Anticipate to Participate to Integrate:
Bridging Evidence-Based Design and Human Factors Ergonomics to Advance Safer Healthcare Facility Design

by

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Abstract

Objective: The primary objective of the thesis is to advance proactive thinking in designing healthcare facilities for safety by constructing theory to bridge gaps between evidence-based design (EBD) and human factors/ergonomics (HF/E).

Background: Adverse events are a pervasive issue in healthcare, with causes and prevention measures under increased scrutiny for the past 15 years. The physical environment can be an underlying condition of safety and healthcare (HC) facility design can be seen as a layer of defense in accident causation theory. However, HC facility design is complicated and complex, and the implications of decisions can be felt for decades. While architects excel at problem solving, they are not fully versed in healthcare work tasks, flow, and function, resulting in complex system interactions. Evidence-based design (EBD) is a process that uses research as a foundation for decision-making in HC facility design. While the EBD process acknowledges the importance of system factors, its focus is on understanding specific facility design interventions on outcomes such as safety, efficiency, quality of care, and satisfaction. HF/E focuses on humans interacting with a system with a goal of optimizing human well-being and overall system performance. Although HF/E recognizes the physical environment as a system component, the ergonomic definition of the environment lacks clarity and influences are frequently considered at a microergonomic level. In summary, EBD supports desired outcomes of a system through building design, while HF/E more often supports desired outcomes of the system through work design.

Methods: The thesis leverages a grant to create a Safety Risk Assessment (SRA) toolkit for HC facility design using: (1) consensus-based methods to develop built-environment considerations for falls in HC facility design, (2) a mixed methods approach to test the SRA in hypothetical scenarios, (3) a mixed methods approach to test the SRA in real-world scenarios, (4) quantitative and qualitative analysis using an inductive and abductive approach to construct grounded theory to develop a core theme and a theoretical framework for proactively considering safety in HC facility design, (5) an extended systematic literature review to identify additional system considerations of the organization and people, and (6) established thinking to advance new theoretical frameworks to achieve the thesis objectives.

Results: Two theoretical frameworks are proposed. The first framework, Safety as Complexity of the Organization, People and Environment (SCOPE) is based on the Dial-F systems model (Hignett 2013). The evolution includes:

- the definition of the ergonomic environment using building design as the most stable element of the system, identifying built environment interventions to mitigate the risk of falls (SCOPE 1.0);
- the addition of non-building design interventions of the system such as organizational and people-based conditions (SCOPE 2.0); and
- the integration of HF/E design principles to reframe thinking about hospital falls (DEEP SCOPE).

The second framework evolves from grounded theory constructed through data from SRA testing proposing safe design as a participatory process to anticipate, participate, and integrate solutions. A participatory ergonomics framework (Haines and Wilson 1998) is integrated with a mesoergonomic framework of inquiry (Karsh, Waterson, and Holden 2014, Karsh 2006) to advance a theoretical framework of participatory mesoergonomics using the SRA and SCOPE content as inputs over the course of a HC facility design project to achieve safety.

Conclusion: The gap between EBD and HF/E can be bridged using safety (falls) as a proactive consideration during HC facility design using theoretical frameworks. These frameworks address (1) the definition of building design and design considerations in the HF/E context and (2) integration of the EBD process with HF/E methods to understand interactions of the system.

Acknowledgements

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Professional. The PhD was made possible by the grant project, primarily supported by the research team at The Center for Health Design (CHD), including Dr. Anjali Joseph (PI), Dr. Xiaobo Quan, and Dr. Upali Nanda, and project manager Catherine Ancheta who coordinated the grant volunteers and seminar logistics. However, it took nearly all of the CHD staff to prepare for and run the seminar for testing the SRA in 2014. Debra Levin, CHD's CEO, provided the flexibility to work and study simultaneously. There were more than 100 volunteers and three healthcare

organizations that participated in the development of the SRA, and I owe gratitude to all those who allowed their diversity, expertise, and thoughts to become a foundation for theory development in the PhD.

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"I know I'm in my own little world…It's okay, they know me here."

Tea Towel, the Tattered Cover Book Store, Denver, CO

Publications

1. Hignett, Sue, Laurie Wolf, Ellen Taylor, and Paula Griffiths. 2015. "Firefighting to Innovation: Using Human Factors and Ergonomics to Tackle Slip, Trip, and Fall Risks in Hospitals." *Human Factors: The Journal of the Human Factors and Ergonomics Society* 57 (7): 1195–1207. doi:10.1177/0018720815593642.
2. Taylor, Ellen, and Sue Hignett. 2014. "Evaluating Evidence: Defining Levels and Quality through Existing Methods." *HERD: Health Environments Research & Design Journal* 7 (3):144-151. doi: 10.1177/193758671400700310.
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8. Taylor, Ellen, Xiaobo Quan, and Anjali Joseph. 2015. "Testing a Tool to Support Safety in Healthcare Facility Design." International Conference on Applied Human Factors and Ergonomics (AHFE) Las Vegas, NV, July.

Manuscripts Underway

9. Taylor, Ellen, Sue Hignett, and Paula Griffiths. 2016a. "Anticipate to Participate to Integrate; Thematic Analysis of Testing a Design Tool for Safety." *Manuscript in preparation*.
10. Taylor, Ellen, Sue Hignett, and Paula Griffiths. 2016b. "Participatory Mesoergonomics: Is There an Ergotect in the House?" *Manuscript in preparation*.
11. Taylor, Ellen, Sue Hignett, and Paula Griffiths. 2016c. "SCOPE in Design: A Theoretical Model of Hf/E and Hospital Falls." *Manuscript in preparation*.

Table of Contents

Figures

Tables

Abbreviations

AAHID: American Academy of Healthcare Interior Designers

ACA: Patient Protection and Affordable Care Act

ACHA: American College of Healthcare Architects

AE: Adverse Events

AHRQ: US Department of Health and Human Services Agency for Healthcare Research and Quality

AIA: American Institute of Architects

AEDET: Achieving Excellence Design Evaluation Toolkit

ASPECT: A Staff and Patient Environment Calibration Toolkit

BH/S: Behavioral Health/Security

BIM: Building Information Modeling

BLS: Bureau of Labor Statistics

BPE: Building Performance Evaluation

BUDSET: Birth Unit Design Spatial Evaluation Tool

CAT: Critical Appraisal Tool

CHD: Center for Health Design, The

CMS: US Department of Health and Human Services Centers for Medicare and Medicaid

DQI: Design Quality Indicator

EBD: Evidence-Based Design

EDAC: Evidence-Based Design Accreditation and Certification

FGI: Facility Guidelines Institute

FMEA: Failure Mode and Effect Analysis

F/PH: Falls/Patient handling

HAC: Hospital-Acquired Condition

HAI: Healthcare-associated infection

HAI/MS: Healthcare-associated infection/Medication safety

HC: Healthcare (as used in HC facility design)

HF/E: Human Factors and Ergonomics

ICD: International Classification of Diseases

IOM: Institute of Medicine

IPD: Integrated Project Delivery

LEED: Leadership in Energy & Environmental Design

MHS: Military Health System

MMAT: Mixed Methods Appraisal Tool

MSR: Mixed Studies Review

NICE: National Institute for Health and Care Excellence

NHS: National Health Service

NDNQI: The National Database of Nursing Quality Indicators™

NPSA: National Patient Safety Agency

PE: Participatory Ergonomics

POE: Post-occupancy Evaluation

PS: Pilot Site

RIBA: Royal Institute of British Architects

RCA: Root Cause Analysis

SRA: Safety Risk Assessment

STF: Slips, Trips and Falls

UK: United Kingdom

US: United States

Preface

A Center for Health Design (CHD) Grant

Seminar in Designing for Patient Safety

In 2011, a one-year AHRQ seminar grant (1R13HS020322-01A1) facilitated by The Center for Health Design (CHD) reviewed seven methods/techniques that might be used in designing for safety. These included link analysis, root cause analysis (RCA), failure mode and effects analysis (FMEA), work sampling (time motion), balanced scorecard, process analysis (process charts/flow charts), and simulation (Joseph et al. 2011). Seminar participants felt the methods were usable, relevant, and feasible, and were generalizable to healthcare (HC) facility design but did not offer enough actionable guidance for design teams.

R13 Grant Program for Large or Recurring Conferences

In January 2012, The Center for Health Design (CHD) submitted an R13 grant proposal to the Agency for Healthcare Research and Quality (AHRQ) to support the development of a Safety Risk Assessment (SRA) toolkit integrating safety in the HC facility design process. The R13 Grant Program for Large or Recurring Conferences supports work that helps to further improved quality, safety, efficiency, and effectiveness of healthcare. One category within the R13 program is dissemination and implementation conferences, "*where research findings and evidence-based information and tools are summarized, communicated and used by organizations and individuals that have the capability to use the information to improve the outcomes… of health care services*" (AHRQ 2012, i57). The toolkit development was intended to support SRA language being submitted for the 2014 Facility Guidelines Institute (FGI) *Guidelines for the Design and Construction of Hospitals and Outpatient Facilities*. The grant was commenced in September 2012.

Grant Goals

In 2008, EBD was defined as "*the process of basing decisions about the built environment on credible research to achieve the best possible outcomes*" (CHD 2015). CHD identified the key project goals for the three-year grant (Table 0-1) as development of an SRA toolkit that uses an evidence-based design (EBD) strategy to

accelerate adoption, integration, and institutionalization of physical environmental design as a means to mitigate patient harm.

Table 0-1. Phases of the AHRQ grant developing a Safety Risk Assessment tool

Grant phase	Description
2012-2013 (year 1) Content	Development of a framework for latent conditions that contribute to adverse events in healthcare facility design for six outcomes areas; review of design features based on literature reviews and expert workgroup consensus; finalize preliminary SRA content for testing at a face-to-face seminar
2013-2014 (year 2) Testing	Pilot testing of SRA with three healthcare organizations undertaking a facility design project; simulation testing of the SRA using hypothetical scenarios with expert workgroups at a face-to-face seminar
2014-2015 (year 3) Dissemination	Final development of SRA tool and dissemination at a national industry conference in the US

The toolkit includes the SRA tool, a safe design roadmap, and instructions and methods for use. With CHD's ongoing role in facilitating the use and value of built environment design research (evidence-based design), this offered an opportunity for me to apply the work being completed for the grant to my PhD.

The Center for Health Design Research Team

CHD researchers supported the grant with defined responsibilities (Table 0-2).

Table 0-2: Researcher roles for the SRA grant

Researcher	Role
Anjali Joseph, PhD, EDAC, Principal Investigator (Grant Years 1-3)	Responsible for project oversight and overall development: scope, budget, schedule, reporting, seminar logistics, liaison to AHRQ and Advisory Committee; Medication Safety coverage in Grant Year 2
Ellen Taylor, AIA, MBA, EDAC (Grant Years 1-3)	Responsible for two topics and liaising with related workgroups: (Falls and Psychiatric [Behavioral Health] Injury), tool development, and further work illustrated in Figure 0-1.
Xiaobo Quan, PhD, EDAC (Grant Years 1-3)	Responsible for two topics and liaising with related workgroups (Infection Control and Patient Handling); added Security in Grant Year 2
Upali Nanda, PhD, EDAC (Grant Year 1 only)	Responsible for two topics and liaising with related workgroups in Year 1 (Security and Medication Safety)

The Case Study Topic: Falls

My interest in patient falls stems from healthcare reform in the United States (US), where reimbursement policy for preventable harm has reinvigorated discussion on serious safety events. I have leveraged the grant scope (and specifically falls) as a platform for exploration in human factors and ergonomics (HF/E) and the systems aspect of healthcare so often missed by professionals in HC facility design. I have pursued the thesis as practice-led research (for HC facility design) leading to new knowledge with operational significance for the practice (Candy 2006).

Relationship of my PhD to the CHD Grant

Figure 0-1 illustrates the grant scope and timeline and the additional rigor afforded by the PhD undertaking, my individual work, and contribution to knowledge.

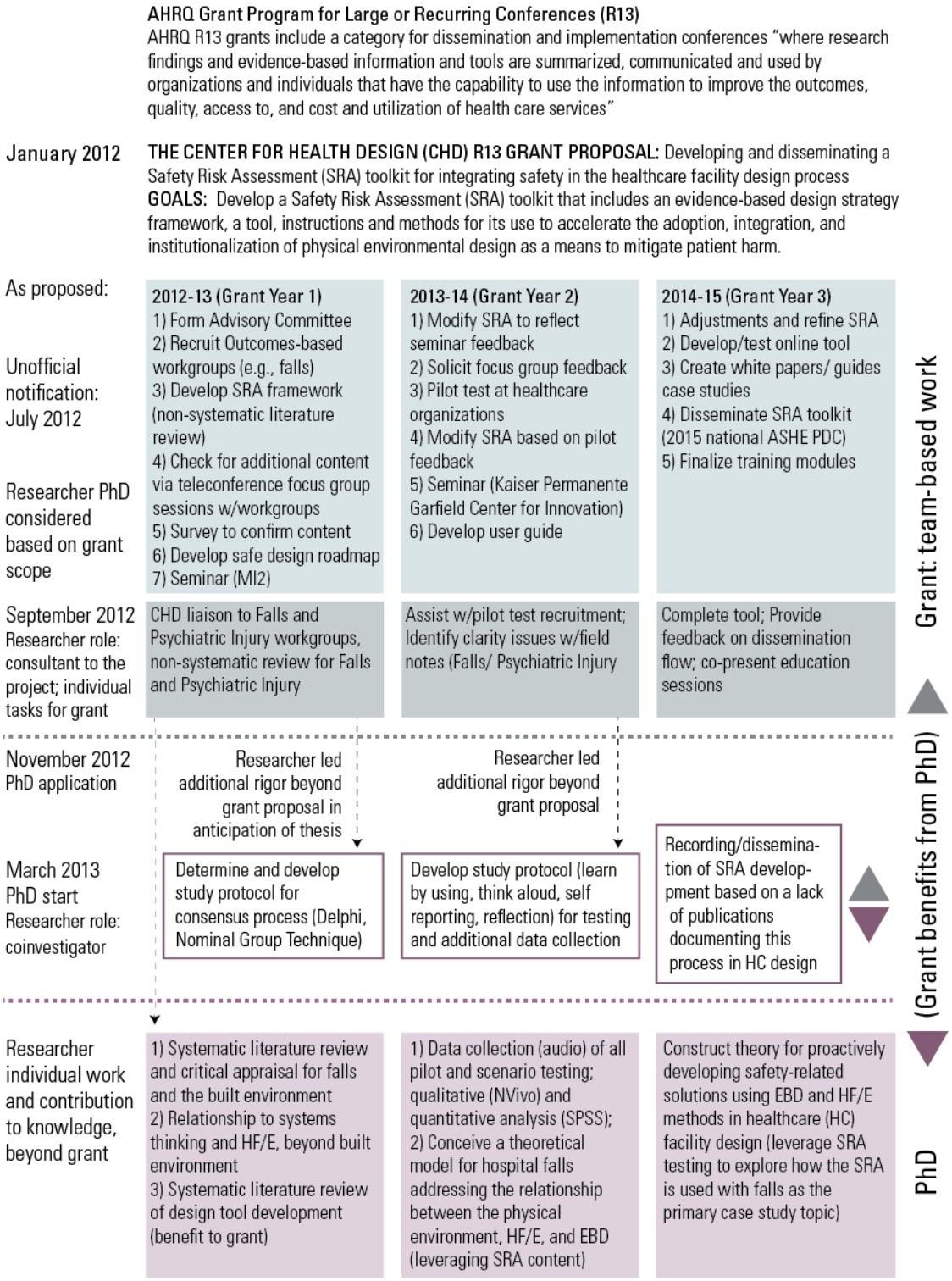

Figure 0-1. CHD AHRQ grant and Taylor PhD (Loughborough Design School)

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1 Thesis Overview

1.1 Problem Statement

While architects excel at problem solving, they are not always fully versed in the interactions of work tasks, flow, and function. Healthcare (HC) facility design is particularly complicated and complex, and in the early phases of design the definition of function often relies on historical data, interviews, observation, and the completion of room data sheets that do not capture the complexity of work as performed versus work as imagined in healthcare environments. Evidence-based design, a process using research as a foundation for decision-making, acknowledges the complexity of interactions in HC facility design, but has focused on understanding specific facility design interventions on outcomes such as safety, efficiency, quality of care, and satisfaction.

In 2000, the International Ergonomic Association (IEA) defined human factors and ergonomics (HF/E) as the "*understanding of interactions among humans and other elements of a system*," and using "*methods to design in order to optimize human well-being and overall system performance"* (IEA 2015). HF/E is sometimes considered in three domains: physical, cognitive, and organizational (Karwowski 2012, IEA 2015) and recognizes that individual abilities and limitations should be considered when optimizing performance (Gurses, Ozok, and Pronovost 2012). HF/E has emerged as a branch of practice in healthcare stemming from the need to address error, teamwork, and communication issues using a systems approach (Catchpole 2013). However,

> Despite the most acknowledged definitions of ergonomics or human factors that ergonomic design of environments bring the same concerns as any other kind of systems, and even though a poor building design affects a whole physical, cognitive and organisational aspects of ergonomics in a given situation, a comprehensive methodology purposed to designing ergonomic buildings is still lacking. (Attaianese and Duca 2012, 187)

The research inquiry of this thesis is to explore how proactive thinking in safety can be used to bridge the domains of EBD (research-based building design supporting a system) and HF/E (understanding humans interacting with a system) in HC facility design.

1.2 Mind the Gap

1.2.1 Facility Design and HF/E

There is a lack of awareness and misunderstanding of HF/E in the field of architecture. The AIA states, "*ergonomic studies typically focus on the interface between humans and furniture or equipment*" (American Institute of Architects 2013, 920). This confusion may stem from the early origins of HF/E in the human-machine (or artefact) interface (Hollnagel 2014a) rather than the more recent advances to system design (Dul et al. 2012). The traditional education of architects and designers also has placed little value on rigorous research methods or the scientific method (Chong, Brandt, and Martin 2010), and in some instances there is a lack of awareness of what may happen in research-focused fields, such as HF/E. For example, Chong, Brandt, and Martin (2010, 311) state, "*the use of physiological responses to environmental stimuli is more recent and more complex.*" While it is more complex, the use of physiological response, from an HF/E perspective, is not recent.

In a paper proposing inter-professional competencies for improving healthcare design Lamb et al. (2010) describe a competency framework that includes: (1) domains of knowledge that shape HC facility design (care processes, organizational culture, physical environment, technology); (2) a recognition of different perspectives from different professions (architecture, industrial design, medicine, nursing, administrators, engineering, human computing); and (3) competencies to integrate diverse perspectives. There is no reference to HF/E and minor references to work process and work cycle.

An ongoing challenge in integrating HF/E and facility design was highlighted by Hall-Andersen and Broberg (2014). The authors cite numerous studies corroborating that when ergonomic information is provided via a document (i.e., standards or handbooks), integration is not ensured, and in fact may go unrecognized, be misinterpreted, or not be integrated into design solutions at all (Hall-Andersen and Broberg 2014). Lu and Hignett (2005) described when ergonomic reasons behind design guidance of NHS Estates Health Building Notes were lacking (or inconsistent across sources), architects ignored or misunderstood the information.

1.2.2 HF/E and the Physical Environment

Building design requires systems-thinking that addresses physical, cognitive, and organizational aspects of user processes. For a successful outcome, design teams must navigate from simple "functions" to a more complete understanding of the user actions the building has to support (Attaianese and Duca 2012). Early design decisions for the physical environment have impact on functionality, and when HF/E is considered late in the process solutions are limited and relegated to microergonomic approaches (Mallam, Lundh, and MacKinnon 2015). HF/E often studies the user, the task, and the task environment as discrete units, and as a result the issues of "*who the users are, what they do, and how their 'lived-in' (e.g., social, technological, organizational) environments constrain them"* is segregated and may obscure important interactions of the system (McNeese et al. 1995, 346). There are many descriptions of the environment from an HF/E perspective (Table 1-1). None considers overall building design as a systems warranting an HF/E approach.

Table 1-1. Descriptions of the physical environment in HF/E sources

Source	Description
International Encyclopedia of Ergonomics and Human Factors, (Karwowski 2006)	Devotes one chapter to workplace and equipment design (ranging from auto interiors to hand tools) and one to the environment (including noise, illumination and vibration)
Handbook of Human Factors and Ergonomics in Health Care and Patient Safety (Carayon 2011)	Describes physical ergonomics as focused on the physical characteristics of the person with design interventions often aimed at reducing physical stress; one chapter devoted to physical ergonomics includes individual built environment components (e.g., space constraints), climate and thermal environments (clothing and heat exchange), air quality, noise, vibration, and illumination (Alvarado 2011), another to musculoskeletal disorders as it pertains to patient handling (Hignett, Fray, and Matz 2011)
Introduction to Human Factors Engineering: Pearson New International Edition (Wickens et al. 2014)	Describes environmental design as "*improved lighting, temperature control, and reduced noise in the physical environment where the task is being carried out*" (Wickens et al. 2014, 4) with reference that the environment can also include the organizational climate. A chapter on engineering anthropometry and workspace design describes considerations such as clearance, reach, and maintenance requirements; adjustability; visibility of displays; component arrangement of displays and controls; and work surface depth and inclination. A chapter on safety and accident prevention describes the physical environment considerations as illumination, noise and vibration; temperature and humidity; fire and radiation hazards; falls; and exits and emergency evacuation
International Ergonomics Association (IEA 2015)	Defines physical ergonomics as "*human anatomical, anthropometric, physiological and biomechanical characteristics as they relate to physical activity. (Relevant topics include working postures, materials handling, repetitive movements, work related musculoskeletal disorders, workplace layout, safety and health.)"*
Human Factors and Ergonomics Society (HFES)	Member research for environmental design has focused on sustainable environments as well as the physical layout of a variety of places, such as the home, office, classroom etc., how to combine ergonomic accessories to create effective and efficient workstations that promote comfort and productivity, and how to provide ambient conditions that promote health and well-being

1.3 Contextual Background

1.3.1 EBD and Healthcare Facility Design

EBD is a relatively recent process that is used in architecture, primarily HC facility design. EBD is defined by different sources ranging from informed intuition (Chong, Brandt, and Martin 2010) to the process of outcomes-based decision-making about the built environment based on credible research (CHD 2015). The Center for Health Design (CHD), the organization that developed evidence-based design and certification (EDAC), defines the EBD as an eight-step process with foundations in research (CHD 2010b):

(1) Define evidence-based goals and objectives,
(2) Find sources for relevant evidence,
(3) Critically interpret relevant evidence,
(4) Create and innovate evidence-based design concepts,
(5) Develop a hypothesis,
(6) Collect baseline performance measures,
(7) Monitor implementation of design and construction, and
(8) Measure post-occupancy performance results.

Hamilton (2003) described four levels of evidence-based practice ranging from staying current with the literature, to hypothesizing expected outcomes, measuring results, sharing lessons learned, and submitting to peer-reviewed journals. Most healthcare design teams acknowledge using some form of EBD (Taylor 2011), and one of the broad outcomes considered in EBD is safety for both patients and staff (Ulrich et al. 2004, Ulrich et al. 2008). The overall process of architectural facility design is expanded in Chapter 1, but the focus of the thesis will be based on EBD in HC facility projects.

EBD has been evolving, and it has been questioned whether EBD (sometimes likened to evidence-based medicine) is a field, research, or a design process that is considered good practice (Hamilton 2009, Stichler 2010a). According to the AIA Research Primer (2009), EBD is considered a topic within design research. Publications that are more recent refer to EBD as a field (Ulrich et al. 2010, Verderber et al. 2014). According to Stichler (2010a, 6), "*the purpose of EBD is to translate existing research findings into practice, or to use research findings to guide decision*

making" as opposed to 'research' that generates new knowledge. Stichler explains that where research is available to inform a design decision, an EBD process should be used; where research does not exist to inform a decision, a research process should be employed.

1.3.2 Safety and Healthcare Facility Design

Hospitals are among the most complex of building types serving stress-filled purposes with competing needs of diverse user groups, intricate organizational structures, and rapidly changing technology (Shumaker and Pequegnat 1989). Hignett (2013) argues that poor design can permeate throughout the system and result in a reliance on behavior changes rather than beginning with a design that does not require behavior change. This is fitting the user to the environment, rather than fitting the environment to the user (Hignett 2013, Dul et al. 2012). Latent conditions of the built environment can contribute to hazards and risk within the system (Henriksen, Joseph, and Zayas-Caban 2009, Joseph and Rashid 2007, Hignett and Masud 2006, Hignett et al. 2010).

Recognizing this, a requirement to conduct an SRA was included in the 2014 Facility Guidelines Institute (FGI) *Guidelines for the Design and Construction of Hospitals and Outpatient Facilities*. In the *Guidelines*, seven components of injury or harm are to be considered in the design of the built environment. These include:

1. Healthcare-associated infection (HAI),
2. Patient Handling,
3. Falls,
4. Medication Safety,
5. Security,
6. Behavioral Health/Psychiatric Injury (e.g., suicide, elopement/absconding), and
7. Immobility (considered with 2 and 3 for the SRA tool).

The *Guidelines* are not prescriptive about how the SRA is conducted.

1.3.3 Patient Safety and Hospital Falls

The problem of patient safety gained international public awareness when the Institute of Medicine (IOM) released the reports, *To Err is Human* and *Crossing the*

Quality Chasm (Institute of Medicine [IOM] 2001, 1999). These reports highlighted that as many as 98,000 people die in US hospitals each year as a result of preventable medical error (Institute of Medicine [IOM] 1999). This was ostensibly due to complex and uncoordinated delivery of care (Institute of Medicine [IOM] 2001).

The impact of the IOM reports was felt globally. Based on the two studies, deaths and permanent disability were extrapolated to be 60,000 patients in the United Kingdom (UK) (Department of Health 2000). However, the burden of patient safety considers preventable harm of all adverse events (AEs), not just those resulting in death or disability. A Canadian study of AEs in several developed countries summarized the percentage of AEs and preventable AEs (Table 1-2). The 7.5% AE rate in Canada equated to 185,000 admissions, with nearly 70,000 potentially preventable (Baker et al. 2004).

Table 1-2. Adverse events in developed countries

Country	Data drawn from:	% patients ≥ 1AE	% preventable
Canada	(Baker et al. 2004)	7.5	36.9
US	(Thomas et al. 2000)	2.9 (3.2*)	Not reported
US	(Brennan et al. 1991, Leape et al. 1991)	3.7	Not reported
Australia	(Wilson et al. 1995)	16.6 (10.6*)	51
UK	(Vincent, Neale, and Woloshynowych 2001)	10.8	48
New Zealand	(Davis et al. 2003, 2002)	12.9	37

* Results from the US and Australian studies were recalculated after standardizing inclusion criteria and definitions. The Australian rate was found to be 10.6% and the Utah/Colorado rate 3.2%.
Source: Adapted from Baker et al. 2004.

In the US, healthcare reform has created a fundamental shift where hospitals are no longer reimbursed for hospital-acquired conditions (HACs) – high-volume, high-cost, largely preventable "never events" or serious adverse events (CMS 2008). Injurious falls (e.g., fracture, dislocation) were deemed a HAC (CMS 2008) and have been a safety focus in the US following:

- reimbursement changes that commenced in 2009,
- additional financial penalties introduced as part of the US HAC reduction program in 2014 (CMS 2013), and
- a sentinel event alert issued by The Joint Commission (The Joint Commission 2015).

Current fall-related HACs are included as part of a composite patient safety indicator score (CMS 2013). The US legislative and regulatory history for safety and falls is illustrated in Figure 1-1.

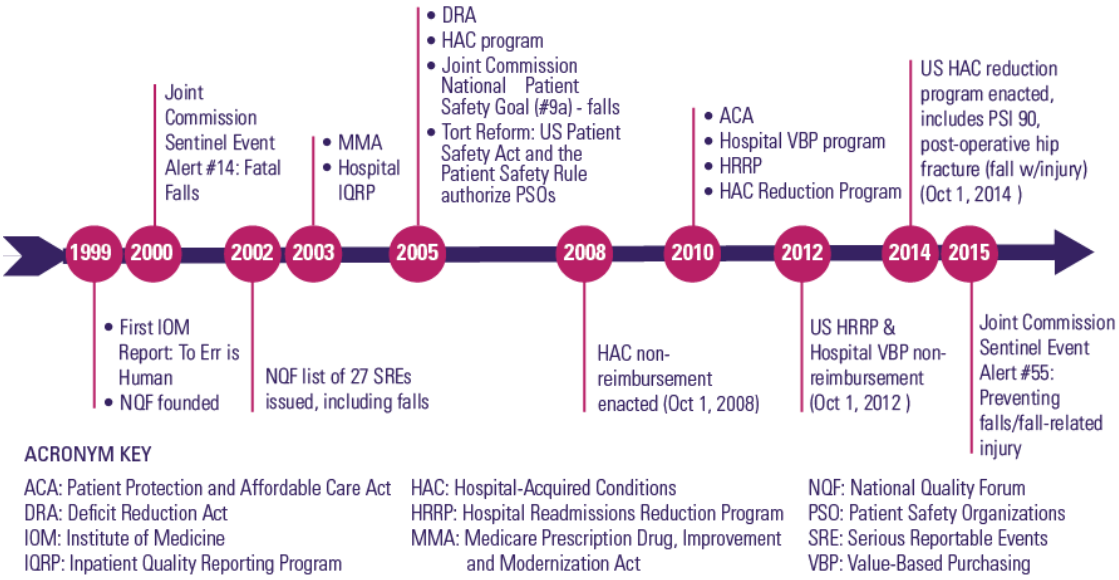

Figure 1-1. US legislative and regulatory environment of patient safety and falls

1.3.4 Healthcare Safety and Human Factors

A key message in the IOM studies was emphasizing error as a systems problem and identifying human factors as an important component of patient safety (Carayon 2011). According to some, the point of investigating preventable adverse healthcare events is primarily to make sense of the factors that contribute to error (Henriksen and Kaplan 2003), but in many evaluations of patient safety the search for causation ends with blame-and-retrain mentality (Catchpole 2013). However, there are often challenges in understanding the problems being solved, especially in the area of healthcare safety.

> By focusing on a limited aspect of what is already known, there may be a danger of missing the larger multi-factorial problem. It may be tempting to focus on simple fixes – the low hanging fruit – rather than address the fundamental underlying issues that take a more prolonged period to study. (Henriksen 2011, 22)

At the same time of the US IOM and UK Department of Health reports, literature was also being published to highlight the potential for HF/E to contribute to

patient safety solutions through theory and applied studies (Gosbee 2002, Nolan 2000, Shojania et al. 2001, Vincent, Taylor-Adams, and Stanhope 1998).

It has been stated that healthcare is arguably more complex than any other broadly equivalent industry and is extremely resource sensitive, making the evidence base critical and the return on investment difficult to gauge (Catchpole 2013). The complexity is further aggravated by the segregation of organizational silos.

> Although health care providers work together, they are trained in separate disciplines where the primary emphasis is the mastery of the skills and knowledge to diagnose ailments and render care. In the pursuit of becoming as knowledgeable and skillful as possible in their individual disciplines, a challenge facing nursing, medicine, and the other care specialties is to be aware of the reality that they are but one component of a very intricate and fragmented web of interacting subsystems of care where no single person or entity is in charge. (Henriksen et al. 2008, 3)

Thinking in HF/E for patient safety has evolved over time. Carayon et al. (2006) describe an evolution in human factors 'engineering' and systems approaches to patient safety from Reason (1990) and Vincent, Taylor-Adams, and Stanhope (1998), to use of the Haddon matrix (Brasel, Layde, and Hargarten 2000), and development of the Systems Engineering Initiative for Patient Safety (SEIPS) model of work system of patient safety (Carayon et al. 2006). In the book *Patient Safety: A Human Factors Approach*, Dekker (2011) traces behavioral and linear Newtonian thinking (representative of a complicated system) into newer views of complexity. The difference is important as complicated systems are described as stable, closed to environment, knowable, and controllable with a pre-existing order of any outcome, whereas complex systems are more than a sum of the parts - always changing due to relationships and interactions between parts (Dekker 2011, 2014, Simon 1962).

More recently, system resilience, Safety-I, and Safety-II have moved the HF/E discussion in a direction of better understanding the everyday performance that usually succeeds (Braithwaite, Wears, and Hollnagel 2015). From a thesis perspective, the built environment acts as a setting for activity (Hollnagel 2014b) that creates visibility for actors and interactions (Hassler and Kohler 2014). It can impede or promote desired safe behaviors. The context of patient safety is expanded in Section 2.3.1.

1.3.5 Macro, Micro, and Mesoergonomics

Healthcare safety has been addressed on the macro, micro, and mesoergonomic levels (Carayon 2011, Fray, Waterson, and Munro 2015, Holden et al. 2015, Karsh 2006, Karsh, Waterson, and Holden 2014). Micro, macro, and meso levels have their origin in organizational theory and behavior. For example, Bronfenbrenner (1977) defines the ecological environment as topologically conceived in a nested arrangement of structures that include microsystems (an immediate setting), a mesosystem (interactions), an exosystem (external influences), and a macrosystem (overarching institutional patterns). Importantly, Bronfenbrenner highlights the complexity of ecological research and posits that the environment, and the process taking place within, must be viewed as interdependent and analyzed in system terms.

The link between organizational management and design and ergonomics was initiated as early as 1980 (Hendrick 1991). Influenced by ecological research (Bronfenbrenner 1979), work organization theories (Klein 1976), and ethics in the workplace (Shipley 1998), Hignett first placed these levels in an ergonomic model (1999). Mesoergonomics as a formal term appeared several years later (Karsh 2006). Influenced by other organizational theorists (House, Rousseau, and Thomashunt 1995), Karsh et al. define mesoergonomics as an integration of microergonomics and macroergonomics across nested performance inputs and outputs (Karsh et al. 2006). The nested mesoergonomic inputs shown in Figure 1-2 include patient/provider – individual; work system/unit – team/group; organization, and external environment - industry). According to the authors, mesoergonomic research can help to understand "*cross-level interactions that shape an outcome of special interest or might be important in helping to scope the design of workplace related improvements or interventions; and, informing the choice of concepts which can be used to further develop theory*" (Karsh, Waterson, and Holden 2014, 47). The framework has been used for several healthcare safety topics such as medication safety (Karsh and Brown 2010), infection control (Waterson 2009), and patient handling (Fray, Waterson, and Munro 2015).

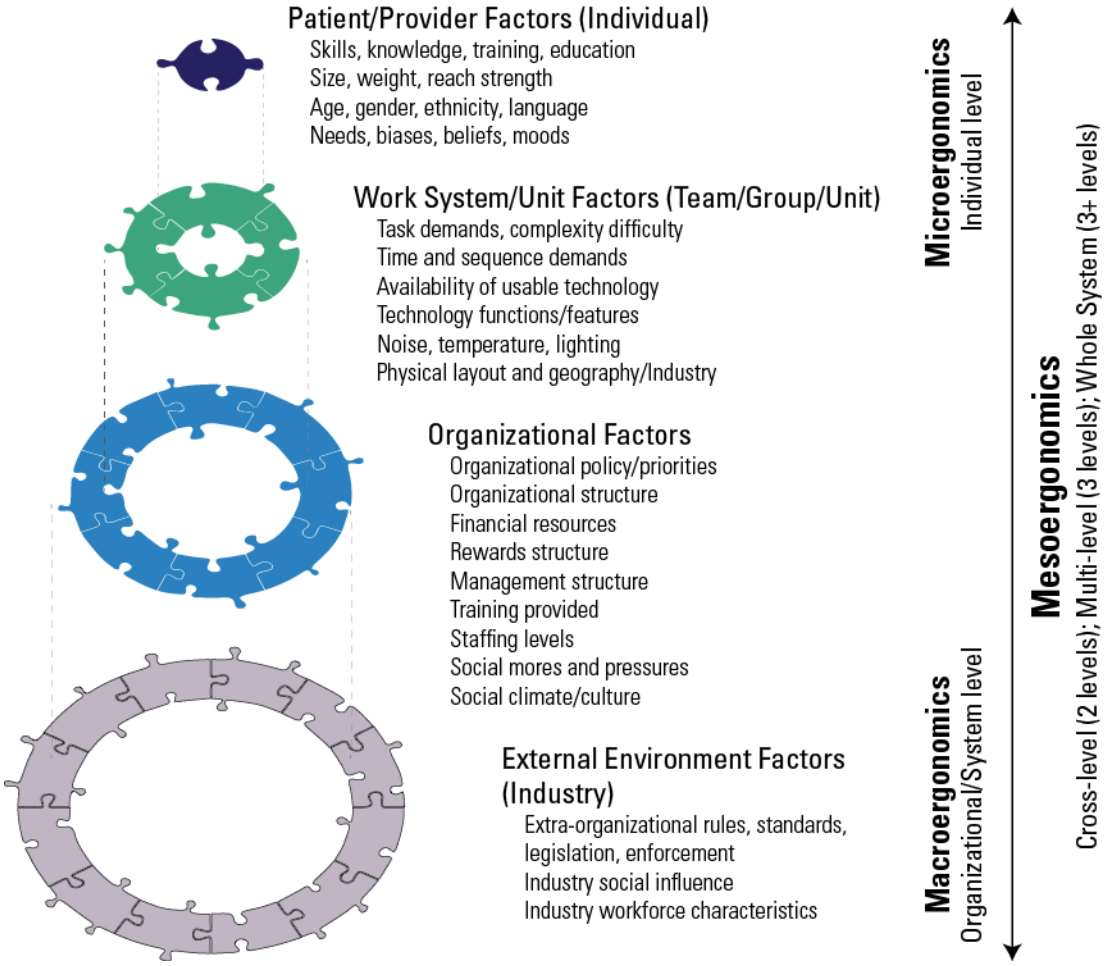

Figure 1-2. A Mesoergonomic Framework
Source: Adapted from Karsh et al. 2006, Karsh, Waterson, and Holden 2014.

1.4 Aims

With gaps between disciplines, safety is clearly a problem of greater complexity than originally perceived and needs a more sustainable solution. The thesis aims to advance safer HC facility design through proactive thinking, informed by use of the SRA, to bridge the domains of EBD and HF/E. This will be explored by reframing HC facility design as an ergonomic problem of fitting the environment to the user by:

1. conceiving a theoretical model that addresses the relationship between HF/E and EBD to better understand the risks and interventions for hospital falls (leveraging content development for the SRA module on hospital falls) and

2. constructing grounded theory to support proactive safety-related solutions using EBD processes and HF/E methods (leveraging grant-based testing to understand how the SRA content is applied, using falls as the primary case study topic).

