STRUCTURAL APPROACHES TO ADDRESS ISSUES IN PATIENT SAFETY

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STRUCTURAL APPROACHES TO ADDRESS ISSUES IN PATIENT SAFETY

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FOREWORD

For decades, leaders in health care administration have looked to the published literature to inform health care processes and operations, and ultimately impact patient safety outcomes. Donabedian's model of Structure-Process-Outcome, as an initial lens through which safety issues have been explored, notes that structure drives process; however, much of health management empirical research has focused on the process and outcomes and then attempted to reverse engineer the structure that may reasonably support process and outcome success. Other models, such as the System Engineering Initiative for Patient Safety model (SEIPS), sought to offer a framework for understanding the structures, processes, and outcomes in health care and their relationships. This volume uses the lens of Donabedian and the SEIPS model to explore the link between the structure of the health care environment and patient safety outcomes. Particularly, the following chapters present techniques to leverage design thinking to improve patient and provider well-being, the impact of environments on vulnerable populations, and ultimately the overall impact we can have on patient experience when looked at from the systems' perspective.

I have always believed that the environments within which we provide care influence the outcomes. In my role as a health care administrator, I continue to engage in quality improvement projects to adjust the structure and context of health care and measure the impact of these changes. There are many parts and pieces to health care environments, and as such, the term "environment" and the impression of the impact therein means many different things to different stakeholders. The patient is often not selective of the environment, but rather seeks out the closest the clinic, hospital, or emergency room during a health care crisis at his or her most vulnerable moment. Therefore, the patient can do little to influence the health care environment but is completely dependent on those who design the health care system. Almost 20 years after the seminal publication of the Institute of Medicine report "To Err Is Human: Building a Safer Health System," much has changed, but much has stayed the same relative to patient safety.

There have been many interventions by hospitals and providers to improve the processes of health care delivery to improve outcomes, but less systems-based thinking has been adopted. Kobler et al. outline systems-based improvements that target hospital design. They explore the practicality of hospital design that affects not only efficiency and effective workflow and operations, but ultimately patient safety improvements. Ray et al. additionally explore environmental change through the introduction of the flexible process model, PROcess for

the Design of User Centered Environments (PRODUCE), which is designed to guide system change. This model was informed and ultimately refined by a series of real-world renovations, relocations, and new builds in a large multihospital health care system. The principles that are succinctly explored in this article are user-centered design, human factors, and in-situ simulation that engages users in the planning, testing, and implementation of physical environment change. This work is an important step toward building a body of literature around the practical process of hospital-based design to improve health care quality.

Limaye et al. subsequently introduce the very real concepts of using a systems modeling approach to reduce the risk of health care-associated infections (HAIs) and in particular focus on the vulnerable population of pediatric intensive care patients. Using a unique approach, they address HAIs in pediatric intensive care by studying several infections rather than a single type, projecting the effects of interventions onto the general patient population, and lastly focusing on both medical and behavioral interventions and comparative effectiveness. The methodology explored is inclusive of simulation, risk analysis, and various statistical techniques. Some of these methods will be familiar to the reader, but the uniqueness of combining these methods in this patient population will be appreciated. Hebert et al. similarly focus on the impact of environments on HAIs but also introduce the very real yet understudied concept of what I would refer to as "hospital geography." In this article, the potential role of geographic information systems (GIS) for infection control in hospitals is introduced and explored in superb detail. The authors outline the relative challenges of implementation of this rarely used tool including the domains of technology, organization, and adaptation. Notwithstanding its difficulties, GIS has tremendous potential in hospital settings where immunocompromised and vulnerable patients could be well served by this innovation.

Furthering the theme of leveraging environmental design and systems thinking to safeguard vulnerable populations, Papautsky et al. describe the use of human factor approaches to develop and conduct an evaluation of the design of a neonatal intensive care unit. Unique to this approach is the multiple stakeholder engagement early in the development phase by engaging in complex cognitive and collaborative work. In business, this is called incorporating the voice of the customer. In medicine, we often forget the voice of the patient and the providers, and as such, this work by Papautsky et al. is particularly poignant. The applicability of this approach in more generalizable settings is additionally explored relative to the work of Buttigieg et al. whereby such interprofessional approaches are taken to understand the impact of environments in an obstetrical setting relative to provider burnout. Often referred to as the forgotten quality metric, burnout among care teams has broad-ranging implications for patient outcomes. Relationships between perceived patient-safe and patient-friendly environments and unsafe performance relative to burnout are measurable; work environments that were created to ensure safe practices are conducive to preventing burnout among employees.

