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MIXED METHODS:

IMPROVING THE ASSESSMENT OF SAFETY CULTURE IN HEALTHCARE

SAFER, SMARTER, GREENER

Acknowledgement
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CONTENT

"A positive culture is essential for safety and sustainability in healthcare"

Sven Mollekleiv, Senior Vice President, DNV GL Sustainability

EXECUTIVE SUMMARY

Safety culture is the way in which organizations live and breathe safety [1-7]. It is the foundation of delivering quality care as a positive safety culture is linked to favorable staff safety behavior and patient outcomes [8-10].

If there is to be improvement in the quality of healthcare, the assessment of safety culture is paramount as the results have the potential to enable an organization to understand its strengths and weaknesses with regards to where they should target change. For example, assessment of safety culture can contribute to the decision making processes for healthcare leaders dealing with challenges related to lack of trust within the organization.

In this position paper, we make the case for using a mixed methods approach, in which quantitative and qualitative methods are combined, to improve the accuracy of results for when a healthcare organization's safety culture is assessed. The mixed methods approach has been tested by DNV GL, Strategic Research and Innovation, Healthcare Program, in healthcare settings in several countries. Early results from the testing and development are outlined in this paper. The results suggest that a mixed methods approach is useful in assisting healthcare organizations to better understand their safety culture in order to improve practices.

Preliminary results of the studies offer suggestions for practical steps for the assessment of safety culture in healthcare: combining quantitative and qualitative assessment. This position paper describes how best to use the results and achieve maximum value for organizational learning.

"[Safety culture matters because] the simple fact that companies with similar technology, management systems, and other pre-conditions to safety have significant differences in their safety performance"

– Sondre Øie, Senior Consultant, DNV GL Oil and Gas

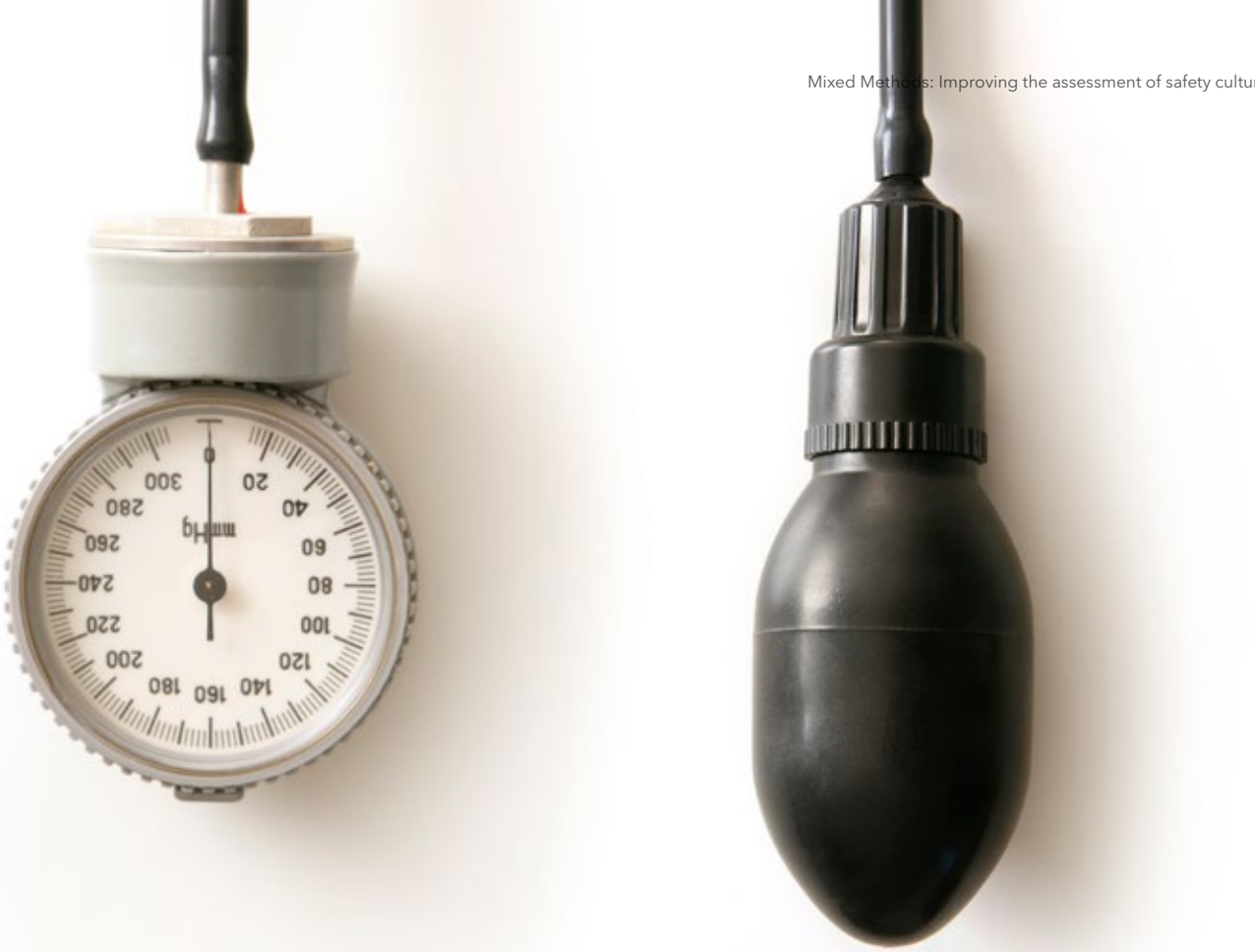
BACKGROUND

DNV GL has worked with safety-critical sectors to safeguard life, property and the environment since 1864. As a global organization operating in more than 100 countries, DNV GL is in a unique position to make a global impact for a safer and sustainable healthcare.

To achieve a safer and sustainable healthcare, it is important for organizations first to follow a quality management system that describes a set of procedures to achieve the desired results [11]. This is because the larger and more complex the organization, the more likely that procedures need to be recorded to ensure everyone is clear on their roles and tasks. A quality management system allows organizations to demonstrate their ability to offer services that consistently meet the needs of end-users, as well as statutory and regulatory requirements. A commitment to continual improvement through organizational learning that develops a positive safety culture, structures and processes in the pursuit of required outcomes is foundational to a quality management system.

In recent decades, research on quality improvement has led to a much greater understanding of the challenges and opportunities for delivering safer care. Strategies and tools, such as checklists, have become standard practice in many countries in the hope to promote further safe and effective healthcare [12-15]. Although these tools and strategies are a vital part of safer healthcare, they can easily fail to be applied in different contexts if leaders disregard the sociocultural context on which such success was initially built. Safety improvement within healthcare organizations requires a deeper change to the cultural practices and social norms within an organization, rather than simply implementing an intervention 'off the shelf'. It is thus essential to investigate the underlying motivation of healthcare staff and to engage them in co-creating a change. Moving toward and securing a positive culture of safety in healthcare is a way for organizations to be proactive to manage risks for end-users.

Research has demonstrated an association between a generative, strong safety culture and positive impact on staff safety behaviors and patient outcomes [8-10]. For example, several studies have found a link between improved safety culture and reduced readmission rates, length of stay and medication errors [8]. The assessment of safety culture is described as a critical part of the journey to achieve safer healthcare [10, 16-18]. This is because safety culture assessment provides valuable information to an organization regarding their managers' and staff's safety related perceptions and attitudes that can be used to identify areas of improvement.



Tools for assessing safety culture are traditionally quantitative, with highly standardized numerical measurements through questionnaires or surveys [10]. Quantitative methods of assessment are particularly useful in providing an overview of staff attitudes and beliefs. In comparison, qualitative assessments that gather data through, for example, interviews or focus groups, can contribute to a better sense of the underlying culture by enabling an in-depth exploration of why an individual or group has a particular set of beliefs and values [19].

Therefore, to capture fully the culture of safety in an organization, an assessment that combines both quantitative and qualitative tools is considered vital. This approach to assessment, termed 'a mixed methods approach', has been tested in hospitals in several countries by DNV GL, Strategic Research and Innovation, Healthcare Program. The mixed methods approach has been met with positive feedback by these hospitals for the deeper understanding of where safety culture stands within the areas being assessed.

To achieve a global impact, we are committed to building partnerships with others to contribute actively to the scale and spread of the mixed methods approach being practiced around the world.