1.5 Objectives and Approach

As outlined in the Preface, the thesis uses the development of the SRA to explore the integration of EBD and HF/E. The research was undertaken in stages (Figure 1-3) to advance a theoretical framework which is presented iteratively throughout the thesis development.

Stage 1: Sets context for HC facility design (EBD, safety, guidance tools); patient safety and hospital falls; and HF/E (patient safety, mesoergonomics; human performance)

Stage 2: Corroborates SRA content through Phase 1 of a systematic literature review to ascertain conditions of and interventions for hospital falls in the physical environment; conceives a preliminary systems model for falls

Stage 3: Develops SRA content through consensus methods (Delphi process and nominal group technique) using expert workgroups

Stage 4: Collects data using mixed methods for the testing of the SRA content through hypothetical scenarios

Stage 5: Collects data using mixed methods for the testing of the SRA content in real-world pilot projects

Stage 6: Analyzes results and constructs grounded theory through a core theme derived from data collection (Stages 4 and 5)

Stage 7: Continues a systematic literature review (Phase 2) of conditions of and interventions for hospital falls beyond the physical environment to conceive a furthered systems model for falls

Stage 8: Conceives and discusses final theoretical models for bridging EBD and HF/E through data of two systematic literature reviews, new literature explorations, and SRA testing

Figure 1-3 shows the stages, context, and boundaries of the proposed exploration, using several filters and the phases of the development of the SRA. This

will be used throughout the thesis as a "signpost" diagram to follow the evolution of theory developed through the thesis.

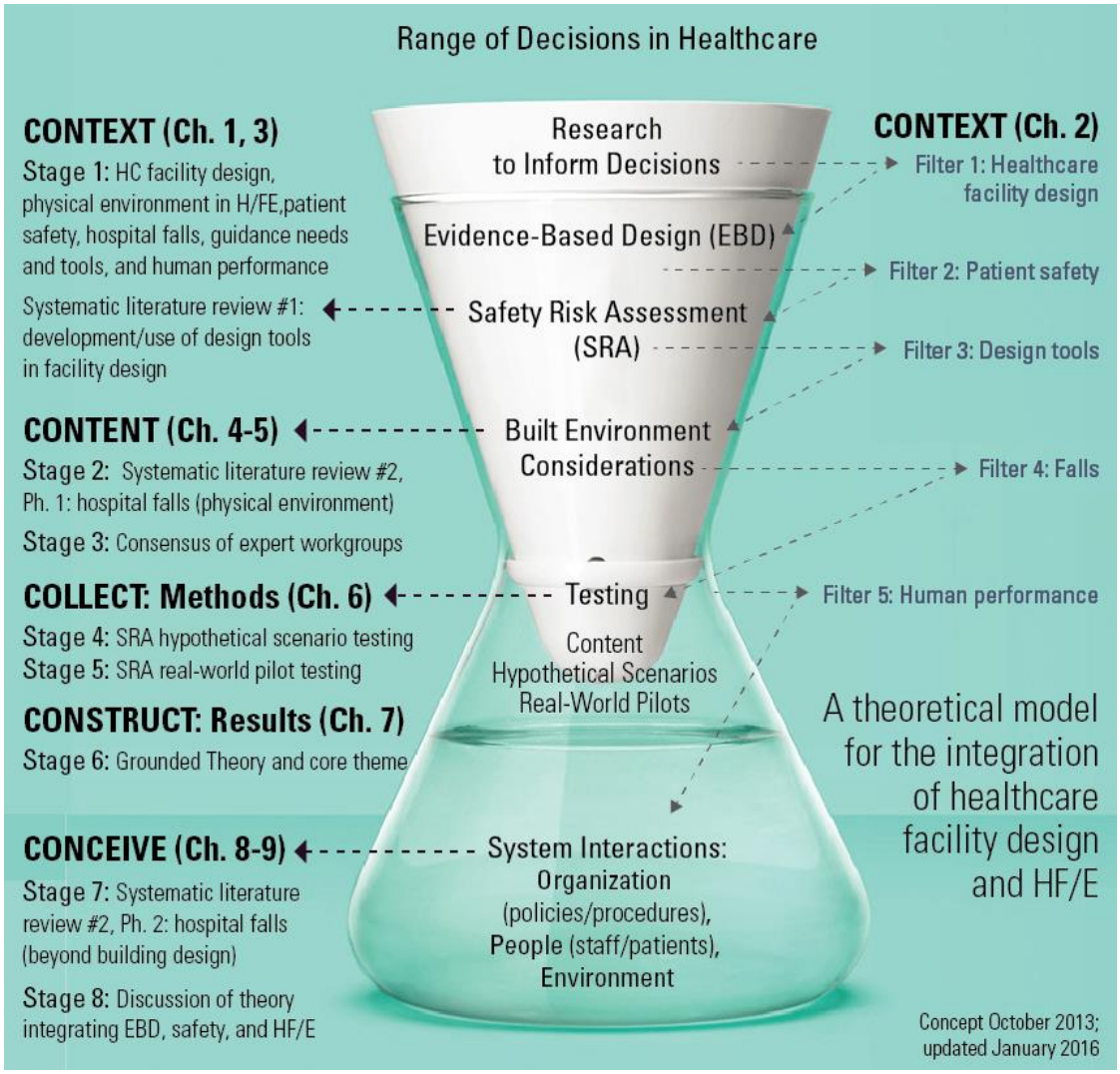

Figure 1-3. Graphic model for thesis structure: stages, context, boundaries

The funnel is used to illustrate the focus created for the thesis, moving from general to specific: a range of decisions in healthcare, with research practice to inform decision-making, as implemented through an EBD process for facility design, and the development of the SRA to proactively identify built environment considerations. The SRA is subsequently tested for usability through real-world and hypothetical settings, but it is also used to understand its additional potential to advance HF/E in HC facility design.

While directing the focus to the built environment, the beaker is used as a metaphor for stirring and mixing – interactions that must be considered in complex systems. Filters are used to refine focus from research-based decision-making in

healthcare, to architecture, and more specifically HC facility design, which leads to the EBD process. Safety becomes a defined goal and objective for an EBD process, leading into the development of the SRA and the context of design methods and tools to guide the understanding of built environment considerations. The SRA tool includes six safety topics. The thesis uses one SRA topic (falls) as the case study for investigation. Human performance is described to consider the synthesis of interactions. The five filters are presented more fully in Chapter 2.

1.6 Thesis Structure

The thesis contains 10 chapters which are summarized in Table 1-3.

Table 1-3. Chapter summary

	Chapter	Summary
	Preface	The preface outlines the context of the grant and illustrates the grant scope and timelines, my individual work, and my contribution to knowledge through the PhD.
	1: Thesis Overview	Chapter 1 provides the problem statement, the thesis aims, the approach, and thesis structure. It identifies the gap between evidence-based design and human factors/ergonomics.
CONTEXT Stage 1	2: Filters that Focus the Thesis	Chapter 2 provides context through the filters used in developing the theoretical model including HC facility design, patient safety, design tools, falls, and human performance. The extended context is important due to the complexity of each of the filters.
	3: Design Guidance: Processes, Methods, Evaluation, Tools	Chapter 3 establishes how tools are developed and used to guide and evaluate facility design.
CONTENT Stage 2-3	4: Systematic Literature Review: Hospital Falls (Phase I)	In Chapter 4, conditions and interventions for falls are identified through Phase 1 of a systematic literature review focusing on the built environment.
	5: Methods - SRA Content Development	The thesis is advanced in Chapter 5 through a consensus methodology used for SRA content development for falls.
COLLECT Stages 4-5	6: Methods – SRA Testing: Hypothetical & Real-World	Chapter 6 includes the development of the mixed methods study protocol and subsequent data collection through testing with real-world projects and their project teams, as well as hypothetical scenarios using expert workgroups.
CONSTRUCT (Stage 6)	7: Results of SRA Testing: Constructing Theory	Chapter 7 of the thesis includes the analysis of mixed method results to develop a core theme through grounded theory.
CONCEIVE (Stage 7-8)	8: Systematic Literature Review: Hospital Falls (Phase II)	In Phase 2 of the systematic literature review for falls, Chapter 8 expands the findings for conditions and interventions surrounding falls to include organizational and people factors.
	9: Discussion	Chapter 9 provides a thesis overview and proposes theoretical models resulting from the thesis undertaking.
	10: Conclusion	The conclusion answers the aims of the thesis, summarizes the contributions, and proposes future work.

1.7 Conclusion

An integrated systems approach has the potential to provide a more comprehensive understanding of the safety problems being addressed in HC facility design. EBD, using research at a foundational level, should be uniquely positioned to advance knowledge and awareness of HF/E approaches. While the use of EBD has been growing, there is criticism that while EBD has advocated a change in how architects work, it has not focused on adequately equipping clients and designers with the means to improve the quality of design (Phiri 2015). The development of the SRA establishes a process for proactively identifying latent conditions in HC facility projects by using research as the basis for safe facility design. The theory and frameworks developed through the thesis will contribute to an understanding of EBD and HC facility design in the HF/E context as an ergonomic problem requiring a systems approach to optimize human performance.

2 Filters that Focus the Thesis

2.1 Chapter Overview

This chapter provides the context for Stage 1 by describing filters that have been used to guide thesis development. The filters move from a general context of HC facility design and patient safety to the specifics of design tools and the case study topic of falls. Human performance is introduced for the context of considering system interactions.

2.2 Filter 1: HC Facility Design

Like clinical aspects of healthcare, HC facility design also bridges a diverse group of disciplines such as architects, interior designers, medical planners, engineers, specialty consultants (e.g., security, information technology), healthcare management consultants, landscape architects, and construction managers/contractors (Joint Commission Resources 2006). The design process is typically segregated by discipline, as well as by individual departmental/specialty user groups, and often results in conflicting goals for service, care, and long-term efficiency. Over the lifespan of the building (and even over the life-cycle of the project development) priorities, models of care, staff, and technology will change.

The unification of stakeholders is presumably "*the common aim of making it better for the user,"* that is to say functional, safe, and usable (Hignett 2013, 2). While the aim may be to reach consensus about priorities and relationships for subjective and objective decisions (Gann, Salter, and Whyte 2003), many examples of inappropriate design can be found (Wilson and Sharples 2015). The field of HC facility design has become increasingly specialized, as evidenced by various certifications and accreditations. For example, in the US these are profession specific: the American College of Healthcare Architects (ACHA) and the American Association of Healthcare Interior Designers (AAHID), and cross disciplinary, such as Evidence-Based Design Accreditation and Certification (EDAC). The first filter of the thesis is the focus on HC facility design as a project type. As cited in Chapter 1, most of these projects use some form of an EBD process.

2.2.1 Design Process

There are numerous models for the design/delivery of healthcare facilities such as design-bid-build, construction manager at risk, design-build, IPD (Integrated Project Delivery), PFI (Private Finance Initiative), or P3 (Public-Private Partnership) (Walrath and Augenbroe 2007, Hellowell 2013). Lean and BIM (Building Information Modeling) are also being used (Walrath and Augenbroe 2007, Burgess and Radnor 2013). While BIM is becoming common in practice to reduce construction conflicts, Lean is a more specialized approach most suited to organizations already refining processes for efficiency (Boyer, Brandenburg, and Wellman 2010). The traditional design-bid-build is still the mainstay of project delivery methods in the US and UK (Construction Management Association of America 2012, RIBA 2013 [About the Plan, Introduction]). The thesis is not focused on delivery and procurement methods, but all delivery methods are both linear and iterative through the life-cycle.

The design process starts with pre-design (strategic planning and programming) and then moves into phases of schematic design, design development, construction documents, and construction. Figure 2-1 was initially developed from information gathered through the prior one-year seminar grant (Joseph et al. 2011) and expanded in the SRA development. A similar process (Figure 2-2) is reflected in the RIBA Plan of Work (RIBA 2013). (In the RIBA workplan, a risk assessment refers to construction safety and the application of UK health and safety legislation and is associated with professional liability.)

	Planning/Programming				Design			Construct	
	Strategic Planning (SP)	Facility Master Planning (MP)	Operational Planning	Functional Program (FP)	Schematic Design (SD)	Design Develop-ment (DD)	Construction Documents (CD)	Bid/Construction Commissioning/Punch List	
Description	Mission; Values; Vision: create clear definition of what the organization will look like (description of services, areas for primary and secondary service, desired financial results); Goals: (quality, physician relations, market share, financial results); Objectives/ Tactics that will be taken over the next one to two years to enable the achievement of the goals	Document: organiza-tional structure/key personnel; Physical space inventory by department/floor, licensed/ operational bed counts, workload data/projections; site/building/zoning/ departmental analysis; development strategies; capital cost consequences of various alternatives/ associated operating costs	Define: staffing; workload history/ forecasting; description of activities, procedures; model of care, hours of operation	Confirm goals, facts, concepts, needs, issues; Define: Function (PP plan w/ critical relationships (diagrams/ adjacency matrices); Form (image, quality, room data sheets, technical/support equipment and furniture, materials, space listing/area tabulations); Economy (budget, life cycle/operating costs); key metric collection	Confirm FP requirements Block diagrams (building, then departments), adjacencies, structural grid, circulation; bubble diagrams (plan/section); renderings/3D visualizations; budget	Additional detail developed: elevations, RCPs, finish schedule, casework, placement of FFE; coordination of A/E disciplines; budget refinement/value engineering	Drawings, specifications (descriptive or performance) and written contract provisions/instruction s for builder (general conditions, etc.)	Bid process	Management of construction contract; RFIs; communication with team, staff, public; infection control risk mitigation COMMISSIONING/PU NCH LIST : Verification of system compliance; list of issues not completed correctly
Stake-holders Participa-tion Activity	Board of Directors; C-suite; Planning Task Force	C-suite; facilities director; dept. directors/heads		Steering Committee, facilities director, user groups	Site visit/assessment; user group meetings; benchmarking; rough mockups; simulation	User group meetings; detailed mockups; simulation			Facilities director, Contractor Transition Planning
Gateway (Sign-off) (at stage completion)	Gateway: Strategic Assessment	Gateway: Business Justification Approval to Proceed		Set budget Project Evaluation Gateway : Certificate of Need	Design milestone: SD sign-off	Design milestone: DD sign-off	Design milestone: CD sign off	Bid substitu-tions; Construction contract/in-vestment pproval	Gateway: Certificate of Occupancy

Figure 2-1. The traditional design process (developed by the author)

STAGES	0	1	2	3	4	5	6	7
TASKS	Strategic Definition	Preparation and Brief	Concept Design	Developed Design	Technical Design	Construction	Handover and Closeout	In Use
Core Objectives	Identify client's Business Case and Strategic Brief and other core project requirements.	Develop Project Objectives including Quality Objectives and Project Outcomes, Sustainability Aspirations, Project Budget, other parameters or constraints and develop initial Project Brief. Undertake Feasibility Studies and review of Site Information.	Prepare Concept Design including outline proposals for structural design, building service systems, outline specifications, and preliminary Cost Information along with relevant project Strategies in accordance with Programme. Agree alterations to brief and issue Final Project Brief.	Prepare Developed Design including coordinated and update proposals for structural design, building service systems, outline specifications, Cost Information and Project Strategies in accordance with Design Programme	Prepare Technical Design in accordance with Design Responsibility Matrix and Project Strategies to include all architectural, structural, and building services information, specialist subcontractors design, and specification in accordance with Design Programme.	Offsite manufacturing and onsite construction in accordance with Construction Programme and resolution of Design Queries from site as they arise.	Handover of building and conclusion of Building Contract	Undertake services in accordance with Schedule of Services
Suggested Key Support Tasks	Review feedback from previous projects.	Prepare Handover Strategy and Risk Assessments. Agree Schedule of Services, Design Responsibility Matrix and Information Exchanges and prepare project Execution Plan including Technology and Communication Strategies and consideration Common Standards to be used.	Prepare Sustainability Strategy, Maintenance and Operational Strategy and review Handover Strategy and Risk Assessments. Undertake third party consultations as required and any Research and Development aspects. Review and update Project Execution Plan. Consider Construction Strategy, including offsite fabrication, and develop Health and Safety Strategy.	Review and update Sustainability Strategy, Maintenance and Operational and Handover Strategies and Risk Assessments. Undertake third party consultations as required and conclude Research and Development aspects. Review and update Project Execution Plan, including Change Control Procedures. Review and update Construction and Health and Safety Strategies.	Review and update Sustainability, Maintenance and Operational and Handover Strategies and Risk Assessments. Prepare and submit Building Regulations submission and any other third party submissions requiring consent. Review and update Project Execution Plan. Review Construction Strategy, including sequencing, and update Health and Safety Strategy.	Review and update Sustainability Strategy and implement Handover Strategy, including agreement of information required for commissioning, training, handover, asset management, future monitoring and maintenance and ongoing compilation of 'As Constructed' Information. Update Construction Strategy and Health and Safety Strategies.	Carry out activities listed in Handover Strategy including Feedback for use during the future life of the building or on future projects. Updating of Project Information as required.	Conclude activities listed in Handover Strategy including Post-occupancy Evaluation, review of Project Performance, Project Outcomes and Research and Development aspects. Updating of Project Information, as required, in response to ongoing client Feedback until the end of the building's life.
Information Exchanges (at stage completion)	Strategic Brief	Initial Project Brief	Concept Design including outline structural and building services design, associated Project Strategies, preliminary Cost Information and Final Project Brief.	Developed Design, including the coordinated architectural, structural and building services design and updated Cost Information.	Completed Technical Design of the project.	'As Constructed' Information.	Updated 'As Constructed' Information.	'As Constructed' Information updated in response to ongoing client Feedback and maintenance or operational developments.

Figure 2-2. Design process in the UK
Source: Adapted from RIBA Plan of Work 2013.

2.2.2 Implications for 'Designing In' Safety

Each phase of design has the potential for different stakeholder involvement and "sign-offs" for decisions in order to move to the next level of development. The last chance for substantive revisions takes place at 25-35% completion, with finishing touches at 80-85% completion (Roper and Payant 2014).

Because each stage in the design process includes decisions that carry forward through the project, changes to previously approved decisions incur additional cost. The further into the project schedule, the more expensive changes become (Figure 2-3). Since the budget is often established before the project is designed, most of these decisions are made in the earliest phases of project planning. If safety is not considered a priority during these early phases, it is likely that features to support the safe delivery of care will not be included. The most significant costs, however, are associated with the long-term implications of adverse events. In this context, "*a single risk can repay investments in risk management where a single unidentified risk can cripple a project or business*" (Loosemore et al. 2006, 6).

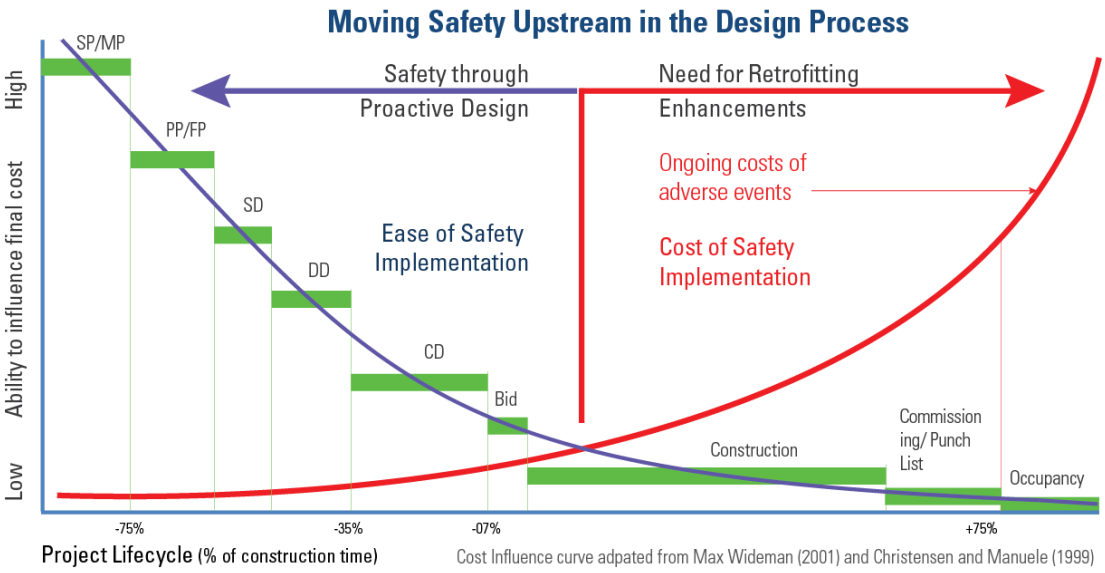

Figure 2-3. Cost-influence curve for safety in healthcare facility design
Source: Taylor, Hignett, and Joseph 2014.

2.2.3 Defining Needs

2.2.3.1 Programming

Architectural programming, often a stand-alone pre-design service, includes reviews of historical data, space surveys, interviews with clients and users, and equipment inventories, as well as the use of existing and projected service volumes

(Grunden and Charles 2012, American Institute of Architects 2001, Boyer, Brandenburg, and Wellman 2010, Sanoff 1989). In some large firms, programming is handed off to a different team for design (American Institute of Architects 2013). The program document marks one of the first client approvals or sign-off of scope, schedule, and budget, after which changes have an increasing potential to impose additional cost.

In healthcare planning, the functional program takes into account patient volumes, historic workloads, staffing requirements and a space program that identifies all of the space types, quantities, and sizes. These are typically based on industry benchmarking, grossing factors (rules of thumb to determine ratios of net to gross square footage), and experience with past projects (Allison and Hamilton 2008, American Institute of Architects 2001, Ballast and O'Hara 2011). It also includes written functional statements. In the US, the FGI Guidelines (Cates and Livingston 2015) define a minimum requirement to include:

- Project purpose;
- Project type and size;
- Construction type/occupancy and building systems;
- Project components and scope;
- Indirect support functions - increased or decreased demands, workloads, staffing requirements, etc. that will be imposed on support functions related to the construction project); and
- Operational requirements (e.g., projected operational use and demand loading for affected departments/project components; operational circulation patterns; and departmental operational relationships and required adjacencies).

Larger projects can result in a functional program that is as long as 200 pages. Challenges with the process include defining true client needs (which may not even be fully known by the client), translating verbalized needs into the programmer's understanding, and making difficult choices in a timely manner (Sanoff 1989, Elf et al. 2015). The approach is criticized for the use of "*parametric sizing, protracted user group input, and the separation or siloing of the owner, project manager, architect, general contractor, and subcontractors*" (Boyer, Brandenburg, and Wellman 2010,

217) and "*personal or experiential preferences of the users*" in establishing requirements (Boyer, Brandenburg, and Wellman 2010, 226).

2.2.3.2 Participation in Design, Participatory Design, and Participatory Ergonomics

User participation is seen as a way to elicit user requirements (Kujala 2003, McNeese et al. 1995), but there are challenges in translating what is meant versus what is said (Garrigou et al. 1995, Gould and Lewis 1985) and in anticipating future work states (Broberg, Andersen, and Seim 2011, Garrigou et al. 1995). Designers often misjudge the impact of artefacts on users (McNeese et al. 1995) and they are rarely engaged in understanding the real work activities for which they are designing (Mallam, Lundh, and MacKinnon 2015).

2.2.3.2.1 Participation in design

User participation is widely acknowledged in design, but it is ill-defined (Kujala 2003). With multiple groups of competing stakeholders, the typical HC facility design team gathers input at various points in the process from hospital leadership, financial stakeholders, community representatives, and segregated user groups who contribute their individual experiences and expertise (Boyer, Brandenburg, and Wellman 2010, Grunden and Charles 2012, Kasali and Nersessian 2015, Shumaker and Pequegnat 1989).

User groups are often composed of department leaders with occasional representation from front-line staff (Grunden and Charles 2012). They are often invited to participate based on their recognized background and expertise within their discipline (Kasali and Nersessian 2015). However, they may be perceived as protecting their own departmental interests (Devenney 2011). Grunden and Charles (2012) describe participation in the early phases of design, with the user group role as a line-by-line review of programming spreadsheets and the number of spaces needed (e.g., offices, exam rooms). Many users may not be familiar with the expectations or implications of their decisions at the various phases of 'sign-off.'

Although practitioners may stress the importance of client participation, there are always issues about who is involved and whether the organization is willing to act upon participant suggestions (Sanoff 1989). Participation processes can view users as passive objects or active sources (McNeese et al. 1995). Considering formal and informal power relationships, participation is not always about decision-making. It

may range from commenting, information giving, consulting, or a full participatory process, which may or may not result in negotiation and joint decision-making (Jenkins and Forsyth 2010, Kujala 2003).

2.2.3.2.2 Participatory design

More than just participation in meetings, participatory design takes into account that the contribution of end-users in the design of space offers a diversity of views and has a positive influence that generates continued insight and knowledge (Luck 2003). Participatory design is identified as a characteristic of an "ideal" client that: appoints a highly motivated project coordinator; forms champion teams as resources; forms user groups to advise about functionality; and forms topic teams to provide innovative solutions (Walrath and Augenbroe 2007). The participatory process is referenced in the EBD process through the use of interdisciplinary design teams (CHD 2010b). These teams are intended to include stakeholders such as the board of trustees and leadership, researchers and designers, vendors/suppliers, patients, staff, caregivers/family/visitors, community partners, community organizations, and donors (CHD 2010b). In this interdisciplinary context staff participation is described in the context of continuous organizational learning and "*participative management—a management style that encourages employees to have a strong decision-making role*" (CHD 2010b, 69). According to CHD, in the context of facility design the goal of staff involvement is to design effective and efficient facilities by engaging clinical staff, as well as other employees, such as housekeeping and information technology.

This team is more often in the context of a five- to 10-member steering committee, with subcommittees resulting for larger projects (CHD 2010a). A steering committee is responsible for the project vision, setting scope for individual task forces or subcommittees, resolving conflicting expectations, and negotiating trade-offs when needed (Joint Commission Resources 2006). However, this interdisciplinary process is not a given. At one extreme, design teams do not engage with user groups (Tzortzopoulos et al. 2006, 673). At another extreme, Lean-led design processes consider the system and start the design process by observing the point of work, analyzing processes through value-stream mapping, and developing a future-state process that guides the development of the design (Grunden and Charles 2012, Boyer, Brandenburg, and Wellman 2010).

According to Boyer, Brandenburg, and Wellman (2010, 233), "*The Achilles' heel of traditional facility design with user groups has been the inclusion of a select few, resulting in design disagreements by the eventual operational residents who were never asked.*" As a result, the balance is not just in who participates, but in how the problem is being considered. The influence of each constituency varies, and user groups are often disadvantaged in effective participation due to four factors that, according to Shumaker and Pequegnat (1989, 174), include:

(1) their interest in and knowledge of the process;

(2) their status within the community and their professional field;

(3) their organizational strength; and

(4) their long-term proximity to the planning and design process.

In some cases it has been suggested that safety is an area that does not benefit from a participatory process where *"professionals can be concerned that giving too much control to users can result in negative outcomes, for example in terms of health and safety"* (Jenkins and Forsyth 2010, 72).

While not developed for HC facility design, a taxonomy by Muller and Kuhn (1993) identifies who participates and when the activity occurs (Figure 2-4).

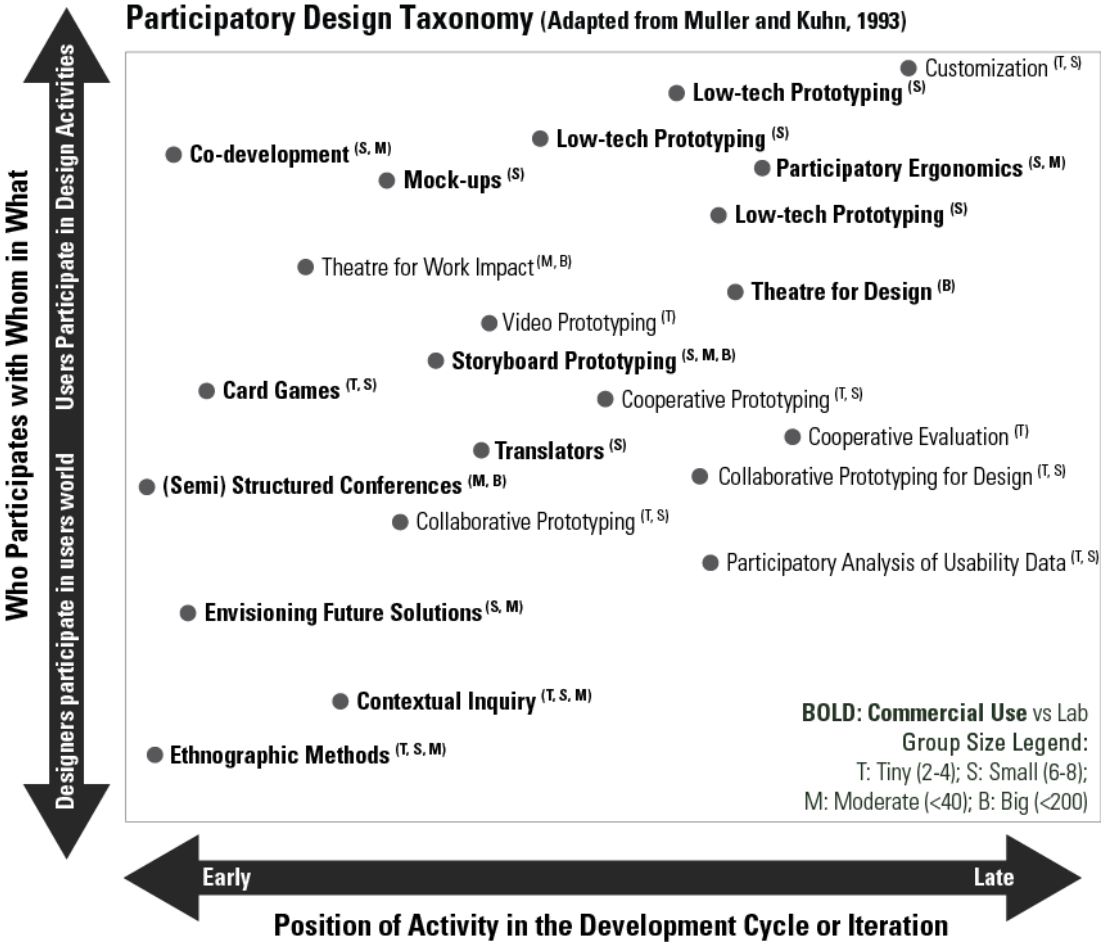

Figure 2-4. Participatory design taxonomy
Source: Adapted from Muller and Kuhn 1993.

2.2.3.2.3 Participatory ergonomics

One method identified within the taxonomy is participatory ergonomics (PE). The most-referenced definition of PE stems from Wilson's 1995 edition of *Evaluation of Human Work*: *"The involvement of people in planning and controlling a significant amount of their own work activities, with sufficient knowledge and power to influence both processes and outcomes in order to achieve desirable goals* (as cited in Haines and Wilson 1998, 5, Wilson and Haines 1998, 330). PE is often considered in the microergonomic context of improving employee health and reducing injury (Henning et al. 2009, van Eerd et al. 2010). Although the taxonomy shows PE later in the process, PE can help define strategic priorities, improve design ideas and solutions, and smooth implementation (Haines et al. 2002, Wilson and Haines 1998), suggesting an earlier use. The use of PE has recently been studied in the context of HC facility design (Andersen and Broberg 2014, Hall-Andersen and Broberg 2014, Broberg, Andersen, and Seim 2011).

2.3 Filter 2: Patient Safety

The second filter of the thesis is to narrow the interest of an EBD process to the topic of patient safety. As shown in Table 1-2, patient harm is a worldwide condition with an unacceptable status quo (Levin 2005), a human toll equivalent to several airline crashes every other day (Leape 1994), and resulting magnitude of harm reported in billions of dollars of waste (Bagian 2012). There are impediments in measuring progress in safety (Wachter 2010), and recent reports find that the numbers may be worse than initially reported (Classen et al. 2011, James 2013). Classen et al. (2011) reported that adverse events in hospitals might be 10 times greater than originally thought, with adverse events occurring in one-third of all admissions. James (2013) updated the IOM estimate based on four "Global Trigger Tool" studies published from 2008 to 2011. The results indicate what is considered a more realistic estimate of 400,000 preventable deaths per year in the US. Additionally, James (2013, 122) concludes serious harm to be "*10- to 20-fold more common than lethal harm.*"

2.3.1 Error and Accident Causation

Adverse events are rarely the result of the actions of one individual; rather, they are systemic in nature. The Swiss cheese model (Reason 1990) is often used to illustrate how defenses, barriers, and safeguards can be used to prevent accidents or adverse events from slipping through. Reason defines holes in the defense as created by "active failures" (unsafe acts committed by people who are in direct contact with the patient or system) and "latent conditions" ("resident pathogens" that may lie dormant in the system for lengthy periods of time). Accidents happen when holes in the system align. While active failures may be difficult to anticipate, latent conditions can be proactively identified as preconditions for error before an accident occurs (Reason 1990, Lawton et al. 2012). This framework has been further developed (Figure 2-5) to include the role of the built environment as a layer of defense with latent conditions of design such as air quality, room occupancy, patient room design, lighting, interior design, noise, unit layout, and access to hand hygiene (Reiling, Hughes, and Murphy 2008, Henriksen, Joseph, and Zayas-Caban 2009, Joseph and Rashid 2007, Henriksen, Kaye, and Morisseau 1993).

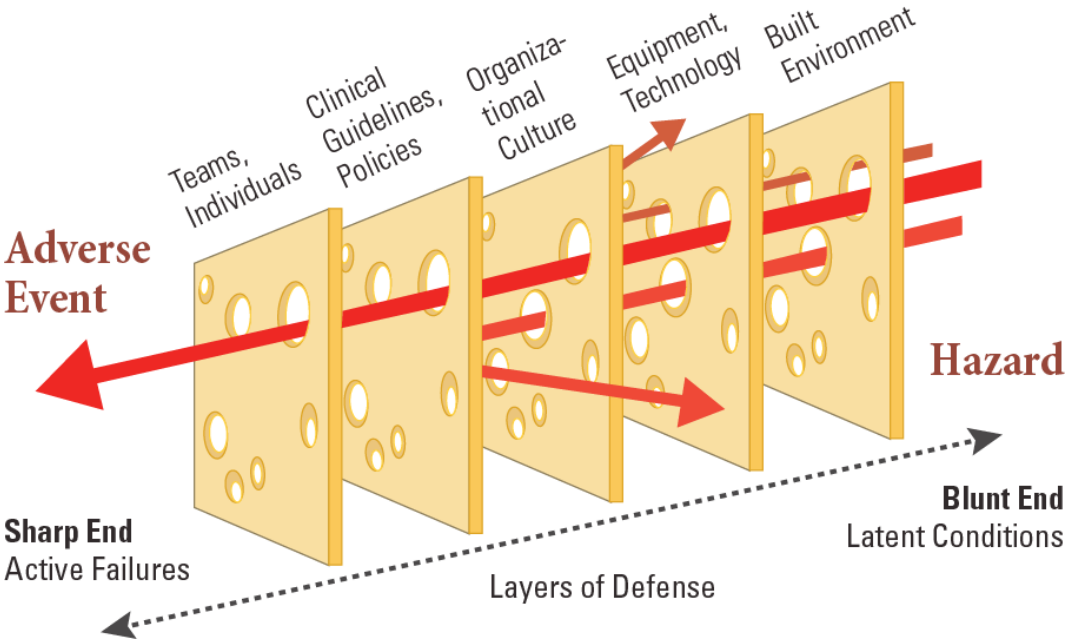

Figure 2-5. Swiss cheese model
Source: Adapted from Joseph et al. 2011, Reason 1990.

As referenced in Section 1.3.4, the evolution of HF/E in patient safety included development by Vincent, Taylor-Adams, and Stanhope (1998), who built on Reason's model and other sociotechnical frameworks to define the factors that influence clinical practice as: institutional context, organizational and management factors, the work environment (described as staffing levels and skills mix; workload and shift patterns; design, availability, and maintenance of equipment; and administrative and managerial support), team factors, individual (staff) factors, task factors, and patient characteristics. There is no further elaboration of the design aspect of the environment. Subsequently, Brasel, Layde, and Hargarten (2000) use the Haddon model developed for traffic accidents (Haddon 1972) to review an emergency medicine event. The authors describe the environment as physical, social, and biological, with the physical environment conditions cited as noise and incorrect X-ray presentation.

2.3.2 Work System Design

SEIPS (Carayon et al. 2006) was developed as a result of the lack of models to guide studies to empirically examine work system design. The SEIPS model of the work system (Carayon et al. 2006) has evolved into SEIPS 2.0 (Holden et al. 2013). SEIPS is based on the Donabedian structure-process-outcome framework (Donabedian 1988, 1966), and the model categorizes the work system, process, and outcomes and

includes technology and tools, tasks, the organization, the person, and the environment. The SEIPS model references the layout of the environment (e.g., visibility), noise, lighting, temperature, humidity and air quality, and workstation design and proposes that plans are reviewed for work flow and questions are asked about the physical environment sources that promote error or safety. The model promotes the structure of the work system, building on prior research for balanced job design to reduce stress (Carayon and Smith 2000, Smith and Sainfort 1989). It was described for application both proactively and reactively by focusing on the design of work (not the design of place).

2.3.3 Resilience, Safety-I, and Safety-II

While Reason's Swiss Cheese model (Figure 2-5) may create an easy-to-understand framework for the role of the environment in safety (one of many defenses), the most recent discussions about safety center on a shift from the "old" notions of safety (Safety-I) to one of resilience engineering (Safety-II). Safety II considers the ability of systems to adapt to variation, disruption, and degradation of expected conditions (Hollnagel and Woods 2006, Woods and Hollnagel 2006). One can see the transition through papers about accident barrier classification and analysis (Hollnagel 1999), to a recognition that a reactive approach was insufficient (shifting to accident prevention and a proactive approach) (Hollnagel 2004), to safety as a dynamic non-event (i.e., the absence of events) using a framework of resilience. The reactive approach of Safety-I should be complemented (not replaced) by proactive Safety-II approaches that attempt to develop ways to support things that "go right" (Braithwaite, Wears, and Hollnagel 2015).