McGrath et al. expand the concept of systems-based thinking and design relative to the broader patient population that is outside the uniquely identifiable

vulnerable populations we might normally study. Failure to rescue remains a patient safety issue that health care institutions of all sorts and sizes continue to deal with and many resources are used in an attempt to address. McGrath et al. use many system-oriented design and implementation activities to establish design objectives; model clinical processes, workflows, and information systems to have accurate risk assessment tools; and ultimately reduce failure to rescue events in real-world hospital settings. Much of what we know of failure to rescue and ways to assess and warn providers of impending clinical changes comes from clinical monitoring. Horwood et al. take risk assessment deeper into the realm of clinical alarms to explore who actually needs to be monitored in hospital settings while still maintaining the highest patient safety practices. Horwood et al. conduct an in-depth, three-year follow-up from the clinical introduction of standardized guidelines for continuous cardiac monitoring (CCM) across a medical center relative to not only mortality, but also efficiency metrics inclusive of the length of stay. Educational needs for sustainability of such system-wide changes are additionally explored within this longitudinal study. In essence, sustainability in environment and system-based design is fundamental to long-term success and must not be minimized.

While many of our system-based studies relative to patient safety have focused on clinical care units, oftentimes for vulnerable patient populations, there are many processes and non-clinical areas that greatly impact patient safety and quality outcomes. Sterile processing of instruments and the preparation of case carts is a fundamental activity in all health care settings. Furthermore, it is reasonable to conclude that ultimate patient outcomes are completely dependent and even vulnerable to these enabling activities. Albert et al. study sterile processing departments and their embedded processes relative to work systems analysis to provide a framework for interventions and improvements. Human factors elements, operational efficiencies, and environmental changes are explored in this uniquely influential non-patient facing entity.

Much of what we do relative to patient care is reactive. In order to truly influence and sustain system-level change, continuous learning and improvement must become cultural norms. This is an important concept, and one that must be embraced to benefit from this volume's systems-based approach to solutions. Quatman-Yates et al. explore, through an ethnographic report, the cultural elements that must be addressed to cultivate a sustainable culture of continuous improvement. Culture, interestingly enough, is truly three-dimensional and can pivot along the individual, social, and structural axes in complex health care settings. Furthermore, the fourth dimension of continuous improvement has to intersect with systems engineering approaches to both analyze and redesign a reliable system. McGrath et al. leverage the cultural, institutional-level, and reliable design features that are needed in complex care delivery systems. The approach needs to be practical and effective as well as inclusive of truly system-based thinking to effectively address the current shortcomings of our health care design strategies.

The ultimate goal of this volume is to demonstrate the role that systems thinking can play in the design of environments and processes within health care

to improve safety. The patients, families, and providers are at the very core of what we do in health care and must continue to be our True North. Ultimately, why do we focus so intently on health care quality improvement? Firstly, it is the right thing to do. Secondly, we have the capacity and knowledge to improve the environment of care. Lastly, if we were the patient, we would want it. And so, as Hefner at al. so nicely summarize and conclude, it is all about optimizing the patient experience; this is why we take the time to define, measure, analyze, prove, and sustain. We can always do better, and do better we must.