"[Safety culture matters because] when people do not accurately take into account risk and safety issues when performing their tasks, incidents and major accidents can [occur]"

- Bill Nelson, Principal Consultant, DNV GL Offshore Oil and Gas, Onshore Pipelines, and Nuclear Power, Environmental and Navigational Risk

"DNV GL is about trust and confidence. For more than 150 years we have assessed safety critical organizations' performance so that end-users can be confident that the services they are using are safe and reliable. Understanding the strengths and weaknesses of an organization's safety culture is core to this because having a positive safety culture is an essential element of producing desired outcomes"

Rune Torhaug, Director, DNV GL Strategic Research and Innovation

"If I look at the mass, I will never act. If I look at the one, I will"

Mother Teresa [22]

The USA (2001): The death of 18-month Josie King resulted from severe dehydration and misuse of narcotics by hospital staff following the treatment of first and second degree burns [23]

Canada (2007): The death of 17-year old Jessica Barnett resulted from receiving no treatment for her treatable heart defect due to misplaced paperwork, misread test results and repeated misdiagnosis [24]

Mexico (2009): The death of 15-year old Roberto Gallardo resulted from misdiagnosis [25]

Argentina (2012): The near death of a new born Tiny Luz Milagros after surviving 12 hours in a coffin due to mistakenly being announced dead 20 minutes after birth [26]

Norway (2009): The death of a two- year old Daniel Flemmen Ødegård resulted from having a breathing tube mistakenly placed in his esophagus instead of his trachea (air pipe) [29]

Japan (2014): The death of 12 children resulted from being mistakenly administered a banned sedation for use on children at Tokyo Women's Medical University Hospital [30]

India (2014): The death of 11 women at a free government-run camp in the central state of Chhattisgarh resulted from sterilization operations gone wrong [31]

Taiwan (2011): Five patients were mistakenly transplanted HIV infected organs [32]

South Africa (2012): Shabbier Nagel's leg was mistakenly amputated when he went for a scheduled heart surgery at Steve Biko Academic Hospital in Pretoria [27]

Australia (2014): Two newborn babies were mistakenly given HIV infected breast milk at Caboolture and Logan Hospitals [28]

"First do no harm"

The map on the previous pages highlights a few of the patient safety incidents that happen around the world every day. They raise the question: how can healthcare that aims to heal and support patients, injure and even kill?

Although healthcare successfully treats and cares for millions of people every day, it remains unacceptably dangerous [34]. Estimates suggest that up to 17% of hospitalized patients experience at least one adverse event [35] of which researchers argue that up to 70% of these could be prevented [35-38].

In the world, annual rates suggest that approximately 10% of the 421 million hospitalizations are associated with some degree of adverse event, making unsafe care "the 14th leading cause of morbidity and mortality, comparable to the burden from tuberculosis or malaria" (p. 813) [39].

"Despite advances in modern medicine, patients around the world are still placed at risk by the very organizations designed to alleviate their illness" (p. 3) [33]

CO-CREATING A SAFER HEALTHCARE

Safer healthcare can be a reality for all. At DNV GL, our vision is one where healthcare creates value by delivering services that are free from preventable harm, personalized to individual needs, seamless in its delivery, effective, efficient and with equitable access (p. 6) [40]. Accordingly, we are committed to making a contribution in improving the culture of safety in healthcare organizations. Improving safety culture in healthcare is arguably an essential aspect of building the foundation for the delivery of safer healthcare because it influences the way in which care is organized and delivered and, therefore, the outcomes produced (see Figure 1) [8].

Safety culture can be defined as the organizational culture that directly or indirectly influences patient safety [1-7]. To be specific, safety culture is the elements or parts of organizational culture that influence the organizational members' attitudes, beliefs, perceptions, and behaviors, which have an impact on the level of safety within the organization [7].

Evidence from safety critical sectors including healthcare suggest that a good safety culture can help make organizations less vulnerable to incidents and accidents [4, 5, 7-10, 41-43]. When the culture 'turns bad', it is likely that failures, such as unintended medical errors, can occur. Therefore, "…achieving a vastly safer [health system] will depend far more on major cultural change than on a new regulatory regime" (p. 11) [44].

"Safety culture is an important indicator for safety performance"

– Koen van de Merwe, Senior Human Factors Consultant, DNV GL Operational Safety

Safety culture is also a leading rather than a lagging indicator of safe healthcare, and by assessing and monitoring their safety culture, an organisation can see if things are as they should be before they start to go wrong and intervene early if needed.

In addition, assessing safety culture after the implementation of a change can serve as a check-up tool to inform leaders how a new change is being sustained in the frontline: closing the feedback loop (Figure 1). Sustainable change requires consistency from leaders to provide a stable environment where staff can maintain their newly learned assumptions, practices, and behaviors. For example, teamwork skills acquired during simulated team training should be easily applied to real world settings. Otherwise, time and effort spent in training staff in a simulator are likely to "resemble time spent in a theme park" (p.1411) [45].

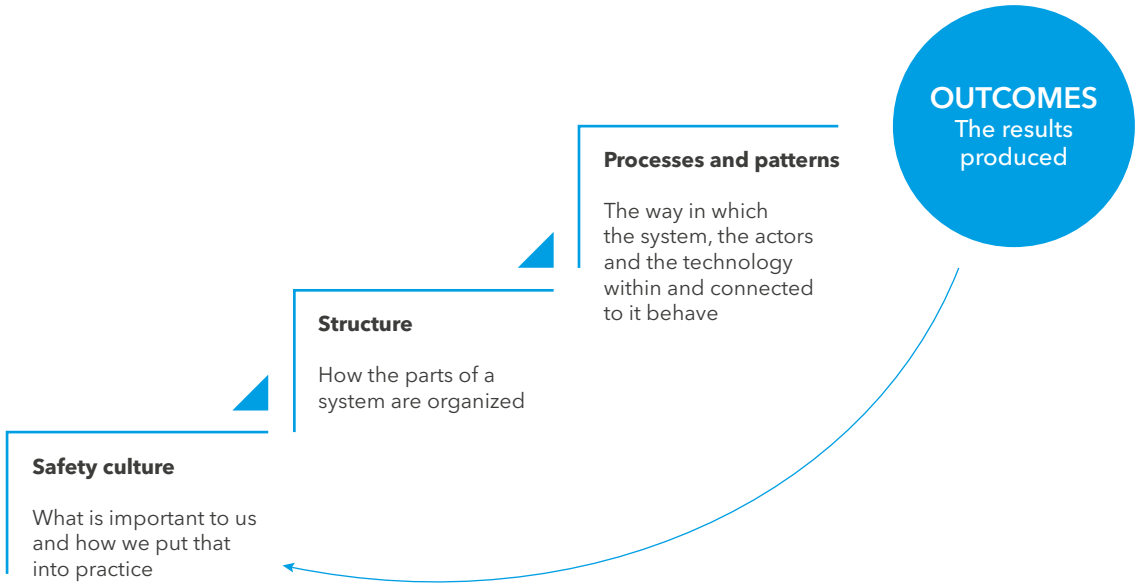


Figure 1. Loop of interactions between safety culture, structure, processes and patterns, and outcomes in healthcare [40]

"Safety culture is the awareness of safety by the people in the organization ...I also like the saying [it's] what we do when no one is watching"

- Tore Relling, Senior Consultant, DNV GL Maritime-Advisory

THE CREATION AND SOCIALIZATION OF ORGANIZATIONAL CULTURE

It is important first to understand how a culture in organizations is created and socialized so that the culture can be re-created and re-socialized within the organization to improve safety practices.

Simply put, organizational culture is created when individuals start to interact (See Figure 2) [4, 46]. During social interactions, individuals project their interpretation of the world onto each other through verbal and non-verbal actions. These social interactions influence assumptions and beliefs that create behavioral patterns among the individuals involved.

Culture then can influence safety when the individuals involved do not consider alternative ways of carrying out a process even when a modification in their actions is needed to prevent an incident. In this way, the culture and the behaviors it fosters become 'taken for granted'.

Organizational culture has attributes that can be visualized as three different layers: artifacts, espoused beliefs and values, and underlying assumptions (See Figure 3) [47]. Because organizational culture depends on characteristics of the interactions of individuals, one should expect multiple cultures, or sub-cultures, within an organization [1].

An example of the multiple cultures is illustrated in Figure 3 with Nurse Anna and Nurse Steve behaving differently with physicians and surgeons in an ICU and in an Operating Theater. See Figure 2 for the process how Nurse Anna and Nurse Steve progressively become the agents themselves that project the different ways to interact with physicians and surgeons in the ICU and the Operating Theater to other new nurses.

In this example, a culture can influence patient safety when Nurse Anna observes something unusual with a patient in the ICU and does not dare to speak up to a physician or surgeon, and, consequently the observation is not being acted upon.