Since its inception, the frameworks of resilience and Safety-II have been applied to healthcare and the built environment (Nemeth et al. 2008, Hollnagel, Braithwaite, and Wears 2013, Braithwaite, Wears, and Hollnagel 2015, Hassler and Kohler 2014). Proponents have urged a proactive approach taking into account that those remote from the clinical front line base solutions on work as imagined, rather than work as performed (Braithwaite, Wears, and Hollnagel 2015). From a resilience perspective, the built structure is one part of a functioning system, such that a hospital needs to adapt through continual rebuilding (both organizationally and physically) (Hollnagel 2014b). Unfortunately, the role of structures is not often described in

Safety-II, and according to Hassler and Kohler (2014, 125) "*the composition and dynamic of the built environment prove to be very complex and attempts at description remain very general.*"

2.4 Filter 3: Design Tools and the SRA

A third filter includes development and use of design tools in EBD. There are currently no readily available tools to proactively consider the design of the built environment as an underlying condition for safety in healthcare environments, other than the highly regulated considerations for life safety (protection from fire, structural failure/collapse) or construction safety (Currie 2009). While some built environment checklists have been developed as audit tools to create a vulnerability measure (MacAlister 2013), these evaluate buildings in use and are not proactive in nature.

In a new summary of available tools for EBD in HC facility design (Phiri 2015), tools are categorized as compliance (i.e., statuary and regulatory compliance); design quality improvement, efficiency and effectiveness; and sustainability. Looking into the future, Phiri highlights the relevance of design tools that are underpinned by evidence to enhance patient safety and well-being, eliminate environmental stressors, and promote healing, recognizing the challenges of limited funding and the country-specific context of healthcare policy, legislation, culture, and published guidelines. The concept of the SRA development precedes Phiri's publication, but as envisioned, the SRA fits within enhancing patient safety and well-being through both compliance and design quality improvement.

To instill a proactive process, there is a need for understanding the integration of hazard and risk reduction. In the case of resilient design, for example, many emergency events are not entirely unexpected and could be reasonably mitigated, but there is currently not a sufficiently proactive role (Bosher et al. 2007). In healthcare, adverse events are also not unexpected. Given the ongoing incidence of harm, using the environment as a strategic tool has the potential to be an enduring and viable approach for improving outcomes but will require new perspectives to encourage innovative design solutions (Steinke, Webster, and Fontaine 2010). Establishing the context of the SRA within available design tools is the focus of Chapter 3. This line of reasoning offers a role for HF/E integration in building design.

2.5 Filter 4: Hospital Falls

There is a range of design decisions to be reconciled in EBD projects, amongst them, safety dangers for both patients and staff. While the SRA includes six topics, this thesis uses falls as a case study topic (the fourth filter) and leverages the consensus development of SRA content for building design considerations. In-hospital falls can be experienced by all occupants of a facility - patients, staff, and visitors.

2.5.1 A Complex and Pervasive Problem

Falls have been referenced in the literature since the 1950s as "*common and a constant source of anxiety*" (Fine 1959, 292), but effective solutions to reduce the risk of falls are particularly complex due to the contribution of intrinsic and extrinsic conditions and an active participant in the event. Falls were chosen as the case study for this thesis due to their scale and complexity. As an adverse event, they are pervasive throughout hospital settings and can occur in both inpatient and outpatient areas, with an impact on patients, staff, and visitors. Falls were recognized as a significant safety issue in 2000 resulting in a sentinel event alert (JCAHO 2000). They wre subsequently included as a national patient safety goal in the US in 2005 (Joint Commission Resources 2004). In many countries, hospital falls are a prevalent safety issue and one of the most common adverse events reported (Choi et al. 2011, Vieira et al. 2011). Injurious falls are also a significant issue (Drahota et al. 2013).

Choi (2011) cites numerous sources reporting that falls are associated with increased length of stay in hospitals and higher healthcare costs associated with additional care, discharges to institutional care, and litigation claims. Approximately 15-30% of falls cause fractures (Lopez et al. 2010), and older people (i.e., over 65) are most at risk (Drahota et al. 2013). It is estimated that 90% of hip fractures in older people are a result of falls (Vieira et al. 2011). As the population of baby boomers ages in the US, reports estimate that this demographic will experience an increase in falls (Kandel and Adamec 2009, Cigolle et al. 2015). One study found the rate of falls for adults 65 and older in the US increased by 8.1% between 1998 and 2010 (Cigolle et al. 2015). Having a fall also introduces psychological harm (Krauss et al. 2008), and the increased fear of falling can lead to reduced mobility, which further increases fall risks (Vieira et al. 2011). A recent report issued by the US Department of Health and Human Services found that as a result of shared aims and a wide range of aligned federal programs and initiatives, the incidence of falls and trauma was reduced by

14.7% from the 2010 baseline through the fourth quarter of 2013. However, inpatient fall rates with injury are rising in other countries (Jorgensen et al., 2015)

Staff is also at risk for slips, trips, and falls (STF). US BLS data (Bureau of Labor Statistics 2009, as cited in Bell et al. 2010) indicate the incidence rate of lost-workday injuries from STFs on the same level in hospitals was 38.2/10,000 employees, 90% greater than the average rate for all other private industries combined (20.1/10,000 employees). In Bell's study spanning a 10-year period, 21% of workers' compensation claims were caused by STFs (Bell et al. 2008). The topic of falls is expanded in Stages 2 and 7 through a systematic literature review and consensus-based process presented in two phases in Chapters 4 and 8.

2.5.2 Dial-F: A Systems Model for Falls

Hignett (2013) proposed the Dial-F systems model to describe patients as active participants in the system. The model reverses a traditional HF/E approach of the person at the center of the system and instead describes system elements in healthcare with respect to the level of flexibility or transience - the duration of action/involvement (Figure 2-6).

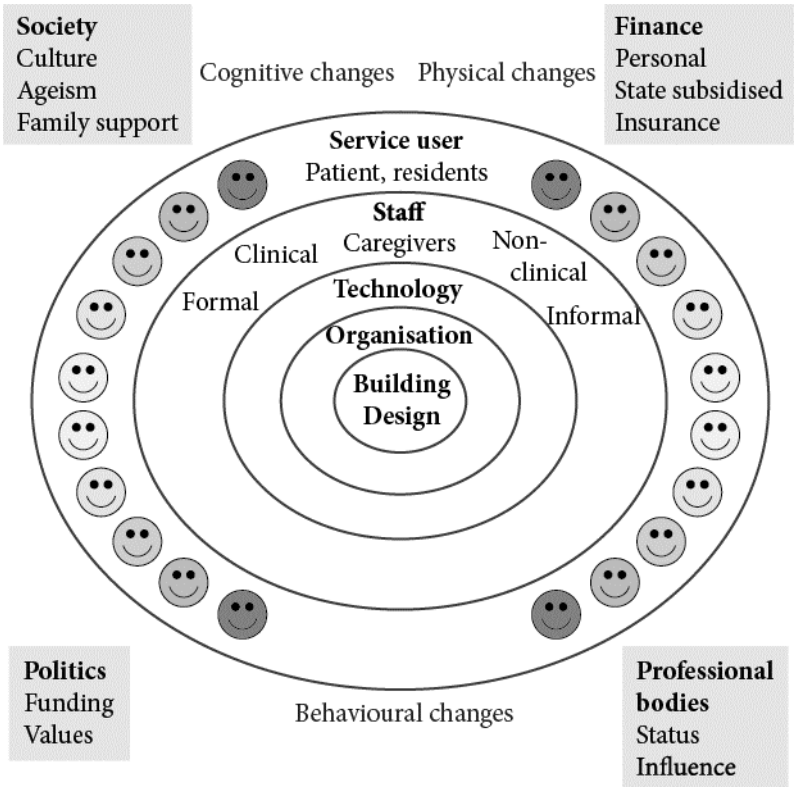

Figure 2-6. DIAL-F model
Image Source: Hignett (2013, 3) © The Health Foundation

This model suggests that the building design is the least frequently changing component and is therefore represented at the core of a falls management system that considers the patient/resident as an active (though transient) member of the risk management endeavor. It has been suggested as a framework for understanding falls in hospital settings (Hignett et al. 2013, Hignett, Youde, and Reid 2014).

2.6 Filter 5: Human Performance—The Body and Brain

Optimizing performance must take into account the capabilities of people using the space. This may be understood through conditions that range from the physical aspects of the body to the sensory aspects of the brain. Wickens et al.'s model of information processing is one framework discussed in the context of human performance (Wickens, Hollands, and Parasuraman 2013, Wickens et al. 2014). This model takes into account the availability of sensory information that is perceived and processed into a decision through the short- and long-term memory. Visual stimulus is cited as being dominant (Noyes 2002). The resulting response creates a new set of conditions to be processed. Our ability to attend to information is described as selective, focused, or divided attention (Noyes 2002, Wickens, Hollands, and Parasuraman 2013). This is also a condition of situational awareness that is conceived as perception (noticing), comprehension (understanding), and projection (anticipation) (Wickens, Hollands, and Parasuraman 2013). However, cognition and psychology is only one side of human design. Other intrinsic aspects, such as user characteristics (anthropometry, biomechanics, and physiology), describe the physical characteristics of the human body that play an important role in functional measurements (Noyes 2002, Wickens et al. 2014). Togther, these influence performance (Figure 2-7).

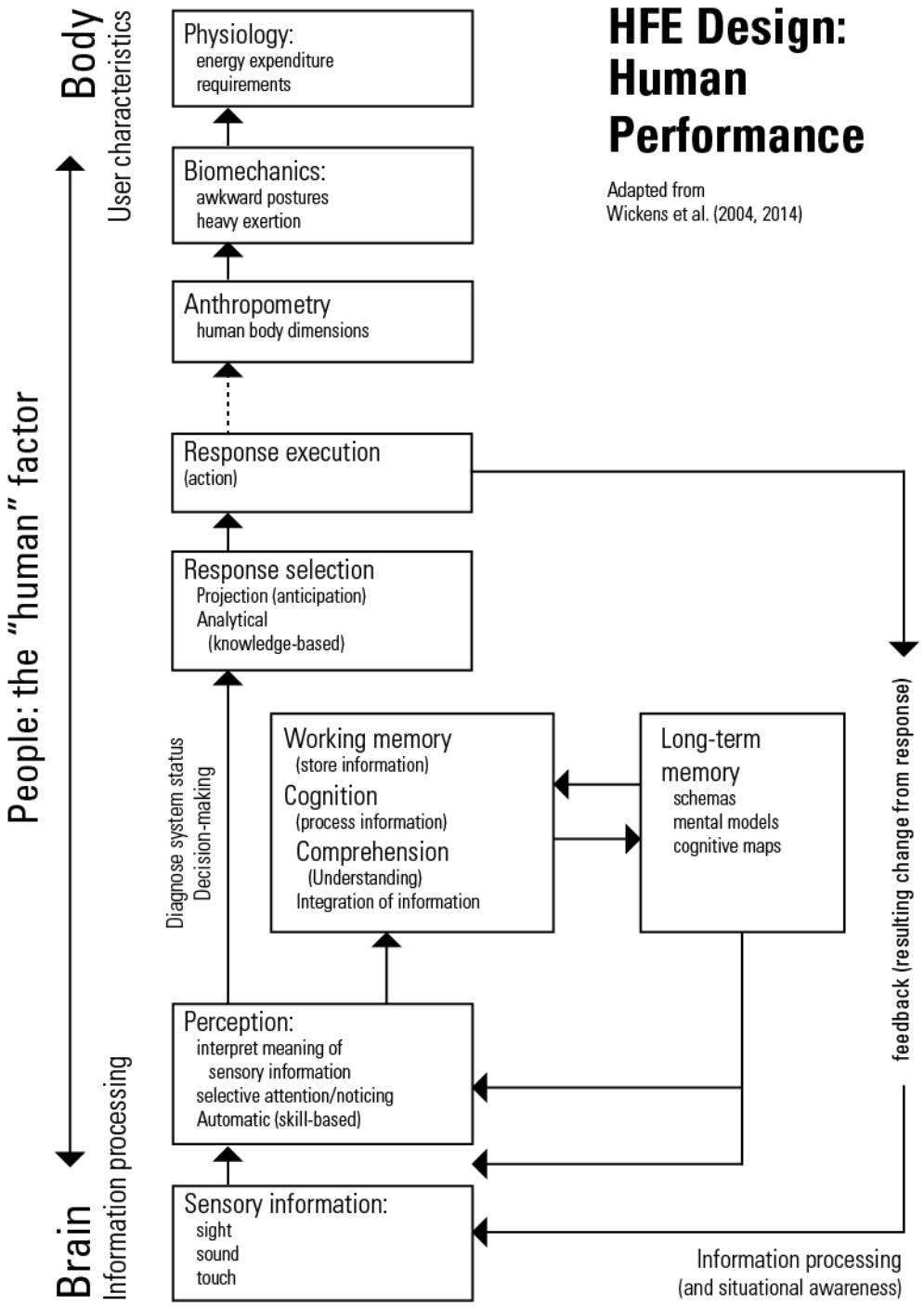

Figure 2-7. Human performance in the context of body and brain
Source: Adpated from Wickens, Hollands, and Parasuraman 2013, Wickens et al. 2014.

2.7 Conclusion

These five filters (HC facility design, patient safety, design tools, hospital falls, and human performance) establish the context for study and provide a platform for theory development through the development and testing of the SRA. The context of facility design is further explored in Chapter 3, while the complexities of hospital falls are presented in detail in Chapters 4 and 8.

3 Design Guidance: Processes, Methods, Evaluation, Tools

3.1 Chapter Overview

This chapter continues Stage 1 context setting through a systematic mixed studies review conducted for the PhD that identified the development and use of methods, evaluation processes, and tools used by architects and design teams during facility design. The review identifies specific tools used in design and investigates themes of tool development and use in order to understand relationships, gaps, and opportunities to bridge EBD and HF/E through the SRA (reported in Chapter 7).

3.2 Aim and Objectives of the Stage 1 Literature Review

Having established the process for early decision-making that might influence use of the SRA, understanding the SRA in context of other tools and processes that might be used in a facility design was also important. A systematic search process was used to find published papers about methods, evaluation, and tool development to enhance design activity (as distinct from research methods to support EBD). The objectives included:

- identifying *development* of specific methods, evaluations, or tools used during facility design (adding rigor to the grant),
- understanding *use* of methods, evaluations, or tools to identify issues that might warrant consideration in the SRA tool (grant-related) and inform theory for integrating HF/E into the SRA process (thesis-related), and
- confirming that no similar tools or processes existed to guide proactive decision-making for safety in healthcare building projects (supporting the contribution to knowledge).

3.3 Methods

3.3.1 Criteria and Search Strategy

The search was limited to English-language papers published in 2002 or later. This date was selected to review work that emerged following a previous research initiative *Learning from our Buildings* (Federal Facilities 2001). This cooperative association of 21 US federal agencies reviewed the practice of post-occupancy evaluations (POEs) and lessons-learned programs to reflect on developments in both in

the US and internationally. The search also excluded papers focused on Leadership in Energy & Environmental Design (LEED), sustainability, and energy performance, as these have very specific objective measures and targets for site sustainability, water efficiency, energy efficiency, material reuse/reduction, and air/thermal/daylight qualities.

The review was undertaken as a mixed studies review. Systematic mixed studies reviews provide a highly practical understanding of complex and highly context-sensitive interventions where synthesis of data or results is required from studies with diverse designs that include qualitative, quantitative, and mixed methods (Pluye and Hong 2014). They have the potential to provide a "*more complete picture of the research landscape in a specific topic area"* (Grant and Booth 2009, 99). The search was conducted in three databases: Medline, Web of Science, and the Avery Index to Architectural Periodicals. (Search terms are included in Appendix A.)

3.3.2 Critical Appraisal

To ascertain study quality for the case study literature review, appraisal worksheets included as part of a nursing research text, *Reading Research, 4th Edition* (Davies and Logan 2008), were originally considered. However, there was no published validation of these tools. As a result, a search for appraisal tools was conducted. Crowe and Sheppard's (2011) study was used as a guide to appraisal methods. The authors offered their own critical appraisal of approximately 45 Critical Appraisal Tools (CAT), including five CAT tools for multiple study types: (Glynn 2006, Pluye et al. 2009, Hawker et al. 2002, MacAuley 1994, Nielsen and Reilly 1985, Rasmussen et al. 2000). Following review of these five papers it was determined that the Mixed Methods Appraisal Tool (MMAT) (Pluye et al. 2009) would provide the most consistent and robust method of evaluation across the study types included in the literature review. Validated subsequent to the Crowe paper, the tool "*can be used to concurrently appraise the methodological quality of qualitative, quantitative, and mixed methods studies*" (Pace et al. 2012, 47). Because of the prevalence of opinion- and theory-based papers, however, not all papers could be evaluated with the MMAT. The critical appraisal was supplemented by another recommendation to quantify hierarchies of evidence for design of the built environment, as proposed by Stichler (2010b) through the algorithm developed by Marquardt and Motzek (2013), as previously reported (Taylor and Hignett 2014a).

3.3.3 Thematic Analysis

The included papers were coded in NVivo 10 (QSR International 2012). Based on a prior qualitative study that investigated the use of design guidance by healthcare architects and planners in the UK (Hignett and Lu 2009), three primary categories of coding were established: design culture, the evidence base, and guidance need.

3.4 Results

3.4.1 Search Results and Screening Flow

The search strategy was originally conducted in August 2013 and updated in November 2015, resulting in 838 references that were systematically screened by title, abstract, and full text for a final inclusion of 22 papers (Figure 3-1). One-third of the papers were expert opinion or theory development.

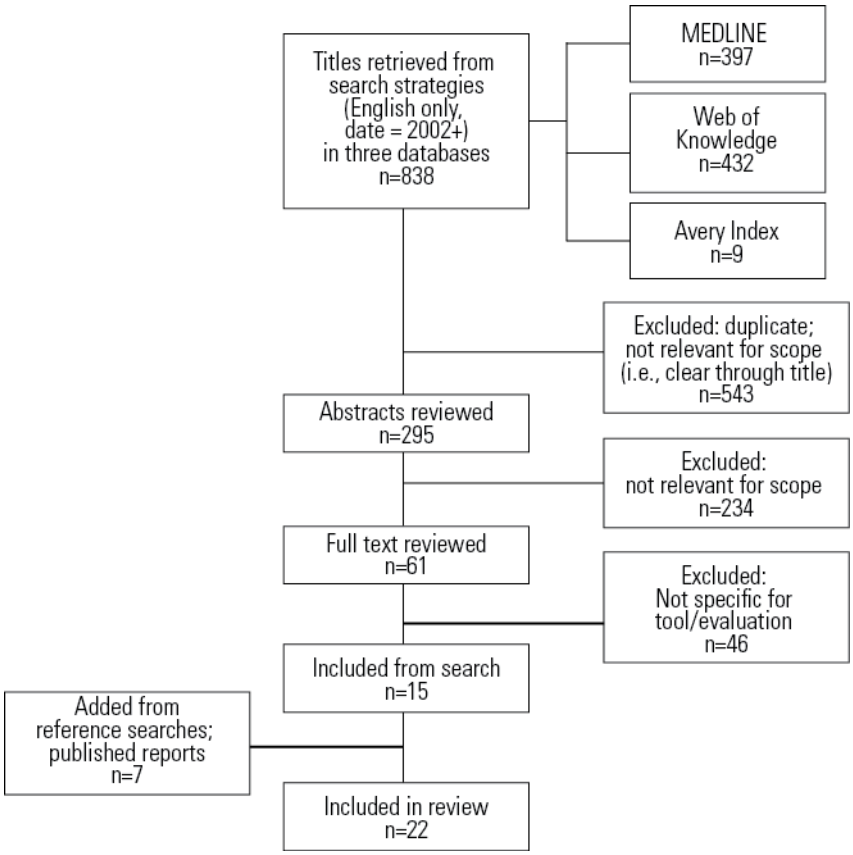

Figure 3-1. Search strategy and inclusion flow – tools literature review

Table 3-1 includes the final papers selected for review. (See the references for full citations and Appendix B for additional tool detail.)

Table 3-1. Final list of sources for review inclusion (methods, tools development)

Included in final review (author/year/title) – full citation in Chapter 11: References	Tool
Attaianese, E. and G. Duca. (2012). Human factors and ergonomic principles in building design for life and work activities: an applied methodology.	Expert opinion
Bartholomew, D. (2005). *Sharing Knowledge*.	Manual/case studies
Bordass, B. and A. Leaman. (2005). Making feedback and post-occupancy evaluation routine 1: A portfolio of feedback techniques.	POE - online resource of resources
Bosher, L. et al. (2007). Realising a resilient and sustainable built environment: towards a strategic agenda for the United Kingdom.	Expert opinion
Clemson, U. and NXT. (2012). *Pathway towards the Development of a Post Occupancy Evaluation (POE) Program and Policy for the Military Health System*.	POE framework/ checklist
Devine, D. A. et al. (2015). Part 1: Evidence-based facility design using Transforming Care at the Bedside principles.	Case study
Edwards, N. (2008). Performance-based building codes: a call for injury prevention indicators that bridge health and building sectors.	Expert opinion
Fleming, R. et al. (2011). *Identifying and overcoming the obstacles to using empirically supported principles in the design of facilities for people with dementia*.	Scored Audit Questionnaire (EAT)
Foureur, M. J. et al. (2010). Developing the Birth Unit Design Spatial Evaluation Tool (BUDSET) in Australia: a qualitative study.	Scored Audit Questionnaire (BUDSET)
Foureur, M. J. et al. (2011). Testing the Birth Unit Design Spatial Evaluation Tool (BUDSET) in Australia: a pilot study.	Scored Audit Questionnaire (BUDSET)
Gann, D. et al. (2003). Design Quality Indicator as a tool for thinking.	Scored Questionnaire (DQI)
Haq, S. and D. Pati. (2010). The research-design interaction: lessons learned from an evidence-based design studio.	Case study
Horayangkura, V. (2012, 16-18 July). *Incorporating Environment-Behavior Knowledge into the Design Process: An Elusive Challenge for Architects in the 21st Century.*	Expert opinion
MacAlister, D. (2013). A physical security evaluation tool for elopement prevention in a behavioural/mental health setting.	Audit Questionnaire
Markus, T. A. (2003). Lessons from the Design Quality Indicator.	Critique (DQI)
O'Keeffe, D. et al. (2012). *Beyond scoring: advancing a new approach to the design evaluation of NHS buildings.*	Critique (AEDET)
Reiling, J. G. et al. (2004). Enhancing the traditional hospital design process: a focus on patient safety.	Case study
Sheehy, A. et al. (2011). Examining the content validity of the birthing unit design spatial evaluation tool within a woman-centered framework.	Scored Audit Questionnaire (BUDSET)
Smith, R. et al. (2012). Validation of the Environmental Audit Tool in both purpose-built and non-purpose-built dementia care settings.	Scored Audit Questionnaire (EAT)
Steinke, C. et al. (2010). Evaluating building performance in healthcare facilities: an organizational perspective.	POE framework
University of Sheffield. (2007). *Disseminating good practice (DGP): developing an exemplar layer for AEDET Evolution and ASPECT design evaluation tools*.	Scored Questionnaire (AEDET)
Whyte, J. and D. Gann. (2003). Design Quality Indicators: work in progress. *Building Research & Information, 31*(5), 387-398.	Scored Questionnaire (DQI)

3.4.2 Critical Appraisal

Evaluating papers using an evidence hierarchy alone resulted in two "levels" of evidence – level 3 for descriptive correlational, qualitative, etc., and level 5 for expert

opinion (Figure 3-2, left column). In using the MMAT (Pace et al. 2012, Pluye et al. 2009) to evaluate the methodological quality of studies within level 3, additional rigor was gained for study evaluation. The resulting matrix (Figure 3-2) offers a visual translation of the final study appraisal. Most papers were missing two of four components within the appraisal criteria. For example, no papers provided details about the process for analyzing qualitative data and none of the qualitative papers expounded on the relationship of the author/researcher on the participants. However, in several cases, the papers were not intended as formal research studies but a way to share experiential lessons learned. Only one paper (Smith et al. 2012), a validation of a new tool as compared to an existing well-regarded and validated standard, was appraised at the highest level of methodological quality.

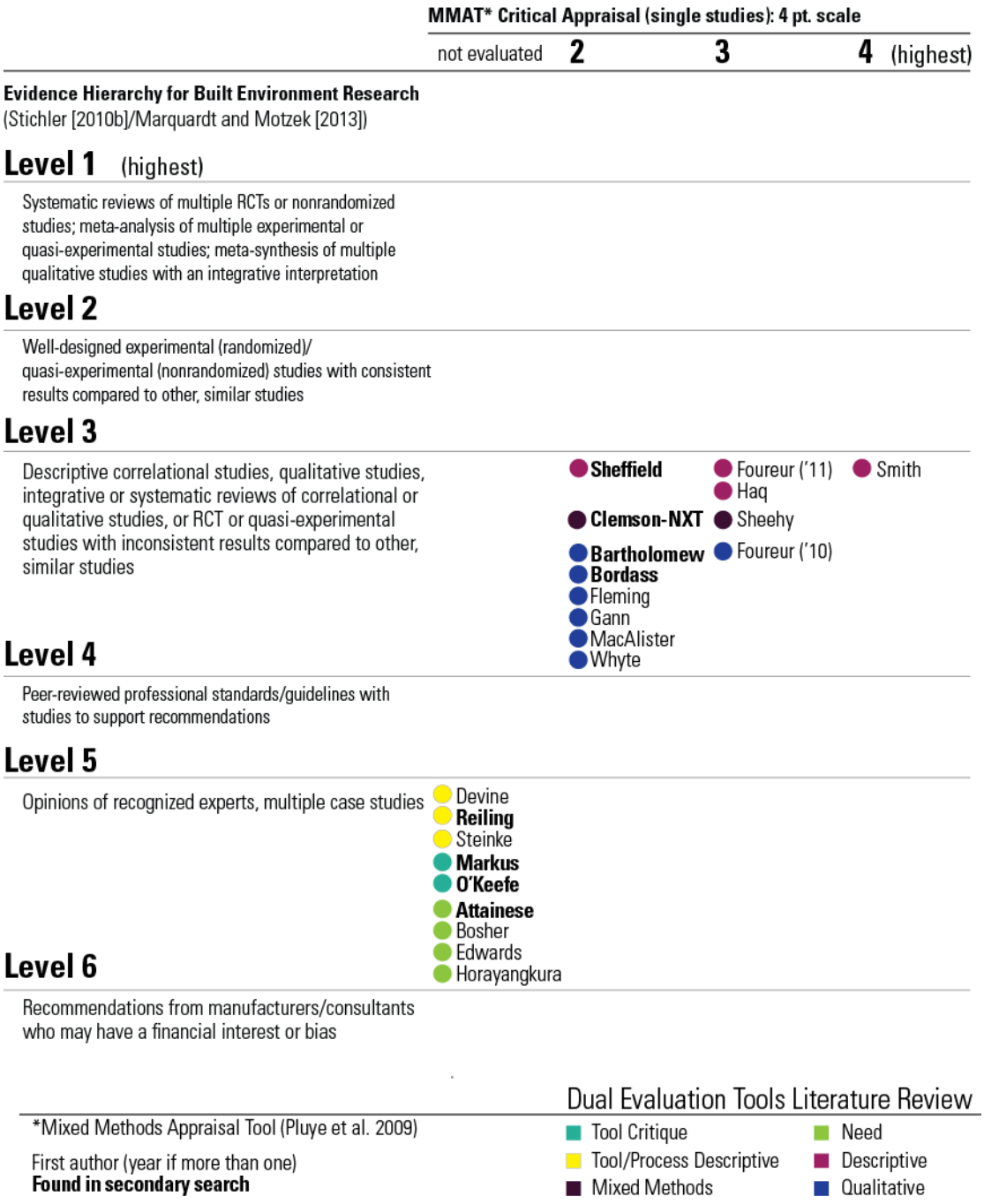

Figure 3-2. Evidence categorization and appraisal matrix for design tools review

3.4.3 Tools

Guidance tools are one approach to manage and disseminate knowledge in facility design. While a number of built environment evaluation tools have been previously developed, this review focused on published results or tool development (new or ongoing) after 2002 – a next-generation assessment (Section 3.3.1). Further described in Appendix B, reviewed tools included AEDET Evolution (being supplemented by the exemplary layer), the Government of Alberta BPE, a Sharing

Knowledge "manual," Design Quality Indicator (DQI), Environmental Audit Tool (EAT), the MHS POE and World-Class Checklist, Usable Buildings, BUDSET (Birthing Unit Design Spatial Evaluation Tool), and the Physical Security Review Checklist.

3.4.4 Themes

The three broad categorizations of themes derived by Hignett and Lu (2009) included new subthemes aligned with the original study, but more suited to the literature being reviewed (Table 3-2).

Table 3-2. Themes and subthemes of the literature review

Broad category (Hignett and Lu 2009)	Original subthemes (Hignett and Lu 2009)	New subthemes
Design culture	Design climate	Existing process
	Participatory design	Users and the design process
Evidence base	Design history	Using knowledge
	International research	Sharing knowledge
	Quality issues	Managing knowledge
Future guidance	Concepts	Direction
	Patient expectations	Change

3.4.4.1 Design Culture

The design process for healthcare architecture is notable for its ability to address complexity, but it also has disconnects. From the findings of the literature review it was suggested that this was promulgated through a culture of existing processes that result from a linear yet iterative series of project tasks; a design climate of competing drivers; the ambiguity about the value of design; the overall context of architectural and HC facility design; the academic education systems, and how users are considered during design.

3.4.4.1.1 Existing processes

Architecture balances artistic expression and aesthetics with functional requirements of diverse user groups that change over time (Attaianese and Duca 2012, Horayangkura 2012), sometimes at the expense of functionality (Horayangkura 2012). A building's "success" is often considered following completion through subjective, peer-reviewed, and often aesthetically driven design awards that recognize the creative endeavor rather than performance (Gann, Salter, and Whyte 2003, Jenkins and Forsyth 2010).

The design process described in Chapter 2 (Figure 2-1 and Figure 2-2) generally moves from the macroscopic scale of strategic planning to detail development (Attaianese and Duca 2012, Reiling et al. 2004), but the process is evolutionary, non-linear, and iterative (Gann, Salter, and Whyte 2003). Architects are given the program objectives, which are then translated into a project brief (UK) or functional program (US). However, the early phases of creating the brief are sometimes seen as obstacle (Fleming, Fay, and Robinson 2011). Historically, the scope of programming has focused on project size, spatial demand, cost and financial constraints, regulations, etc., and is highly determined by the individual nature of the project, the programmer, and the paying organization (Horayangkura 2012).

In the context of healthcare design, projects can take seven or more years from concept to occupancy, with the likelihood of needs changing substantially over the course of development (Clemson University and NXT 2012). For a care provider, facility projects may be once-in-a-lifetime event, and they often rely on design teams providing "*variations on things they [designers] or others have done before*" (Bartholomew 2005, 15). The design concept and subsequent detail is often advanced by generic principles (Foureur et al. 2011) and guidelines, mandatory standards, sustainability, efficiency, and budgets, rather than people's actual needs, abilities, and limitations (Attaianese and Duca 2012, Foureur et al. 2010). Environmental psychology and related research may help bridge this gap (Haq and Pati 2010, Horayangkura 2012), but there is a lack of professionals with expertise to integrate environment-behavior knowledge in the programming process, and this level of consideration is not likely to be achieved in the context of time and budget limitations (Horayangkura 2012). There is rarely an explicit goal for safety (Reiling et al. 2004).

The evaluation of options is a negotiation between the designers and the other stakeholders until consensus is reached (O'Keeffe, Thomson, and Dainty 2012). The negotiation is balanced by competing drivers that include:

- building performance versus use (Attaianese and Duca 2012),
- subjective versus objective measures (Sheehy et al. 2011, Gann, Salter, and Whyte 2003), and
- budgetary decision-making for the initial costs of needs and investment in good design and the long-term implications of resulting services that can be offered and outcomes such as safety (e.g., falls); clinical performance (e.g.,

reduced length of stay); user experience (e.g., improved satisfaction); and financial performance (e.g., hard/soft operating costs) (Fleming, Fay, and Robinson 2011, Devine et al. 2015, Steinke, Webster, and Fontaine 2010).

Since the budget is established in early phases, a result can be downstream "satisficing" – incorporating acceptable but suboptimal solutions (Attaianese and Duca 2012, Gann, Salter, and Whyte 2003, Brand 1995, Simon 1956). There is potential for unintended consequences in the compromise of negotiation, including potential safety hazards (Reiling et al. 2004). If these go undetected during design, they may require expensive infrastructure changes during construction or post-occupancy (Foureur et al. 2011, Clemson University and NXT 2012, Reiling et al. 2004).

There is also an ambiguity in design value, and building design is not often tied to strategic value (Steinke, Webster, and Fontaine 2010). There is more recently a focus on process improvement in design and construction activity rather than quality or functionality of design (Gann, Salter, and Whyte 2003). While there are sometimes references to both technical and sociological performance indicators, measures that bridge these indicators are not easily found (Edwards 2008).

Additionally, while healthcare design is a collaborative process, a culture of individual creativity is apparent, resulting from the architectural education system that may result in "unique aesthetic criteria" and a preponderance to design for professional recognition at the expense of functionality (Horayangkura 2012). In most cases undergraduate specialization is not addressed, although caregivers may assume such training was in place (Fleming, Fay, and Robinson 2011). This creates gaps between expectations and reality during HC facility design.

Lastly, adverse events are typically calculated as incidence over time (e.g., X/1,000 patient days), but this may hide important relationships between the risk of injuries and the built environment, where causal links are largely absent from the research literature (Edwards 2008). According to Edwards (2008), the time period for these rates do not take into account the variation of time spent in one location over another. For example, when exposure was taken into account, stairs are among the most hazardous of environmental features for falls, yet stairs are identified as the location for only a small percentage of fall events. Additionally, the person-centric orientation of metrics (e.g., incidence rates, cumulative incidence rates, and attributable risk) is consistent with health sector goals, but reflects the dominance of

behavioral solutions (Edwards 2008) rather than built environment conditions associated with injury. This may create challenges in translation for design.

3.4.4.1.2 Users and the design process

Architects design in social, political, and cultural contexts (Gann, Salter, and Whyte 2003), but in some instances tools to support the design process provide little guidance with respect to social relations within the building or the organization (O'Keeffe, Thomson, and Dainty 2012). The built environment as a system includes "*the combination of the user, the product, the task and the environment in which it all takes place*" (Attaianese and Duca 2012, 189), and the design team must shift attention from technical building functions to how users (staff and patients) actually perform tasks and work (Foureur et al. 2011, Clemson University and NXT 2012, Attaianese and Duca 2012). Despite the fact that healthcare settings are under a continuous cycle of remodeling, rebuilding, or expanding (Reiling et al. 2004, Foureur et al. 2010), feedback that integrates users, interpretation, and practice are not widely used as a source of information during design (Gann, Salter, and Whyte 2003). Architects often learn about user needs and expectations from stakeholders that do not occupy the final product (Haq and Pati 2010). Ultimately, when an environment was not suited to the task people either adapt their behavior to their environment or adapt the aspects of environment they can control (e.g., seating, glare, heat) to make the best of the situation (Horayangkura 2012). Many HF/E studies (that should be positioned to inform this process) consider buildings as a minor element of the context of use rather than a possible focus of the ergonomic design itself (Attaianese and Duca 2012). Additionally, HF/E considerations are often not initiated early in the design process (Reiling et al. 2004), and empirical studies in HF/E often focus on the machines, equipment, furniture, and tools that address strain or injury rather than on design considerations shaping the whole building (Attaianese and Duca 2012).

Success of participation was often reliant on the ability of a user to understand person-centered design principles and their capacity to work closely with architects and designers (Smith et al. 2012) or become a sounding board (Devine et al. 2015). For example, even when the end-users are included in the design process their input can be difficult to transfer, given the lack of common language and the use of jargon used by different professionals (Gann, Salter, and Whyte 2003, Markus 2003, Whyte and Gann 2003). It was also important that participants understand and embrace the

goals for the project (Bosher et al. 2007). One study found that the combination of clinical managers and architects with similar awareness of the project design principles had a statistically significant impact on the quality of design (Fleming, Fay, and Robinson 2011).

Participation of users was briefly mandated in the UK (O'Keeffe, Thomson, and Dainty 2012), and participation in design (Section 2.2.3.2) was one potential process that can deepen understanding of the environment-behavior relationship. This may be especially true when focused on a specific goal such as safety (Reiling et al. 2004). Needs and expectations of all user groups can be elicited from direct and indirect users (Attaianese and Duca 2012) and an interdisciplinary process can identify competing needs (Bosher et al. 2007). This offers a balance between recommendations and budgets through continuous engagement and oversight from leadership or an advisory council (Devine et al. 2015, Reiling et al. 2004, Steinke, Webster, and Fontaine 2010).

Current practice may preclude user information being transferred in a way that effectively contributes to the design process (Gann, Salter, and Whyte 2003). This can be caused by a combination of influences: the separation of design from ownership and use (Haq and Pati 2010, Horayangkura 2012, Gann, Salter, and Whyte 2003); tensions that exist within varied stakeholders of project teams (partially due to differences in styles of problem solving and semantics) (Gann, Salter, and Whyte 2003); or disciplinary boundaries between stakeholders (Bosher et al. 2007).

Design tools can support the process of user inclusion and identification of needs. For example, the DQI was envisioned as a value-add process to guide priorities and relationships by creating a common understanding of multiple individuals and user group views (Gann, Salter, and Whyte 2003, Whyte and Gann 2003). The EAT was developed to provide a valid and reliable way to judge the quality of a physical environment built for residents with dementia (Smith et al. 2012).

3.4.4.2 Evidence Base

Using, sharing, and managing knowledge needs to consider transforming evidence into useful information. The ability to effectively share and integrate information depends on both language and learning styles.

3.4.4.2.1 Using knowledge

The range of information used to inform design spans from tacit (in someone's head) to explicit (conveyed by impersonal medium) (Bartholomew 2005) and can include everything from academic research to trade publication to individual experience (Haq and Pati 2010). Research shows that architects prefer to learn through direct personal experience or by asking a colleague, and engineers prefer abstract, broadly-applicable principles and established rules (Bartholomew 2005), but information still needs to be understandable to all participants (Gann, Salter, and Whyte 2003). Bartholomew (2005) proposed that a written record was appropriate where the information was complex or difficult to convey by word of mouth, while stories and conversation were better-suited for *explaining* ideas. According to Bartholomew, verbal translation made it more difficult to capture information in a way that made it genuinely useful and easy to share – it became tacit knowledge for those present at the time.