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CASE STUDY: MORE PATIENT SAFETY BY DESIGN – SYSTEM-BASED APPROACHES FOR HOSPITALS

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ABSTRACT

Since the publication of the report "To Err Is Human: Building a Safer Health System" by the US Institute of Medicine in 2000, much has changed with regard to patient safety. Many of the more recent initiatives to improve patient safety target the behavior of health care staff (e.g., training, double-checking procedures, and standard operating procedures). System-based interventions have so far received less attention, even though they produce more substantial improvements, being less dependent on individuals' behavior. One type of system-based intervention that can benefit patient safety involves improvements to hospital design. Given that people's working environments affect their behavior, good design at a systemic level not only enables staff to work more efficiently; it can also prevent errors and mishaps, which can have serious consequences for patients. While an increasing number of studies have demonstrated the effect of hospital design on patient safety, this knowledge is not easily accessible to

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clinicians, practitioners, risk managers, and other decision-makers, such as designers and architects of health care facilities. This is why the Swiss Patient Safety Foundation launched its project, "More Patient Safety by Design: Systemic Approaches for Hospitals," which is presented in this chapter.

Keywords: Hospital design; information dissemination; medical error; patient safety; system-based interventions; systemic approach

INTRODUCTION

A hospital is a complex system where many different experts work together, carrying out difficult activities, often under time pressure. In such a demanding environment, errors do occur. Although medical errors are, ultimately, always made by individuals or teams, their root cause is generally the interaction between humans and their environment (Reason, 2000). Safety can be created, therefore, by designing a system that makes errors unlikely and supports the hospital staff in doing things right. Ever since the US Institute of Medicine report "To Err Is Human: Building a Safer Health System" came out in 2000 (American Institute of Medicine, 1999), much research has been conducted on patient safety, often focusing on human behavior. Consequently, many initiatives implemented since then have focused on behavioral aspects. These person-based initiatives aim to improve patient safety by changing the behavior of individual health care professionals through training, double-checking procedures, and standard operating procedures (SOPs). System-based interventions (such as the simplification of processes, improvements to the work environment, or standardization) have received less attention to date, even though they produce more substantial improvements because they rely less on the individual safety behavior of employees (Trbovich & Shojania, 2017). In fact, quality expert Edward W. Deming estimated that around 94% of problems and improvement possibilities may be system-based (Deming, 2000).

Despite a great number of patient safety initiatives since 2000, there is still a long way to go to create a safer health care system (Aiken et al., 2018; Kellogg et al., 2016; Makary & Daniel, 2016). One reason for the limited progress of patient safety in recent years could be that wrong conclusions are drawn from event analyses in hospitals. Kellogg et al. (2016), for example, showed that professionals often draw conclusions out of error analysis that intend to improve people's behavior. The authors examined the types of solutions proposed in root cause analysis (RCA) over an eight-year period at a major academic medical institution. RCA is a process used by hospitals in an attempt to reduce adverse event rates, although its benefits in a health care context have not yet been studied extensively. They gathered data on all state-reportable adverse events analyzed by means of an RCA, and the proposed solutions were studied. In 106 RCAs, 731 solutions were proposed. The most common proposals involved training (20.0%), followed by process changes (19.6%), and policy reinforcement (15.2%). The solutions suggested for changes to forms and other paperwork, the physical environment, and the IT

structure were all less than 5%. In this context, the authors also provided evidence that the number of retained foreign bodies (i.e., foreign bodies left inside a patient after an operation), a serious event in surgery, was unaffected by the proposed measures, highlighting their relative ineffectiveness. These results are astonishing as the safety research literature has suggested interventions that direct people's behavior are less effective than interventions at a system level (St. Pierre & Hofinger, 2014; Trbovich & Shojania, 2017).

One example of system-based interventions are improvements in hospital design. Given that a working environment has considerable potential to affect how people behave, one that is poorly designed will tend to favor preventable adverse events such as infections, patient falls, and mix-ups (Joseph, Henriksen, & Malone, 2018; Ulrich et al., 2008). Conversely, good design at a systemic level can help to promote error-free processes and make the best use of people's potential. This means designing a work environment that helps prevent medical errors or that even makes incorrect actions and processes impossible by forcing people to act in a certain way. As Reason (2000) put it, "Countermeasures are based on the assumption that though we cannot change the human condition, we can change the conditions under which humans work" (Reason, 2000, p. 768).