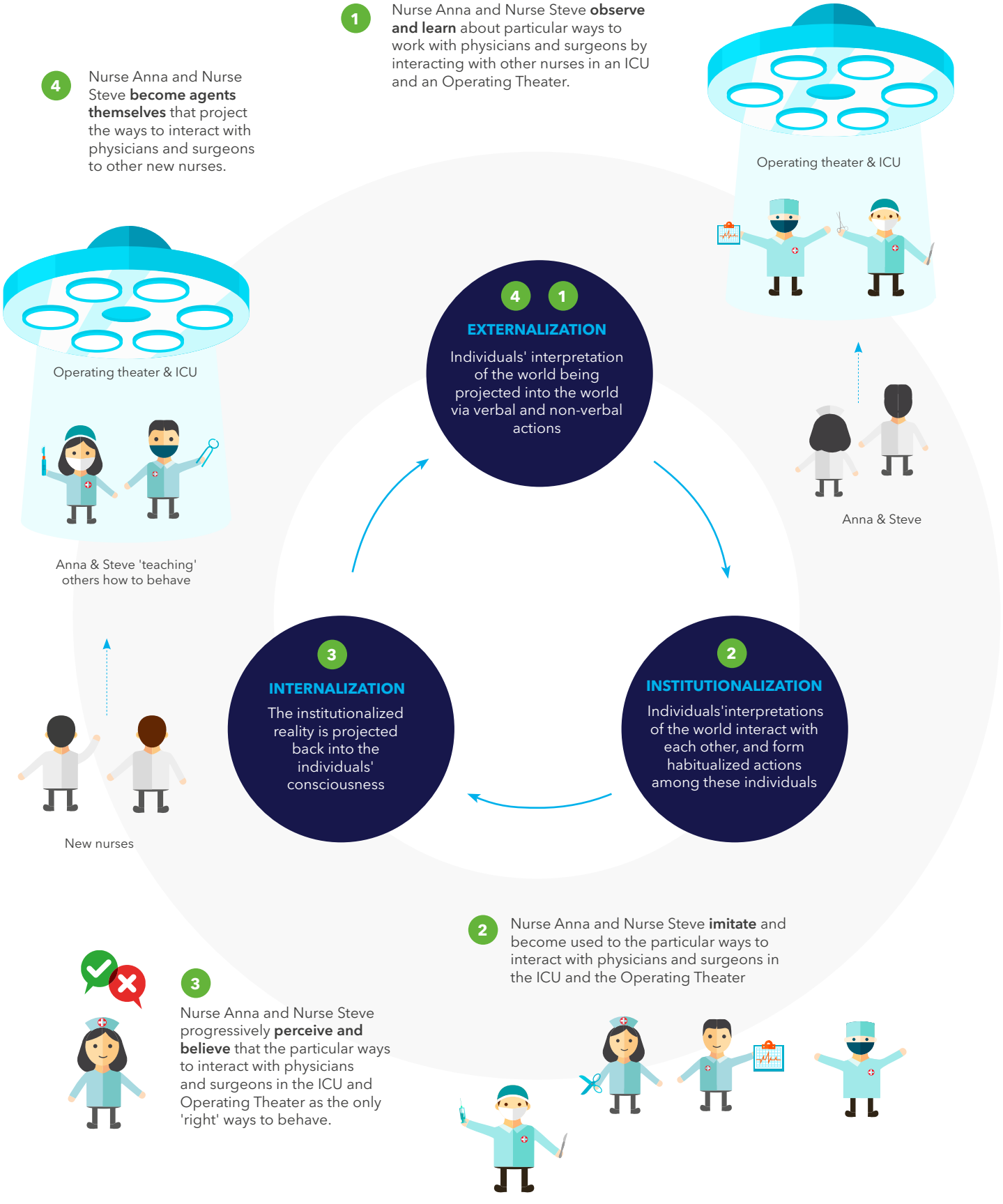


Figure 2. Illustration on how culture is created and an example of the socialization of culture [4, 46]

NURSE STEVE AT THE OPERATING THEATER

NURSE ANNA AT THE ICU

Nurse Steve is observed laughing together with some physicians and surgeons.

ARTIFACTS
Observable behaviors, visible formal organizational structures and processes

Nurse Anna is observed having very limited conversation with physicians and surgeons, even avoiding eye contact with them.

Nurse Steve said that the physicians and surgeons in the Operating Theater are very approachable and friendly.

ESPOUSED BELIEFS AND VALUES
Beliefs and values articulated by the individuals involved. However, the articulated beliefs and values may not always be consistent with their behaviors. This inconsistency is explained by the deepest layer: 'Underlying Assumptions'

Nurse Anna said that the physicians and surgeons in ICU are aloof and 'scary', "Better to talk with them as little as possible".

Nurse Steve explains that, "It is just the way it is that everyone working here is part of one big family".

UNDERLYING ASSUMPTIONS
Unconsciousness, taken-for granted beliefs, perceptions, thoughts and feelings. The ultimate sources of values and actions.

Nurse Anna explains that, "It is just the way it is that nurses and physicians and surgeons are two different teams in the ICU".

Figure 3. Layers of culture after being created with an example [47]

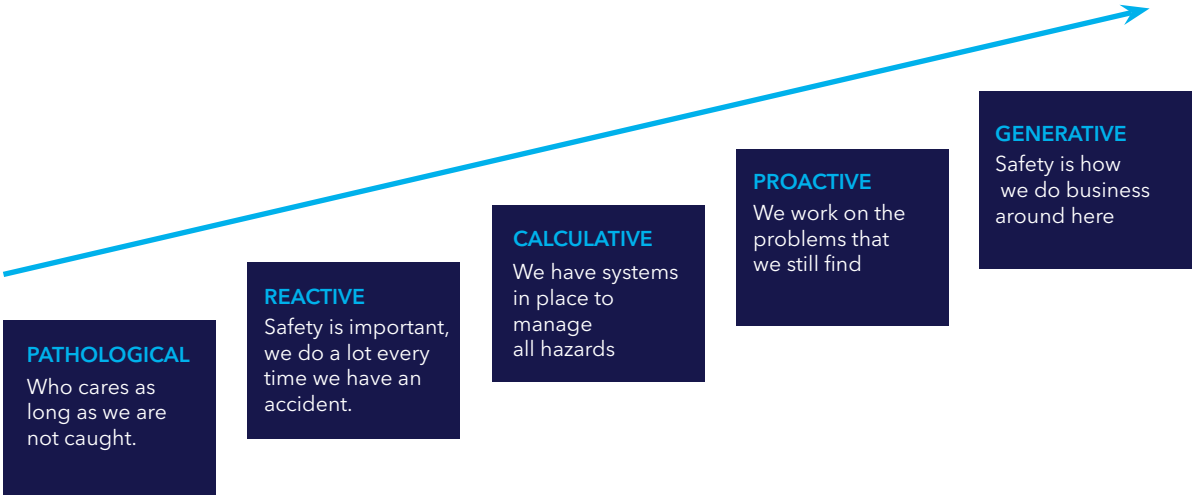


Figure 4. Evolution of safety culture [5, 6]

THE IDEAL SAFETY CULTURE

The maturity of a safety culture can range from pathological (preoccupations with power, needs, and glory) to generative (preoccupations with the mission) [5], as illustrated in Figure 4 [6]. The closer an organizational culture is to demonstrating the characteristics of the generative level, the safer the culture is.

In addition to the patients and their families, the healthcare staff involved in unintended healthcare errors are also negatively impacted and are subject to a great amount of suffering, for which they are defined as the 'second victims' [48-50]. Even when an error is unintended and the result of underlying system failures, healthcare staff involved in an incident are too often blamed and inappropriately punished through dismissal from their post, prosecution and loss of license to practice [48, 49].

Unfortunately, the act of 'criminalizing' the healthcare staff involved has a paradoxical effect for the organizations' good intent of improving patient safety (See Figure 1). Such responses imply that the error happened only because of the healthcare staff member involved and that it must have been due to incompetence, inexperience, or lack of dedication. As a result, attention is diverted from the investigation of systematic improvements that could decrease future errors.

GENERATIVE SAFETY CULTURE: 'SAFETY IS HOW WE DO THINGS AROUND HERE'

When an organization has achieved the most mature cultural level (i.e. a generative safety culture), the organization will demonstrate the following characteristics [51]:

- **An open culture.** The organizational members are prepared to look proactively at the weaknesses in the design and delivery of care and to report their errors and near misses. As part of this process, data are analyzed, fed back to staff and translated into shared actions to lessen risk.
- **A flexible culture.** The organization respects the skills and knowledge of front-line staff, which allows control and authority (combined with support) to pass to experts closest to patients.
- **A just culture.** The organizational members agree on and understand acceptable and unacceptable levels of behaviors. Within the organization, there is an atmosphere of trust and accountability, rather than an absence of blame, in which people are encouraged to report and discuss safety-related information and where procedures are in place to identify and manage poor performance.
- **A learning culture.** There is a willingness and competence to draw appropriate conclusions from risk management and safety management information systems, together with a will to implement reform where it is indicated.

THE IMPACT OF ORGANIZATIONAL CULTURE ON RISK: A SYSTEMS UNDERSTANDING

For safety culture to be successful, it must influence all the members of an organization. Taking a systematic approach to safety is considered critical in ensuring that the system will provide a continuous cycle of improvement.

Like healthcare, other safety-critical sectors such as aviation and oil and gas, are also considered as a complex system. Despite the rapid evolution of technology and increased complexities characterized by the aviation and oil and gas industries, these safety-critical industries have achieved global recognition for their extraordinary safety performance [52]. Sadly, the healthcare industry has not made similar strides in its approach to safety and has been described as "a decade or more behind other safety-critical industries in its attention to ensuring basic safety" (p. 5) [53].

Within a linear system, the source of error is easy to identify as events precede the accident in a fixed order. However, due to the complexity of the system, healthcare is made up of many networks of components (i.e., hospitals, clinics, patient homes, nursing homes, rehabilitation units, families, and patients) and nonlinear interactions on different scales (i.e., the patient, family, medical centre, and government). These networks and nonlinear interactions can often produce unintended incidents that are difficult to detect through traditional linear analysis logic.