Design tools (e.g., checklists) were sometimes developed to guide this use of knowledge. However, there were critiques that by not incorporating "design knowledge" into tools, the tools became narrow and context-independent (O'Keeffe, Thomson, and Dainty 2012). This can be remedied. The benefit of DQI (as proposed by the developers) was that conversation could be initiated and informed by tangible and intangible aspects of perceptions of all stakeholders (Gann, Salter, and Whyte 2003). Methods to help synthesize data have also been developed through the US MHS, where teams used the World-Class Toolkit to consider 28 design drivers (13 mandatory, based on the strength of empirical data) and 105 design strategies (Clemson University and NXT 2012). However, information also needed to be available at the right time. "*A piece of evidence that is highly relevant to the visioning or programming phase may not enjoy such relevance to the designer involved in subsequent design phases*" (Haq and Pati 2010, 83), and the 2013 online version MHS checklist delineated by phase as well. In developing guidance tools, there was also skepticism related to scoring. In a critique of the DQI, the practice of scoring was questioned if the aim of the tool was to inform dialogue (Markus 2003).

An important step in using knowledge guidance during design was a formal appraisal of the evidence to be used by the design team (Devine et al. 2015) and follow-up to ensure the goals are being met for each departmental area (Reiling et al.

2004). Given the lengthy timeframe for projects, there was potential for new evidence to span the period of the project, rather than just an initial search (Devine et al. 2015). According to Attaianese (2012), who cited multiple studies, the ability to adopt HF/E perspectives, for example, relied on the availability of HF/E standards or EBD case studies that evaluated the effect of the built environment. One source of information often overlooked was lab-based studies in ergonomics or biomedical engineering (Edwards 2008).

Synthesizing this range of information was found to be difficult when information was in the form of both physical parameters (e.g., light levels) and subjective conditions (perception of warmth) (Gann, Salter, and Whyte 2003) or when the information was more difficult for a designer to translate. One case study examined the relationship between the sources of evidence and the sources actually used to create design solutions (Table 3-3).

Table 3-3. Sources and use of evidence

Source type	Used as evidence	Used to develop design solutions
Peer-reviewed scientific journals	54%	23%
Trade publications, magazines, books	46%	60%
Anecdotal, experience, interviews		17%
Source: Haq and Pati 2010.		

While peer-reviewed journals were a primary source of evidence, they were less meaningful as a source for solutions, illustrating a gap in interpretation of more rigorous evidence (Haq and Pati 2010).

3.4.4.2.2 Sharing knowledge

Although there is no universally accepted name, tool, or definition for a POE (also known as facility performance evaluation or environmental design audit, among others), POEs are one formal process for sharing information, (Steinke, Webster, and Fontaine 2010). A POE often focuses on the assessment of building performance from an improvement perspective (a reactive process), rather than the consideration of users' needs during the whole flow of the building design process (Steinke, Webster, and Fontaine 2010), but it is the only realistic way to gauge the gap between expectations and performance (Attaianese and Duca 2012). Some argue that "building performance evaluations" (BPE) include more emphasis on operational features such as the needs of patients and families or productivity factors (Clemson University and

NXT 2012, Steinke, Webster, and Fontaine 2010). Unfortunately, formal POEs are not always conducted and results are not always available (Bordass and Leaman 2005). Attempts to make building performance assessment and POE routine have largely failed due to resources and complexity (Bordass and Leaman 2005) and two-thirds of respondents to a survey believed POE reports are 'hardly read at all,' while the remainder felt they are only 'read by a few' (Bartholomew 2005). Additionally, POEs are not part of a base service of the design architect and often require expertise other than design (Horayangkura 2012).

While POEs are reactive in nature, they can be modified for proactive thinking and decision making in the earliest stages in the project life-cycle to foster discussion (Bordass and Leaman 2005, Clemson University and NXT 2012, Gann, Salter, and Whyte 2003, University of Sheffield 2007, Steinke, Webster, and Fontaine 2010, Horayangkura 2012). Importantly, proactive approaches need to be "*systematically built into the planning and design processes rather than added on as an afterthought*" (Bosher et al. 2007, 236). Studies included in the review also referenced proactive approaches that include:

- A focus on the intent (guiding principles) as part of a proactive approach (Reiling et al. 2004, Gann, Salter, and Whyte 2003),
- Using evidence in team meetings to construct design recommendations (Devine et al. 2015),
- Providing exemplars (University of Sheffield 2007),
- Using foresight as a systematic process to leverage tacit knowledge (Bartholomew 2005), and
- Using a structured tool to track changes between design iterations over the life-cycle of the project (Gann, Salter, and Whyte 2003, Steinke, Webster, and Fontaine 2010).

One study found that team members (client and designers) valued the experience of discussing an evidence-based evaluation of their facilities and found it improved their understanding of design issues. They speculated that a similar discussion during the planning stage might provide even greater benefits (Fleming, Fay, and Robinson 2011). The US MHS has been advancing its own standardized approach to design evaluation that allows access to findings and conclusions, addresses outcomes measuring patient-centered care, and acts as a proactive method to

modify guide plates, design recommendations, and other institutional processes (Clemson University and NXT 2012).

3.4.4.2.3 Managing knowledge

Collecting and classifying the volume of information was also a consideration. Reiling et al. (2004) enlisted experts from outside the industry to inform conditions where robust evidence was not available. Foureur at al. (2010) relied on both an established framework espoused in Christopher Alexander's *Pattern Language* and subsequent expert panels to classify data being used to develop the BUDSET (Birthing Unit Design Spatial Evaluation Tool). Devine et al. (2015) used the Robert Wood Johnson Foundation/Institute for Healthcare Improvement "Transforming Care at the Bedside" to establish a framework for topic investigation. Unfortunately, in many building-related industries, knowledge management was weak and the information was left on the shelf (Bordass and Leaman 2005). Even for those that pursued endeavors of knowledge management, it took a year or two to "*get the practicalities right, for people to change their working habits, and for visible benefits to start flowing*" (Bartholomew 2005, 6).

Practical challenges to managing knowledge included understanding the knowledge needs; organizational culture; access to research documents; attributes of research data; the presentation format of research findings to suit varied stakeholders; and pervasive use and development of knowledge-sharing systems (Haq and Pati 2010, Bartholomew 2005). At a basic level, information was managed in an easy to use format such as a matrix of prioritized opportunities relative to the budget (Reiling et al. 2004). Other programs planned for elaborate websites that provided searchable functions for tools, reports, and best practices (Bordass and Leaman 2005, Clemson University and NXT 2012, University of Sheffield 2007, Steinke, Webster, and Fontaine 2010). These management tools need to offer efficiency as time saved in extracting information for design purposes is directly proportional to financial savings for the project (Haq and Pati 2010).

The students in the Haq and Pati study (2010) attempted to derive a classification system to manage knowledge that was eventually abandoned. Their primary tier of classification was relatively simple to categorize (e.g., patient safety, system efficiency), but the lower tiers were problematic to define, as the issues often

did not have a 1:1 relationship to the parent topic and instead included a "many-to-many relationship" where a type of setting was associated with multiple factors (Haq and Pati 2010). The author of one audit reported that converting more than 500 pages of information into a format that could accurately describe a current state for executives was critical (MacAlister 2013). In this case, the audits for each unit were analyzed and information from the 16 categories and 62 subcategories were summarized and scored into nine broad areas of focus for each unit and then prioritized into a recommended course of action.

Whereas evidence-based medicine engages physicians as the primary agent for interpretation, in EBD designers find themselves in a new role of needing to assess the relevance of evidence (Haq and Pati 2010). In working with design teams, forms of visual representation need to be considered so users can both quickly and readily understand what is being communicated (Gann, Salter, and Whyte 2003, University of Sheffield 2007, Whyte and Gann 2003). This may involve a radical departure in the way evidence is typically presented to offer increased accessibility to designer audiences (Haq and Pati 2010). Value might be added through the intersection of building and healthcare sector databases (Edwards 2008).

The knowledge translation process has been characterized in four stages: awareness, agreement, adoption, and adherence (Fleming, Fay, and Robinson 2011). This process was effectively used in more than one study, where teams were created to address specific topic areas (Devine et al. 2015, Reiling et al. 2004). In both of these studies, the process included awareness through discussions of the available evidence (whether written or in the form of external expertise), agreement through participation in user group meetings, adoption through use of tangible forms of translation (i.e., mock-ups), and adherence through continuous engagement and follow-up for prior decisions.

While development of knowledge management systems is one hurdle, maintenance is the second, due to vested interests and budget cuts (Bordass and Leaman 2005). Some online databases have transitioned to obsolescence. For example, the UK Department of Health NHS Estates developed the Knowledge Information Portal (KIP) to house guidance and tools, such as A Staff and Patient Environment Calibration Toolkit (ASPECT) and Achieving Excellence Design Evaluation Toolkit (AEDET) Evolution tools (University of Sheffield 2007). This was

replaced by the 'Safer Environment Database' in 2005, which was accessible to government and NHS users at no charge, but included an annual subscription fee for private sector users (National Resources for Infection Control 2011). Unfortunately, Space for Health closed in March 2013 due to the "*consequence of Central Government's drive in England to provide as much web-based information as possible via its gov.uk website*" (National Health Estates 2013). The "obsolete" AEDET has been superseded by the multi-stakeholder-developed DQI, (DQI 2013), managed by the private sector through licensing fees (Gann, Salter, and Whyte 2003). While fees are not prohibitive in the context of an overall project budget, the costs are not insignificant and can be a barrier if not included as a budget item during the programming phase. (*Note*: In February 2014, completing the five-stage DQI for Health in the UK was estimated between £10,495 and £22,495, depending on the project complexity (DQI 2014). Currently, a quote must be requested.) Under a separate company in the US (November 2015), a single DQI "leader key" that allows for unlimited responses to the DQI questionnaire within a 10-day period is $2,500, but the certified DQI facilitator is additional and the process requires a minimum of five surveys (i.e., $12,500) from design through post-occupancy (DQI 2015). Other repositories, such as the BPE database discussed in Steinke, Webster, and Fontaine (2010), never got funded (Knudtson, personal communication, May 2014).

3.4.4.3 Guidance

3.4.4.3.1 Direction

Environment behavior interactions are seen as a crucial component to grow expertise in both programming and social design (Horayangkura 2012). Several authors expressed the importance of more in-depth integration of existing benchmarks or successful projects (Bordass and Leaman 2005, Clemson University and NXT 2012, University of Sheffield 2007, Whyte and Gann 2003, Fleming, Fay, and Robinson 2011) and user input to consider the complex behavioral aspects and human responses affecting design (Horayangkura 2012, O'Keeffe, Thomson, and Dainty 2012, Fleming, Fay, and Robinson 2011, Bartholomew 2005, Reiling et al. 2004). Others promoted a higher level of collaboration throughout the project life-cycle, with problem solving and solution testing through diverse stakeholder input that included clinicians, nurses, risk managers, HF/E specialists, medical informaticists, equipment specialists, interior designers, and patients (O'Keeffe, Thomson, and Dainty 2012, Reiling et al. 2004,

Devine et al. 2015). This may require new contractual and relational incentives to motivate teams in different ways toward different goals (O'Keeffe, Thomson, and Dainty 2012) and a recognition that time-consuming and labor-intensive additions to the design process can provide benefits for innovation and design considerations (Reiling et al. 2004).

3.4.4.3.2 Change

Most papers provided opinions about opportunities for change that included communication; information filters and gates; education and awareness; and interface with regulations. It has been suggested that using tools and techniques in a systematic way throughout the project life-cycle could improve communication and the quality of discussion through a standardized distribution process of results to inform decision-making (Clemson University and NXT 2012) or through the use of the tool or technique itself (Whyte and Gann 2003, Bartholomew 2005, Clemson University and NXT 2012, Devine et al. 2015, Reiling et al. 2004). Emphasis needs to be placed on timely access to information in order to ensure consistent direction (Fleming, Fay, and Robinson 2011). For example, the Clemson University and NXT report (2012) recommended a shift from the POE "Building in Use" approach to a full life-cycle POE offering six feedback loops: (1) market/needs analysis; (2) effectiveness review; (3) programming review (where designers can learn from past POEs); (4) design review; (5) commissioning; and (6) POE. This was also supported by Reiling et al. (2004) where the authors identified the importance of ongoing evaluation of the existing facility and processes to understand contribution to error. Another author suggested a process of "*negotiated consensus*" where workshops are held prior to sign-off as "*a symbolic act of documented consensus*" and compliance (O'Keeffe, Thomson, and Dainty 2012, 8).

Education and awareness might start with schools producing architects with better environment-behavior knowledge (Horayangkura 2012, Fleming, Fay, and Robinson 2011). An overarching challenge in the field has been general awareness of the need to design for safety in ways that may inherently change the design process (Reiling et al. 2004). In real-world settings, defined processes to help teams design for safety and understand the interplay would alleviate the condition of "flying blind" in effectively establishing a focus on safety (Reiling et al. 2004) while creating collaboration and synergy amongst team members (Devine et al. 2015).

Finally, while architects and owners are generally not in favor of increasing regulations (Fleming, Fay, and Robinson 2011), regulatory frameworks are also influential in defining features of the built environment. Improvements in this area, such as performance-based codes, were deemed critical to reducing injuries related to the built environment (Edwards 2008). However, the regulatory side of managing risks (such as building codes) can reduce risk unevenly and it could be necessary to integrate additional considerations (e.g., insurance) for effective mitigation (Bosher et al. 2007).

3.5 Discussion

The development of design tools extends far beyond the tool itself. Underlying conditions of existing processes and considering users in design have a significant influence on how tools might effectively be incorporated into the design process. Using, sharing, and managing knowledge are equally complex and tools may benefit the process by offering a distillation of relevant information. The challenge is in providing the information in an easily accessible, updatable, and maintainable format. The review also identified the challenges of integrating the environment-behavior and person-fit considerations within the existing paradigms of facility design. Guidance needs indicated a required paradigm shift in the existing process of both education and professional design with respect to how teams consider environment-behavior interactions, user engagement, and communication over the life-cycle of the project.

Lastly, metrics to describe the problem can be challenging in understanding causality. In order to help researchers classify external causes of injuries (e.g., how the injury was caused, physical objects causing injury, location, and activity at time of the injury), the WHO has developed the International Classification of External Causes of Injury (ICECI). It now has a related classification in Chapter XX of the International Classification of Diseases (ICD) to allow database comparison that may enhance development of injury preventive strategies (McKenzie et al. 2012). This is a complicated system of 68,000 codes and correct data entry is required for substantive impact in this area, but this may offer additional meaning for understanding risk in HC facility design.

When Stage 1 of the study was conducted, this was the first systematic review undertaken to identify the themes that underlie both the development and use of tools

in the architectural design process. Key points derived from this review were used to understand the context for the SRA tool development and testing and have been previously reported (Taylor et al. 2014). More recently, a book has undertaken a review of EBD tools (Phiri 2015). Phiri uses a taxonomy of compliance, design quality, efficiency and effectiveness, and sustainability to categorize tools. He discusses the three-point challenge of the evaluation with respect to fully quantifiable building materials science, functional planning, and fully subjective and aesthetic perceptions. Phiri describes the benefits of design tools as benefiting patient well-being and safety, eliminating environmental stressors, and reducing stress.

Categories	Design Tools
Improving Compliance with Statutory and Other Require-ments	**Premises Assurance Model (PAM):** "A system-wide, nationally consistent approach to providing organisation board-level assurance of the quality and safety of premises in which NHS clinical services are delivered. The rigorous self-assessment methodology uses robust evidence, metrics and measurements to demonstrate that a health care provider's premises achieve the required statutory and nationally agreed standards on safety, efficiency, effectiveness and staff/patient (user) experience." **Activity DataBase (ADB):** "Relates uniquely to health care and is well-regarded in the industry. Contractors in the health care sector point out that ADB data is used on 95% of all health care projects."
Design Quality Improvement	**Achieving Design Excellence Evaluation Tool Kit (AEDET):** "A sector-specific version of the industry standard Design Quality Indicator (DQI) widely adopted in the UK to establish a shared set of terms and concepts through which all those involved in the design process can map its quality." **A Staff & Patient Environment Calibration Tool (ASPECT):** A plug-in for AEDET Evolution – "Can help communicate and allow sharing of values, clarify design strengths to build on, weaknesses to be overcome while identifying opportunities for improvement of the architectural health care environment." **Design Quality Indicator (DQI):** "A method of evaluating the design quality and construction of new buildings as well as the refurbishment of existing ones, including police stations, office buildings, college and university buildings, libraries, and many other civic and private building projects. The process involves a wide group of people responsible for the design and construction, those who will use the building or are affected by it." DQI for Health: Launched in March 2013 in certain cases succeeding AEDET Evolution (above) which is no longer supported by the Department of Health. **Design And Risk Tool (DART):** "Estimates and manages the risks involved in a design under ProCure21 NHS Building Procurement, aids the client to make informed decisions when evaluating the inherent risks for specific design proposals." **Inspiring Design Excellence and Achievements (IDEAs):** "Initiates the design of health care places through considerations of people (patients, staff and visitors), medical equipment and furniture to respond to emotional and functional requirements of health and social care delivery."
Enhancing Efficiency and Effectiveness	**Strategic Health Asset Planning and Evaluation (SHAPE):** "A web-enabled evidence-based application which informs and supports the strategic planning of services across a whole health geographical economy in order to deliver health and social care more efficiently and effectively while enabling decisions to be made closer to the patients (and all those people) that will be affected by them."
Achieving Sustainability in the Architectural Health Care Estate	**Building Research Establishment's Environmental Assessment Method (BREEAM):** "Sets the standard for best practice in sustainable building and construction design and has been widely acknowledged as the measure to describe a building's environmental performance. Credits are awarded in nine categories according to performance which are then aggregated or added together to produce a single overall score on a scale equivalent to 'Pass', 'Good', 'Very Good', 'Excellent' and 'Outstanding' rating." **Chartered Institution of Building Services Engineers (CIBSE) TM22 (Energy Assessment & Reporting Methodology (EARMTM)):** "A method for assessing a building's energy and services performance that can be handled by using a spreadsheet approach to consider feedback and operational performance and therefore allows building owners, facilities managers and designers to reconcile, for example, the total electrical use against various end uses."

Figure 3-3. EBD tools for healthcare design
Source: Phiri 2015, 4, Table 1.1 © Routledge

However, all of the included tools in Phiri's book (Figure 3-3) are UK-centric. Some of the tools Phiri discusses are included in this systematic review (e.g., AEDET,

DQI) and some were excluded due to subject matter (e.g., energy, sustainability) or date criteria after 2001. Other tools not included in the review (e.g., DART) were less focused on design and more intent on defining risk during project procurement (e.g., delays, cost overruns), while others did not include any published information on the development process (PAM). Consistent with the findings of the systematic review presented in this chapter some tools (Activity Data Base) have been retired since the book production (Department of Health 2012).

3.6 Limitations

There were several limitations to the review. There was not a single outcome defined for the review, and there was generally a lack of published research about the development and use of tools in the facility design process. Where studies have been published, key words were inconsistently used and it was difficult to find known tools through the systematic process. Additionally, many processes, if published, took an anecdotal or descriptive approach. Another limitation is the potential overlap of findings, as multiple studies pertaining to a single tool were included. This was intentional and offers strength to the review as well, as the papers reported on different phases of development. Most papers were written from the participant or developer perspective, and only two included papers were independent reviews of an identified tool - the DQI. While some studies may have been context specific as different countries incorporate different models of care, different project delivery methods, and different building codes, the international perspectives of the papers in the review (i.e., UK, US, Canada, Australia, Thailand) also illustrated the commonality of themes. Lastly, two independent reviewers did not conduct study selection and quality appraisal; rather one worked under the guidance of the doctoral advisor.

3.7 Conclusion

To better establish the context for the development of the SRA tool from a research perspective, a systematic literature review was conducted in Stage 1 of the thesis. The aim of the review was to understand how tools that inform architectural design are both created and used. Using a previously established framework to evaluate guidance in design (Hignett and Lu 2009), the included papers (most theoretical in nature) were analyzed for themes pertaining to: (1) design culture (existing process and user considerations); (2) use of evidence (using, sharing, and

managing knowledge); and (3) guidance (the need for direction and change). A dual appraisal method (Taylor and Hignett 2014a) evaluated the evidence hierarchy and assessed the methodological quality of all studies included in the review. The review revealed a paucity of published research that details the development of design tools used in facility design. It was also confirmed there was no available tool to proactively and systematically integrate safety during the design of healthcare facilities.

4 Systematic Literature Review: Hospital Falls (Phase I)

4.1 Chapter Overview

As outlined in the preface, preliminary content development for the SRA toolkit was developed through a non-systematic traditional literature review (Grant and Booth 2009) for all risk component categories (e.g., infection control, medication safety, falls). This included industry best practice and a variety of gray sources. The consensus development process based on this content is presented in Chapter 5. However, the traditional review of falls conducted for the grant was followed by a two-phase systematic review for the thesis. This chapter presents Stage 2 - content developed through the first phase of a systematic mixed studies literature review to explore, appraise, and confirm aspects of the physical environment (building design) contributing to or mitigating the risk of hospital falls. The two phases were subsequently used to conceive a theoretical model for understanding the risks and interventions for hospital falls that addresses the relationship between HF/E and EBD (reported in Chapter 9).

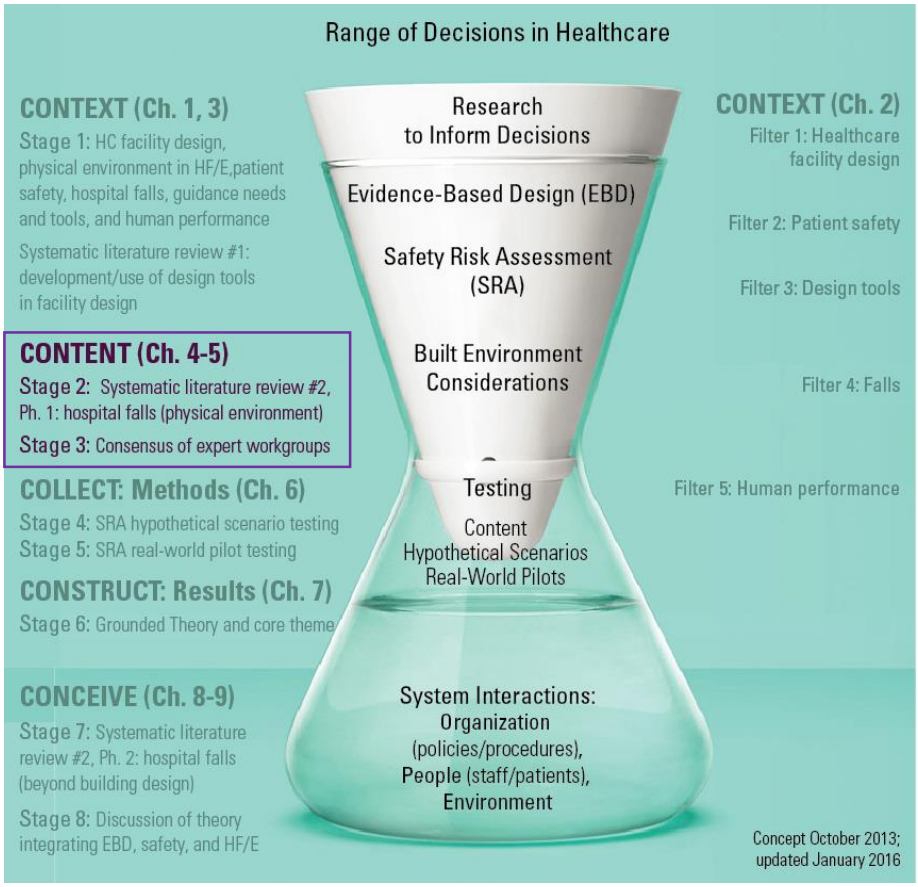

Figure 4-1. Chapters 4-5 signposting (content)

4.2 Aim and Objectives of the Stage 2 Literature Review

Leveraging content development for the SRA module on hospital falls, the primary aim, and first phase of the review presented in this chapter, was to explore and appraise aspects of building design that would allow facility designers and related project teams to take a proactive approach to the latent conditions that can contribute to the risk of falls. A secondary aim was to confirm grant-identified design conditions. A second phase of the review (Stage 7, presented in Chapter 8) was to capture non-building considerations for falls to further the HF/E systems approach to mitigate the pervasive risk of falls.

4.2.1 The Persistent Challenge of Hospital Falls (Rationale)

A significant number of patients are falling, many sustaining injury that sometimes results in death (Table 4-1). In the UK, falls data (formerly collected by the National Patient Safety Agency [NPSA]) is now being collected by the NHS Commissioning Board Special Health Authority and are reported as part of a broad category of patient accidents. In the US, the National Database of Nursing Quality Indicators (NDNQI) gathers nursing-sensitive quality indicators data subject to the CMS non-payment rule (including falls) from more than 2,000 US hospitals (Press Ganey 2015). This represents more than one-third of registered US facilities (American Hospital Association 2016).

Table 4-1. Magnitude of falls and falls with injury in the US and UK

Source	Data period	Reported outcome	Low/minor moderate injury (of injuries)	Severe/ major injury/death (of injuries)	Fall rates
UK NHS Commissioning Board Special Health Authority (acute and community hospitals) (Windsor 2015)	2010-2013	949,793 falls; 29.3% injury; 493 deaths	98.4%	1.5%	
UK NHS Commissioning Board Special Health Authority (mental health [MH] hospitals) (Windsor 2015)	2010-2013	121,805 falls; 43.5% injury; 43 deaths	99.1%	0.9%	
UK NHS National Patient Safety Agency data (National Patient Safety Agency [NPSA] 2010)	1 Oct 2008 - 30 Sep 2009	283,438 IP falls; 33.8% injuries	98.8%	1.2%	5.6/1,000 PD (3.8/1,000 PD [MH] 8.6/1,000 PD [community hospitals])
UK NHS NPSA data (Donaldson, Panesar, and Darzi 2014)	1 June 2010 - 31 October 2012	2,010 deaths		10% hospital deaths related to falls	

Source	Data period	Reported outcome	Low/minor moderate injury (of injuries)	Severe/ major injury/death (of injuries)	Fall rates
2011 US National Database of Nursing Quality Indicators (NDNQI) (Staggs, Mion, and Shorr 2014)	2011 (6,539 medical (M) surgical (S) and M-S units (1,464 NDNQI participating hospitals)	166,883 total falls; 21.5% injuries	94.4% minor/ moderate	5.6% deaths	Overall rate: 3.44/1,000 PD (Range: 3.82/1,000 PD (M, S, M-S))
US NDNQI (Bouldin et al. 2013)	July 2006-September 2008	315,817 falls; 26.1% injuries	95.4% minor/ moderate	4.5% major/deaths	Overall rate: 3.56/1000 PD (Range: 2.76-4.03/1,000 PD [M, S, M-S units])
US NDNQI (He, Dunton, and Staggs 2012)	2004-2009; 37,000 observations (8915 units in 1,171 hospitals				Range (lowest to highest): 1.27-1.34/1,000 PD in Critical Care to 7.06-8.12/1,000 PD in rehabilitation units
US NDNQI data (National Quality Forum 2011)	1st Q 2011, 10,455 units				Rates: 0.28.PD (critical care) - 1.33/PD (critical access units); Rates with injury range: 0/1,000 PD (4.2%of reporting organizations) - 31.5 /1000 PD in one small ICU unit

Costs of hospital falls vary, but one US study estimated operational costs for fallers with serious injury were $13,316 more than non-fallers, with the length of stay increased by 6.3 days (Wong et al. 2011). As a result of healthcare reform and related reimbursement in the US, there has been a concerted focus to reduce hospital falls, specifically those that result in harm. The NDNQI database reveals a steady decline of injurious falls from 1.12/1,000 patient days in 2007 to 0.93/1,000 in 2012 (American Nurses Association 2012). A recent update on the improvement in hospital acquired conditions (HACs) also found a 14.7% reduction in falls and trauma from 2010 baseline through 4th Quarter 2013 (US Department of Health & Human Services (HHS) 2014). However, even as the inpatient fall rate in the US may be decreasing, large variations in the fall rate at both the hospital and the unit level is indicative of an ongoing challenge of controlling for this adverse event (He, Dunton, and Staggs 2012). Moreover, inpatient fall rates with injury are rising in some countries (Jørgensen et al. 2015), as well as in some unit types (e.g., surgical) (He, Dunton, and Staggs 2012).

4.2.1.1 Intrinsic Factors

Falls are caused by intrinsic and extrinsic factors, with most falls associated with intrinsic factors (Hendrich 2006). Intrinsic risk factors are associated with characteristics integral to each individual. These factors include age, weight, and gender, as well as previous falls, reduced vision, mental status deficits, development stage (for children), acute illness, chronic illness, mobility or balance disorders, misperception of the environment, or loss of consciousness (Tzeng and Yin 2008, Vassallo et al. 2000, Schaffer et al. 2012). One of the foremost predictors of patient falls is a prior fall in the past year (Degelau et al. 2012), with age as a contributing factor (Calkins, Biddle, and Biesan 2012).

Brandis (1999) found that 77% of falls occurred in people over the age of 60 and others have reported that those over the age of 65 are at higher risk for falls with serious injury (Anderson et al. 2014). The National Patient Safety Agency in the UK (NPSA) reported that 82.2% of falls occurred in patients aged over 65 years, 67.6% in patients aged over 75 years, and 34.0% in patients aged over 85 years, with data indicating that patients over 85 years are at the highest risk of falls (National Patient Safety Agency [NPSA] 2010). Due to age and age-related factors, many studies focus on the 65 and older demographic (Jørgensen et al. 2015, Gelbard et al. 2014, Tsai et al.).

4.2.1.2 Extrinsic Factors

Extrinsic factors are the external conditions that can include environmental factors, but also include staff communication, risk assessments, medications, care planning, and unavailable or delayed care provision (Tzeng and Yin 2008, Choi et al. 2011, Healey 1994, Schaffer et al. 2012, Vassallo et al. 2000). While one author stated that 10-15% of falls are caused by the environment alone (Hendrich 2006), another study reported that 25% of falls were extrinsically driven (Cox et al. 2015). Schaffer et al. (2012, 11) state, "*the interactions of these [external] environments may result in increasing or decreasing the risk for a fall and the potential for injury as a result.*" Additionally, of sentinel events voluntarily reported to The Joint Commission in the US (events resulting in death or permanent loss of function), the data from 2004-2015 indicated that 41.6% of fall sentinel events have a root cause in the physical environment (The Joint Commission 2016).

4.2.2 The Complexity of Preventing Falls

There is rarely a single cause of a fall, and most falls prevention programs include a multifactorial (bundled) approach that makes it difficult to quantify the effect of any particular intervention (Oliver, Healey, and Haines 2010, Tung and Newman 2014, Bell et al. 2008, Miake-Lye et al. 2013). With respect to extrinsic factors, there is a lack of research to systematically examine environment-related interventions for falls in hospital settings (Choi et al. 2011, Calkins, Biddle, and Biesan 2012). Most falls researchers do not include building features as discrete variables, making it virtually impossible to determine the relative role of the built environment on falls and fall risk (Gulwadi and Calkins 2008). Furthermore, while environmental modifications are often referenced in multifactorial interventions, the solutions are typically drawn from expert opinion and identification of correlated risk factors (Oliver, Healey, and Haines 2010). With this complexity in mind, the first phase of the literature search was conducted to understand the range of potential built environment conditions associated with falls (the case study topic). A mixed studies approach (Section 3.3.1) was taken for a practical understanding of complex and highly context-sensitive interventions with the aim of developing a more complete picture of the research (Pluye and Hong 2014, Grant and Booth 2009).

4.3 Method: Criteria for Inclusion, Search Strategy, and Screening Flow

4.3.1 Inclusion and Exclusion Criteria

Data was extracted from English language full-text studies meeting the following inclusion criteria:

- risk factors (correlations) or interventions related to falls and/or falls with injury;
- qualitative and/or quantitative results (a mixed methods approach);
- populations of patients (adult and pediatric) or staff;
- conducted in hospital settings;
- a primary outcome of falls/falls with injury rates (reductions/increases), or
- identified factors contributing to falls and possible interventions derived from qualitative analysis.

Studies that only reported intermediate outcomes such as incontinence, gait, or postural sway were excluded, as were community- or home-based falls and those in long-term care settings.

4.3.2 Identification and Selection of Studies

Key words were assembled from Medical Subject Headings (MeSH) terms in papers retrieved from the previous grant-related search. The most common terms across papers were used and supplemented through alternate considerations and various combinations of the key words (Appendix C). Three databases were used (Medline, CINAHL, and Web of Science), supplemented by a search using the CHD Knowledge Repository (http://www.healthdesign.org/knowledge-repository).

Five literature reviews found through the search parameters were included to identify any additional physical environment conditions not found during the first phase, as well as to identify additional non-built environment components and strategies included in fall-prevention programs. After identifying additional design considerations, a bibliography review was conducted with original sources retrieved and evaluated for inclusion based on the stated search criteria. Titles and abstracts retrieved from the three databases and literature review bibliographies were screened for duplication and then reviewed for relevance. (To avoid citation duplication or secondary citations, the literature reviews were not included in the final thematic analysis.) Finally, the remaining full texts were reviewed for final inclusion. The search was initially conducted in May 2013 and updated in December 2015.

4.3.3 Critical Appraisal, Data Extraction and Analysis

Literature reviews found through the search were evaluated using the AMSTAR appraisal tool, validated by Shea et al. (2009). Each appraised review established different criteria for inclusion and analysis (e.g., outcomes such as falls or intermediate outcomes related to falls; populations such as adult inpatients; and settings such as acute-care hospitals or long-stay settings). Each review took a different approach to summarizing and reporting findings, and as a result, each was analyzed for thematic frameworks (Table 4-2).

Table 4-2. Frameworks of prior patient falls synthesis

First author (year)	Framework used for synthesis and reporting
Choi (2011)	Multi-systemic model: physical environment (e.g., environmental assessment/modifications, unit layouts/nurse station locations, acuity-adaptable rooms, furniture, flooring); care processes (e.g., visual signs, assessments, education, rounding); technology (e.g., footwear, alarms, electronic beds)
Gulwadi (2008)	Environmental correlates of falls: spatial, interior characteristics, sensory characteristics, uses of the environment
Hempel (2013)	Implementation factors; interventions (15, including "other"); adherence
Miake-Lye (2013)	Benefits and harms; implementation factors; costs
Spoelstra (2012)	Safety culture; assessments; interventions; post-fall follow-up/quality improvement; integration with medical records

Single studies were evaluated using the process described in Section 3.3.2 and previously reported (Taylor and Hignett 2014a). Data for single studies were extracted and analyzed in NVivo 10 (QSR International 2012). Extraction included population, sample size, study duration, setting, interventions, and outcomes. Results were exported into Excel for formatting purposes.

Falls data were inconsistently reported (e.g., falls per 1,000 patient days, number of falls, percent reduction) and therefore were not suited to a meta-analysis to establish a quantifiable effect of interventions. Similarly, due to a lack of homogeneity in outcomes and the mixed methods nature of the review, funnel plots or forest plots were not created to evaluate publication bias. Rather, thematic analysis for a narrative synthesis was conducted to identify the range of factors and the main themes and then explore the themes within and across the included studies (Mays, Pope, and Popay 2005, Popay et al. 2006). This is particularly suited to a systematic review with diverse evidence (Popay et al. 2006). Coding was conducted in multiple stages – firstly, to refine codes following initial coding and secondly, to consolidate overlapping codes.

4.4 Results

4.4.1 Search Flow

The search flow is illustrated in Figure 4-2.

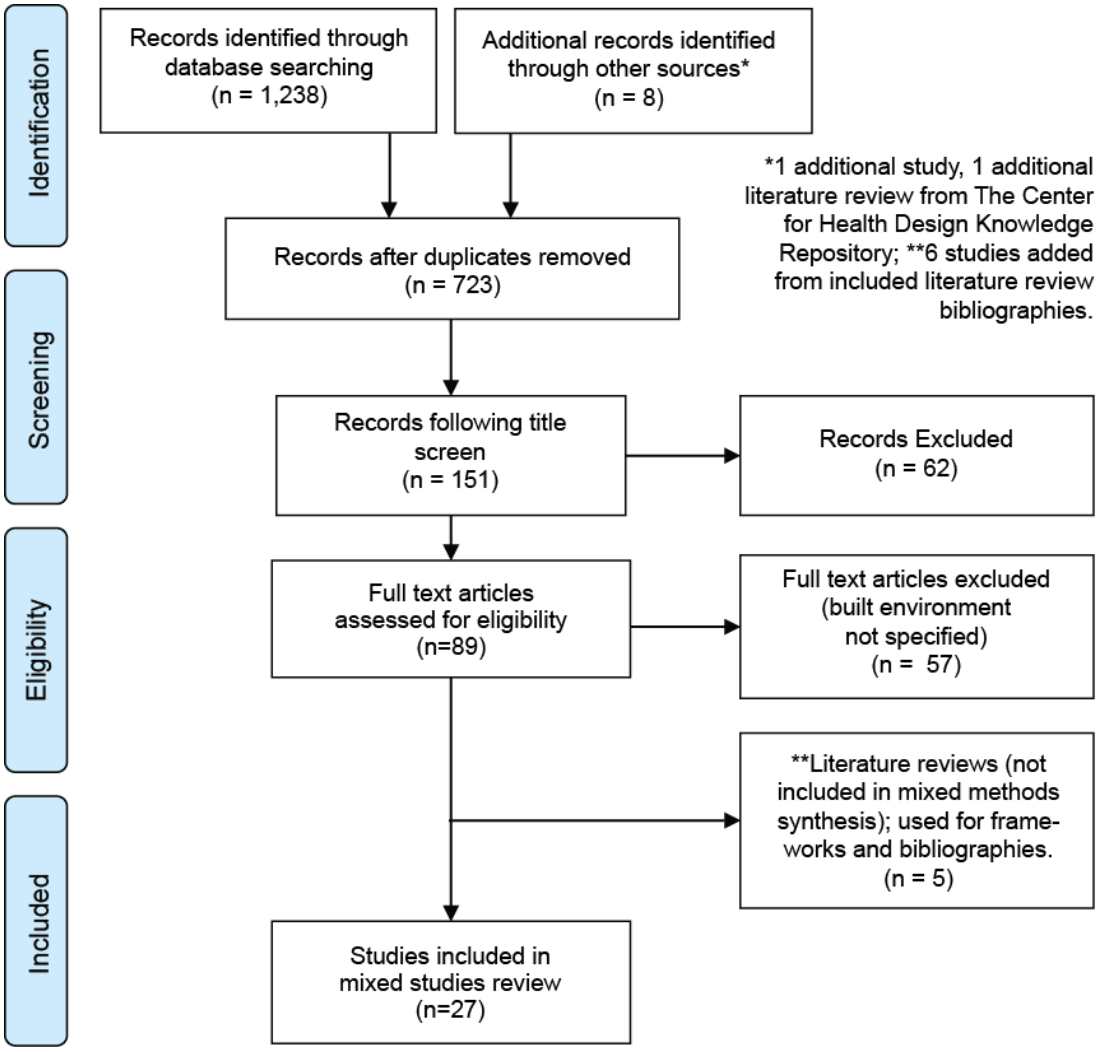

Figure 4-2. Search strategy and inclusion flow - hospital falls literature review

Following the 2015 update, 27 single-study papers were included for review Table 4-3). An additional summary (Table 12-4, Appendix D) was created to establish the overlap of the included studies from the non-systematic search conducted in 2012, the updated PhD search, and the five literature reviews. (Some of the papers were published following the initial 2012 search date.)

