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *Br Med J*. 2007;334:79.
31. Olsen S, Neale G, Schwab K, et al. Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place. *Qual Saf Heal Care*. 2007;16(1):40-44.
32. Christiaans-Dingelhoff I, Smits M, Zwaan L, et al. To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports? *BMC Health Serv Res*. 2011;11:49.
33. de Feijter JM, de Grave WS, Muijtjens AM, et al. A comprehensive overview of medical error in hospitals using incident-reporting systems, patient complaints and chart review of inpatient deaths. *PLoS One*. 2012;7:e31125.
34. Flott KM, Graham C, Darzi A, et al. Can we use patient-reported feedback to drive change? The challenges of using patient-reported feedback and how they might be addressed. *BMJ Qual Saf*. 2017;26:502-507.
35. Ashley L, Jones H, Thomas J, et al. Integrating patient reported outcomes with clinical cancer registry data: A feasibility study of the electronic patient-reported outcomes from cancer survivors (ePOCS) system. *J Med Internet Res*. 2013;15:1-19.
36. Hewitt TA, Chreim S. Fix and forget or fix and report: a qualitative study of tensions at the front line of incident reporting. *BMJ Qual Saf*. 2015;24:303-310. doi: 10.1136/bmjqs-2014-003279
37. Jeffs L, Berta W, Lingard L, et al. Learning from near misses: from quick fixes to closing off the Swiss-cheese holes. *BMJ Qual Saf*. 2012;21:287-294. doi: 10.1136/bmjqs-2011-000256
38. Macrae C. The problem with incident reporting. *BMJ Qual Saf*. 2016;25:71-75. doi:10.1136/bmjqs-2015-004732
39. National Patient Safety Foundation. Free From Harm: Accelerating Patient Safety Improvement Fifteen Years After "To Err Is Human." Boston, MA, USA: National Patient Safety Foundation; 2015.
40. Gandhi TK, Berwick DM, Shojania KG. Patient safety at the crossroads. *JAMA*. 2016;315:1829-1830. doi:10.1001/jama.2016.1759
41. Schutz W. Profound Simplicity: Foundations for a Social Philosophy. Hoboken, NJ: John Wiley & Sons; 1982.

42. Pham JC, Girard T, Pronovost PJ. What to do with healthcare Incident Reporting Systems. *J Public Heal Res*. 2013;2:27.
43. Leiden University Medical Center. *Annual Report*. Leiden, the Netherlands; 2015. https://www.lumc.nl/ove/att/80212012710221/1284574/jaarverslag-2015 (Accessed 20 April 2018).
44. Deeny SR, Steventon A. Making sense of the shadows: priorities for creating a learning healthcare system based on routinely collected data. *BMJ Qual Saf*. 2015;24:505-515. doi:10.1136/bmjqs-2015-003934
45. Macrae C. Early warnings, weak signals and learning from healthcare disasters. *BMJ Qual Saf*. 2014;23:440-445. doi:10.1136/bmjqs-2013-002685
46. Dekker SWA. The bureaucratization of safety. *Saf Sci*. 2014;70:348-357. doi:10.1016/j.ssci.2014.07.015
47. VvAA / FMS. *Administratiedruk Medisch Specialisten: Enquête (Ont)regel de Zorg [Dutch]*. https://www.demedischspecialist.nl/sites/default/files/20171117_DEF%20Rapport-administratiedruk-specialisten.pdf (Accessed 20 April 2018).
48. Schuurman A, Bos S, de Wit K, de Graaf R, Wiersinga W. A day in the life of a medical resident on the ward [Dutch]. *Ned Tijdschr Geneeskd*. 2018;161:D2480.
49. De Carvalho PV, Gomes JO, Huber GJ, Vidal MC. Normal people working in normal organizations with normal equipment: system safety and cognition in a mid-air collision. *Appl Ergon*. 2009;40:325–340.
50. Dekker SWA. *Drift into Failure: From Hunting Broken Components to Understanding Complex Systems*. Farnham, UK: Ashgate Publishing Co, ed..; 2011.
51. Hollnagel E, Hounsgaard J CL. *FRAM – The Functional Resonance Analysis Method – A Handbook for Practical Use of the Method.* Middelfart, Denmark; 2014. http://functionalresonance.com/onewebmedia/FRAM_handbook_web-2.pdf (Accessed 9 February 2017).
52. Hutter MM, Rowell KS, Devaney LA, et al. Identification of Surgical Complications and Deaths: An Assessment of the Traditional Surgical Morbidity and Mortality Conference Compared with the American College of Surgeons-National Surgical Quality Improvement Program. *J Am Coll Surg*. 2006;203:618-624.
53. Rutter H, Savona N, Glonti K, et al. The need for a complex systems model of evidence for public health. *Lancet*. 2017;390:2602-2604. doi: 10.1016/S0140-6736(17)31267-9
54. Hollnagel E, Wears R, Braithwaite J. *From Safety-I to Safety-II: A White Paper.* Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.; 2015. https://resilienthealthcare.net/wp-content/uploads/2018/05/WhitePaperFinal.pdf (Accessed 9 February 2017).