As a result, healthcare safety researchers and practitioners have adopted the lessons learned from other more successful safety-critical industries in both the conceptualization and practice of understanding incidents and accidents in healthcare. By taking a systematic approach to safety, healthcare organizations are encouraged to embrace discussions of factors related to the systems, processes, structure, and equipment within the organization that influences the likelihood of an error, rather than focusing on the individuals.

THE SWISS CHEESE MODEL (SCM)

The Swiss Cheese Model (SCM) [54] is used here to illustrate and understand medical errors in

"The minute an adverse event occurs, that caregiver is no longer a caregiver. He or she is your patient."

-Julie Thao, Former nurse and Texas Medical Institute of Technology (TMIT) patient safety champion and patient advocate team member [81]

healthcare. The SCM is commonly used as an accident causation model within various safety-critical sectors. This model describes that failure more often than not involves the concurrence of several contributing factors arising from different levels of the system. The SCM is thus complementary with risk analysis theory and design in complex systems.

Although the SCM has been subject to some criticism, its popularity is due to its consideration of a complex system with many networks and interactions. Within the SCM, contributing factors can occur from a wide range of domains from unsafe acts, such as a physician prescribing the incorrect dosage, to organizational errors, such as leaders who do not support a reporting culture or the managing of errors for fear of litigation.

Within the model's metaphor, the cheese slices represent a series of layers or barriers that contain holes that unsystematically, open and close. The *holes* – unintended weaknesses and latent factors - must align before an error occurs. When all the holes are aligned, an accident occurs. The model demonstrates that the majority of errors in complex systems, such as a healthcare organization, are rooted in the culture and system (See Figure 5).

WAYNE JOWETT STORY [55]: ILLUSTRATING THE SWISS CHEESE MODEL

On January 4, 2001, 18-year-old Wayne Jowett presented to Queens Medical Center Nottingham (QMC) for chemotherapy treatment as part of his medical maintenance program following the successful treatment of leukemia. Wayne died after a toxic cancer drug was mistakenly injected into his spine.

The Department of Health (DoH) inquiry reported Wayne died as a result of a "complex amalgam of human organizational, technical and social interactions" (p. 40) at the hospital where he received the injection [56]. Figure 5 illustrates the incident.

The death of Wayne Jowett illustrates how human, technical and organizational contributing factors in healthcare can come together and result in error. To date, efforts to improve safety and resolve unintended medical errors are commonly reactive, rather than proactive.

Reactive approaches to safety, such as accident investigations, although at times vital, do not always target the critical components of the system required to make improvements. A proactive approach to safety requires the examination of a system prior to an accident with regard to its organizational influences. Therefore, an organization that is characterized by a culture of continuous effort towards the goal of maximum attainable safety is vital to the success of patient safety [57].

"The implementation of a robust quality management system to support the delivery of healthcare both supports and is dependent on the development of a shared culture and an organizational mindset that promotes openness and the will to improve"

Stephen McAdam, Global Healthcare Technical Director, DNV GL

Assessment results of safety culture can be used as indicators for patient safety. Efforts to understand and improve safety culture target the first *cheese slice*.

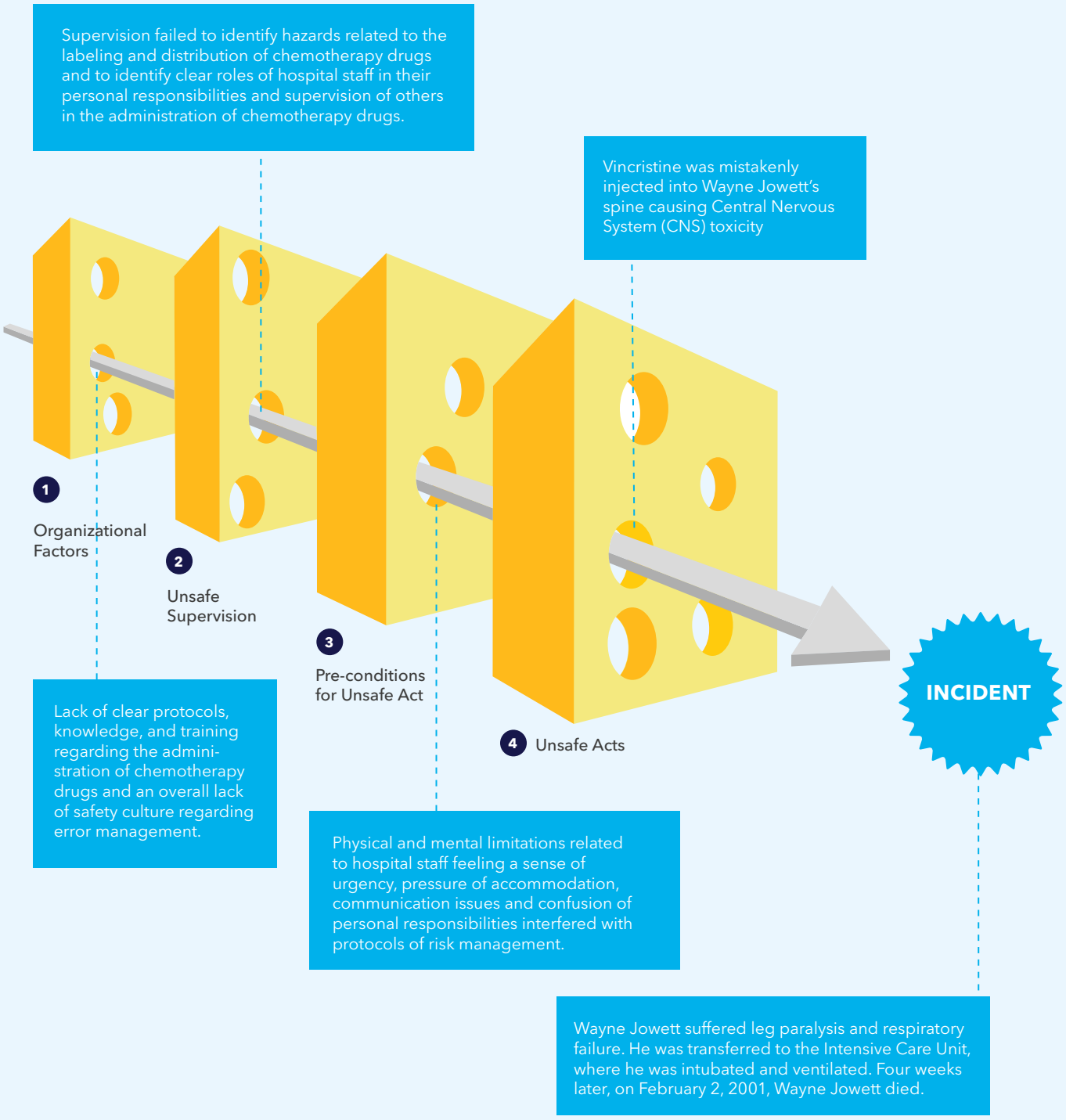


Figure 5. The Swiss Cheese model illustrates the contributing factors led to Wayne Jowett's tragic death [54]

MIXED METHODS FOR SAFETY CULTURE ASSESSMENT

"One size does not fit all"

In understanding safety culture, one should avoid repeating the *blind men and the elephant* tale (See Figure 6) [58]. The tale highlights that it is easy for us to disregard perceptions that are different from our own in understanding a phenomenon. In fact, understanding safety culture requires a robust method of assessment that can capture different perceptions and facilitates a structured exploration of underlying values and beliefs [59]. This is especially because safety culture is not a tangible thing that is readily observable. Mixed methods assessments can thus produce a more accurate profile by taking into account different perspectives and facilitating the development of a plan for improvement [19].

A mixed methods approach for assessing safety culture combines qualitative and quantitative tools in an effort to gain a better sense of the underlying culture (See Table 1 for a summary of benefits). Quantitative assessment tools are standardized and include numerical measurements through, for example, questionnaires or surveys. In contrast, qualitative assessment tools for safety culture can be employed through, for example, interviews or focus group.

Research has demonstrated benefits to the mixed methods approach for tailoring and implementing improvements within organizations [4, 10, 41]. Mixed methods approaches are more effective in assessing safety culture than using one method alone [10, 19, 60-63] because "the use of safety culture surveys as the only method of assessing safety culture is often of limited value in identifying strategies to potentially improve the safety culture" (p. 497) [64]. Despite this, the majority of tools to assess safety culture in healthcare are quantitative such as based on surveys or questionnaires [10].