Table 4-3. Final list of sources for review inclusion (hospital falls)

Included in final review (author/year/title) – full citation in Chapter 11: References
1. Barker, Anna et al. 2013. "Reducing Serious Fall-Related Injuries in Acute Hospitals: Are Low-Low Beds a Critical Success Factor?"
2. Bell, Jennifer L. et al. 2008. "Evaluation of a Comprehensive Slip, Trip and Fall Prevention Programme for Hospital Employees
3. Brandis, Susan. 1999. "A Collaborative Occupational Therapy and Nursing Approach to Falls Prevention in Hospital Inpatients."
4. Calkins, Margaret P., Stacey Biddle, and Orion Biesan. 2012. Contribution of the Designed Environment to Fall Risk in Hospitals.
5. Cozart, Huberta Corazon Thiam. 2009. "Environmental Effects on Incidence of Falls in the Hospitalized Elderly."
6. Dacenko-Grawe, Lydia, and Karyn Holm. 2008. "Evidence-Based Practice: A Falls Prevention Program That Continues to Work."
7. Donald, I. P. et al. 2000. "Preventing Falls on an Elderly Care Rehabilitation Ward."
8. Drahota, Amy et al. 2013. "Pilot Cluster Randomised Controlled Trial of Flooring to Reduce Injuries from Falls in Wards for Older People."
9. Dykes, Patricia C. et al. 2009. "Why Do Patients in Acute Care Hospitals Fall? Can Falls Be Prevented?"
10. Fonda, David et al. 2006. "Sustained Reduction in Serious Fall-Related Injuries in Older People in Hospital."
11. Goodlett, Debbie et al. 2009. "Focusing on Video Surveillance to Reduce Falls."
12. Gowdy, Marie, and Shawn Godfrey. 2003. "Using Tools to Assess and Prevent Inpatient Falls."
13. Gutierrez, Felipe, and Kevin Smith. 2008. "Reducing Falls in a Definitive Observation Unit: An Evidence-Based Practice Institute Consortium Project."
14. Healey, Frances. 1994. "Does Flooring Type Affect Risk of Injury in Older in-Patients?"
15. Hitcho, Eileen B. et al. 2004. "Characteristics and Circumstances of Falls in a Hospital Setting: A Prospective Analysis."
16. Krauss, Melissa J. et al. 2008. "Intervention to Prevent Falls on the Medical Service in a Teaching Hospital."
17. Lopez, Karen Dunn et al. 2010. "Cognitive Work Analysis to Evaluate the Problem of Patient Falls in an Inpatient Setting."
18. Mosley, Amy et al. 1998. "Initiation and Evaluation of a Research-Based Fall Prevention Program."
19. Ohde, Sachiko et al. 2012. "The Effectiveness of a Multidisciplinary Qi Activity for Accidental Fall Prevention: Staff Compliance Is Critical."
20. Schaffer, Patricia L. et al. 2012. "Pediatric Inpatient Falls and Injuries: A Descriptive Analysis of Risk Factors."
21. Shorr, Ronald I. et al. 2012. "Effects of an Intervention to Increase Bed Alarm Use to Prevent Falls in Hospitalized Patients: A Cluster Randomized Trial."
22. Tzeng, Huey-Ming, and Chang-Yi Yin. 2008. "The Extrinsic Risk Factors for Inpatient Falls in Hospital Patient Rooms."
23. Vassallo, Michael et al. 2000. "An Epidemiological Study of Falls on Integrated General Medical Wards."
24. Vieira, Edgar Ramos et al. 2011. "Risks and Suggestions to Prevent Falls in Geriatric Rehabilitation: A Participatory Approach."
25. Warren, Christopher J., and Hugh C. Hanger. 2013. "Fall and Fracture Rates Following a Change from Carpet to Vinyl Floor Coverings in a Geriatric Rehabilitation Hospital. A Longitudinal, Observational Study."
26. Wayland, Larry et al. 2010. "Reducing the Patient Fall Rate in a Rural Health System."
27. Wolf, Laurie et al. 2013. "Fall Prevention for Inpatient Oncology Using Lean and Rapid Improvement Event Techniques."

4.4.2 Critical appraisal

Most of the studies included fall into a mid-range "level" of evidence. The additional critical appraisal (MMAT) defined the methodological strength of the studies, one-third receiving the full allocation of points (Figure 4-3). The most common missing component of the papers was sufficient patient demographics to evaluate whether pre- and post-test groups were comparable (Brandis 1999, Barker et al. 2013, Ohde et al. 2012, Healey 1994, Wolf et al. 2013, Calkins, Biddle, and Biesan 2012, Mosley et al. 1998). In other studies it was not possible to determine whether the sample was representative of the population (Lopez et al. 2010, Mosley et al. 1998, Goodlett et al. 2009, Gutierrez and Smith 2008, Vieira et al. 2011) or whether the data collection tool or measures were clearly validated (Schaffer et al. 2012, Gowdy and Godfrey 2003, Mosley et al. 1998, Krauss et al. 2008).

In a small number of studies, attrition rates were high (Cozart 2009, Donald et al. 2000), outcome data was not 80% complete (Krauss et al. 2008) and site selection may have been subject to bias (Calkins, Biddle, and Biesan 2012). In qualitative studies, it was not always possible to tell whether the sources of qualitative data (i.e., informants) were representative of the study sites (Dykes et al. 2009, Gutierrez and Smith 2008), how the data were analyzed (Gutierrez and Smith 2008), or how the researcher may have influenced the study through their own interactions (Vieira et al. 2011).

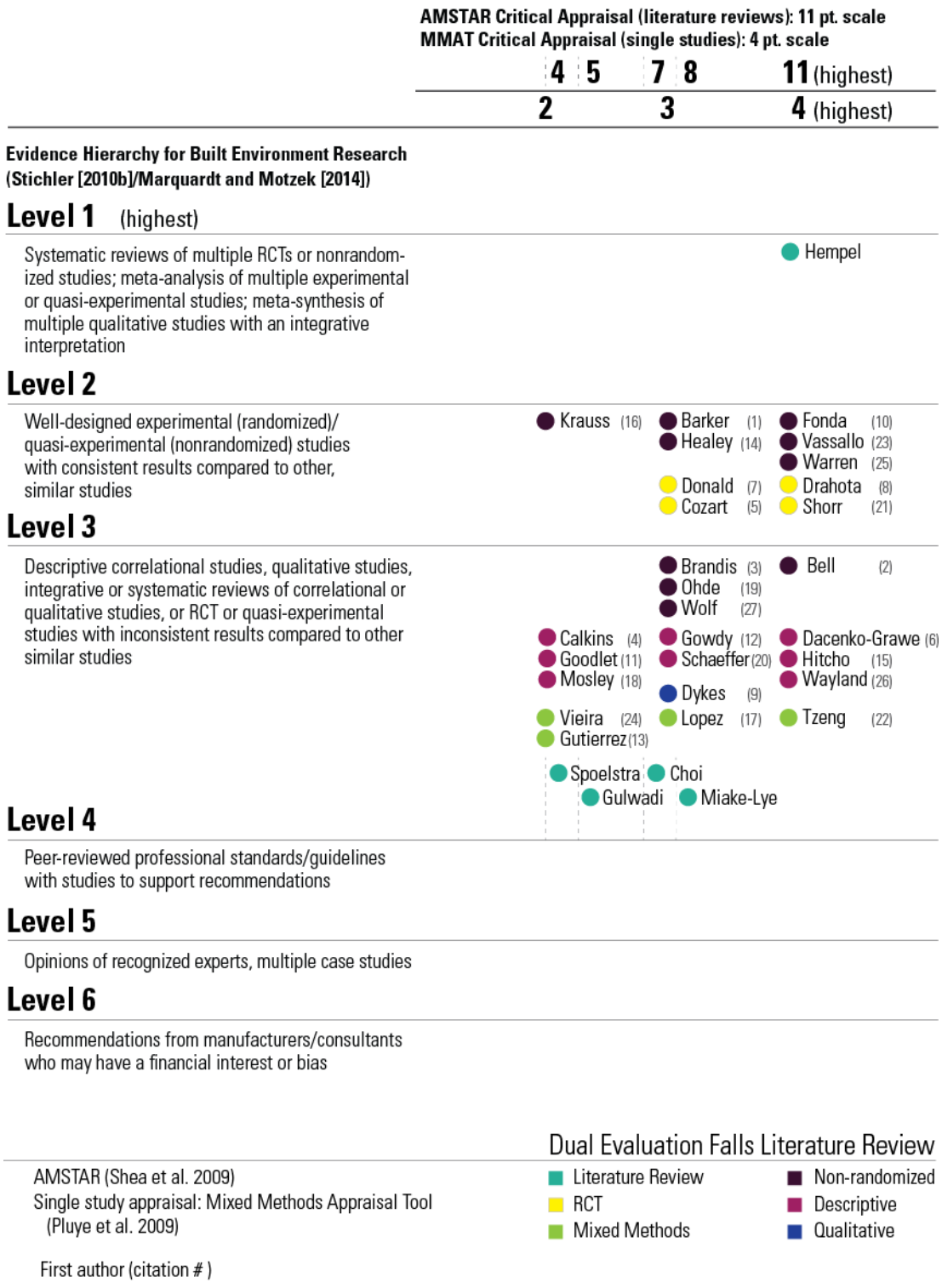

Figure 4-3. Evidence categorization and appraisal matrix for falls review

4.4.3 Study Characteristics

4.4.3.1 Population Sample, Sample Size, Study Length, Setting

While all of the studies were conducted in inpatient settings, there was a range of hospital and unit types (Appendix E). Study timeframes also varied dramatically from as few as three months to as many as 11 years.

4.4.3.2 Interventions and Outcomes

Most prevention programs include multifactorial interventions that include a combination of individual, environmental, and interactive factors (Calkins, Biddle, and Biesan 2012, Gulwadi and Calkins 2008, Vassallo et al. 2000, Ohde et al. 2012, Spoelstra, Given, and Given 2012). Figure 4-4 illustrates the complexity of the problem by identifying the number of multifactorial interventions and conditions present to prevent falls, with as many as 37 conditions found in one study.

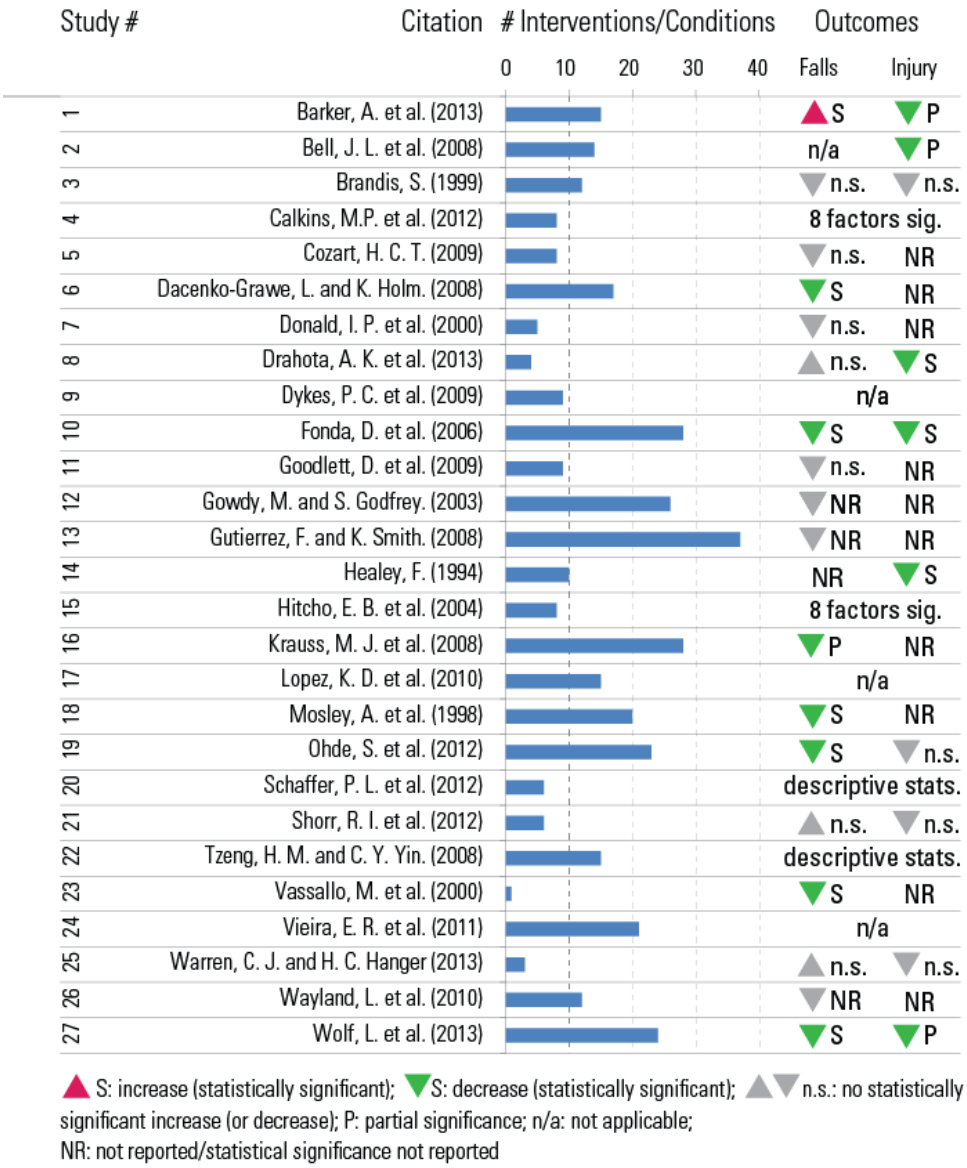

Figure 4-4. Literature review studies and number of multifactorial conditions

Five studies evaluated the characteristics and risk factors of falls without intervention (Calkins, Biddle, and Biesan 2012, Hitcho et al. 2004, Schaffer et al. 2012, Tzeng and Yin 2008, Vieira et al. 2011). As shown in Figure 4-4, fewer than half of the included papers reported some aspect of their results (e.g., falls, injury) with statistical significance, while six studies reported outcomes that did not reach statistical significance (Brandis 1999, Cozart 2009, Donald et al. 2000, Goodlett et al. 2009, Shorr et al. 2012, Warren and Hanger 2013). Three studies reported outcomes without reporting whether there was statistical significance or not (Gowdy and Godfrey 2003, Gutierrez and Smith 2008, Wayland et al. 2010). Four studies that reported a decrease in falls with injury also found an increase in the overall rate of falls (Barker et al. 2013, Drahota et al. 2013, Shorr et al. 2012, Warren and Hanger

2013). This increase was statistically significant in only one study (Barker et al. 2013). A second summary (Appendix F) provides extracted data for the interventions, general outcomes (including characteristics of falls), and specific outcomes of fall rates and/or reductions, and in some cases, data about injurious falls.

4.4.4 Summary of Evidence

The mixed results associated with bundled interventions, often inconsistent across studies, can make decisions about what to include as part of any type of falls prevention program challenging. The lack of research is creates a challenge for design teams engaged in the renovation or new construction of healthcare facilities, where outcomes of some decisions will be felt for decades.

4.4.4.1 Preliminary Thematic Analysis

Due to the number of interventions included in the reviewed studies, and based on the architectural design focus of the review, the first phase of literature review was to perform a thematic analysis with attention on the physical environment conditions, adding broad factors pertaining to people (staff and patients) and organization (operational and clinical policies and procedures). The initial 2013 model focused on the physical environment and is reflected in Figure 4-5, providing a visual summary of the themes (nodes) that were: (1) correlated to the occurrence of falls (C), (2) part of an intervention, but not individually quantified (i.e., included as a multifactorial "bundle") (N), or (3) individually quantified through empirical research (Q).

The environmental design conditions were initially categorized using the framework established by Gulwadi and Calkins (2008): spatial organization, interior characteristics, sensory attributes, and uses of the environment. As shown in the preliminary model, there were few studies that empirically evaluated built environment conditions (in this case flooring) as they pertain to hospital falls. It should be noted that following the 2015 update, additional empirical study topics included low beds, video surveillance, and bed alarms. However, even when empirically studied, the solution was most often accompanied by best practice additions, such as clearing clutter, providing adequate lighting, and testing for vision and hearing deficiencies (Healey 1994), or part of a bundle, such as the case of low beds that were one component of a larger falls-prevention intervention (Barker et al. 2013).

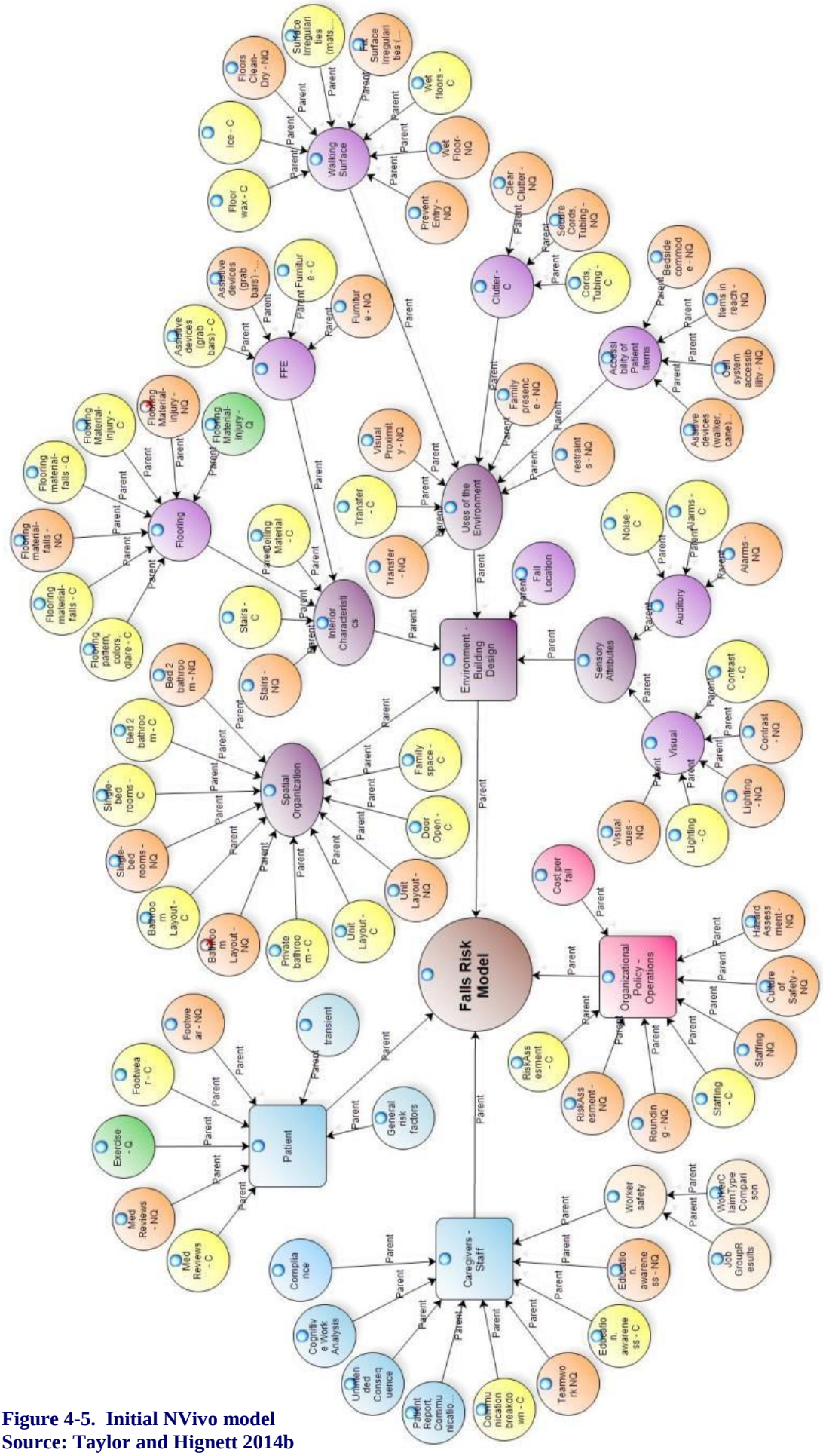

Figure 4-5. Initial NVivo model
Source: Taylor and Hignett 2014b

4.4.4.2 Defining the Environment: A Framework of Physical Ergonomics

Another aim of the review was to frame findings in an HF/E context. As described in Chapter 1, environment can have different meanings in HF/E. From an HF/E perspective, the human-environment interface (Carayon 2011) often overlaps with HF/E domains of cognition and organization, but the focus is often air quality, noise, illumination and vibration, or more locally, workstations, individual products, or equipment and furnishings, rather than the larger-scale concepts associated with spatial layouts or with other aspects of the system (Sanders and McCormick 1993, Wickens et al. 2014, Stanton et al. 2005, Carayon 2011, Attaianese and Duca 2012).

As a result of this lack of clarity, the thesis defines four subset "components" of the HF/E environment that have been drawn from the literature: ambient environment, workspace envelope, personal workspace, and products (Karwowski 2012, Carayon, Alvarado, and Hundt 2007, Wilson and Corlett 2005). The derived definitions follow:

1) Workspace Envelope (WE): the wider workplace including the building characteristics, arrangement of personal workspace (PW) components, and space constraints
2) Personal Workspace (PW): the layout of the "workstation" or immediate area of use, including the relationship of equipment, furniture, and controls to the user (including anthropometrics)
3) Products (Pr): the selection/specification of equipment, furniture, or controls
4) Ambient Environment (AE): the physical environment of thermal, air, noise, and illumination considerations

At the start of the research project, there were few acknowledgements that the patient played an active part in HF/E thinking. More recently, experts in the field have started developing models to recognize patient activities or "work" (Hignett 2013, Hignett et al. 2013, Holden, Schubert, and Mickelson 2015, Valdez et al. 2014). Because many of the falls design considerations were centered on patient activity or condition, the subset components of the physical environment include the patient's personal workspace (e.g., the bed area, the bathroom), workspace envelope (e.g., the room layout), the ambient environment (e.g., noise, light), and products (e.g., patient furniture, call systems). This classification was used for the review.

4.4.4.3 Risk Factors (Correlates) for Falls

Understanding the correlates of falls is important to best determine the solutions, especially solutions in the built environment that may be latent conditions for a risk of falling (e.g., visibility). Not all of the included studies included an analysis of the correlates of falls within their own study or organization, especially as they pertain to the environment. In most cases, investigators drew upon the literature to identify the issues considered in a falls prevention program. For those studies that investigated specific correlates, they included a variety of conditions pertaining to the physical environment, the organization (operations, policy, and procedures), and people (patients and staff).

Not surprisingly, the most commonly cited correlates pertain to intrinsic patient conditions (as described in Section 2.5), most often frailty and balance, cognition deficits, and age. Intrinsic risks for falls are summarized in Table 4-4.

Table 4-4. Intrinsic correlates of hospital falls

Category	Intrinsic conditions	Citations
People: **Patients**	Frailty and balance	(Fonda et al. 2006, Wolf et al. 2013, Donald et al. 2000, Drahota et al. 2013, Gowdy and Godfrey 2003, Gutierrez and Smith 2008, Hitcho et al. 2004, Lopez et al. 2010, Ohde et al. 2012, Schaffer et al. 2012, Vieira et al. 2011, Wayland et al. 2010)
	Cognition deficits	(Fonda et al. 2006, Wolf et al. 2013, Brandis 1999, Drahota et al. 2013, Goodlett et al. 2009, Gowdy and Godfrey 2003, Gutierrez and Smith 2008, Healey 1994, Hitcho et al. 2004, Schaffer et al. 2012, Vieira et al. 2011)
	Age	(Barker et al. 2013, Brandis 1999, Dacenko-Grawe and Holm 2008, Drahota et al. 2013, Gowdy and Godfrey 2003, Healey 1994, Hitcho et al. 2004, Lopez et al. 2010, Vieira et al. 2011, Wayland et al. 2010)
	Overestimation of abilities	(Fonda et al. 2006, Gowdy and Godfrey 2003, Hitcho et al. 2004, Mosley et al. 1998, Vieira et al. 2011, Wayland et al. 2010, Wolf et al. 2013)
	Incontinence	(Fonda et al. 2006, Wolf et al. 2013, Drahota et al. 2013, Hitcho et al. 2004, Mosley et al. 1998)
	Prior fall	(Brandis 1999, Healey 1994, Hitcho et al. 2004, Lopez et al. 2010, Wolf et al. 2013)
	Overall medical condition	(Wolf et al. 2013, Brandis 1999)
	Language/ communication barriers	(Fonda et al. 2006, Gutierrez and Smith 2008)
	Gender: Men: more multiple falls than women; women more likely to be injured More women than men falling on carpet as compared to vinyl	 (Healey 1994) (Hitcho et al. 2004)
	Hearing and vision	(Vieira et al. 2011)

It should be noted that one study focused on pediatric populations (Schaffer et al. 2012) while another (Hitcho et al. 2004) found nearly half of inpatients who fell were younger than 65 years old and the risk of injury was just as likely in ages under 65. The authors suggested that ill patients may experience common contributors to falls (e.g., cognitive impairment, impaired mobility) regardless of age.

Extrinsic risk factors identified in the included studies (organization, people, and environment) are summarized in Table 4-5.

Table 4-5. Extrinsic correlates of hospital falls

Category	Extrinsic conditions	Citations
Organization	Staffing:	
	Patients left unattended	(Tzeng and Yin 2008)
	Higher staffing levels correlated to more falls	(Brandis 1999, Krauss et al. 2008)
	Turnover (staff/leadership)	(Wolf et al. 2013)
	Maintenance:	(Wolf et al. 2013, Tzeng and Yin 2008, Vieira et al. 2011, Bell et al. 2008, Brandis 1999, Healey 1994, Hitcho et al. 2004, Mosley et al. 1998).
	Contamination of surfaces – ice, rain, urine	
	Waxed floors	(Bell et al. 2008)
People: **Patients**	Footwear	(Fonda et al. 2006, Vieira et al. 2011, Wolf et al. 2013, Tzeng and Yin 2008, Mosley et al. 1998, Schaffer et al. 2012)
	Medications	(Vieira et al. 2011, Wolf et al. 2013, Tzeng and Yin 2008, Schaffer et al. 2012)
	No walking aids	(Vieira et al. 2011, Tzeng and Yin 2008, Mosley et al. 1998)
	Lack of familiarity with the space	(Mosley et al. 1998, Vassallo et al. 2000, Wayland et al. 2010)
	Transfer movements (e.g., bed to chair)	(Cozart 2009, Mosley et al. 1998, Tzeng and Yin 2008,)
People: **Staff**	Communication breakdowns	(Tzeng and Yin 2008, Lopez et al. 2010, Gutierrez and Smith 2008, Gowdy and Godfrey 2003, Dykes et al. 2009)
	Cognitive overload/workload	(Wolf et al. 2013, Tzeng and Yin 2008, Lopez et al. 2010)
	Reflex injuries during patient assistance that preclude the fall prevention underway	(Fonda et al. 2006)
Environment: **Workspace Envelope**	Unit layout (visibility)	(Vassallo et al. 2000, Brandis 1999, Calkins, Biddle, and Biesan 2012, Goodlett et al. 2009, Hitcho et al. 2004, Wolf et al. 2013)
	Clutter (tripping hazards)	(Wolf et al. 2013, Bell et al. 2008, Hitcho et al. 2004, Mosley et al. 1998, Tzeng and Yin 2008, Vieira et al. 2011)
	Bathroom location	(Wolf et al. 2013, Tzeng and Yin 2008, Brandis 1999, Calkins, Biddle, and Biesan 2012, Krauss et al. 2008)
	Distance to bathroom	(Tzeng and Yin 2008, Krauss et al. 2008)
	Flooring:	
	Floor type as a factor (generically)	(Fonda et al. 2006)

Category	Extrinsic conditions	Citations
	More falls on linoleum as compared to vinyl, VCT, ceramic tile, wood laminate	(Calkins, Biddle, and Biesan 2012, Schaffer et al. 2012)
	Floor transitions (the thickness change from one material to another)	(Drahota et al. 2013, Ohde et al. 2012, Lopez et al. 2010) While identified as a risk, no falls were recorded in Drahota study
	Lack of space for family within the room	(Calkins, Biddle, and Biesan 2012)
	Doors in patient rooms not open/out of the way (due to spatial conflicts)	(Calkins, Biddle, and Biesan 2012)
	No patient lifts	(Calkins, Biddle, and Biesan 2012)
	Shared rooms and bathrooms/no bathrooms	(Calkins, Biddle, and Biesan 2012)
	Floor color and patterns	(Calkins, Biddle, and Biesan 2012, Fonda et al. 2006)
	Level change (stairs, curbs)	(Bell et al. 2008)
	Cords and tubing	(Tzeng and Yin 2008)
Environment: **Personal Workspace**	Bathroom layout - fewer falls with sidewall toilet as compared to directly across from the entry	(Calkins, Biddle, and Biesan 2012)
	Call system inaccessibility	(Mosley et al. 1998)
	Bedside commodes	(Hitcho et al. 2004)
	Lack of/poorly positioned permanent assistive devices (e.g., grab bars)	(Calkins, Biddle, and Biesan 2012, Brandis 1999, Mosley et al. 1998, Lopez et al. 2010)
Environment: **Products**	Furniture (generic)	(Fonda et al. 2006)
	Bedrails - used as restraint	(Brandis 1999, Mosley et al. 1998, Hitcho et al. 2004, Tzeng and Yin 2008)
	Unstable/unmovable furniture	(Bell et al. 2008, Vieira et al. 2011);
	Inability to put beds in low positions	(Brandis 1999, Tzeng and Yin 2008, Wolf et al. 2013)
	Bed/chair alarms – movement alert (e.g., unavailable, inaudible, deactivated, irregularly used)	(Wolf et al. 2013, Lopez et al. 2010, Vieira et al. 2011, Tzeng and Yin 2008)
Environment: **Ambient Environment**	Poor lighting - toileting at night	(Fonda et al. 2006, Mosley et al. 1998, Tzeng and Yin 2008, Vieira et al. 2011, Wolf et al. 2013, Lopez et al. 2010)
	Noise (e.g., alarms, overhead paging that hampers sleep)	(Calkins, Biddle, and Biesan 2012)

With respect to environmental extrinsic risk factors, two studies (Calkins, Biddle, and Biesan 2012, Wolf et al. 2013) found rooms with direct visibility or close proxmity to nurse stations were correlated to higher rates of falls, but the authors of both studies indicated this may be a result of the highest risk patients being placed in those rooms. Underlying factors of bathroom location were inconsistent. One study reported that while the bathrooms were located on the headwall (presumably closer to the bed), there were obstacles in the patient path, including a sink (Wolf et al. 2013). Another reported (with surprise) that there were more falls when the bathroom was

located on the headwall (Calkins, Biddle, and Biesan 2012), and a third referenced the patient's disorientation to bathroom location (Mosley et al. 1998). Two studies considered the correlation between falls and the distance to the bathroom, with no additional details about the physical location (Tzeng and Yin 2008) and no statistical significance when the bed was closest to the bathroom (Krauss et al. 2008).

4.4.4.4 Environment Interventions for Falls Prevention

Interventions in the environment spanned the four subset physical environment categories, as shown in Figure 4-6. The interventions are discussed in more detail in the subsection categories of workspace envelope (Section 4.4.4.4.1), personal workspace (Section 4.4.4.4.2), products (Section 4.4.4.4.3), and ambient environment (Section 4.4.4.4.4).

While there may not be a direct correlation to the overall quality of a study and a particular component within an intervention bundle, identifying the frequency of an intervention (vote counting) can illustrate preliminary patterns across studies (Popay et al. 2006), even if not intended as a more definitive conclusion that might result from a meta-analysis. As bundles rarely comprise the same set of interventions, this serves as a useful method to analyze, synthesize findings, and lastly, in the context of the appraisal, gauge the possible "weight" behind particular solutions.

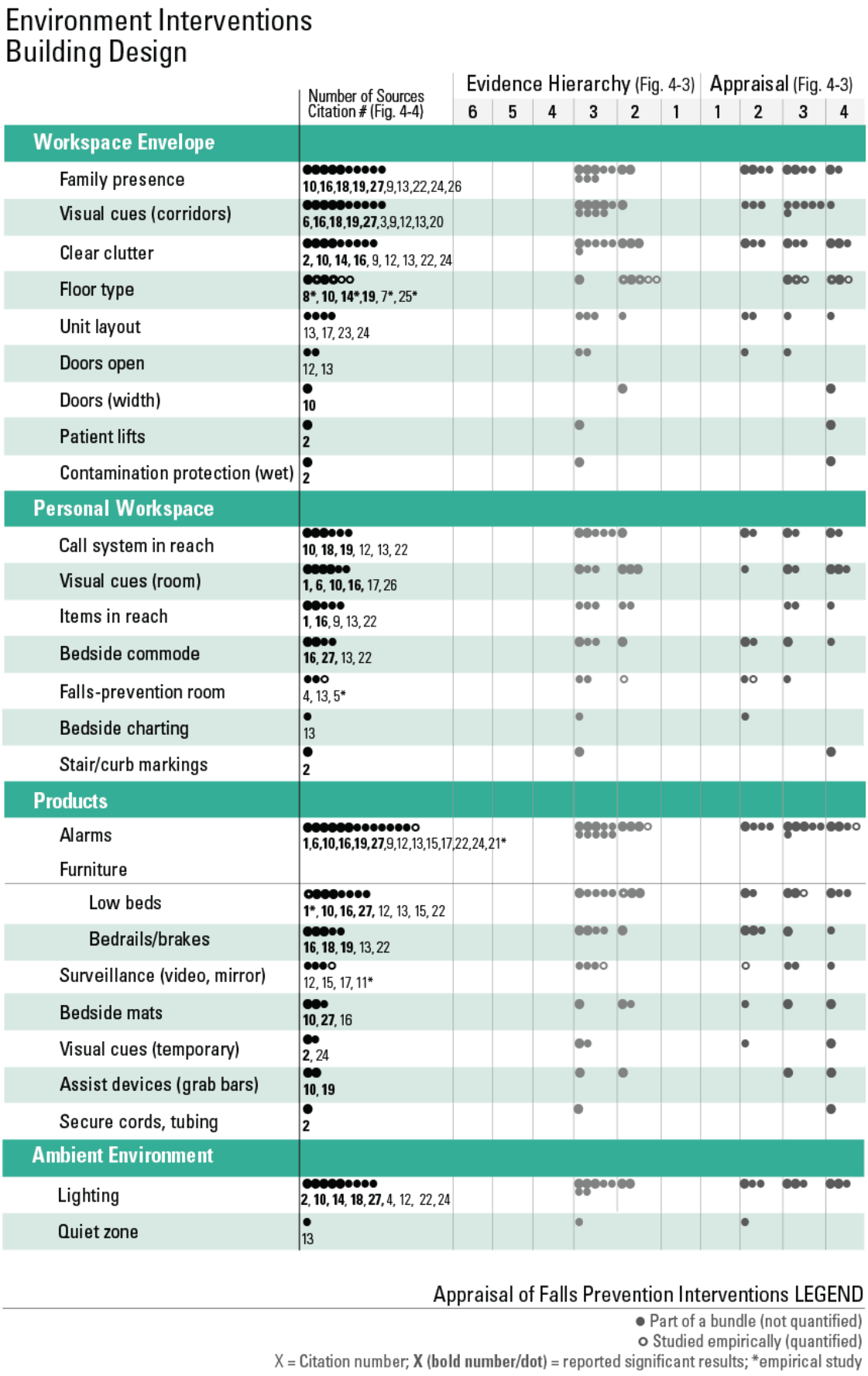

Figure 4-6. Physical environment interventions to mitigate falls

4.4.4.4.1 Workspace envelope

Within the workspace envelope, some interventions addressed the directly related workspace envelope correlates of falls including family presence, clearing clutter, flooring, unit layout, open doors, and patient lifts.

Family presence. Multiple studies of varying quality appraisal referenced the importance of family presence in a falls prevention program (Figure 4-6). Family presence interventions included education and awareness, but also entailed family staying with the patient (Gutierrez and Smith 2008, Krauss et al. 2008, Mosley et al. 1998) and assisting where possible (Ohde et al. 2012, Tzeng and Yin 2008). This finding implies the need for space for family to stay 24/7, a feature often included in more recent patient room designs. One study noted that families were a difficult aspect to control, as participation was voluntary (Tzeng and Yin 2008). Another study found that while relatives should be involved, family members had little to add in a conversation about falls, raising a concern that they did not perceive falls prevention as their role (Vieira et al. 2011). This highlighted the need for a proactive and active partnership (Wolf et al. 2013) and family engagement that extended beyond mere physical presence. Half of the studies referencing family presence reported statistically significant results as part of the overall study.