Since the early 2000s, an increasing number of studies have demonstrated that hospital design affects patient safety (Ulrich et al., 2008). Evidence-based design is defined as the process of basing environment design decisions on credible evidence, with the goal in this context of improving health care outcomes, including safety (Center for Health Design, 2018). However, this knowledge is not easily accessible to clinicians, practitioners, risk managers, or decision-makers in the health care setting. This was the reason for the launch of a project with the title "More Patient Safety by Design: Systemic Approaches for Hospitals" by the Swiss Patient Safety Foundation, which is presented in the following. Some of the results included in this chapter have also been published in a brochure that was one of the outputs of the project (Kobler & Schwappach, 2017).

CONCEPTUAL FRAMEWORK

Any study dealing with hospital design and its impact on human behavior is based on an analysis of human factors, such as the study of the interrelationships between humans, the tools they use, and the environments in which they live and work (Weinger, Pantiskas, Wiklund, & Carstensen, 1998). In the context of patient safety, this means that hospital design should support staff behavior while, at the same time, minimizing risk. Many different aspects of hospital design can affect patient safety. For example, the incidence of falls may increase if the flooring is slippery. Poor lighting affects the performance of employees, increasing their likelihood of making errors. From the perspective of patient safety, hospital design is a diverse, complex, and far-reaching issue. Taking a structured approach, we divided it into four dimensions. As shown in Fig. 1, in each of them the right design decisions can affect patient safety in a substantial way.

Fig. 1. Dimensions of Patient Safety and Design. *Source*: Kobler and Schwappach (2017). Used with permission.

Directly Reducing Risks

This dimension comprises all aspects of design that constitute a risk or that may directly reduce risk if the relevant decision is taken. Material properties are the crucial factor here. All design aspects under this dimension represent an opportunity or a risk for patient safety, regardless of human behavior. For example, the materials used for surfaces and air filters can have a direct effect on infection rates in hospitals (Joseph et al., 2018; Pati et al., 2017; Ulrich et al., 2008; Zimring et al., 2013).

Optimizing Latent Conditions, Supporting Staff Performance Levels

Organizational and systemic factors such as light and noise are also latent conditions that affect employee performance (e.g., the ability to concentrate and situational awareness) in all areas of work (Reason, 2000). This increases or reduces the likelihood of errors. Occupational health and health promotion departments have long since realized the importance of these factors in maintaining employee health. Their impact on employee performance is also highly relevant for patient safety.

Encouraging Intuitive, Safety-promoting Behavior

This dimension comprises all design aspects that have a positive effect on employee behavior in relation to patient safety. The purpose of design interventions in this dimension is to make it easier to behave correctly than to behave

incorrectly. In this dimension, every intervention is aimed at promoting safety-relevant behavior. Staff can be helped to comply with safety rules intuitively by relevant design (Ulrich et al., 2008). Door handles in the operating theater designed to be opened with the elbow are one example, making it easier to comply with rules on hygiene. Some of these approaches are so-called nudging solutions. The behavioral psychology concept of a "nudge" is defined as any aspect of the choice architecture that alters people's behavior in a predictable way without forbidding any options or significantly changing their economic incentives (Thaler & Sunstein, 2016). This concept is also used in health care settings to influence, for example, people's safety-promoting behavior (see section "Nudging to Raise Compliance").

Creating a Health-promoting Environment

Many studies have shown that hospital design can have a direct effect on patient recovery and well-being (Ampt, Harris, & Maxwell, 2008; Luetz et al., 2016). This is referred to as healing architecture (Nickl-Weller & Nickl, 2013). In addition to the impact of noise on patient recovery (Luetz et al., 2016), for example, a positive correlation has been identified between access to nature and health outcomes (Ampt et al., 2008). Patients in rooms with windows looking out on a garden, for instance, had far shorter hospital stays, had to take fewer analgesic drugs, and tended to suffer fewer complications than those in rooms with a view of a brick wall (Ulrich, 1984). The impact of design on patient recovery is particularly well-documented in intensive care (Caruso, Guardian, Tiengo, Dos Santos, & Junior, 2014; Luetz et al., 2016).

In the following, further analysis focuses on the design of the work environment for professional staff in hospitals. It looks mainly at design aspects that optimize latent conditions (B) and positively influence safety-related human behavior (C). While this is not to minimize the importance of the other two areas (A and D), these have already been covered by many studies and initiatives which can be found elsewhere (Ampt et al., 2008; Bayramzadeh, Portillo, & Carmel-Gilfilen, 2018; Karsh, Holden, Alper, & Or, 2006; Nickl-Weller & Nickl, 2013).