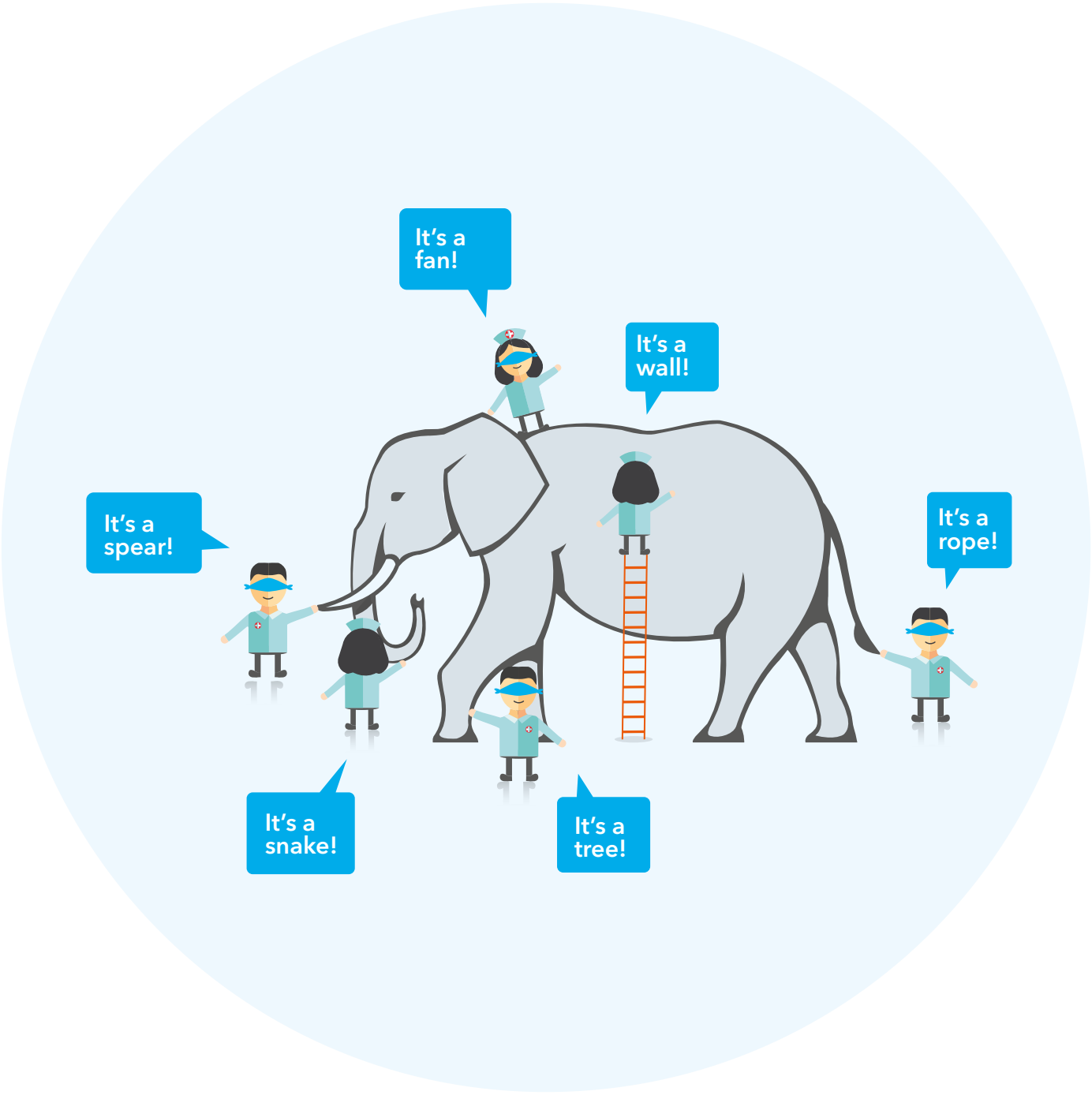


Figure 6. The tale of blind men and an elephant originated in India [58]

	QUANTITATIVE METHOD	BENEFITS OF MIXED METHODS	QUALITATIVE METHOD
Objectives	Comparative: Which groups demonstrate good and poor safety culture, what are the strengths and weaknesses of the areas being assessed, and benchmarking within and between hospitals	To gather multiple perspectives to have a better understanding of the sociocultural conditions of the areas being assessed as a basis for improvement	Explorative: To understand underlying issues and motivation, meanings and attitudes, e.g. the mechanism behind the groups that demonstrate good or poor safety culture
Perspectives	Superficial: To cover the greatest possible number of respondents for assessment	To have an overview and understanding of the strengths and weaknesses of the areas being assessed	Depth: To gather the richest and most descriptive possible information
Form of data collection	■ Numerical data gathered from structured instruments such as surveys or questionnaires ■ Instruments are likely to be relatively economical	Multiple forms allow multiple perspectives	■ Qualitative data (e.g. interview transcriptions, texts) gathered using, for example, interviews, focus groups, policy textual analysis and direct observations ■ Gathering qualitative data is usually time and resource consuming
Data analysis	Data are analyzed using statistics to find differences between and within groups. This analysis can be used to target areas for further analysis using qualitative assessment.	Overview from quantitative assessment and rich description from qualitative assessment provide a more accurate understanding of the safety culture being studied	Data are analyzed to search for patterns, themes, and holistic features
Results	Different safety culture profiles between and within groups	Stimulating organizational learning: 1. Corroborated findings can be used for groups to learn from each other's strengths 2. Findings can be used for tailoring improvement efforts for specific areas	■ Themes and patterns ■ Explaining quantitative data ■ Discovery to other relevant topics

Table 1. Different characteristics of quantitative and qualitative methods and the benefits of mixed methods for safety culture assessment [19, 21]

TESTING MIXED METHODS IN HEALTHCARE SETTINGS

DNV GL has piloted a mixed methods approach for the assessment of safety culture in healthcare settings. Seven different hospitals based in Scandinavia, the United Kingdom, and China participated in the studies (See Figure 7). Participants were from different clinical areas such as maternity, the medical assessment unit, and surgery unit.

For the purpose of this position paper, the benefits of the mixed methods approach in one Scandinavian hospital will be discussed below. This study illustrates the importance of combining qualitative and quantitative methods in assessing safety culture to gain a deeper understanding of the culture within an organization.

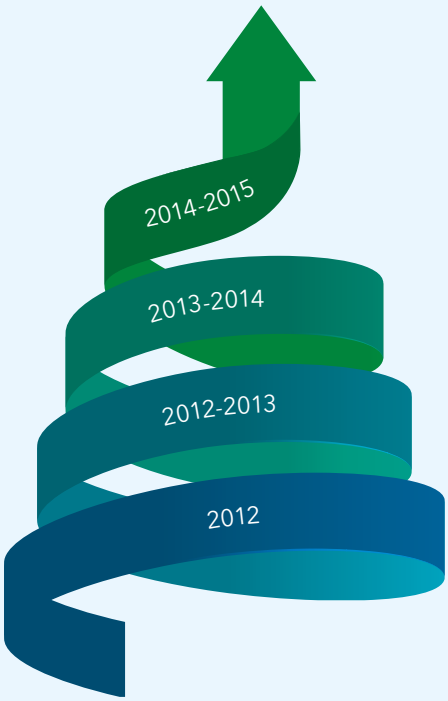
The topics underpinning safety culture, such as the importance of teamwork and management, are universal. This is reflected in the research, including the validation of a safety culture survey such as the safety attitudes questionnaire (SAQ) in different countries [42, 65-75]. The precise terms used, however, are different in local cultures and contexts. For example, the occupational titles of clinical staff and how a hospital is organized differ from organization to organization and country to country. As a result, DNV GL is adapting and refining the methods for each setting in which they are used. The early results presented here are from the initial work in Scandinavia. Future publications will describe the methods and results from other countries i.e. the UK and China.

SEQUENTIAL MIXED METHODS APPROACH

This means that prior to conducting a qualitative assessment, such as interviews, a quantitative assessment and subsequent analysis is conducted [20, 21] (See Figure 8). This sequence is important for the following reasons:

- **Survey results identify areas of improvement.** A quantitative analysis of the safety culture assessment can provide the organization clues to which areas are more problematic than others. The organization can then target these areas for the qualitative assessment interviews to explore 'why' the areas demonstrate pathological and some others demonstrate generative safety culture.

- **Survey results assist in hypothesis development.** A qualitative analysis of the safety culture assessment can provide the organization information to develop a hypothesis that can be further explored through a qualitative assessment. For example, if an organization has pre-selected specific units to be assessed, the survey results can provide information about the units' strengths and weaknesses before exploring them deeper with interviews. Even if the units have similar survey results, interviews will still provide valuable information because the underlying issues of the units may not be similar, and the differences between them can directly influence improvement efforts.



04 **2014-2015**
6th and 7th pilots on combined survey, interviews, and a work-shop in public and private Maternity hospitals in China.

03 **2013-2014**
4th and 5th pilots on combined survey, interviews, and a workshop in two other hospitals in the UK.

02 **2012-2013**
2nd and 3rd pilots on combined survey and interviews in two hospitals in the UK.

01 **2012**
1st pilot on combined survey and interviews in a hospital in Scandinavia.

Figure 7. On-going development of DNV GL pilot studies in safety culture assessment (Dated December 2014).

THE USE OF SURVEYS AS A METHOD FOR QUANTITATIVE RESEARCH

There are multiple survey tools that assess safety culture in healthcare, but there are only a few that publish the process of validation of the surveys [8-10, 76] such as the Safety Attitudes Questionnaire (SAQ) [18] and the Hospital Survey for Patient Safety Culture (HSOPSC) [16, 77].

For DNV GL's pilot studies, the SAQ 'short form' [78] was used and distributed to the participants using paper-based or electronic based formats or both, according to the local requirements. In general, it took participants 10-20 minutes to complete the survey. The SAQ is publicly available and has been translated and validated into many different languages [42, 65-75]. The SAQ has previously been validated in healthcare in several countries including the UK, USA and New Zealand. The validation of the SAQ was based on more than 10,000 clinician participants in 203 clinical areas.