Clearing clutter. While many references are generic to providing a clutter-free environment (Gutierrez and Smith 2008), this was defined in several papers as keeping floors and walkways clear of objects (Bell et al. 2008, Gowdy and Godfrey 2003, Krauss et al. 2008); ensuring a clear path around the bed (Fonda et al. 2006); ensuring unobstructed access to the bathroom (Dykes et al. 2009, Tzeng and Yin 2008); and removing items not being used from the unit/ward (Healey 1994). This latter recommendation was supported by feedback from patients, families and staff that additional storage was required (for patient personal items as well as medical equipment) and that objects and equipment should be returned to their proper place when not in use (Vieira et al. 2011). Vieira et al. also articulated a staff concern that crowding from furniture or closings (i.e., door swings) in the patient's path of travel should be considered. The studies referencing clutter-free spaces spanned a range of quality appraisal and while not all of the included papers reported statistically significant outcomes, removing clutter was also deemed a "common-sense" intervention by participants in one study (Dykes et al. 2009).

Flooring. One study (Fonda et al. 2006) generically cited the need for non-slip flooring in the bathroom (which is a code requirement in most countries), and one study referenced eliminating height discrepancies between flooring materials (Ohde et al. 2012). However, several other studies empirically investigated specific flooring materials and the implications of fall rates or falls with injury when comparing one flooring material to another. Although this intervention generally required some form of renovation or construction (and therefore was less referenced within the many bundled interventions), studies reporting these interventions were appraised at higher levels of methodological quality.

The most studied flooring comparison was carpet and vinyl (Donald et al. 2000, Healey 1994, Warren and Hanger 2013), but the results were not consistent and did not always include statistically significant results. In Healey's retrospective study (1994), the analysis of four years of accident forms revealed there were no more falls on carpet than on vinyl, but the incidence of injury from falls was lower on the carpeted floors than on vinyl (15% on carpet as compared to 91% on vinyl). Donald (2000) found more patients fell on the carpet floor than vinyl, but the results were not statistically significant and the time period was relatively short (nine months). Additionally, the small number of falls on vinyl made comparison of injury impossible. The third study (Warren and Hanger 2013) found no significant difference in fall rates between the two materials in a pre- and post-comparison, but also found these findings varied by ward type. There were non-significant trends of lower fall rates on carpet in some wards (i.e., stroke and general wards) but a statistically significant higher rate of falls on carpet in the psychiatric ward over the year prior and following the installation of new flooring.

In a pilot cluster randomized control trial, Drahota et al. (2013) compared a specialized sports flooring applied over concrete subfloor to in situ flooring (on concrete subfloor) at eight sites in the bed areas. The results indicated this shock-reducing flooring may have reduced injuries, but may have also increased the overall risk of falling. The study also found tradeoffs relative to the rollability of the surface from a staff perspective. (It should be noted his floor type is not recommended by the manufacturer for this type of setting.)

Optimizing Unit Layout. Optimizing unit layout often pertained to visibility but the layout may have also affected nurses' and other caregivers' cognitive load

contributing to risk factors for patient safety. In one natural experiment of three unit types, authors found the nuclear layouts in two units (where 85% of patient beds were visible from either one or two nursing stations) contributed to a significantly lower number of falls than on a unit with visibility of only 20% of the patient beds (Vassallo et al. 2000). Lopez et al. (2010) referenced functional adjacencies, noting that when the location of functions such as medication preparation and charting precluded ongoing surveillance of patients, workarounds occurred. The authors suggested that design strategies should relocate indirect care tasks closer in physical proximity to the bedside. While most studies did not offer details about location of nursing stations or primary activities, one study established satellite nursing stations outside patient rooms (Gutierrez and Smith 2008).

A second aspect of unit layout and workflow included storage, previously discussed as part of removing clutter. The issue was the location of storage to be convenient and accessible to facilitate use. Storage modifications were suggested by Vieira et al. (2011), where study participants recommended reorganizing the unit, even converting a patient room into an equipment storage area to provide easier access.

Open Doors. Another consideration to improve visibility to the patient and/or the patient bathroom was the ability to leave doors open, which was referenced in two less rigorous studies (Gowdy and Godfrey 2003, Gutierrez and Smith 2008). Maintaining privacy, however, was recognized as a conflicting consideration for this intervention (Gutierrez and Smith 2008).

Patient-Handling Devices. Patient lifts were recognized in a single study (Bell et al. 2008) that concurrently addressed both patient-handling injuries and STF injuries.

Workspace Envelope Interventions for Risks in 'Organization' and 'People'. Other interventions in the workspace envelope addressed risk correlates in the categories of 'Organization' and 'People' outlined in Table 4-5. For example, an organizational policy of maintaining clean and dry surfaces was in conjunction with locations for umbrella bags and areas to store ice-melt to mitigate the risk of wet or slippery floors (Bell et al., 2008). This has implications for storage, as well as ensuring temporary weather-related protections do not become clutter.

Visual cues in the workspace envelope category addressed communication breakdowns and were incorporated in 10 of the included studies, most in the mid-

range of quality appraisal and half of which reported statistically significant outcome results. Visual cues often included hallway signage for patient rooms that incorporated color or a graphic, such as falling leaf or falling star (Dacenko-Grawe and Holm 2008, Mosley et al. 1998, Gutierrez and Smith 2008, Gowdy and Godfrey 2003, Krauss et al. 2008). One study did not specify the location (Schaffer et al. 2012). This strategy was often part of a set of visual cues that may have also included signage inside the room and colored patient wrist identification bracelets used to visually alert staff (and family) to a patient's fall risk. However, there was a sense of visual overload that made signage cues less effective.

Numerous studies also referenced visual cues through posters to educate both staff and families about prevention programs (Brandis 1999, Dykes et al. 2009, Mosley et al. 1998, Ohde et al. 2012, Wolf et al. 2013). Materials in one study included photographs to portray correct use of interventions (Brandis 1999). Participants in the study by Dykes et al. (2009) felt educational materials were especially important for nurse assistants who were less likely to receive the most recent patient report communication. However, the study participants believed there was a lack of necessary detail about the fall risk detail and recommended actions (perhaps best communicated through pictograms).

4.4.4.4.2 Personal workspace

Accessibility. Within the personal workspace, there were also direct relationships to the identified personal workspace risk factors identified in Table 4-5. This included ensuring the call system was within reach (Fonda et al. 2006, Gowdy and Godfrey 2003, Gutierrez and Smith 2008, Mosley et al. 1998, Ohde et al. 2012, Tzeng and Yin 2008); ensuring that personal items such as phones, water, over bed table, canes, and walkers were within reach (Tzeng and Yin 2008, Gutierrez and Smith 2008, Krauss et al. 2008, Barker et al. 2013, Dykes et al. 2009); or providing bedside commodes (Gutierrez and Smith 2008, Krauss et al. 2008, Tzeng and Yin 2008, Wolf et al. 2013).

Personal Workspace Interventions for Risks in 'Organization' and 'People'. Additional interventions addressed the 'People (Patient)' risk factors (Table 4-5) by providing visual cues such as falls alert or yield signage either at the bed within the patient room (Barker et al. 2013, Fonda et al. 2006, Lopez et al. 2010,

Wayland et al. 2010) or on the patient whiteboard where different language for the patient might be incorporated (Dacenko-Grawe and Holm 2008). Details about the mobility program were also included in a whiteboard strategy (Krauss et al. 2008). Some studies referenced visual interventions both outside and inside the room (Krauss et al. 2008). Visual cues extended beyond signage, however, with one study highlighting the need to clearly identify level changes (i.e., stairs, curbs) by providing visual cues to changes in elevation with contrasting strips or contrasting/yellow warning paint (Bell et al. 2008). While the study focused on staff safety for STF, this intervention affects everyone using the facility, including patients and families.

From a caregiver and staff perspective, bedside charting was an intervention in one study, with portable computers provided for nurses to complete documentation within the line of sight to patients (Gutierrez and Smith 2008). Lastly, a comprehensive intervention included fully equipped dedicated falls-prevention rooms for high-risk patients (Calkins, Biddle, and Biesan 2012, Cozart 2009, Gutierrez and Smith 2008). This essentially eliminates the organizational policy requiring nurses to determine custom interventions following a falls risk assessment. Even though one study empirically investigated this strategy, none of the included studies referenced statistical significance in the overall study outcomes.

4.4.4.4.3 Products

Alarms. By far, the most prevalent product intervention in the physical environment was the inclusion of alarms to alert staff to movement, which was included in more than half of the studies (Figure 4-6) of varied appraisal levels. Only six of these studies reported statistically significant results. Two of the six were significant only in a subset of the results. The single study investigating the use of alarms empirically (Shorr et al. 2012) found that while alarm use increased, no statistically or clinically significant effect was found on fall-related events.

Alarms ranged from (1) more permanent solutions that were integrated within furniture (mostly beds) and needed to be activated and reset (Gutierrez and Smith 2008) to (2) more temporary solutions that included pads or mats used under bed sheets, on chairs, or at the bedside. These most frequently alerted within the patient room (Dacenko-Grawe and Holm 2008, Lopez et al. 2010) or in both the patient room and nurse stations (Shorr et al. 2012). Additional temporary measures included

inexpensive motion detectors located near the floor that were used in conjunction with bed alarms (Gowdy and Godfrey 2003), or devices attached to the patient (Ohde et al. 2012).

In some of the studies alarm type and details of use were not specified (Dykes et al. 2009, Fonda et al. 2006, Barker et al. 2013, Hitcho et al. 2004, Krauss et al. 2008, Tzeng and Yin 2008, Vieira et al. 2011), while in other studies an algorithm for use was reported (Wolf et al. 2013). One study (Lopez et al. 2010) identified the inconsistent use of alarms as a workaround to visibility and proximity issues; however, usability was also cited as a significant barrier (i.e., sensitivity, problematic user interfaces, and difficult to hear). In some instances, alarms were specified for use if the patient was confused, impulsive, forgetful of limitations, or unable to follow directions (Gutierrez and Smith 2008, Dacenko-Grawe and Holm 2008, Ohde et al. 2012).

Furniture. A second consistently referenced intervention was furniture selection – most often pertaining to bed height (Fonda et al. 2006, Gutierrez and Smith 2008, Hitcho et al. 2004, Krauss et al. 2008, Mosley et al. 1998, Tzeng and Yin 2008, Wolf et al. 2013, Gowdy and Godfrey 2003). Beds with brakes were also cited as an intervention (Hitcho et al. 2004, Tzeng and Yin 2008). These are standard in new beds, but may not always be present or operational in older equipment. One empirical study that evaluated the use of specialty low-low beds (lowering to the floor) found a statistically significant reduction in falls with injury with a ratio of one low-low bed to three standard beds as compared to prior phases of the study with one low-low bed to nine or more standard beds (Barker et al. 2013).

Another aspect of the bed selection was bedrails. Some studies suggested split bedrails with the bottom part down on the exit side, offering some support but allowing patient egress (Cozart 2009, Mosley et al. 1998, Ohde et al. 2012). Others suggested the rails remain up, although detail was not provided to define whether this was a similar split-rail "up" pattern to the other included studies (Gutierrez and Smith 2008). Mosely et al. (1998) and Ohde et al. (2012) reported statistically significant results overall in their respective studies with the rails in the split configuration (foot end down). There were incidental references to two other furniture considerations such as appropriate seat height for chairs (Fonda et al. 2006) and recliners located in

the hallways (Gutierrez and Smith 2008). While not explicitly stated, hallway furnishings may have been used as rest locations during mobilization programs.

Product-based interventions also included video surveillance or hallway mirrors to improve visibility of patients where structural limitations precluded a more direct intervention (Gowdy and Godfrey 2003, Hitcho et al. 2004, Lopez et al. 2010, Goodlett et al. 2009) and non-slip mats at beds and chairs (Fonda et al. 2006, Krauss et al. 2008, Wolf et al. 2013).

While clutter might include tripping hazards such as cords, one study pertaining to staff hazards specifically cited the need to consider cord bundlers and cord containers at computers, medical equipment (including in surgical suites), and even kitchen equipment (Bell et al. 2008). The same study suggested beveled protective cord covers and retractable cords for phones in patient rooms and at nurse stations to reduce tripping hazards associated with electronic equipment.

Grab bars are required in certain spaces by code such as the US Standards for Accessible Design (US Department of Justice 2010), but several studies referenced interventions to supplement code requirements. This included the installation of additional permanent grab bars in bathrooms (Ohde et al. 2012) or low-cost supplements in the bed area, such as stand-alone, portable handrails requiring no special installation (Ohde et al. 2012) or vertical bed poles secured to the floor and ceiling that are used to assist patients to transfer more independently (Fonda et al. 2006).

With respect to visual cues, one study referenced temporary visual cues that included glow-in-the-dark commode seats or glow-in-the-dark toilet signs (Fonda et al. 2006). Two studies referenced the need to visually alert users to wet or slippery floors by consistently installing wet floor signs (Vieira et al. 2011, Bell et al. 2008), including sign styles that were more noticeable – 48” tall, flashing lights, or pop-up tent-style signs (Bell et al. 2008) or more accessible - wall-mounted wet floor signs providing convenient access to products to identify a wet floor (Bell at al. 2008). Bell at al. (2008) also suggested temporary beveled-edge walk-off mats, but in new construction, this can be an integrated recessed-style mat.

4.4.4.4.4 Ambient environment

Interventions in the ambient environment included lighting and quiet zones, which corresponded to the identified risk factors of poor lighting and noise associated with alarms and paging. Multiple studies of varying appraised quality included lighting as part of their bundled solution (Figure 4-6), although the intervention descriptions were not always specific. Several studies referenced the need for some form of lighting at night, whether it was continuous or was motion activated (Fonda et al. 2006, Mosley et al. 1998, Tzeng and Yin 2008, Gowdy and Godfrey 2003). One study was more specific to highlight that patient areas should never be completely dark and that low-level lighting was safer than changes from light to dark (Healey 1994). Others referenced the location of lighting. In one study, lighting was located under the bedframe and two feet above the floor close to the bathroom (Wolf et al. 2013), and in another, night lights were located in the bathroom (Vieira et al. 2011). One staff-focused study highlighted the need for adequate lighting in all work areas, whether interior or exterior (Bell et al. 2008). While five studies that analyzed fall outcomes using a lighting strategy had statistically significant results, one study investigating the built environment correlates to falls (Calkins, Biddle, and Biesan 2012) found no significant relationship between falls and lighting, nightlights, or the number of lights the patient can control. With respect to noise and its relationship to falls, one study identified inclusion of a quiet zone (Gutierrez and Smith 2008), although there were no further details offered. The statistical significance of results in this study was not reported.

4.5 Discussion

To optimize outcomes, defining solutions to mitigate the risk of patient falls can be considered from a conceptual framework of stability (Hignett 2013, Tzeng 2011, Tzeng and Yin 2008). Such a framework recognizes that education and information, along with rules and policies, have been identified as the two lowest levels within the hierarchy of intervention effectiveness, as they attempt to "fix people" and are ineffectual when used alone (Institute for Safe Medication Practices [ISMP] 1999). According to the ISMP, the highest level of intervention, a forcing function, attempts to fix the system by designing so that an error is harder to make, and it is inherently more stable than interventions that rely on correct human actions and performance. The design of a healthcare facility can be considered in some

respects a forcing function. An organizational policy may include leaving the door open or keeping the floor clean and dry – the rules and regulations that are less effective. However, a door can only be left open if it has been designed so that it does not impede egress or block other common functions of care, and maintaining a clean and dry floor can be accomplished more easily if there is protection from the weather (e.g., a canopy or integral walk-off mat) and cleaning supplies are located in convenient and accessible locations. Interventions need be considered in the context of additional interactions and functions. As an example, where ambient conditions might be mediated through design (e.g., selection of materials, inclusion of low-level night lighting), they may also be affected by day-to-day operations (e.g., policies and systems used for paging, integrated alarm alert systems, unobstructed lighting). An integrated design that considers the complexities of falls requires an understanding of the policies and procedures to be supported, as well as a model of care that defines workflow and related tasks.

4.5.1 Stability of the Built Environment

While the Dial-F systems model (Hignett 2013), described in Section 2.5.2, represents building design as the core of stability, there are additional levels of permanence within the built environment, and the impact of some decisions is more long-lasting than others. Furniture can be moved and flooring can be replaced as part of life-cycle maintenance, but spatial organization related to room and unit layout can be a bigger challenge if change is needed due to structural and service components (e.g., plumbing).

Stewart Brand (1995) explored how and why buildings change over time and categorized ‘shearing layers’ according to varying rates of change. These six layers: site, structure (ST), skin (SK), services (SV), scenery/space plan (SC), and set/stuff (SE), have a rate of change from daily to the life of the building (Table 4-6).

Table 4-6. Shearing layers

Shearing layer	Life	Descriptions
Site	Eternal	Geographical setting, the urban/suburban location, legally defined lot
Structure (ST)	30-60 years	The foundation and load-bearing elements; rarely changes due to expense/difficulty
Skin (SK)	20 years	Exterior surfaces may change for aesthetics or state of good repair
Services (SE)	7-15 years	Internal workings that wear out or become obsolete: communications wiring, electrical wiring, plumbing, fire sprinkler systems, HVAC and moving parts (e.g., elevators, escalators)
Scenery/Space (SC)	3+ years	Interior layout of walls, ceilings, floors, and doors
Set/Stuff (SE)	Daily to monthly	Furniture and components that move regularly

Source: Adapted from Brand 1995.

In the synthesis of physical environment interventions, shearing layers were identified based upon the building design characteristic/design feature and an estimated asset life, as defined by the American Hospital Association (American Hospital Association 2013). In this manner, furniture (a "set/stuff" item that may change location frequently) becomes a "services" item, as the design factor related to the conceptual framework of stability is the life-cycle replacement consideration.

4.5.2 SCOPE: Safety = Complexity * (Organization + People + Environment)

Safety is a result of the Complexity of interactions with the Organization, People, and Environment (SCPE), with building design at the core. The result of organizing the environmental interventions according to HF/E environment categories and shearing layers is an expanded framework of Hignett's (2013) Dial-F systems model (Section 2.5.2), termed SCOPE 1.0 (Figure 4-7). This visualization identifies many environment interventions that have been tested or used as part of a multifactorial bundle, as they relate to the levels of permanence.

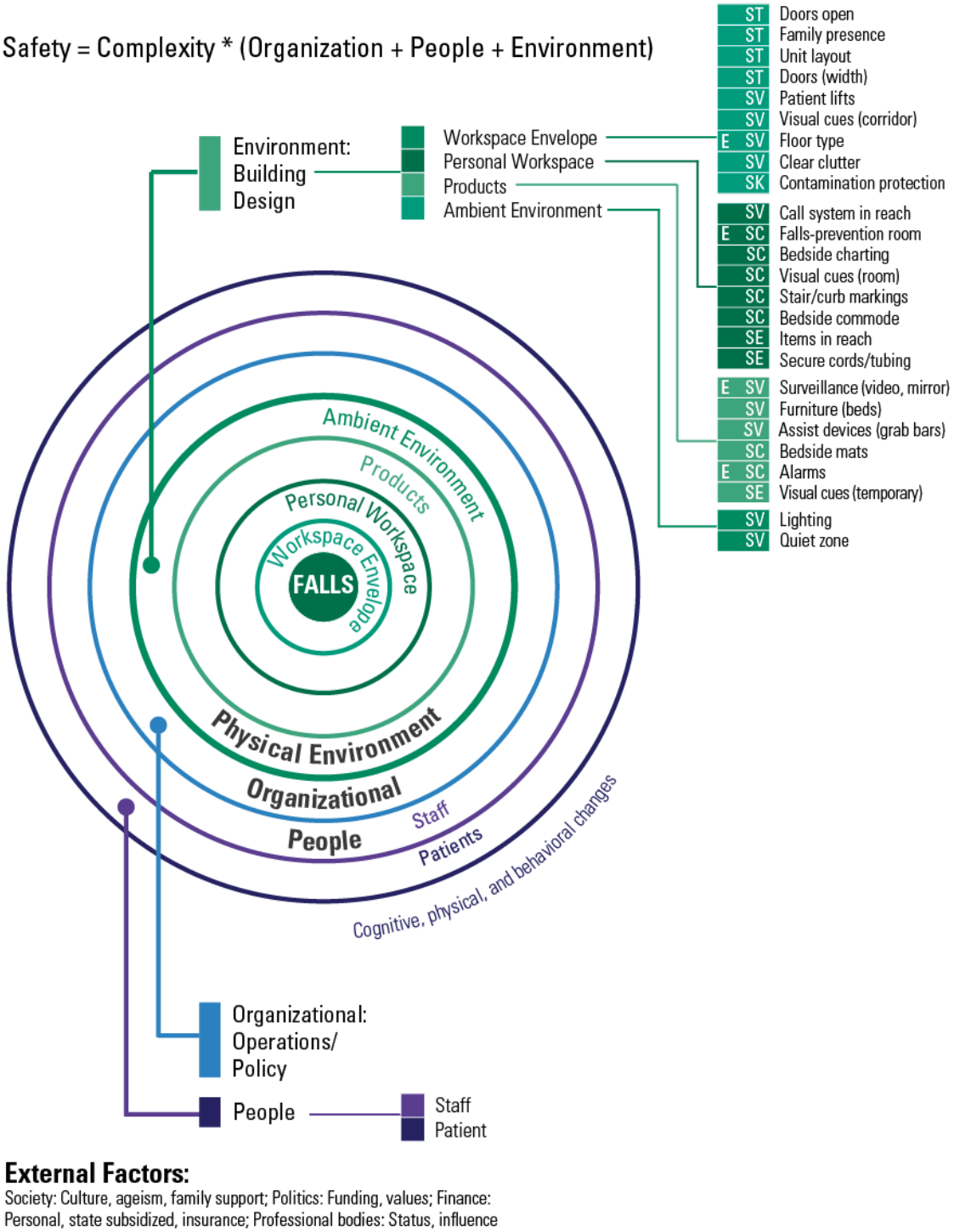

Figure 4-7. SCOPE 1.0: Safety = Complexity * (Organization + People + Environment)

In this framework, design considerations affecting the structure of the facility should be paramount. The ability to visualize considerations simultaneously can generate discussions surrounding the potential interactions. This is developed more fully in Chapter 8.

4.6 Conclusion

Stage 2 of the thesis included the first phase of a systematic literature review conducted in two phases. As the built environment is often an undefined factor in literature that tackles falls prevention, the primary aim of the first phase of the falls systematic review was to explore and appraise aspects of the built environment that would allow facility designers and related project teams to take a proactive approach to the latent conditions that can contribute to the risk of falls. A secondary aim of the first phase of the review was to corroborate findings of the first non-systematic review that identified built environment conditions that contribute to the risk of falls. Most of these conditions were also identified through the non-systematic review conducted in 2012. (A comparison is provided in Appendix G.) The specific design considerations pertaining to falls were included in the preliminary SRA tool that was subsequently assembled for testing (discussed in Chapter 5).

Visual summaries were created to represent the complexity of multiple interventions and resulting outcomes for both falls and falls with injury (Figure 4-4 and Figure 4-6). It was clear from the number and prevalence of interventions, as well as the range of appraised quality, there is no single or obvious prescriptive facility design solution. However, as summarized in the SCOPE model (Figure 4-7), falls prevention is inextricably linked to organizational issues (operations, policies, procedures) and people (patients and staff). These issues are further explored in Chapter 8.

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5 Methods - SRA Content Development

5.1 Chapter Overview

Chapter 5 presents content resolution for the SRA tool (Stage 3). The chapter includes a brief overview of consensus methods used in research, the selected methods for data collection in developing SRA content (the Delphi process and nominal group technique [NGT]), assembly of participant workgroups (expert panels), results leading to SRA content for testing, limitations, and conclusions. The study design was afforded additional rigor through the PhD by using a more structured consensus process described in this chapter in lieu of the originally proposed telephone focus groups. The content resulting from Stage 3 was used for testing the SRA (Chapters 6 and 7), leading to emergent theory for proactively developing safety-related solutions using EBD and HF/E methods in HC facility design (Chapters 7 and 9).

5.2 Methods Overview: Expert Consensus

Consensus methods are often used where there is contradictory, inconclusive, or limited amounts of available evidence (Verhagen et al. 1998, Jones and Hunter 1995, Cantrill, Sibbald, and Burtow 1996). They are typically designed to combine the knowledge and experience of experts (Verhagen et al. 1998). They also typically include a wider range of information than that found in quantitative methods alone, while providing a way for decisions to be made (Jones and Hunter 1995). Gallagher (1993) summarized the relative benefits of several methods (Table 5-1).

Table 5-1. Benefits of several data collection methods

Advantages	Delphi	NGT	Brainstorm	Focus group
Difficult for dominant participants to control	Yes	Yes	No	Possibly
Avoids 'quick decision-making'	Yes	Yes	No	Possibly
Provides support to allow identification of personal problems and self-disclosure	No	Yes	No	Yes
Allows measurement of importance of ideas/items to individuals	Yes	Yes	No	Possibly
Encourages minority concerns/options to be voiced	Yes	Yes	No	Possibly
High degree of task completion	Yes	Yes	No	Possibly
Generates a high number of comments/ideas	Yes	Yes	Possibly	Possibly
Avoids pursuit of a single train of thought ('focus-effect')	Yes	Yes	No	Yes
Participants value social interaction - group cohesiveness	No	Possibly	Yes	Yes
Source: Adapted from Gallagher et al. 1993.				

5.3 Consensus Methods for Stage 3 Content Development

The data collection flow is shown in Figure 5-1.

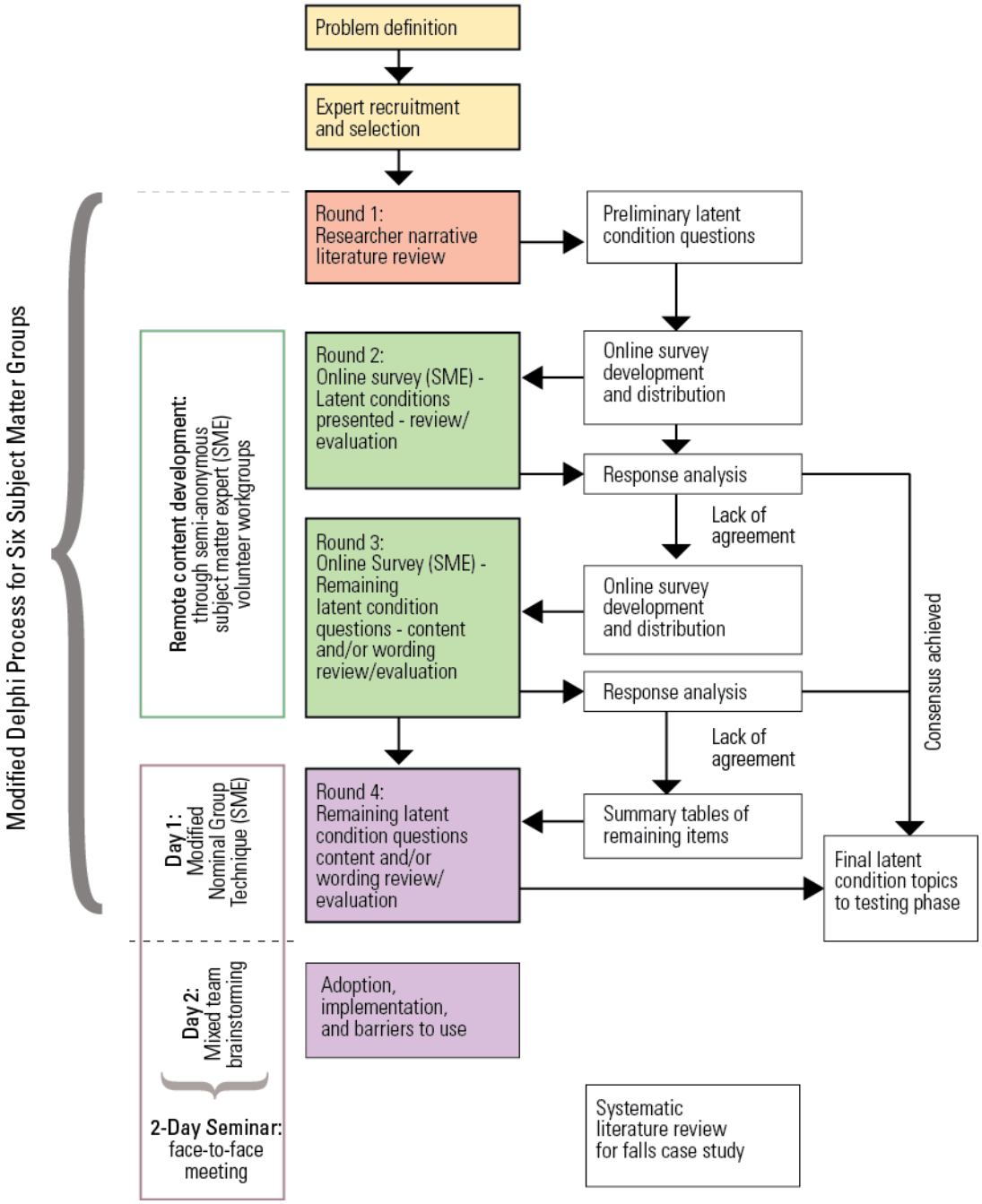


Figure 5-1. SRA study flow – Stage 3 data collection (content development)

Two consensus methods commonly used in healthcare and medicine-related research are the Delphi process (a multi-stage process described in Section 5.3.1) and the NGT (a controlled discussion described in Section 5.3.2) (Jones and Hunter 1995, Fink et al. 1984, Cantrill, Sibbald, and Burtow 1996, Harvey and Holmes 2012). Due to the variation of information (both quantity and quality) available for the multiple

risk components, the geographic dispersion of participants (excepting the single scheduled seminar), the potential for dominant personalities, and the need to complete tasks to derive a final agreed-upon result, a modified Delphi process was used in rounds 2-1 leading up to the SRA seminar (Figure 5-1). With a desire for task resolution and a need to balance dominant personalities and minority views at the face-to-face seminar, a modified NGT was used at the seminar to resolve final content issues (round 4).

5.3.1 Delphi Process Summary

Delphi is the procedure for eliciting opinions from a group, preferably one made up of experts or knowledgeable individuals. Surveys are usually distributed over three or four iterations of feedback or "rounds" and are considered complete when there is a point of diminishing return or convergence of opinion has been reached (Fink et al. 1984). RAND (2013) developed the Delphi method in the 1950s as a forecasting method, and it is recognized as a method for efficient and structured group communication (von der Gracht 2012).

The method entails a group of experts who reply anonymously to a questionnaire and subsequently receive feedback in the form of a statistical representation of the "group response," after which the process repeats itself. The goal is to reduce the range of responses and arrive at something closer to expert consensus. As opposed to firm "knowledge" and information with no backing (speculation), the use of educated opinions is a middle ground. The results are often perceived as being more acceptable by a group (Dalkey, Brown, and Cochran 1969,). It is not suited for times that personal contact is desired (Fink et al. 1984).

Whereas group decision-making can suffer from the incidence of dominant individuals, irrelevant "noise" that is generated (unrelated to problem solving) and group pressure for compromise, the Delphi procedure addresses this through:

- anonymity (reducing dominant personalities by using questionnaires or online surveys and formal communication controlled by the experimenter),
- controlled feedback (results of the previous iteration reported as a summary to respondents), and
- statistical "group response" to reduce pressure for conformity.

With partial anonymity, panelists may know of identities, but do not have interaction or know of individual opinions (Woudenberg 1991, Riggs 1983). Partial anonymity can also increase compliance (Woudenberg 1991).

5.3.1.1 Evaluating Statements

Some studies using the Delphi method use Likert scales to evaluate content and group responses. For example, studies using a 9-point evaluation scale set criteria for agreement or importance as 7 or more and disagreement or lack of importance as 3 or less (Lee et al. 2013, Creamer et al. 2012, Elwyn et al. 2006). However, in one study to develop consensus around determining quality of a randomized control trial (Verhagen et al. 1998), simplified structured questions were included such as "Should this item be included into the criteria list?" or "Do you agree with the rewording this time?" The answer options used 5-point Likert scales (totally agree–totally disagree) or a "yes/no/don't know" answer format. Participants were also allowed to offer reasons for their choices. The feedback report included the opinions and arguments of the panelists. Participants were allowed to suggest alternative wording and to add extra items, and in subsequent rounds items were reworded based on the arguments in the prior round. Participants were asked to select the original or reworded option (Verhagen et al. 1998).

5.3.1.2 Accepted Consensus Rates

There is no single definition of a consensus among participants, and a review of consensus methods found a variation across studies (von der Gracht 2012, Boulkedid et al. 2011). Each research team must evaluate the problem being addressed and determine acceptable agreement rates and cutoff points for adoption (Boulkedid et al. 2011), which may include: 1) support by at least X% of participants; 2) X number of top-scoring topics following a specified number of rounds; 3) topics with a defined median score or higher; 4) topics with at least 51% of the vote and the highest importance rating; 5) topics with low scores, as deemed by X% of the panel are dropped (Fink et al. 1984). The stricter the criteria, the harder it is to obtain consensus (Fink et al. 1984, von der Gracht 2012). One review found that while percentage level for agreement is a common interpretation, there are many levels used, ranging from 55 to 100% (Powell 2003). A number of studies use 70% as a cut-off (Lee et al. 2013, Creamer et al. 2012). However, in 28% of studies, the method to

determine agreement was not stated or was unclear (Powell 2003). Stability of responses along an interval scale can also be used (Linstone and Turoff 1975).

Delphi is sometimes modified to include communication between panel members. When completed after the last round, this can serve as "post-group consensus," an opportunity to evaluate the extent to which participants agree with the overall final results or the estimates of other panelists (von der Gracht 2012). This can be by teleconference (Wilson et al. 2010) or physical meeting when reaching a consensus is difficult or consensus is unclear (Boulkedid et al. 2011). While this contradicts one of the basic rules of the Delphi procedure, individual dominance, the lack of discussion can hamper clarification of disagreement rationale (von der Gracht 2012). Boulkedid et al. (2011) found that 69% of studies reviewed included some form of meeting, 56% between rounds, and 44% after the last round. Von der Gracht suggests the NGT as a way to gather information from relevant experts.

5.3.2 Nominal Group Technique (NGT) Overview

With the NGT, ideas can be generated and problems solved in a single meeting (Ryan, Scott et al. 2001). The nominal group process is a structured meeting using a focus group setting to gather qualitative information from a group of experts and facilitate decision-making (Jones and Hunter 1995, Harvey and Holmes 2012). It was developed in the 1960s to support social psychological research and has since been employed in a wide range of fields including healthcare (Harvey and Holmes 2012). It is used where individual ideas are needed, but the final outcome is group consensus (Sink 1983). Because the process is highly controlled and discussion occurs during the later stages of the session, the group is essentially "*in name only, or nominally*" (Gallagher et al. 1993, 77). NGT requires strong and experienced facilitation (Gallagher et al. 1993, Fink et al. 1984) and follows a structured process that includes (Sink 1983):

- Silent generation of ideas (5-15 minutes): Participants are asked to develop a list of ideas on specific topics, individually and without discussion.
- Sharing ideas—round-robin: At the end of the first period of time, the most important ideas on the list are presented (round-robin). This is repeated until the lists are exhausted. The information is recorded on a chart, allowing everyone to see the composite result.

- Group discussion and clarification: A group discussion follows to evaluate ideas. Duplicate ideas are consolidated.
- Voting and ranking.

One study reviewed reported a modification to the NGT for a large group of 30 participants. Rather than silently generating ideas from scratch, the ideas for silent consideration were pre-generated based on several questions (e.g., "What was good about the curriculum/course?", "What were the weaknesses/areas for improvement?") (Dobbie et al. 2004). According to the authors, this shortened the process and increased the practicality of the exercise.

5.4 Participant Workgroups (Expert Panels)

The Delphi and NGT methods selected for content development use expert panels. In consensus methods, there are few structured rules about who to include as participants, "*except that each must be justifiable as in some way 'expert' on the matter under discussion*" (Jones and Hunter 1995, 378) and "*they are representative of their profession, have power to implement the findings, or because they are not likely to be challenged as experts in the field"* (Fink et al. 1984, 981).

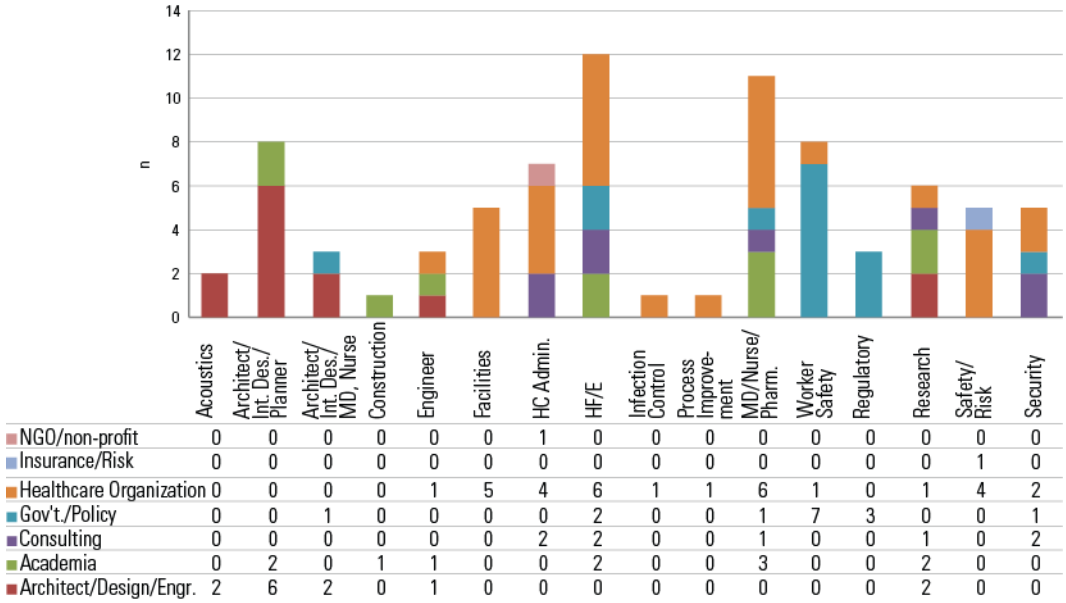
5.4.1 Panel Size

The optimal number of subjects in a Delphi study does not reach any consensus in the literature. Some studies indicate that 10-15 subjects could be sufficient if the background of the Delphi subjects is homogeneous, while others find the majority of Delphi panels are between 15 and 20 respondents (Hsu and Sandford 2007). However, there are documented panels of between 10 and 1,685 (Powell 2003). Powell also notes that the panel does not need to be a statistically representative sample, but rather is "*assessed on the qualities of the expert panel rather than its numbers*" (2003, 378), with sources citing heterogeneity as an important factor in producing reliable responses (Powell 2003, Boulkedid et al. 2011). The group size has an effect on accuracy (as tested for factual information) and reliability (using the premise that "n" heads is better than one) (Dalkey, Brown, and Cochran 1969). Dalkey, Brown, and Cochran found that reliability increased linearly between three and 11 participants while accuracy continued to improve up to the maximum group size tested of 29. However, management of larger groups can be complicated and costly (Fink et al. 1984), and large groups may result in low response rates (Hsu and Sandford 2007,

Fink et al. 1984). Fink et al. (1984) note that in addition to the individual needs of the project, different methods may have different requirements, such as a group size of fewer than 15 for NGT.