The framework presented in Fig. 2 gives a simplified overview of how solutions from these dimensions (B, C) can influence undesirable events by aiming at latent conditions and the behavior of health care professionals.

An example is used to illustrate the interrelationships: Infections, for example, are a major patient safety issue. One problem is the relatively low hand hygiene compliance in hospitals (compliance with safety rules). To improve compliance by enhancing awareness, quality managers can organize training sessions. It must be kept in mind, however, that training is directed at individuals and is therefore less effective than changes at a system level (Trbovich & Shojania, 2017). To improve compliance with safety rules, quality managers might do better to focus on design solutions. One cause of low compliance with hand hygiene rules could be that there are too few dispensers or that they are positioned inconveniently. Birnbach et al. (2010) showed, for example, that it is possible to raise compliance with hand hygiene rules significantly by placing the

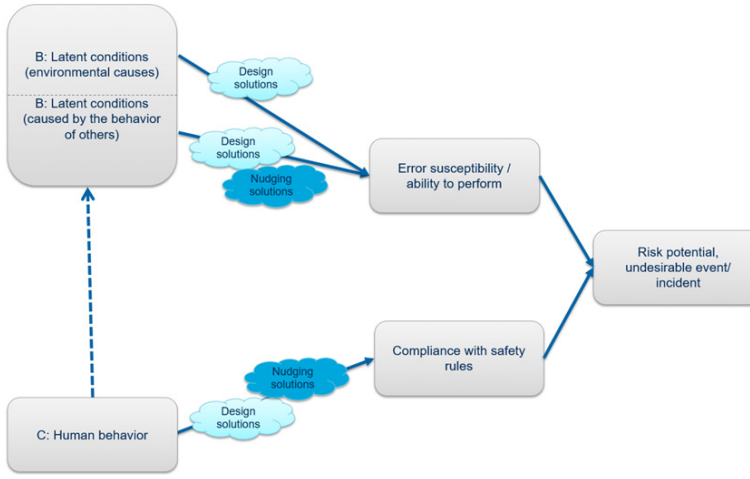

Fig. 2. Conceptual Framework Design and Patient Safety. *Source*: Authors' own figure.

dispensers in the field of view next to the patients' beds (nudging solution). This is a good example of how, by making a simple design change (i.e., changing the number and placement of the dispensers), a system-level intervention can enhance hand hygiene without the need for further awareness-raising measures (Birnbach et al., 2010).

APPROACH

As stated before, the aim of our project was to consolidate research and practitioners' expertise and to disseminate patient safety design knowledge among health care professionals.

As a first step, the project identified the main emergent topics in the field through a comprehensive literature review. We reviewed scientific and gray literature in the field of patient safety and hospital design/architecture to gain a broad understanding of topics and projects. We did not restrict ourselves to a specific time period; most of the literature found appeared after 2000.

In a second step, we organized two expert workshops with 24 experts in Switzerland. We identified the experts by searching for projects in the health care sector that involved design and patient safety aspects. Additionally, we used our professional network to obtain recommendations. The expert panel consisted of hospital architects, engineers, designers, quality managers, physicians, occupational health specialists, health care professionals, risk managers, and other decision-makers in the health care setting.

The first expert discussion aimed at identifying main topics and good practices in the field. To sharpen the experts' focus of the project, they were

given an input presentation. Afterward, we invited the experts to brainstorm and thus create good practices in this area, which were then allocated to the two design dimensions (B and C; see also the conceptual framework in the section "Conceptual Framework"). The solutions supplied by participants came from concrete projects they had conducted and scientific literature they had cited.

After the workshop, the project team synthesized the collected information and divided it into eight categories: noise, lighting, interruptions, heterogeneity of rooms, standardization, visibility of patients, multifunctionality, and compliance with safety rules.