The SAQ is a 36 item questionnaire assessing 6 safety culture topics (or 'dimensions') including safety climate, teamwork climate, perceptions of management, job satisfaction, stress recognition and working conditions. The SAQ responses are given on a 5-point Likert scale (1 = disagree strongly, 2 = disagree slightly, 3 = neutral, 4 = agree slightly, 5 = agree strongly) including a 'not applicable' option for each item.

THE USE OF INTERVIEWS AS A METHOD FOR QUALITATIVE RESEARCH

Consistent with the sequential mixed methods approach, following the analysis of the quantitative data, interviews were conducted.

Interview guide and structure

The focus of the interviews was on having a discussion to confirm and understand survey results and the safety culture in general. An interview guide originally developed within transportation sector

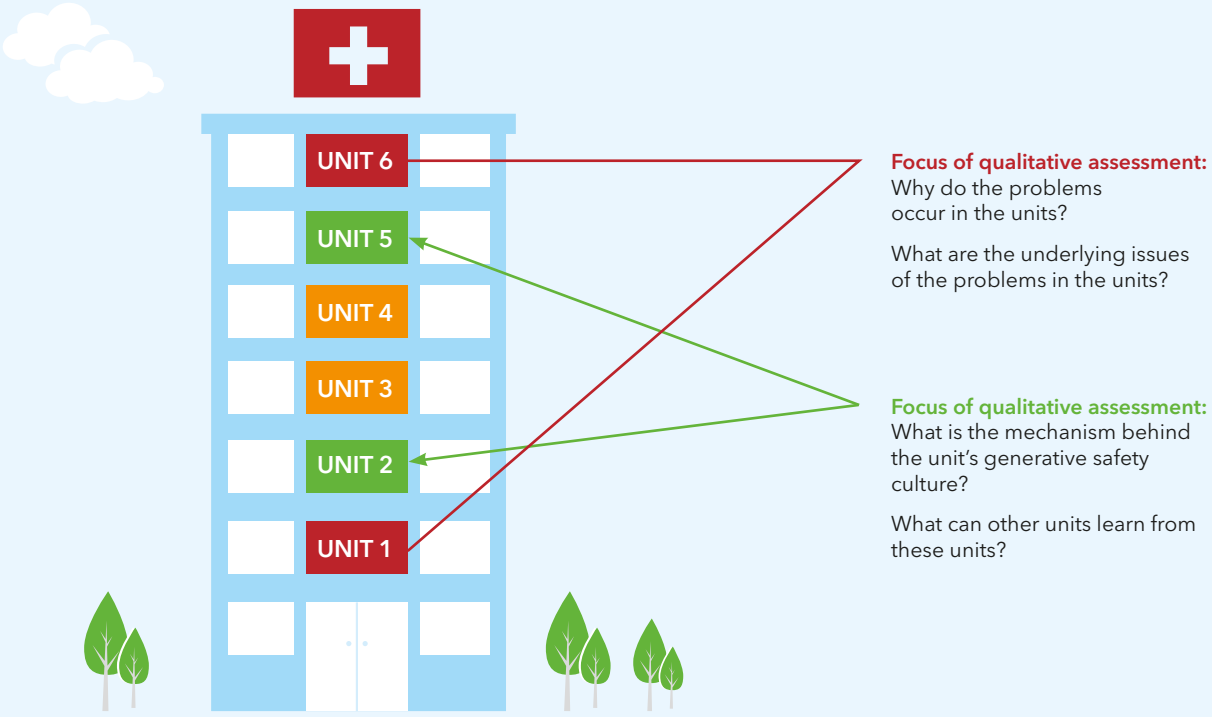


Figure 8. Illustration on an example of the sequential mixed methods approach
(**Red:** Pathological safety culture, **Orange:** Reactive safety culture, **Green:** Generative safety culture)

at DNV GL was adapted to healthcare and the SAQ by DNV GL researchers with Human Factors and healthcare backgrounds. The adapted interview guide consists of a series of questions focused on the interviewee's experiences of his or her daily practices related to patient safety (e.g. the quality of communication between professional groups, practices in organizational learning related to efforts to improve patient safety).

The interview guide was designed for use as a semi-structured interview. In the pilot studies described here, interviews lasted from 30 to 90 minutes and were conducted by DNV GL personnel in the hospital sites and by phone. The aim and use of the semi-structured interview was to allow new ideas to be brought up, elicit dialog, giving freedom for the interviewer to tailor and probe questions to the interviewees. Examples of interview questions were "How safe do you think your area is for patients?" and "Describe what senior management do to make patients safe?"

The components of safety culture addressed in the guide included, but were not limited to:

- Safety climate
- Teamwork
- Perceptions of senior/hospital management's commitment to patient safety
- Perceptions of unit/ward management's commitment to patient safety
- Stress recognition
- Job satisfaction
- Working conditions
- Compliance and attitudes to procedures, policies, rules and guidelines
- Conflicting goals
- Incident reporting and learning
- Staff recommendations to improve patient safety

Selection of interviewees

An appropriate sample size for interviews is the one that can answer the research questions to the point that no new themes are identified by

additional participants [79]. This is because the focus of interviews is to achieve data saturation, which is a situation where researchers do not hear new themes, explanations or information anymore in the sample being studied.

In DNV GL's pilot studies, the participating hospitals received a set of criteria for selecting interviewees from DNV GL to represent variations in years of experience, job descriptions, and professional groups. As a starting point, the rule of thumb for an initial sample size was 10-20% of the number of staff working in the areas being assessed. For example, 20% sample size was used in a unit with only 25 staff. Whereas, 10% sample size was used for a bigger unit with, for example, 150 staff. If the data were not saturated after the last planned interview, new interviews were scheduled until data saturation was achieved.

Anonymity and confidentiality

The pilot studies complied with all ethical and legal standards relating to anonymity and confidentiality. Participation to interviews was voluntary. Interviewees were assured that the interviews would be confidential, without any possible identification of the individual from their responses. The exception to this, which was explained to potential participants in advance, was that if an interviewee revealed something that had to be disclosed (such as the abuse of a patient), then confidentiality could not be maintained. All interviewees were given a Participant Information Sheet and a consent form to sign including the option to not participate or retract at any time during or after the interviews prior to submission of the results to the hospital management. Interviewees were also instructed on how to obtain feedback from the study.

Interview responses were tape-recorded and/or noted by DNV GL personnel. The recordings and notes were kept confidential and stored on a secure, password protected DNV GL's system. Only the research team had access to the original data. Original data will be stored for three years (the life of the project) and will be permanently removed through controlled destruction. All themes included in the reports to the hospitals were anonymous and cannot be linked to any individual.

EXAMPLE FINDINGS

This section briefly highlights two examples from the first pilot study using the mixed methods approach conducted in a Scandinavian hospital that specifically demonstrates the complementary use of interviews for explaining the variance in survey results.

OVERVIEW

The safety culture assessment pilot was facilitated May 2012 in conjunction with the National Patient Safety Campaign that required hospital staff to complete three of six dimensions (i.e. safety climate, teamwork climate, and perceptions of management) of the Safety Attitudes Questionnaire (SAQ) short form.

The DNV GL pilot study selected survey data from eight units where staff had an indirect or direct role in the care of the elderly with hip fractures. This participant group was selected due to their involvement with patients who have a relatively high incidence of deep post-operative surgical site infections. Deep wound infections require a prolonged course of treatment and can have serious consequences for the patients with comorbidities and a low level of overall health.

A total of 259 staff from the eight units participated in the survey, providing a response rate of 70.3%. From September to December 2012, interviews with a total of 29 staff involved in the care of the 'elderly with hip fractures' were conducted by DNV GL personnel.

EXAMPLE 1: INTERVIEWS RESULTS OFFER OPPORTUNITY FOR FURTHER EXPLORATION

The complementary use of interviews to survey results provided a benefit in the study for gaining additional details to the survey data in explaining the *how* and *why* to hospital personnel survey responses. Specifically illustrating this are results derived from the teamwork climate dimension of the SAQ. The teamwork climate dimension measures the perceived quality of collaboration between personnel. Graph 1 shows that overall participants endorsed relatively high scores on this dimension, with an average score of 3.9 on a scale of 1 to 5, suggesting that the majority of the participants in this survey agreed that their work units had a relatively positive teamwork climate.

When the survey results were examined more closely, results revealed more variable responses by professions (i.e. physicians and nurses). For example, on the item “the physicians and nurses here work together as a well-coordinated team” physicians were more likely to endorse that they strongly agreed with this statement, whereas nurses were likely to endorse neutrality to this. Although these

differences were subtle, it offered a potential area for further exploration through interviews with the staff in the units.

Interviews offer insight

Interviews revealed that although participants agreed their work units had a relatively positive teamwork climate, such as emphasizing positive experiences within collaboration of different professional groups, limitations regarding the access and availability for collaboration with senior physicians were discussed as a concern.