5.4.2 Recruitment and Participation

The SRA development was planned as a multi-disciplinary collaborative process using homogeneous subject matter experts with heterogeneous backgrounds to evaluate content proposed for the tool. Workgroup leaders for the risk component topics were recruited from the grant awardee's (CHD) network. Six volunteer workgroups (10-20 per group) were formed to represent heterogeneous views in healthcare and facility design (Figure 5-2).



	Acoustics	Architect/ Int. Des./ Planner	Architect/ Int. Des./ MD, Nurse	Construction	Engineer	Facilities	HC Admin.	HF/E	Infection Control	Process Improve-ment	MD/Nurse/ Pharm.	Worker Safety	Regulatory	Research	Safety/ Risk	Security
NGO/non-profit	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Insurance/Risk	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Healthcare Organization	0	0	0	0	1	5	4	6	1	1	6	1	0	1	4	2
Gov't./Policy	0	0	1	0	0	0	0	2	0	0	1	7	3	0	0	1
Consulting	0	0	0	0	0	0	2	2	0	0	1	0	0	1	0	2
Academia	0	2	0	1	1	0	0	2	0	0	3	0	0	2	0	0
Architect/Design/Engr.	2	6	2	0	1	0	0	0	0	0	0	0	0	2	0	0

Figure 5-2. Content workgroup volunteers – primary roles/employment (n=81)

Workgroup participants were recruited as a purposive criterion sample based upon experience, reputation, subject matter expertise, and interest for the particular topic areas. The recruitment of workgroup participants followed a two-phase process. First, CHD's network of experts was used to generate potential candidates. This was followed by gathering recommendations from each workgroup leader to access industry experts that might not be known to the research team. Expertise was drawn from a variety of fields such as architecture, facilities management, medicine, HF/E, occupational health, and healthcare administration. Recruited participants were recognized industry experts (e.g., through publication, reputation) or had an expressed

interest and practical experience of the topic (e.g., through nursing management, design, employment specialty). The highest representation included HF/E specialists and clinicians. The highest percentage of participants was employed by healthcare organizations (e.g., nursing, facilities, ergonomics).

The expert workgroup for falls was also heterogeneous with respect to primary roles and employment (Figure 5-3).

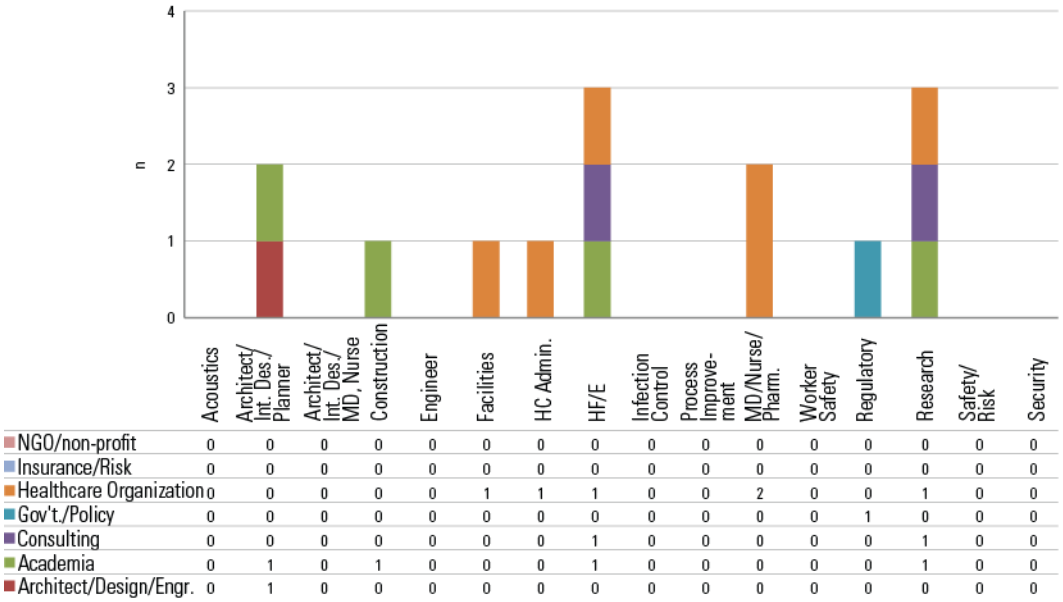


Figure 5-3. Falls content workgroup volunteers – primary roles/employment (n=14)

HF/E specialists and researchers, in both practice and academia, represented the highest number of participants, followed by clinicians in healthcare organizations, and architects/interior designers in practice and academia. Teleconferences were held with each expert panel to provide a project overview.

5.4.3 Delphi Process Implementation

Table 5-2 summarizes the traditional Delphi Method and the process and modifications instituted for content development of the SRA. The implemented process is further described in sections 5.4.3.1 through 5.4.3.4 with a subset section addressing the case study topic, falls.

Table 5-2. Description of Delphi process rounds

	Traditional Delphi process	Implementation for SRA development
Round 1:	An open-ended questionnaire is used to solicit specific information about a content area from the expert panel. This is used by the study researchers to develop a questionnaire for Round 2 (Hsu and Sandford 2007).	A modification was incorporated for Round 1 (Section 3.3.2.1), generating preliminary concepts through a narrative literature review. According to several literature reviews/studies using the Delphi process, an acceptable and common modification of the Delphi process format uses a structured questionnaire in Round 1 that is based upon an extensive review of the literature (Hsu and Sandford 2007, Powell 2003, Verhagen et al. 1998, Cantrill, Sibbald, and Burtow 1996, Boulkedid et al. 2011). Boulkedid et al. (2011) found 62% of studies used this modification.
Round 2:	Each expert panel participant receives a questionnaire and is asked to review the items collected through information provided in the first round. Panelists may be required to rate or "rank-order" items to establish preliminary priorities among items. In this round, consensus begins forming and the actual outcomes can be presented among the participants' responses (Hsu and Sandford 2007).	A questionnaire was developed based upon the conditions found during the literature review for each category. The survey was distributed using an online format (Survey Monkey). Questions were asked about: - Inclusion - Wording - Estimated risk For detail and modifications, see Section 5.4.3.2.
Round 3:	As a result of round two, areas of disagreement and agreement are identified. Panelists receive another questionnaire that includes the items and ratings summarized from the previous round. Panelists are asked to revise judgments or to specify the reasons for disagreement. This round provides the opportunity to clarify information and re-evaluate judgments of the items (Hsu and Sandford 2007).	A questionnaire was developed based on the results of Round 2. The survey was distributed using an online format (Survey Monkey). Questions were asked about items of disagreement. Results from Round 1 were included (the percentage of agreement and any relevant explanatory notes included by panel participants): - Inclusion - Wording - Estimated risk This is consistent with a traditional Delphi process. See Section 5.4.3.3 for detail.
Round 4+	Rounds continue in a similar manner (if needed) until consensus is achieved, based upon criteria predetermined by the research team (Hsu and Sandford 2007).	Remaining items of disagreement were resolved using a modified NGT. This was used to achieve the same level of consensus used for prior rounds using the Delphi method, as discussed in Section 5.4.3.4.

5.4.3.1 Delphi Round 1—Literature Review

Although predetermining content in Round 1 may introduce bias by limiting the topics for consideration (Keeney, Hasson, and McKenna 2001), the first round of the Delphi process was a list of preliminary considerations generated from a literature review in keeping with an evidence-based design approach. This is an accepted modification to the open-ended questionnaire to generate ideas (Hsu and Sandford 2007, Powell 2003, Verhagen et al. 1998, Cantrill, Sibbald, and Burtow 1996, Boulkedid et al. 2011). As described in Chapter 4, a traditional (non-systematic) literature review (Grant and Booth 2009) was conducted for falls. This falls topic

review resulted in 36 environmental design items for consideration in the Delphi process. Most were corroborated through the systematic review, as described in Chapter 4 and Appendix G.

5.4.3.2 Delphi Round 2

5.4.3.2.1 Online survey #1 (based on literature review)

Following the literature review, a second teleconference with each expert panel oriented the participants to the process, and workgroup volunteers received an invitation to participate in their workgroup topic survey. Participants were advised that the complete survey would take 60-90 minutes and was to be completed within a two-week window. A PDF document that summarized the content was included as an attachment for reference (Figure 5-4). The link provided in the invitation was specific to participant email address, allowing responses to be saved automatically if the participant wanted to stop and finish the survey at another time.

Respondents were asked to evaluate:

- how the tool would best be sorted (e.g., risk component, hazard location);
- whether the item should be included in the SRA tool (yes or no);
- why or why not (optional);
- whether the wording was agreeable (yes or no);
- rewording suggestion (optional); and
- their own expert opinion about the risk associated for the consideration.

The online survey also included a summary of the design-related questions to be evaluated with additional information indicating whether the questions are supported by: "R" research (empirical or literature review); "C" a consensus document (another established guideline or white paper); "O" other (expert opinion or best practice recommendation); "Fb" a requirement included in the body of the 2014 FGI *Guidelines*; or “Fa, appendix language (suggested but not required). The questions were grouped by built environment category or latent condition (Figure 5-4, Appendix H).

Question Summary (falls)

The following questions will be reviewed. You will be asked a series of questions about each individual item. You can print this page if you'd like a reference as you move through the individual items.

KEY: "R" research (empirical or literature review); "C" a consensus document (another established guideline or white paper); "O" other (expert opinion or best practice recommendation); "F" included in the 2014 FGI Guidelines (either the body or appendix language)

VISIBILITY

1. Is the bathroom visible from the bed? (R, Fa)
2. Does the unit shape and configuration allow visibility to all patient rooms, including with a normal walking pattern? (R, Fa)
3. Do charting areas include visibility to the patient? (R, Fa)
4. Do nurse seating locations allow for direct accessibility to the room with visibility of patient head? (R, Fa)
5. If direct proximity is not possible, is visual patient monitoring available (e.g. video surveillance)? (R, Fa)

ACCESSIBILITY

1. Are bed/chair alarms in use to alert staff to potential exit and fall risk? (R, O, Fa)
2. Are call buttons within easy reach of the bed, patient chair, and bathroom activities? (R, O, Fb)
3. Has space been provided for fall alert signage at the door and/or the patient bed? (R)

ENVIRONMENTAL HAZARDS

1. Is the entrance protected from weather? (O, Fa)
2. Are bedrails/restraints present - with use minimized? (R, O, Fa)
3. Does furniture have components that could trap patients (e.g. lap trays)? (R, Fa)
4. Have fall risks from equipment (e.g. procedure table) been considered? (R, O, Fa)
5. Are walking surfaces designed to be clear of surface irregularities? (C,O, Fa)
6. Are smooth transitions between flooring used? (R, Fb)
7. Are paths of travel clearly visible (e.g. not confused by patterns, high-gloss finish, and obstructions)? (R, Fa)
8. Are materials and colors selected to provide contrast and differentiation between the floors and walls? (R, Fa)
9. Is carpeting secured to the floor? (R, C, Fb, Fa)
10. Are floors protected from spills and wet conditions? (R, C, O, Fa)
11. Are floors slip-resistant in potential wet areas (e.g. bathrooms, entrances, kitchens) and on ramps and stairs? (R, Fb, Fa)
12. Does the room layout provide clear and unobstructed paths of travel? (R, C, O, Fa)
13. Is space provided on the opening side of the patient toilet room door to facilitate the use of equipment and/or assistive devices? (R, Fa)

ERGONOMICS

1. Are grab bars and hand rails located to support patients while ambulating to the toilet? (R, Fa)
2. Are additional grab bars and hand rails mounted in the bathroom to allow varying support heights? (R)
3. Are grab bars located on either side of the toilet to support patients getting up and down toileting? (R, Fa)
4. Are mechanical lifts being used to assist staff in the manual transfer of patients? (R, Fa)
5. Have beds been selected to afford low height positions and brakes? (R, C, O, Fa)
6. Has adjustability and flexibility been considered in furniture selection? (O, Fa)
7. Has toilet accessibility been considered (e.g. height) (R, O)
8. Are flooring and subflooring materials selected to mitigate injury in the event of a fall? (R, Fa)

OTHER INTERIOR LAYOUT (FAMILY FRIENDLY ENVIRONMENT, PROXIMITY)

1. Is there space for families to be present in the patient room to encourage communication with caregivers about falls and increase the level of patie surveillance? (R, Fa)
2. Is the bathroom located in close proximity to the bed? (R, Fa)

LIGHT/NOISE LEVELS

1. Has lighting been designed to eliminate abrupt changes in light levels? (R, C, Fa)
2. Is low-level lighting available in nighttime/dark conditions? (R, O, Fa, Fb)
3. Has lighting been designed to allow flexibility to adjust levels between the surgical operating area and other areas of the room? (Fb, O)
4. Is noise controlled through the use of wireless communication systems(e.g. paging, alarms, etc?) (R, Fa)
5. Is noise controlled through the material selection (e.g. flooring, acoustical panels)? (R, Fa)

Figure 5-4. Round 1 Survey Monkey summary (conditions from the literature review)

Individual email reminders were sent to those who did not respond through the final day of the survey. There was no official communication between workgroup

members during the survey process or following completion of the first round. Response rates for Round 2 ranged from 81-100% across the six groups. After the surveys had been closed, analysis was conducted to determine what items should be included in the Round 3. Seventy percent was used as the consensus level for all items. Those questions garnering 70% for inclusion and wording were considered as "final" content, and those with 70% consensus to *not* include were deleted. Those topics that did not gain a 70% consensus for inclusion and/or wording were incorporated into Round 3.

5.4.3.2.2 Case study (falls) Round 2

There were 12 respondents in the first online survey. Twenty questions received 70% consensus for both inclusion and wording. An additional 10 questions achieved consensus for inclusion but not wording, and six questions did not achieve consensus for inclusion (Figure 5-5).

Figure 5-5. Delphi Round 2 results for falls (first online survey)

5.4.3.3 Delphi Round 3

5.4.3.3.1 Online survey #2

Round 3 content included the list of the questions that received more than 70% inclusion consensus (i.e., 70% or more of the respondents agreed that the issue should be included in the SRA tool). However, some of the included items did not achieve consensus on wording. For these items, alternate wording was proposed and posted below the original wording so respondents could state a preference for the new or original wording. Questions that did not receive consensus for inclusion (31-69% agreement) were also included in the survey. With respondent comments from the prior round as to why or why not the item should be included, participants were asked to reconsider the inclusion of the question. Response rates ranged from 75-100% across workgroups.

5.4.3.3.2 Case study (falls) Round 3

Fifteen people responded to the second online survey for falls. Four more questions achieved consensus for inclusion and wording, six questions for inclusion but not wording, and three had no consensus for inclusion. In this round, most of the items had been accepted for inclusion but were reworded to clarify the intent of the initial statement (Figure 5-6). The rewording did not always achieve consensus and as a result, some items were brought to the fourth round of the Delphi process, where NGT was used for resolution of nine considerations.

Figure 5-6. Delphi Round 3 results for falls

5.4.3.4 Delphi Round 4: Modified NGT

5.4.3.4.1 Modified NGT implementation

Data collection was concluded with a two-day seminar in Washington, DC in June 2013. During this seminar workshop, a 2-hour session and 1-hour session were used for data collection, with the balance of time providing background, context, issues for consideration (e.g., organizational safety culture), and group review of expert panel progress and results. A modified NGT was scheduled for two hours on the first day of the workshop seminar as the final and fourth round of the Delphi process. Any items that had not received consensus for inclusion or wording were brought forward to the face-to-face workshop seminar. Individual evaluations and a round-robin process were envisioned to allow each participant a voice in the final decision. The votes, comments, and revisions were recorded by a scribe on large format (24" x 36") sheets (Figure 5-7).

Consensus items: FALLS

Action needed	Latest version	New version (if needed)	Inclusion Round 3	Inclusion Round 4	Wording Round 3	Wording Round 4
Wording only	1. New Alt: Is the bathroom designed so the door can remain in an open position and out of the way of traffic yet is still visible from the bed?					
Wording only	2. New Alt: Do work stations and charting areas include visibility to the patient?					
Discuss inclusion and wording	3. New Alt: Are bed/ chair alarms accessible to alert staff of a potential exit and fall risk?					
Wording only	4. New Alt: Besides the bed call button, are other alarm systems (e.g. chair, bathroom) within easy reach of patients (e.g. reach radius for the 5th percentile female - approximately 25")?					
Discuss inclusion and wording	5. New Alt: Does furniture specification selection reduce restraints and promote independent mobility?					
Wording only	6. New Alt: Do selected flooring patterns and finishes minimize high contrast between colors, patterns and light intensity?					
New wording OK, but inclusion needs to be discussed	7. Are grab bars and hand rails in the bathroom mounted to support people of varying heights?					
Wording only	8. Rd 2 Modification: Has lighting been designed to provide flexibility and control of light levels between the surgical operating area and other areas of the room (e.g. dimmers, lighting scenarios) for multiple procedure types?					
Wording only	9. Rd 2 Modification: Are individual nurse communication systems used to minimize noise from overhead paging and alarms?					

Figure 5-7. Workgroup large-format worksheet for final consensus

5.4.3.4.2 Case study (falls) Round 4 (NGT)

There were 10 seminar participants in the falls workgroup, which was facilitated by the falls workgroup leader. I was present to observe the session. While the group started with NGT, the workgroup found the process to be cumbersome and

proceeded with an open discussion to resolve disagreements on wording or inclusion. Whereas NGT is intended to commence with a silent generation of ideas and round-robin discussion to mitigate dominant personalities and include minority positions, participants felt this was taking too long. As I observed, there was active listening and the discussion was balanced with everyone participating. Post-seminar surveys also indicated a high level of satisfaction and no comments indicated ideas were thwarted. Following debate of each open item, votes were captured on the large-format sheet (Figure 5-8). The same 70% consensus criteria were used to finalize content and eight more questions garnered consensus with one deleted. This resulted in 32 items.

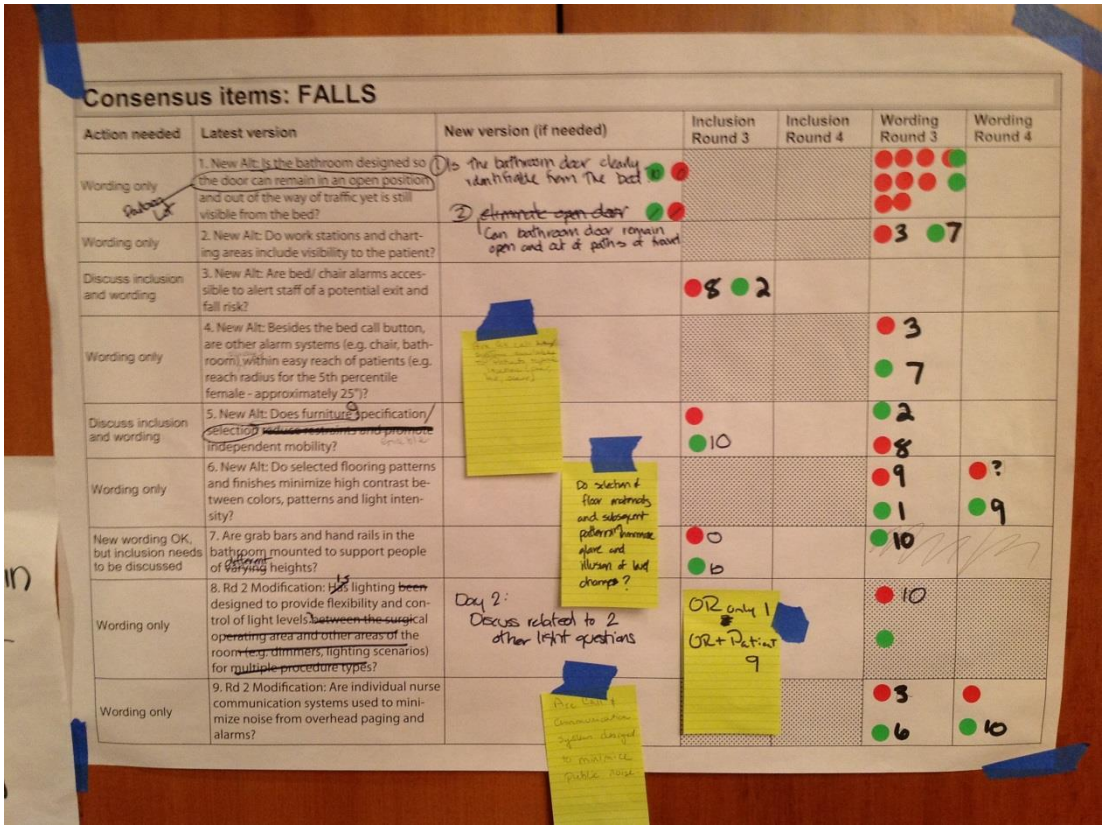


Figure 5-8. Falls workgroup worksheet for final consensus (gallery walk display)

Following the 2-hour session, worksheets were brought to a central area for all expert panels to review in a "gallery walk." Workgroup members could comment on items in other areas and mark any areas of concern. Later in the seminar, each workgroup had the opportunity to review their content again and make any consensus-based adjustments.

5.5 Content Development Flow and Results (Falls Case Study)

Over the course of the Delphi rounds, the case study topic (falls) decreased from 36 items to 32 final items after four rounds of evaluation. The flow of the falls workgroup is presented in Figure 5-9. As context for testing, the final content for the test tool is presented in Appendix H. The test tool included the built environment category (e.g., unit layout), underlying environment latent condition category (e.g., visibility), a rationale statement, and the final question (subsequently transformed into a statement for testing).

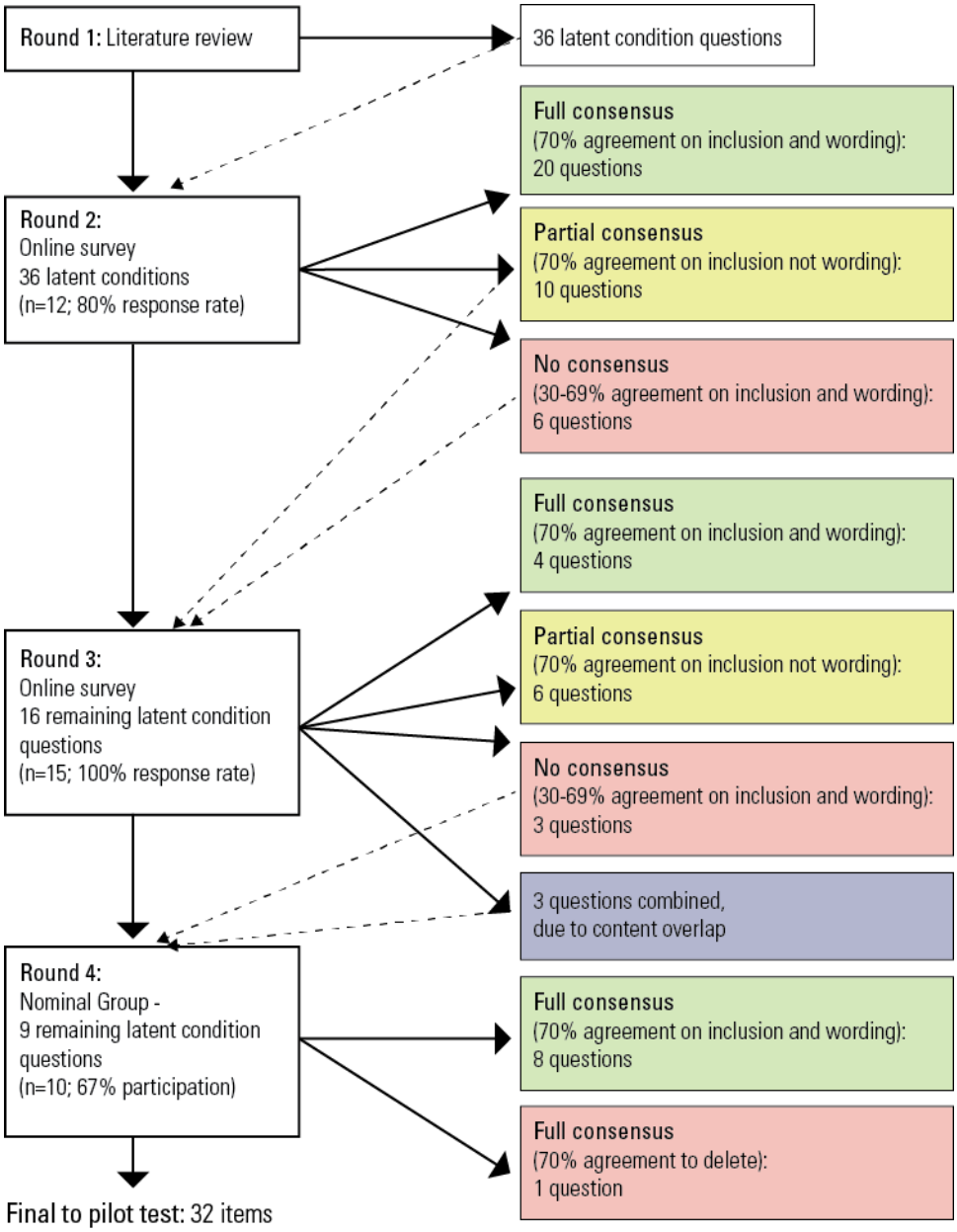


Figure 5-9. Sequence of falls group consensus

5.6 Limitations

There were several limitations to the content development. Firstly, the timing of the grant literature review preceded the start of the PhD, thus the systematic review undertaken for the PhD was used as corroboration of initial findings. Secondly, the use of a literature review as the first round of a Delphi method may have introduced bias from a single researcher conducting the literature review to develop content. To account for this, workgroup participants were asked to provide suggestions for missing content and sources of information based on the summary sheets (e.g., citations, primary interventions, outcomes) they were provided. Likert-scale scoring was not used in rating the questions being reviewed. Rather, a yes-no response was used to minimize perceived difficulty in completing the questionnaires. Lastly, as described, the nominal group technique was perceived as cumbersome by some groups at the seminar and while the voting process for consensus was still used, the discussion surrounding conflicts was less structured than planned. Observation suggested the discussion was still balanced.

5.7 Conclusion

Preliminary content for the SRA was finalized in Stage 3. As a result of the PhD, a more rigorous approach was adopted and consensus methods were evaluated, culminating in a process that included a modified Delphi process and nominal group technique. This resulted in a more systematic approach for establishing preliminary content for inclusion in the SRA tool (Taylor et al. 2014). While the expert groups were formed around safety topics, the teams of recognized experts were multi-disciplinary (e.g., clinical, design, HF/E) to offer a range of perspectives. Each team worked individually in content development for their topic, with findings and final content shared across groups during the first face-to-face consensus seminar in 2013. Through this process, a common goal (built environment conditions for safety and the individual safety topic) aligned the perspectives of multiple disciplines.

While each group focused on their assigned topic, there was also an interest that developed in other categories, resulting in a “gallery walk” at the consensus seminar to share progress and ideas from other groups. The integration of design considerations across safety categories became a topic of discussion following Stage 3, but there was more focus on how the information could best be filtered by phase of the

project, as well as the type of project or project space (e.g., operating suite versus inpatient unit). This was all part of an expressed desire to streamline the process and reduce overload of a busy project team (in essence creating a more prescriptive use of the tool).

Overall, while the consensus process worked well to align multiple points of view, most groups were insistent on discussing the faults in the existing design paradigm, consistent with the findings of Chapter 3. The lack of time, the use of historical data and separate (non-user) teams to develop the functional requirements of a project, and a lack of accountability for outcomes related to design were all expressed frustrations during the consensus seminar. Many hoped that the SRA could break down some of these barriers. At this stage, there was no readily apparent alignment of EBD and HF/E, other than the inclusion of considerations based upon traditional physical ergonomics (e.g., lighting level).

Chapter 5 provided an overview of data collection methods for content development. While a considerable amount of work in Stage 3 was brought forward as part of the grant project that funded the broader project within which this PhD was situated, this stage is included to establish the context for the additional data collection in Stages 4 and 5. As indicated in the preface, this was the starting point to differentiate between work to support the grant and work undertaken as part of the PhD. Appendix M provides further detail about grant-specific development of SRA content.

6 Methods – SRA Testing: Hypothetical & Real-World

6.1 Chapter Overview

Testing of the SRA is reported in two chapters. Chapter 6 reports data collection methods for Stage 4 (hypothetical scenario testing) and Stage 5 (real-world pilot testing). This chapter outlines the purpose and goals of the study, the final content used in testing, study design, and mixed methods analysis techniques for the SRA testing. Preliminary qualitative analysis is presented as part of the qualitative methods description. Chapter 7 reports the final qualitative and quantitative results of the SRA testing with the construction of theory evolving from analysis (Stage 6).

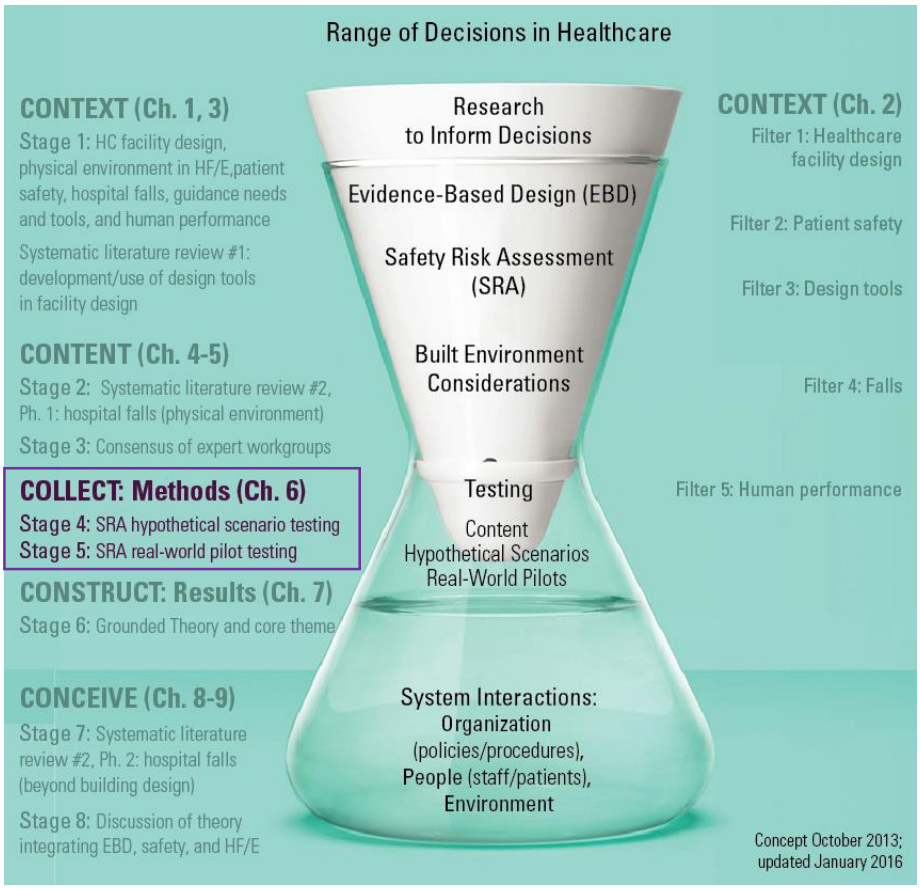


Figure 6-1. Chapter 6 signposting (collect)

6.2 Statement of the Problem

As reported in Chapter 3, there was a paucity of published research that details the development of design tools used in HC facility design, and there was no available tool to proactively and systematically consider safety for EBD projects. This is

despite the increasing focus on reducing adverse outcomes (Institute of Medicine [IOM] 2001, 1999, Classen et al. 2011, James 2013, Wachter 2010) and the growing awareness that the built environment plays a role in mitigating these conditions (Joseph and Malone 2012, Reiling, Hughes, and Murphy 2008, Henriksen, Joseph, and Zayas-Caban 2009, Joseph and Rashid 2007, van Beuzekom et al. 2010, Hignett 2013).

6.3 Purpose and Goal of the Study

The purpose of the study in Stages 4 and 5 included further development, refinement, and understanding of the use and potential of the SRA by engaging healthcare design stakeholders. The goal of the testing was two-fold. The tool is focused solely on the built environment, and a grant goal was tactical - addressing the tool for:

- usability (e.g., content clarity, flow, redundancy),
- feasibility (resources and time), and
- relevance (applicability, novelty) of the SRA tool in the HC facility design process.

From the thesis perspective, the testing allowed an opportunity to strategically understand how the tool might support the IEA definition of human factors and ergonomics adopted in 2000: *understanding of interactions among humans and other elements of a system*, and using *methods to design in order to optimize human well-being and overall system performance* (IEA 2015).

Questions included:

1) Can the SRA effectively focus a discussion around design and safety for staff and patients?
2) Does the SRA process foster collaboration and integration of different points of view?
3) Can a systems perspective, beyond the environmental considerations, be introduced into the SRA process for HC facility design?

The intended outcome of Stages 4 and 5 was to leverage SRA testing to evolve a theoretical approach to advance the use of HF/E when considering safety in the HC facility design process.

6.4 Final Stage 3 Content Results (for Falls Case Study)

As described in Chapter 5, 32 items for the case study topic of falls were included after four rounds of evaluation (Figure 5-9). Most of the initial items were reworded to clarify the intent of the initial statement. The final content that was moved into pilot testing included the category, the environmental condition of the hazard (categories previously established by CHD - Joseph et al. 2014), the rationale, and question (Appendix H).

6.5 Study Design: Stages 4 and 5

6.5.1 Mixed Methods Approach

The study took a convergent mixed methods perspective. According to Pluye and Hong (2014, 30), mixed methods research is an approach "*in which a researcher or team of researchers integrates (a) qualitative and quantitative research questions, (b) qualitative research methods and quantitative research designs, (c) techniques for collecting and analyzing qualitative and quantitative data, and (d) qualitative findings and quantitative results.*" A convergent mixed methods design is the most common of mixed methods (Pluye and Hong 2014, Creswell and Clark 2010) and entails concurrent timing of the quantitative and qualitative aspects during the same phase of the research process, keeps the methods independent during analysis, and then mixes the results in interpretation to develop a more complete understanding of the phenomenon (Creswell and Clark 2010), illustrated in the study protocol (Figure 6-2).

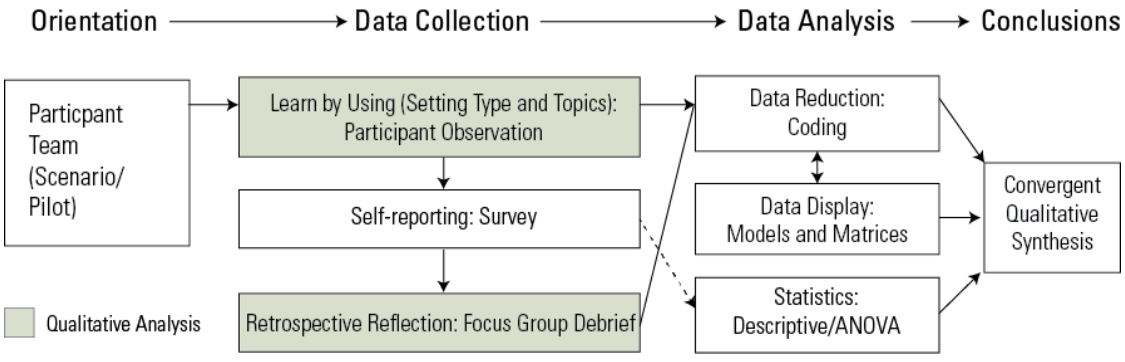


Figure 6-2. Convergent mixed methods Stage 4-5 study protocol design

6.5.1.1 Qualitative Study Component

In qualitative research, the researcher collects and interprets data, becoming part of the research process through an open and flexible design (Corbin and Strauss

2014). Corbin and Strauss emphasize that qualitative research is often used to explore the experiences of participants, explore an area not yet thoroughly researched, and take a holistic approach to the study of phenomena. Rather than starting with a theoretical construct a priori, an open approach was employed and methods consistent with grounded theory were used. Introduced in their 1967 book, *The Discovery of Grounded Theory*, grounded theory is defined as "*derived theory from data, systematically gathered and analyzed through the research process"* (Strauss and Corbin 1998, 12). It allows concepts to evolve from data collection during the research process (i.e., not chosen prior to the research start) with a constant comparative analysis, resulting in a synthesis of the themes and patterns across multiple cases (Corbin and Strauss 2014, Thornberg and Charmaz 2014).

Corbin and Strauss (2014) explain the choice for grounded theory as a method that "*can be used to gain new insights into old problems, as well as to study new and emerging areas in need of investigation*" (Corbin and Strauss 2014, 11). This is an approach suited to investigating EBD and HF/E, as architecture and space have often been conceived from a phenomenological approach to develop "*authentic conceptual portrayals of the various dimensions of the person-environment relationship*" (Seamon 1982, 121) - the interaction with an artefact. Grounded theory, however, is intended to conceive a general explanation of a process, action, or interaction, where theory might explain practice or provide a framework for additional research (Strauss and Corbin 1998, Creswell 2012).

The use of a literature review in grounded theory is not straightforward. Concerns have centered on the creation of bias in an inductive process (Dunne 2011), but more recent views advocate the use of a literature review to establish context (Thornberg and Charmaz 2014) and help explain findings during analysis of emergent theory (Dunne 2011). However, new literature searches are also conducted later in the process to explore ideas that evolve from the data (Dunne 2011).

In conducting this study, the initial context was established through an overview of the HC facility design process (Section 2.2) and the systematic review of the development and use of tools in facility design (Chapter 3). These will be used for the basis of discussion in Chapter 7 with additional literature and emergent concepts to be discussed in Chapter 9.