In a third step, we presented the categories to the experts during a second workshop and discussed them. The experts were able to add further good practices. In the second part of the workshop, the experts ranked the categories, agreeing on five topics as having the highest potential to improve patient safety by design in hospitals: lighting, noise, interruptions, standardization, and nudging to enhance compliance.

In a fourth step, the project team developed a practitioner-oriented brochure, which has been published in three Swiss national languages (German, French, and Italian) and in English. The brochure contains an introduction to a systemic approach to patient safety and hospital design and good practice examples of our five topics. They are illustrated by combining research findings, examples of design measures, and key questions for analysis in hospitals. To disseminate the brochure among practitioners in Switzerland, it is distributed via various electronic channels to health care professionals in hospitals (e.g., physicians, nurses, quality managers, patient safety experts, and facility managers) as well as hospital architects, designers, and researchers.

In a final step, a symposium with renowned national and international speakers was conducted in April 2017 to bring together experts from different fields, inform about national and international safety improvement projects and research, and encourage discourse in Switzerland on systemic approaches to improve patient safety.

PROJECT RESULTS: GOOD PRACTICES FOR IMPROVING PATIENT SAFETY BY DESIGN

In this subchapter, the identified five core topics of patient safety are presented in detail and scientific evidence for their impact is reviewed. The topics play a role throughout many hospital routines and thus affect a large number of staff members.

Optimizing Lighting

Light is a key design parameter that can have a direct effect on patient safety. For example, a direct correlation exists between light intensity and medication errors. Tasks that require good vision can be performed better in good lighting conditions (Boyce, Hunter, & Howlett, 2003). Buchanan, Barker, Gibson, Jiang,

and Pearson (1991) showed that medications are dispensed with significantly fewer errors at lighting levels of 1,500 lux compared with a lighting intensity of 450 lux (2.6% versus 3.8%) (Buchanan et al., 1991). It is important for the light intensity to be adjusted to reflect the specific activity taking place. Generally, bright light has a positive impact on both patients and staff. The need for good lighting increases with age (Edwards & Torcellini, 2002). Bright light is particularly important where critical tasks such as distributing and administering medications are performed (Ulrich et al., 2008). It should be borne in mind, however, that very bright light can be blinding, which, in turn, causes stress. Situational adjustment of lighting to reflect the activity to be performed should be considered. Lighting in patient rooms might be adjusted during examinations or consultations to keep staff and patient alert, facilitate clinical observations, and minimize the risk of mix-ups. In addition to lighting levels, light intensity should be taken into account, as this can affect staff alertness or determine whether colors are reproduced correctly or incorrectly (e.g., with respect to skin tone). The right balance between competing aspects such as patient safety and well-being needs to be struck when deciding on lighting conditions (e.g., screen displays of equipment in the patient's room at night). Light is therefore a major latent condition that affects staff performance. Changing the lighting conditions is a type of system-based intervention that is relatively simple to implement and does not require major building activities.

Noise Reduction

There are many sources of noise in hospitals, and noise levels can be substantial (Ampt et al., 2008). In fact, since the 1960s, noise levels in hospitals have increased steadily around the world (Ulrich et al., 2008). High noise levels cause stress, fatigue, and distraction in professional staff and interfere with communication flow. This makes noise a significant source of error in hospitals, particularly when staff are carrying out critical tasks or have to rely on their working memory (Berglund, Lindvall, Schwela, & Team WHOO and EH, 1999). Unforeseen noises, in particular (such as the ringing of a telephone), are distracting, interrupt work steps, and thus promote errors (Leather, Beale, & Sullivan, 2003). Noise is a latent condition that has a key effect on professionals' performance.

The World Health Organization (WHO) recommends keeping background noise levels below 35 dB during the day and no more than 30 dB at night (Berglund et al., 1999). However, Ulrich et al. (2008) found in their review that actual noise levels in hospitals are usually considerably higher (Busch-Vishniac et al., 2005; Ulrich et al., 2008). The Joint Commission, an organization that accredits and certifies nearly 21,000 health care organizations and programs in the United States, also stresses that noise is a potential risk factor for medical and nursing errors. The level of environmental noise should, therefore, be low enough for personnel to hear and understand one another at all times (The Joint Commission on Accreditation of Healthcare Organizations, 2004).