Specifically, nurses, residents and junior physicians revealed in the interview that while it was understood that senior physicians had many tasks, there were specific frustrations related to the perception that they were often unavailable and inaccessible. For example, several interviewees mentioned that they were at times hesitant to telephone senior physicians, due to fear of disturbing the physicians and from past negative experiences over the phone with these professionals.

This perception that senior physicians had many tasks was also reflected in the interviews with senior physicians such that they experienced a limited opportunity to access information due to time pressure.

Conclusions

The survey results revealed a topic for further exploration, which was the collaboration between physicians and nurses. Complementing this result with interviews was necessary to understand the underlying issue which was the need for more access to senior physicians.

Improvement efforts thus could be targeted to tackle the issue by, for example, supporting senior physicians with regard to their work load management and finding means to better incorporate opportunities for communication and teamwork with the nurses, residents and junior physicians.

Graph 1: Average scores within the teamwork dimension by survey question

EXAMPLE 2: INTERVIEWS EXPLAIN VARIATIONS ON SURVEY RESULTS

Findings from the survey analysis demonstrated variations between units regarding their perceptions towards the management's commitment to patient safety (See Graph 2). For example the perception of management was rated much higher for surgeons, emergency room, and ICU staff over staff in the surgical ward. Understanding the discrepancy between units in their perception of management's commitment to safety offered an area of exploration for interviews.

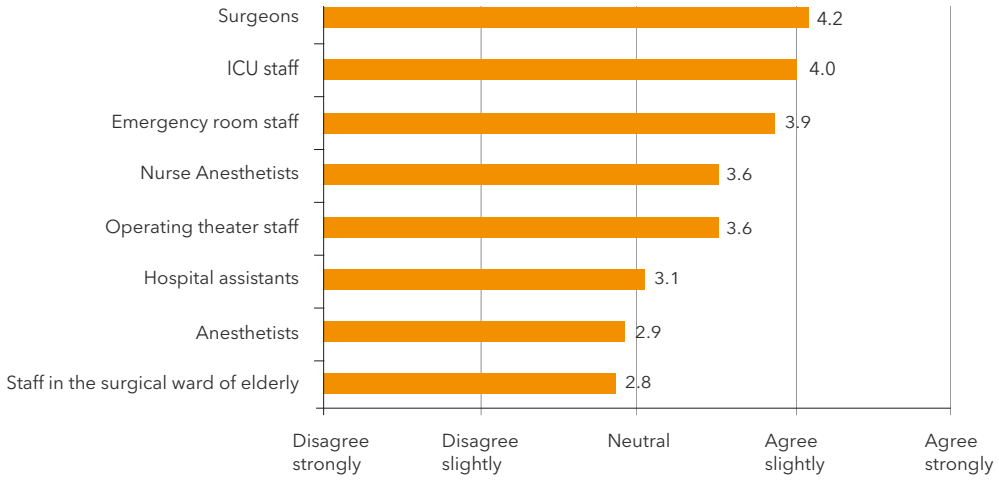
Interviews offer insight

Interviews revealed that most hospital staff believed management is concerned with patient safety; however, there were concerns related to the management's communication of their commitment. Specifically, surgeons, emergency room and ICU staff seemed to observe more communication activities in practice that confirmed their perceptions regarding management's commitment to patient safety than did staff in the surgical ward.

Conclusions

The perception of a strong, consistent leadership is an important factor for a generative safety culture and it is important that management clearly communicates and demonstrates that safety must be prioritized [17]. The additional insight provided by staff in the interviews contributed to a more complete cultural understanding regarding the staff's underlying assumptions to why there were variations to the perception of management's commitment toward patient safety.

Interviews revealed a lack of communication by management on safety as it was perceived by the surgical ward, thus providing opportunity for the organization to improve management's involvement and communication to this specific unit to their efforts and commitment to safety.



Graph 2: Average scores by participating unit show variations in perceptions of management's commitment to patient safety

ADDING FURTHER VALUE: THE BENEFITS OF A FACILITATED WORKSHOP AFTER MIXED METHODS ASSESSMENT

Reflections on the feedback from the first three pilot studies related to how healthcare organizations can best understand and use the assessment results for their benefit. Recognizing a need, a workshop was developed with the aim to support relevant leaders, managers and patient safety champions to make the best use of the results (see Figure 9). The workshop was included in the 5th and 6th pilot studies and facilitated by DNV GL personnel.

The main activities of the workshop were:

- To present and discuss the assessment results
- To prioritize areas for improvement within the respective areas being assessed
- To initiate action planning and the next steps related to improvement

The workshop should be considered as a forum to discuss how to use the results to achieve maximum value for the area being assessed. In doing this, it is crucial to use the assessment results to highlight not only poor performing areas, but also especially good practices. Understanding how good practices work is probably more significant for cultural changes than efforts to diminish poor practices [80]. It is then strongly recommended that results are used to stimulate organizational learning across units, areas, or any relevant groups.

Figure 9. Triangulation of DNV GL mixed methods approach to assess safety culture in healthcare

"Safety culture is a difficult problem to assess and then address. We have really valued being part of DNV GL's research process as it's important to continually develop new tools in this hugely important area."

- Andrew Seaton, Director of Safety, Gloucestershire Hospitals NHS Foundation Trust

OVERCOMING CHALLENGES FOR ORGANIZATIONS ASSESSING THEIR OWN SAFETY CULTURE

It can be challenging for organizations to assess their own safety culture using the mixed methods approach. The challenges may include:

- Organizational members may find it difficult to remain objective and unbiased during the interpretation of assessment results. This may be especially true for organizational member's that conduct interviews for the qualitative assessment. This is because the organizational members are part of the creation of the culture themselves. The qualitative interviews demand an ability to step outside of the culture and reflect critically on the values and beliefs expressed to avoid an unintentional interpretation of the interview responses to suit the interviewer's perspective.

- Due to the sensitive nature of topics that are assessed within safety culture, staff may have concerns regarding anonymity and confidentiality of their responses if the assessment is carried out by their managers or co-workers.

- The process of a safety culture assessment relies on people with the appropriate skills and knowledge to be available to conduct it. This often presents challenges to organizations because those skills may not be present within an organization.

These challenges can be avoided by inviting an external organization that can play an independent role to provide a more objective assessment with skilled professionals in the field.

The benefits of inviting an external organization to assess safety culture were reflected in the feedback to DNV GL of the pilot studies. For example, in two pilot studies, interviewees provided positive comments such as:

- "I did not know what to expect initially. However, I felt I was able to speak freely when questioned. "

- "I felt I was able to talk freely knowing that it was completely confidential. "

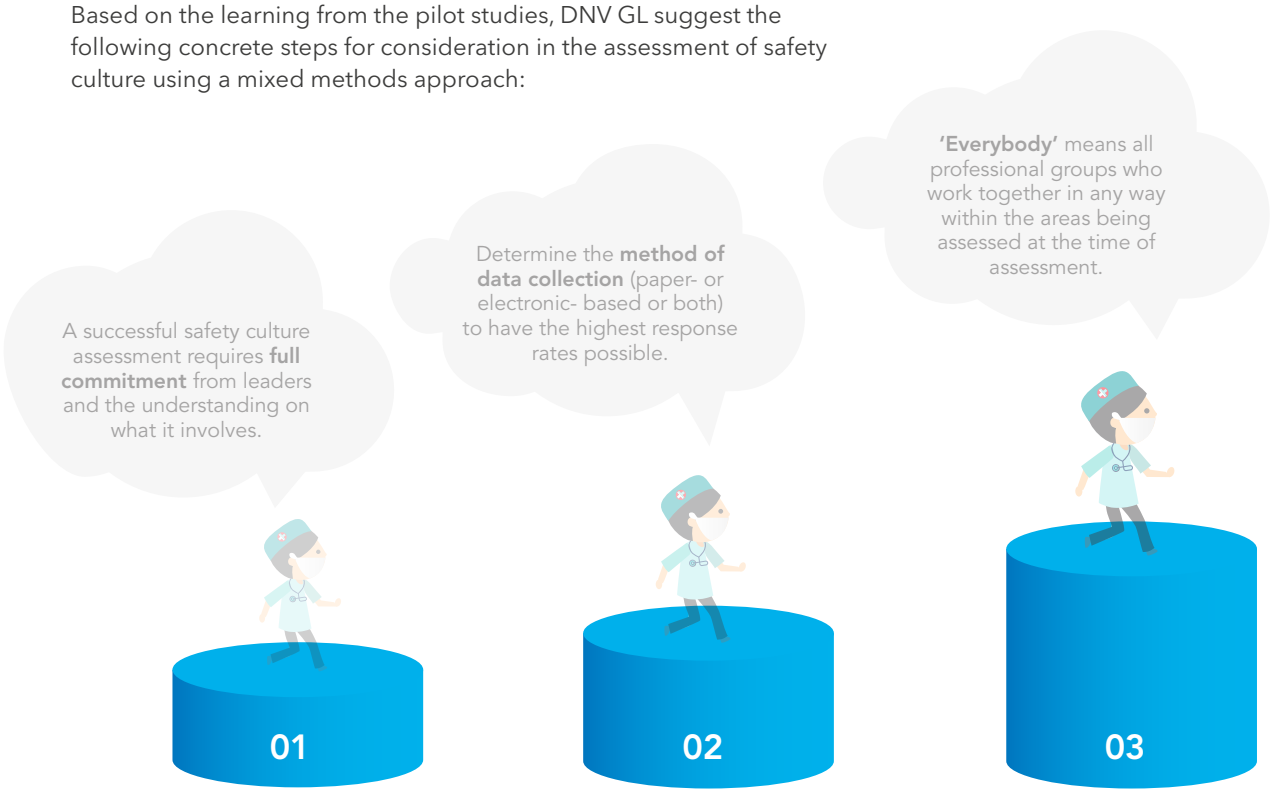
- "Made me feel comfortable throughout. Thank you."
- "I don't like doing interviews but was made to feel welcome plus put at ease. "
- "Very satisfied. All questions clearly explained and plenty of time given to explain my answers."
- "Helpful made you feel at ease, hope it goes on to make a difference on the wards."
- "Made me think more of the organisation as a whole. Interviewer was very good at getting me to look at wider picture."