55. Hollnagel E. Before you begin building the model. http://functionalresonance.com/how-to-build-a-fram-model/index.html Published 2016 (Accessed 5 April 2018).
56. Hollnagel E. *The ETTO Principle - Efficiency-Thorougness-Trade-Off: Why Things That Go Right Sometimes Go Wrong.* Farnham, Surrey, UK: Ashgate Publishing; 2009.
57. Shorrock S, Leonhardt J, Licu T, Peters C. *Systems Thinking for Safety: Ten Principles - A White Paper. Moving towards Safety-II.*; 2014. https://www.skybrary.aero/bookshelf/books/2882.pdf (Accessed 20 April 2018).
58. Braithwaite J, Wears RL, Hollnagel E. Resilient health care: Turning patient safety on its head. *Int J Qual Heal Care*. 2015;27:418-420.
59. Card AJ. The problem with 5 whys'. *BMJ Qual Saf*. 2017;26:671-677. doi:10.1136/bmjqs-2016-005849
60. Dieckmann P, Clemmensen M, Lahlou S. How the medication room really dispenses the medication. In: *Resilient Health Care Net (RHCN) Meeting*. ; 2016. http://resilienthealthcare.net/onewebmedia/Dieckman_RHCN-5.pdf (Accessed 5 April 2018).
61. Dekker S. *Just Culture: Restoring Trust and Accountability in Your Organization*. Boca Raton (FL): CRC Press; 2016.

62. Dekker SWA, Hugh TB. A just culture after Mid Staffordshire. *BMJ Qual Saf*. 2014;23:356-358. doi:10.1136/bmjqs-2013-002483
63. Fairbanks RJ, Wears RL, Woods DD, et al. Resilience and resilience engineering in health care. *Jt Comm J Qual Patient Saf*. 2014;40:376-383.
64. Bracho A. People Are Solutions, Not Problems and Other Chronic Health Lessons Learned. http://www.ihi.org/communities/blogs/people-are-solutions-not-problems-and-other-lessons-learned (Accessed 21 April 2018).
65. Hollnagel E. *Introduction to the Resilience Analysis Grid (RAG)*.; 2015. http://erikhollnagel.com/onewebmedia/RAG Outline V2.pdf (Accessed 5 April 2018).
66. Clay-Williams R, Hounsgaard J, Hollnagel E. Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implement Sci*. 2015;10:125.
67. Baines RJ, Langelaan M, de Bruijne MC, et al. Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ Qual Saf*. 2013;22:290-298.
68. Landrigan C, Parry G, Bones C, et al. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med*. 2010;363:2124-2134.
69. Langelaan M, Broekens M, de Bruijne M, et al. *Monitor Zorggerelateerde Schade 2015/2016: Dossieronderzoek Bij Overleden Patiënten in Nederlandse Ziekenhuizen*.; 2017. https://www.nivel.nl/sites/default/files/bestanden/Rapport_Monitor_Zorggerelateerde_Schade_2017.pdf (Accessed 5 April 2018).
70. Vincent CA. Analysis of clinical incidents: a window on the system not a search for root causes. *Qual Saf Heal Care*. 2004;13:242-243.
71. Huzzard T, Hellström A, Lifvergren S. Whole System in the Room: Toward Systems Integration in Healthcare. *Health Commun*. 2017;0:1-9.
72. Saurin TA. Removing Waste While Preserving Slack: The Lean and Complexity Perspectives. In: LC3 2017 Volume II – Proceedings of the 25th Annual Conference of the International Group for Lean Construction (IGLC), Walsh, K., Sacks, R., Brilakis, I. (eds.), Heraklion, Greece, pp. 217-224.
73. Hounsgaard J. Using FRAM as a Quality Improvement Tool in Health Care. In: *The FRAMily Meeting*. Munich, Germany; 2013. http://functionalresonance.com/onewebmedia/FRAMily_2013_Hounsgaard.pdf (Accessed 20 April 2018).
74. Catchpole K, Neyens DM, Abernathy J, Allison D, Joseph A, Reeves ST. Framework for direct observation of performance and safety in healthcare. *BMJ Qual Saf*. 2017;26:1015-1021. doi:10.1136/bmjqs-2016-006407
75. Braithwaite J, Churruca K, Ellis L, et al. Complexity Science in Healthcare - Aspirations, Approaches, Applications and Accomplishments: A White Paper. Vol 1. Sydney, Australia; 2017. http://aihi.mq.edu.au/resource/complexity-science-healthcare-white-paper (Accessed 5 April 2018).
76. Reed JE, Howe C, Doyle C, et al. Simple rules for evidence translation in complex systems: A qualitative study. *BMC Medicine*. 2018;16:92. doi: 10.1186/s12916-018-1076-9