Similarly, the workshop received positive responses:

- "I was very satisfied with the service! The facilitators were extremely clear in everything that they said + made some excellent points."
- "Generated discussion and useful ideas to take forward."
- "Good day – all knowledgeable about subject."
- "[DNV GL] Staff very knowledgeable. Friendly. Interactive. Informative."
- "Excellent presentation and participant involvement."
- "We were encouraged to think but the method was more coaching than instructing. The key bit is "will we change"? "
- "Learning new process"
- "A useful exercise that will inform future plans."

LESSONS LEARNED:
Steps for conducting safety culture assessment using mixed methods

Based on the learning from the pilot studies, DNV GL suggest the following concrete steps for consideration in the assessment of safety culture using a mixed methods approach:



DEFINE COMMITMENT AND IMPORTANCE OF THE ASSESSMENT FOR THE ORGANIZATION BEING ASSESSED

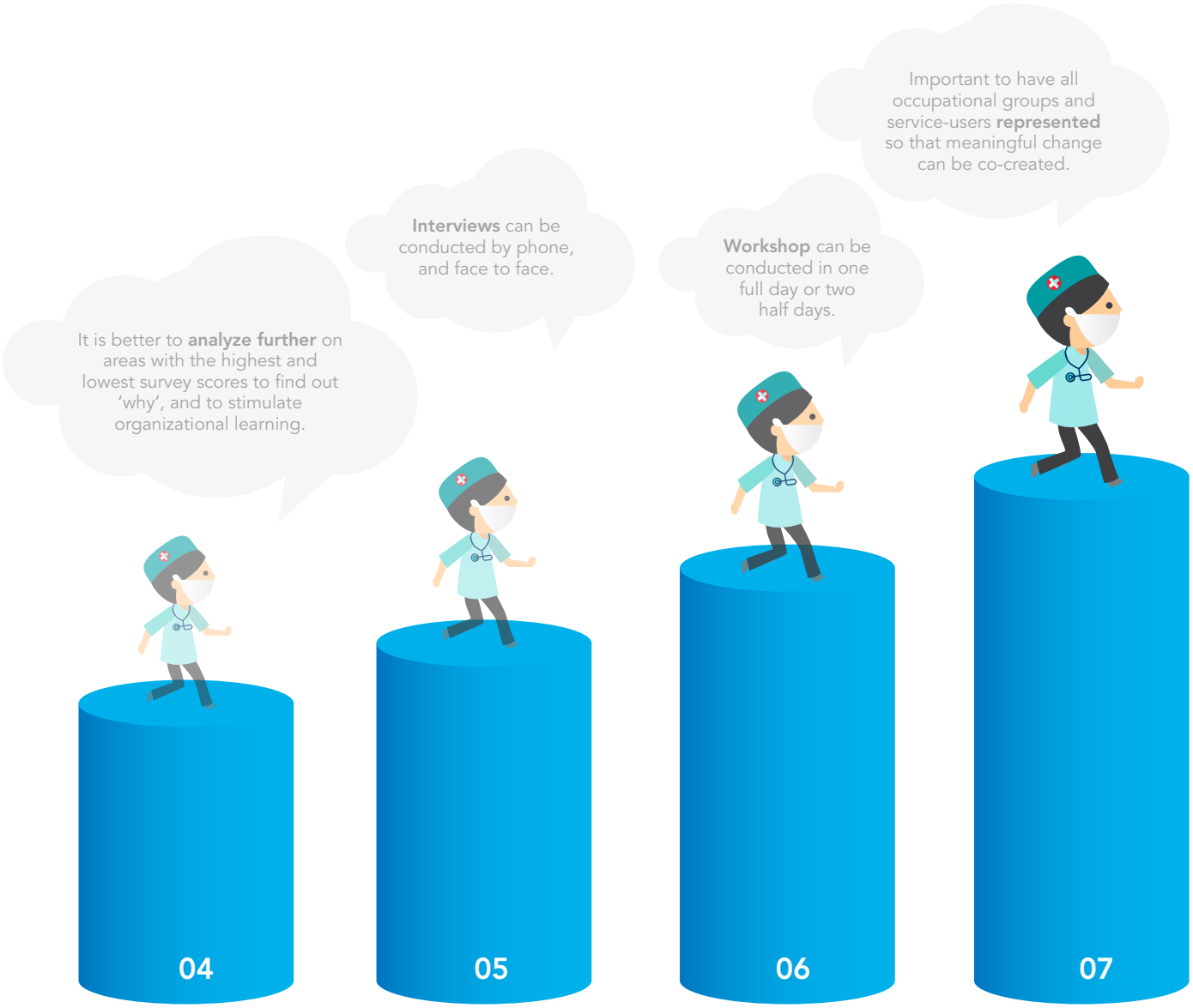
Recognizing and understanding the importance of safety culture assessment and how results are to be used within the organization.

SELECT AREAS FOR ASSESSMENT

Determining the scale of the assessment such as organization-wide, several big areas, or a clinical area.

CONDUCT A SAFETY CULTURE SURVEY

Inviting everybody involved within the area being assessed to participate in the survey.



BASED ON THE SURVEY RESULTS, SELECT FEWER AREAS FOR FURTHER ANALYSIS

Several units, departments or groups with highest or/and lowest survey scores may be selected. If all areas are to be assessed further, this step is to be omitted.

INTERVIEW STAFF WITHIN THE SELECTED AREAS

Interviews are to include representatives from all groups involved in the area(s).

CONDUCT THE WORKSHOP

The aims of the workshop are: (1) to understand and make sense of the results, (2) to prioritize areas for improvement, and (3) to initiate action planning.

FEEDBACK

A report is produced to document the results and workshop's conclusions.

CONCLUSIONS

Healthcare organizations are increasingly becoming aware of the importance of transforming organizational culture to improve patient safety. Safety culture assessment is a vital, proactive step to improving patient safety. Based on DNV GL's continuing pilot studies, there are several conclusions to make with regards to safety culture assessment in healthcare:

- It is important to use a mixed methods approach (combining quantitative and qualitative methods) to assess safety culture in healthcare if results are to be used for an improvement or a change. This is because mixed methods enable an organization to gain an overview of their safety culture strengths and weaknesses before exploring in depth within particular contexts.

- An independent party such as DNV GL is best to conduct a mixed method safety culture assessment.

  - Core to safety culture assessment is the ability to provide an open and friendly environment for staff in an area being assessed. This is to make staff feel safe and secure to give their most honest, valuable opinions about topics that can be sensitive to them. Accordingly, assessment and data should be treated confidentially. An independent party such as DNV GL can serve as a neutral organization to conduct the assessment.

  - In addition, 'outsiders' can be more observant of the culture than the organizational members who are part of the creation of the culture.

- Staff engagement and appreciation are key to make a change sustainable.

  - A change should be started by empowering staff of all levels towards what has been working well, to pinpoint the stronger areas.

  - Change implementation should aim to make the stronger points more sustainable and win over weaker areas.

"I believe there is very little likelihood for long lasting effects of measures to optimize the performance of staff if, for example, management and employees are not working towards a common safety goal, and if there is no ownership of safety issues"

– Fenna van de Merwe, DNV GL Senior Consultant, Safety, Risk and Reliability

"As a [hospital] we are always looking for the best techniques to improve safety performance so we were keen to be part of DNV GL's pilot study."

- Jamie Maxwell, Head of Quality Safety and Compliance, University Hospital of North Staffordshire NHS Trust

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NOTES

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It also provides certification services to customers across a wide range of industries. Combining leading technical and operational expertise, risk methodology and in-depth industry knowledge, DNV GL empowers its customers' decisions and actions with trust and confidence. The company continuously invests in research and collaborative innovation to provide customers and society with operational and technological foresight. DNV GL, whose origins go back to 1864, operates globally in more than 100 countries with its 16,000 professionals dedicated to helping their customers make the world safer, smarter and greener.

DNV GL Strategic Research & Innovation
The objective of strategic research is through new knowledge and services to enable long term innovation and business growth in support of the overall strategy of DNV GL. Such research is carried out in selected areas that are believed to be of particular significance for DNV GL in the future. A Position Paper from DNV GL Strategic Research & Innovation is intended to highlight findings from our research programmes.

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