6.5.1.2 Quantitative Study Component

The quantitative component of the study included a Likert-scale survey. Each group (scenario workgroups or pilot test teams) completed the survey following each use of the SRA tool (after each scenario module or pilot test). The 5-point scale ranged from "1: Strongly Disagree" to "5: Strongly Agree." During the scenario testing, this survey was conducted online prior to a verbal debrief, and during the pilot tests, the participants completed a paper-based survey prior to a focus group debrief. The survey developed for the grant was intended to provide self-report evaluation of tool usability (U), feasibility (F), generalizability (G), and relevance (R). Twelve questions used at pilot sites were not included during scenario testing, with the research team's goal to both reduce the time to complete the survey (as it would be used multiple times) and balance applicable content. Content comparison is provided in Table 6-1.

Table 6-1. Survey question comparison and reporting short names

Survey question	Abbreviated short names	Evaluation	Scenario	Pilot
The SRA tool was easy to use in this setting	Easy to Use	U	x	x
The time needed to use the tool was adequate	Enough Time	U	x	x
Training would be helpful to use this tool	Training	U	x	x
Guidance from a facilitator or moderator would help in discussing considerations	Guidance (person)	U	x	x
The rationale and consideration statements provided me with enough guidance to discuss specific options	Guidance (rationale/ content)	R	x	x
Reverse Coded: The tool would require significant resources (people, equipment, space)	Resources	F	x	x
The tool yielded new information or insights related to the design project	Insight	R	x	
Use of the tool resulted in a substantial improvement to the safety of the design	Improved Design	R	x	
This tool can be used in different types of project scopes	Different Scopes	G	DB	x
This tool can be used in different types of healthcare settings	Different Settings	G	DB	x
An overview of the goals of the tool prior to use is required	Overview (tool goals)	U	D	x
An order of magnitude cost benefit would be helpful	Cost-Benefit Useful	U		x
The SRA tool easy is to understand	Understandable	U	S	x
White papers or opinion papers on the various topics will be helpful to understand the issues	Guidance (papers)	R	D	x
The tool is relevant to my work during the design process	Relevant	R		x
This tool should be used before the budget is set	Early Use (budget)	R		x
This tool should be used at multiple phases of the project to validate and check decisions	Feedback Loop	R		x

Survey question	Abbreviated short names	Evaluation	Scenario	Pilot
Safety is specifically identified in our project vision	Safety Culture in Place	R		x
Reverse Coded: There were items we could not consider because our budget was already set	Budget Constraints	F		x
Reverse Coded: This tool duplicates other processes I already use	Duplicate Processes	R	DB	x
LEGEND: U - tool usability; F:feasibility; G: generalizability; R: relevance S: Seminar goal; DB: workgroup debrief; D:marketing and education module				

Deleted survey content during hypothetical scenarios included consideration for relevance without a real-world setting (e.g., budget/costs, safety culture of the organization) and bias as a result of an increased level of familiarity with the tool content from the expert workgroups who developed the content (easy to understand). Some questions were more suited for inclusion in the overall seminar goal discussion, workgroup debrief, or marketing and education module. Two questions were included as a result of scenario-specific activities intended to induce changes to the design.

6.5.2 Overall Testing Process and Flow

Testing was conducted in Stage 4 through hypothetical scenarios, using a combination of returning members of the expert workgroups established in Stage 3 and new recruits to balance the types of professional roles of the testers. Stage 5 of the study included testing at three hospital sites whose team was undertaking a facility design project. All agreed to voluntary participation. (Lunch was provided, but no financial incentives were paid to the organizations or individual participants.) The sites initially identified in the grant were unable to participate for various organizational reasons. As a result, a purposive sample was recruited to meet the goals of the originally identified pilot sites (geographic diversity, different stages of design, varied organizational size). These sites included one professional connection to the researcher at each site, were located in geographically diverse areas, and were in different stages of their design project. Each organization was part of a larger, well-respected health system, and by coincidence, all tested an oncology-related project (one new-build and two renovations).

The initial plan was to complete pilot testing prior to scenario testing, but a lack of participant pilot site confirmations led to delays. The schedule was adjusted to conduct one pilot test prior to the scenario testing, with the remaining pilot sites

following the group event (Figure 6-3). Benefits from the revised schedule allowed iterative data collection and analysis, which is a more robust protocol for qualitative methodology.

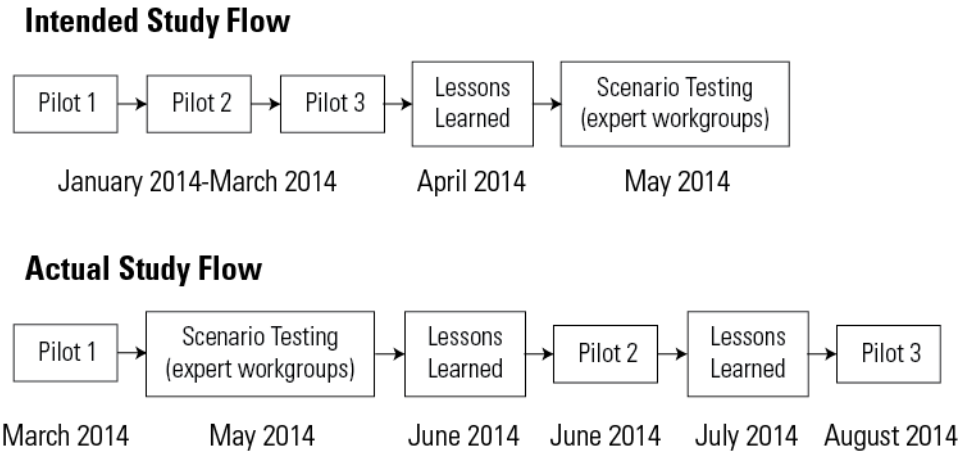


Figure 6-3. Stage 4-5 study flow

Ethics approval was received from Loughborough University (18 October 2013). Informed consent was delivered verbally and via a PowerPoint slide at the start of each pilot test (Appendix I). Participants could leave at any time during the session. Testing of hypothetical scenarios at the live seminar incorporated informed consent as part of the onsite sign-in. Participants were also asked to sign non-disclosure agreements, as there were reportedly unfinished versions of the tool being circulated following the Stage 3 seminar.

6.5.3 Stage 4: Hypothetical Scenario Testing

6.5.3.1 The Test Site

Hypothetical testing was conducted at Kaiser Permanente's Garfield Innovation Center. As a living laboratory, the use of the facility is conditioned on interactive user participation, not just traditional table-and-chair meetings. As a test site for many of Kaiser's standards (operational and design), there are several existing mock-up spaces, such as patient rooms, an operating room, nursing stations, and outpatient clinics. Three setting types were developed for teams to use as part of the testing process. These included a meeting format, a low-fidelity mock-up (less detailed), and a high-fidelity mock-up (more detailed).

The meeting format was set in one of two open spaces (Blue Sky and Hobby Lobby). The low-fidelity mock-up used prefabricated wall modules and furniture

(e.g., a stretcher, IV pole) from the stock of onsite materials and was supplemented by cardboard boxes with taped images to represent other items in the space (e.g., handwash sink, storage cabinets). The high-fidelity mock-up scenarios used two existing patient rooms, one an older version of a prior room standard and one a newer rendition of the labor and delivery room (LDR). These were fitted with final finishes, furnishings, and equipment (e.g., bed, casework) and included non-functioning fixtures (e.g., sinks, toilets). Module locations are shown in Figure 6-4.

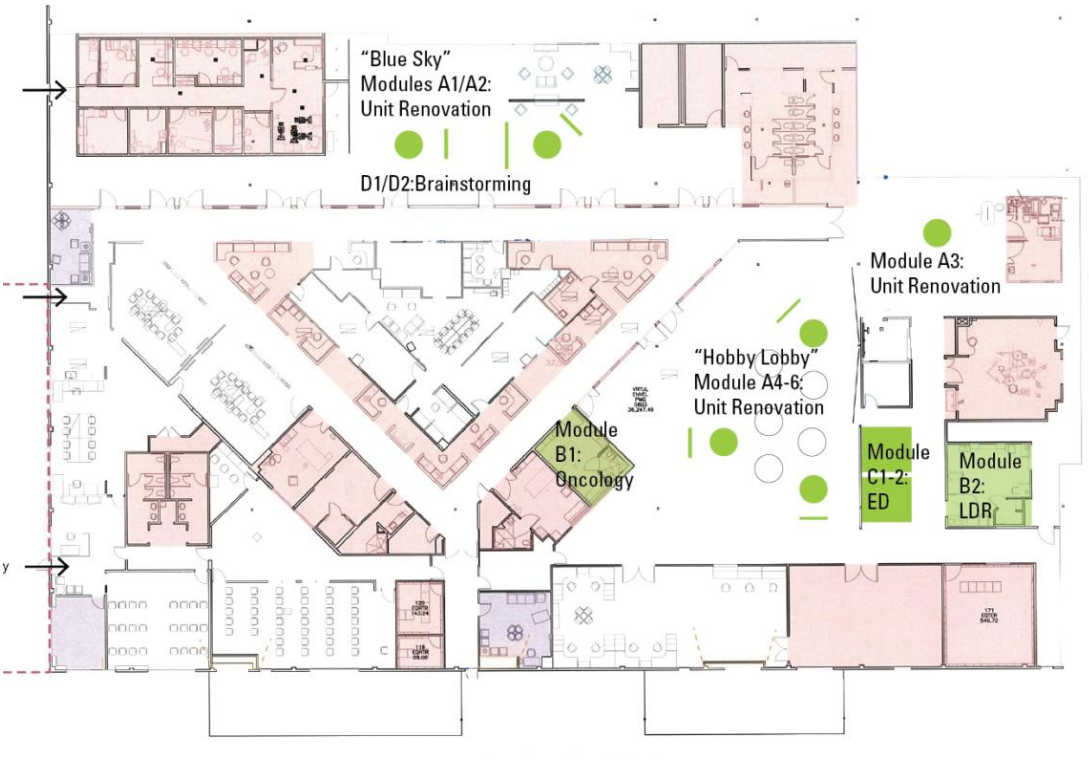


Figure 6-4. Garfield Center for Innovation test module locations (Stage 4)

6.5.3.2 Scenarios

Scenarios can help prompt the decisions made during design and establish participant communication (Bødker 2000), but the term scenario suffers from a lack of definition (Bradfield et al. 2005). In this project, the scenarios were neither intended as "horizon planning," nor methodological tools for decision making by creating multiple futures for discussion (Bradfield et al. 2005, Amer, Daim, and Jetter 2013), nor to understand the specific tasks and work processes that should be supported (Hägglund, Scandurra, and Koch 2010, Park 2011). Rather, as in some human computer interaction studies, the scenarios were used as stories to elaborate what people try to do with the system and what interpretations are derived (Carroll 1999).

They became a starting point for seminar activities, where it was left to the participants to decide how and how much to use the scenarios (Bødker 2000).

Four hypothetical scenarios were developed, based on combinations of data from real projects. Most plans were provided by healthcare organizations and anonymized. Additional demographic data were assembled from publicly available census records or town/city reports.

The meeting format incorporated a unit renovation at a community hospital. Originally envisioned as one of the pilot sites, the project had been delayed for several reasons, one being that there had not been a final decision made as to unit type. This lack of decision was incorporated into the scenario and the groups had to work within the context of the existing structural grid. The low-fidelity mock-up was an Emergency Department (ED) exam room (Figure 6-5). The scenario offered teams two unit layout options, as provided by the healthcare organization that had considered two configurations. With the low-fidelity mock-up, groups were encouraged to move objects and adjust the layout in any way they felt better addressed the SRA content.

Figure 6-5. Stage 4 low-fidelity mock-up – ED exam room

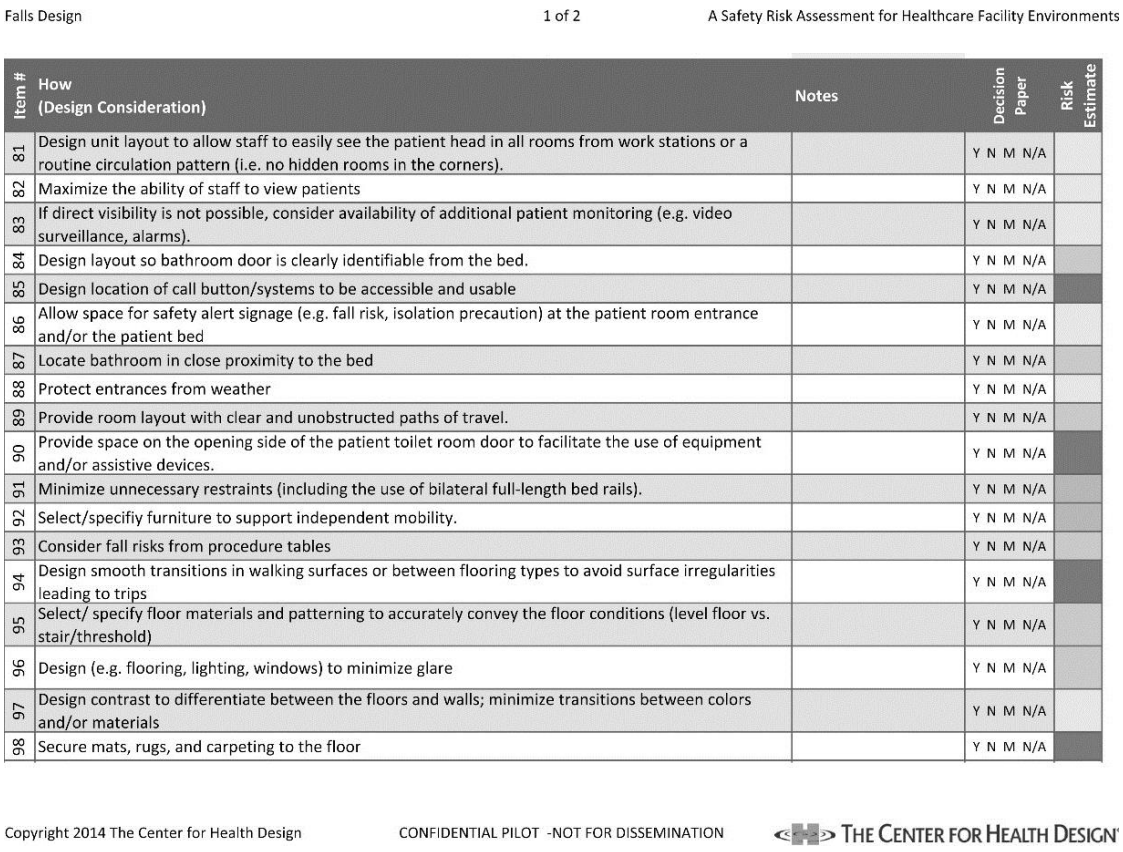
As a result of the differences in the available high-fidelity spaces, two scenarios were developed, one for each room type. The older room standard (Figure 6-6) incorporated a scenario of a short-term oncology unit renovation. Teams were provided with a unit plan and instructed to consider safety-specific modifications that could serve as interim solutions while a new project was being designed.

Figure 6-6. Stage 4 high-fidelity mock-up - oncology unit renovation scenario

The LDR (Figure 6-7) was used as a hypothetical benchmarking visit – allowing a design team to consider options they might want to incorporate into their own project.

Figure 6-7. Stage 4 high-fidelity mock-up - LDR benchmarking scenario

The scenarios were presented in a letter-size book format and were provided electronically prior to the seminar. These included a "charge," a summary of the primary aim of what the group was expected to accomplish as a result of the exercise. The scenarios are included in Appendix J. The tool content (Figure 6-8) was printed on large-format sheets (24" x 36") and clipped to easels for the group to record their own notes. The tool content was not provided in advance of the sessions, but was the same for each of the group's modules - the same falls and patient handling considerations were reviewed for each module and scenario.



Falls Design 1 of 2 A Safety Risk Assessment for Healthcare Facility Environments

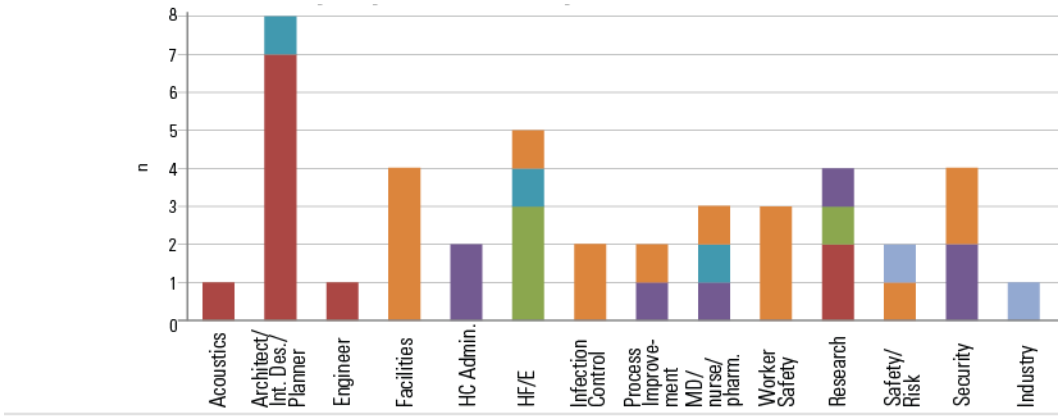
Item #	How (Design Consideration)	Notes	Decision Paper	Risk Estimate
81	Design unit layout to allow staff to easily see the patient head in all rooms from work stations or a routine circulation pattern (i.e. no hidden rooms in the corners).		Y N M N/A	
82	Maximize the ability of staff to view patients		Y N M N/A	
83	If direct visibility is not possible, consider availability of additional patient monitoring (e.g. video surveillance, alarms).		Y N M N/A	
84	Design layout so bathroom door is clearly identifiable from the bed.		Y N M N/A	
85	Design location of call button/systems to be accessible and usable		Y N M N/A	
86	Allow space for safety alert signage (e.g. fall risk, isolation precaution) at the patient room entrance and/or the patient bed		Y N M N/A	
87	Locate bathroom in close proximity to the bed		Y N M N/A	
88	Protect entrances from weather		Y N M N/A	
89	Provide room layout with clear and unobstructed paths of travel.		Y N M N/A	
90	Provide space on the opening side of the patient toilet room door to facilitate the use of equipment and/or assistive devices.		Y N M N/A	
91	Minimize unnecessary restraints (including the use of bilateral full-length bed rails).		Y N M N/A	
92	Select/specifiy furniture to support independent mobility.		Y N M N/A	
93	Consider fall risks from procedure tables		Y N M N/A	
94	Design smooth transitions in walking surfaces or between flooring types to avoid surface irregularities leading to trips		Y N M N/A	
95	Select/ specify floor materials and patterning to accurately convey the floor conditions (level floor vs. stair/threshold)		Y N M N/A	
96	Design (e.g. flooring, lighting, windows) to minimize glare		Y N M N/A	
97	Design contrast to differentiate between the floors and walls; minimize transitions between colors and/or materials		Y N M N/A	
98	Secure mats, rugs, and carpeting to the floor		Y N M N/A	

Figure 6-8. Sample consideration sheet used in scenarios

6.5.3.3 Expert Workgroup Participants

Six teams were assembled and established according to areas of risk category expertise (e.g., falls, infection control). All participants from Stage 3 (purposive criterion sample) were invited to participate in Stage 4. Sixty-two percent of the Stage 4 seminar participants returned from Stage 3. Additional recruits (a purposive sample) included architects and designers who specialized in HC facility design, a category that had fewer participants in Stage 3, as a result of the nature of the content development expertise. Teams were combined to address potentially overlapping areas of interest (i.e., falls and patient handling; security and psychiatric/behavioral health injury).

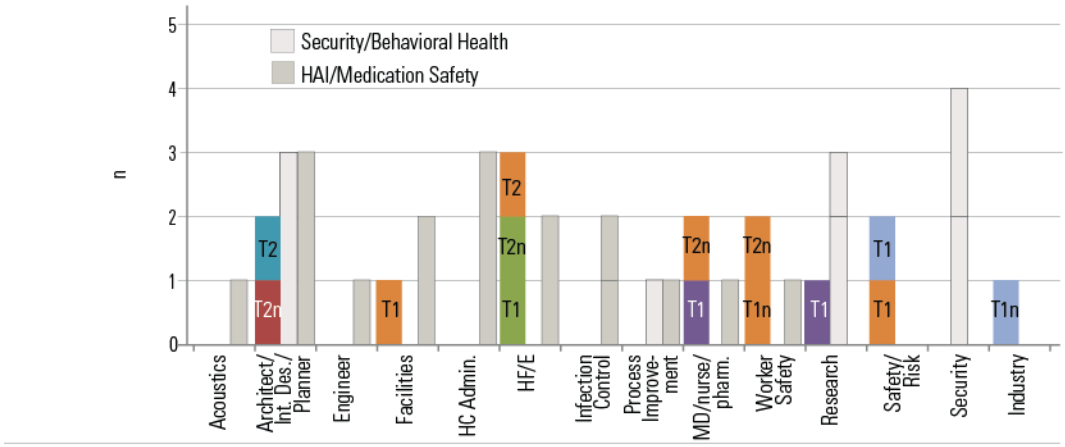
The primary roles and employment categories of participants are illustrated in Figure 6-9. Up to eight participants were envisioned for each group, with a focus on topic expertise. There were eight participants who had originally committed to Stage 4 that were unable to attend. Five of these were in the falls/patient handling groups (one falls, four patient handling). One of the participants provided a replacement with similar expertise.



	Acoustics	Architect/ Int. Des./ Planner	Engineer	Facilities	HC Admin.	HF/E	Infection Control	Process Improve-ment	MD/ nurse/ pharm.	Worker Safety	Research	Safety/ Risk	Security	Industry
NGO/non-profit	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Insurance/Risk/Industry	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Healthcare Organization	0	0	0	4	0	1	2	1	1	3	0	1	2	0
Gov't/Policy	0	1	0	0	0	1	0	0	1	0	0	1	0	0
Consulting	0	0	0	0	2	0	0	1	1	0	1	0	2	0
Academia	0	0	0	0	0	3	0	0	0	0	1	0	0	0
Arch/Des/Engr	1	7	1	0	0	0	0	0	0	0	2	0	0	0

Figure 6-9. Stage 4 participant primary professional roles and employment; n=41

The two combined workgroups for falls and patient handling (Team 1 and team 2) included 57% returning participants and a diverse range of expertise (Figure 6-10). Of these, half participated in the Stage 3 falls content development and half participated in patient handling content development.



	Acoustics	Architect/ Int. Des./ Planner	Engineer	Facilities	HC Admin.	HF/E	Infection Control	Process Improve-ment	MD/nurse/ pharm.	Worker Safety	Research	Safety/ Risk	Security	Industry
Insurance/Risk/Industry	0	0	0	0	0	0	0	0,1,0	0	0	0	1,0,0	0,2,0	1,0,0
Healthcare Organization	0	0	0	1,2,0	0,0,3	1,0,0	0,0,2	0	1,0,0	0,0,3	0	1,0,0	0	0
Gov't./Policy	0	1,0,0	0	0	0	0,0,1	0	0	0,0,1	0	0	0	0	0
Consulting	0	0	0	0	0	0	0	0,0,1	1,0,0	0	1,0,0	0	0,2,0	0
Academia	0	0	0	0	0	2,0,1	0	0	0	0	0,1,0	0	0	0
Architect/Design/Engr.	0,0,1	1,3,3	0,0,1	0	0	0	0	0	0	0	1,1,0	0	0	0

Color reflects employment (in legend); T1 or T2 reflects team number (F/PH1, F/PH2); n = new participant
Numbers reflect each topic group: Falls/Patient Handling, Security/Behavioral Health, HAI/Medication Safety

Figure 6-10. Stage 4 combined F/PH teams - professional roles and employment; n=14

Team 1 included two returning participants from the Stage 3 falls group and four returning participants from the patient handling group. One member of Team 1 participated on Day 2 only. Two returning members of the falls group participated in

Team 2, but four prior patient handling experts were part of the last-minute cancellations (Table 6-2). In addition, several of the participants in Team 2 had travel commitments on Day 2 of the seminar and only participated on Day 1. Despite the resulting imbalance of team size, the groups were not reorganized. This was in part to maintain the team dynamic for Team 1 developed during Day 1 and in part to see if the smaller group would have an effect on how they completed the scenarios.

Table 6-2. Combined falls and patient handling workgroup makeup and participation

Team 1		**Team 2**	
Planned	Actual	Planned	Actual
Falls, Research, Consultant	Day 1-2	Falls, Arch, Gov't./Reg.	Day 1-2
Falls, Facilities, HC org	Day 1-2	Falls, HF/E, Academic	Day 1
Falls, Clinician, HC org	Cancel, work	*New, Work Safety, HC org*	*Day 1-2, substitute*
PH, Worker Safety, Consultant	Day 1-2	*New, Designer, A/D/E*	*Day 1-2*
PH, Risk, HC org	Day 2	*New, HF/E, Academic*	*Day 1*
PH, HF/E, HC org	Day 1-2	PH, Clinician, HC org.	Cancel, work
PH, Risk, Insurance/Industry	Day 1-2	PH, Nursing, Risk	Cancel, weather
New, Worker Safety, HC org	Day 1-2	PH, Clinician, HC org.	Cancel, weather
New, Industry, Insurance/Industry	Day 1-2	PH, HF/E, HC org.	Cancel, weather

6.5.3.4 Data Collection

6.5.3.4.1 Data collection flow

As illustrated in Figure 6-3, the two-day session started with an orientation, followed by a series of test sessions (modules) where participants used the tool in a the hypothetical scenario. All teams started with the meeting format, then in a round-robin method completed the low-fidelity and high-fidelity testing, as well as a module for considering dissemination, and an overall team debrief before concluding the event. This is further detailed in Figure 6-11.

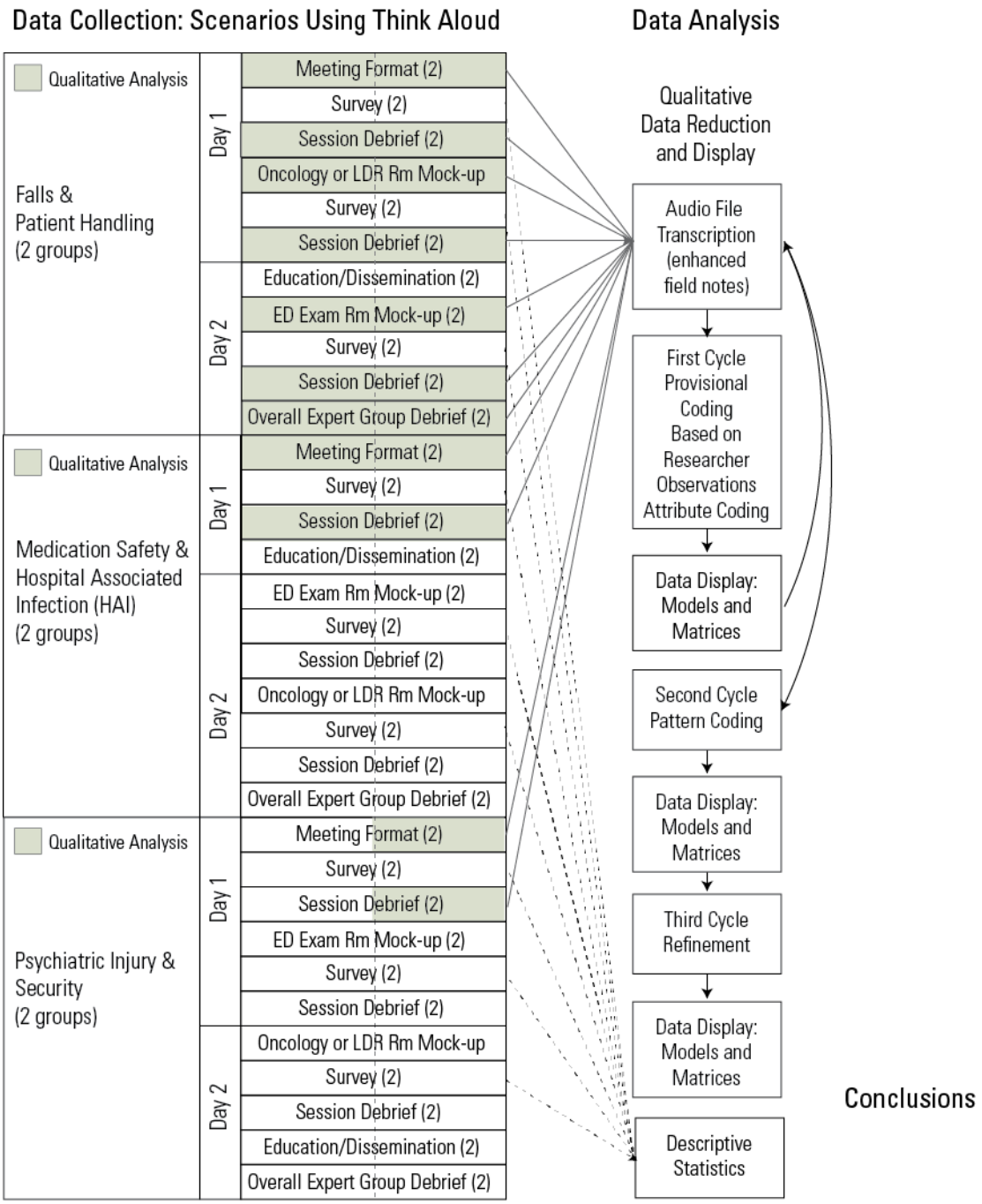


Figure 6-11. Teams and data collection flow (Stage 4)

6.5.3.4.2 Think-aloud

The teams were encouraged to use a think-aloud process where the participants were asked to articulate their thoughts and explanations while moving through the various considerations in each scenario (Ericsson and Simon 1993). Van Someren, Barnard, and Sandberg (1994, 1) cite this process as suited to the architectural design process where accounts of how people design may be described "*neatly in terms of the formal design methods that they acquired during their professional training, whereas*

the real design process deviates from these methods." The think-aloud protocol records what is being said and used as data to gain insight into the design process and methods of human problem-solving (van Someren, Barnard, and Sandberg 1994). Additionally, according to Nielsen, Clemmensen, and Yssing (1994), think-aloud studies can be effective to evaluate usability with small sample sizes, in some cases finding 75% of usability issues with only four to five participants.

6.5.3.4.3 Facilitation

At the start of each module, the workgroup was asked to reread the scenario and select a workgroup member scribe for each module and topic. The scribe led the group through the exercise and recorded any salient points related to the design considerations. Each team's time was monitored by a staff member of Kaiser Permanente, who moved with the group over the course of the two-day session. Their role was solely to manage the group's progress, keep time, and prompt debrief discussions. They did not facilitate how the group approached the discussion, although they were instructed to be aware of and mitigate dominant personalities. Each session was also attended by a CHD staff member, whose role it was to take field notes related to duplications and content clarity for the grant. Following the first module (meeting format) the note taker (CHD staff) stayed with a single setting (e.g., ED exam room). CHD staff did not moderate or facilitate testing but provided clarification on the seminar format when needed. Each module was followed by completion of a brief online survey (Survey Monkey) and short focus group debriefs (Table 6-3).

Table 6-3. Time allocation for modules

Task	Time
Review scenario narrative and identify workgroup scribe	5 min
Complete 1st assigned SRA component	35 min
Complete 2nd assigned SRA component	35 min
Complete survey	5 min
Group debrief	10 min
TOTAL	**90 min**

6.5.3.4.4 Scenario test recording

All sessions were recorded using digital audio devices (Philips DVT8000 Voice Tracer Meeting Recorder or Zoom H2n). These were selected for their ability to capture voices in all areas of the space (360-degree coverage when hung from the

high-fidelity ceiling or placed on a table, 270-degree coverage when mounted on the low-fidelity wall). The audio files were used to supplement field notes and create a partial transcription, which was expanded following multiple stages of coding (Richards 2006) during qualitative analysis.

6.5.3.5 Role of the Researcher

During scenario testing, I observed the workgroups and took notes in two modules (meeting and low-fidelity), offering clarification for the seminar flow when needed (Table 6-4). However, there were instances when a specific question was directed to me about the module intent, as well as occasions when I would remind participants to articulate their thought process.

Table 6-4. Mapping of researcher observation and analysis

Researcher modules	Researcher observation/notes/ audio recording	Concurrent modules analyzed	Observation by other CHD staff: Audio recordings analyzed by researcher
Module A (Day 1): Meeting	Group 1: Falls/Patient Handling	Module A: Meeting	Groups 2, 4, 5, 6: Group 3 faulty recording
Module C2 (Day 1) (low-fidelity mock-up)	Group 4: Psychiatric Injury/Security	Modules B1, B2: (high-fidelity mock-up)	Groups 1, 2: Falls/Patient Handling
Module C2 (Day 2) (low-fidelity mock-up)	Group: 6: HAI/Medication Safety	Module D1, D2: Marketing Dissemination	Groups 1, 2: Falls/Patient Handling
Module C2 (Day 2) (low-fidelity mock-up)	Group 2: Falls/Patient Handling	Module C1 (low-fidelity mock-up)	Group 1: Falls/Patient Handling
Day 2 Debrief	Group 1: Falls/Patient Handling	Day 2 Debrief	Group 2: Falls/Patient Handling

6.5.4 Stage 5: Real World Pilot Testing

6.5.4.1 Pilot Site Recruitment and Selection

Real-world projects were sought in varied regions of the US and in different stages of the design process - block diagrams, schematic design, and design development. Following challenges in final commitments from previously recruited sites (i.e., projects put on hold/delayed, lack of resources and/or time), a second recruitment strategy was employed, requesting assistance from participants in the expert workgroups. An opportunistic sample was selected from Barnes Jewish Healthcare (BJH) in St. Louis, MO, the University of California Irvine Medical Center (UCI) in Irvine, CA, and the Memorial Sloan Kettering Cancer Center (MSK) in New York, NY.

6.5.4.1.1 Pilot site 1: BJH

The selected project at BJH was a new oncology unit in design development (Figure 6-12). By design development, most decisions have been made, and there is little opportunity for change without a budget implication, so the nature of the discussion had the potential for differences from the other two pilot sites.

This team tested five topics: falls, infection control, patient handling, security, and medication safety. Prior to starting the test, the team decided to allocate 20 minutes per section in order to complete as much of the five risk categories as possible. Out of seven participants, three were only available for their topic area of the meeting (i.e., an ergonomist for patient handling, an epidemiologist for infection prevention, and a pharmacist for medication safety).

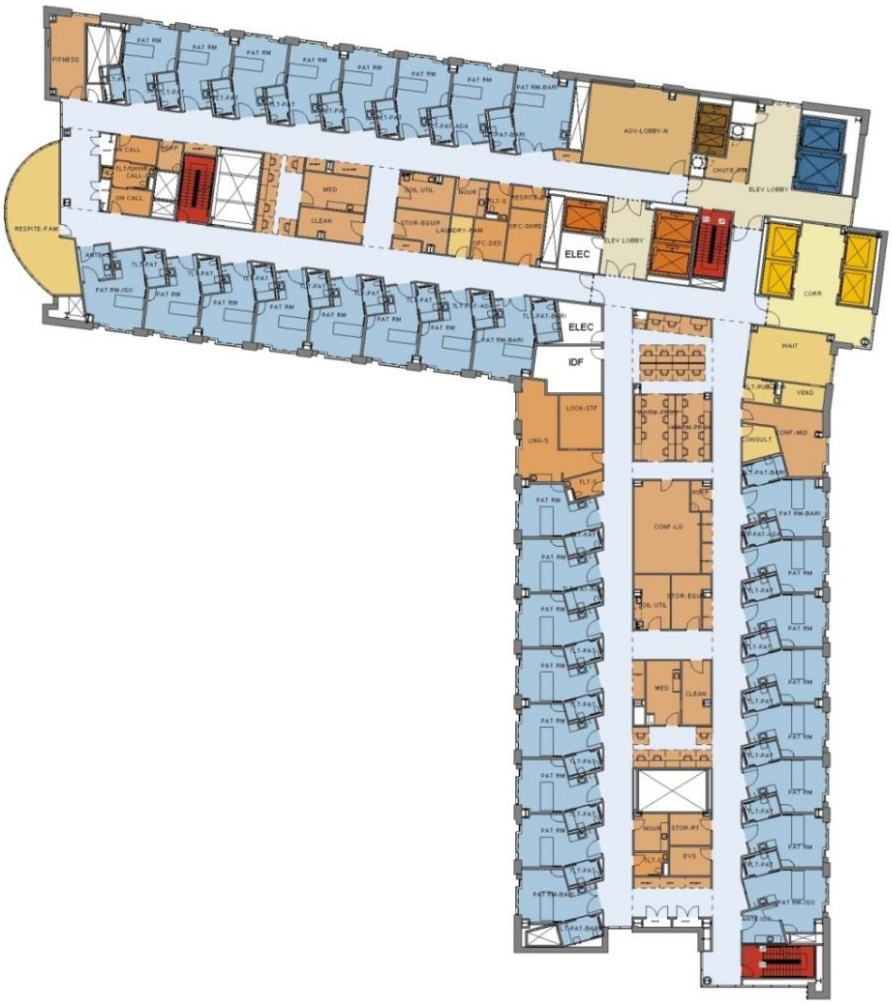


Figure 6-12. Stage 5 pilot site 1 design development plan
Source: © HOK Architects, California.

6.5.4.1.2 Pilot site 2: UCI

The project used for evaluation at the second site was a complete unit renovation in the master planning phase. The proposal was to renovate a neuropsychiatry unit with only 12 beds into an oncology unit (Figure 6-13).

The only activity that had been completed prior to the pilot session was a "test fit," where architects determine space availability based upon the limitations of the existing structural grid and building exterior envelope (e.g., windows). Three conditions were tested: an all-private room configuration, an all-semi-private room configuration, and a hybrid model. The hybrid concept was brought to the evaluation, and spaces were shown as block diagrams with little functionality established prior to the pilot testing session.

Figure 6-13. Stage 5 pilot site 2 unit renovation master plan "test fit"
Source: © Taylor Architects, California (no researcher relation).

UCI was the first pilot following the scenario testing, and some of the duplications and clarity had been addressed prior to the pilot. In addition, similar considerations were grouped, based upon feedback from testing with the scenarios. This group tested infection control and medication safety. Prior to starting the test, the team asked about time and I encouraged them to have the discussion they needed given the early phase of design, rather than work to a specific schedule. Thirteen participants were present for the duration of the test. One left prior to the focus group debrief.

6.5.4.1.3 Pilot site 3: MSK

The test project at pilot site 3 was an oncology unit renovation in the middle of the schematic design phase (Figure 6-14).

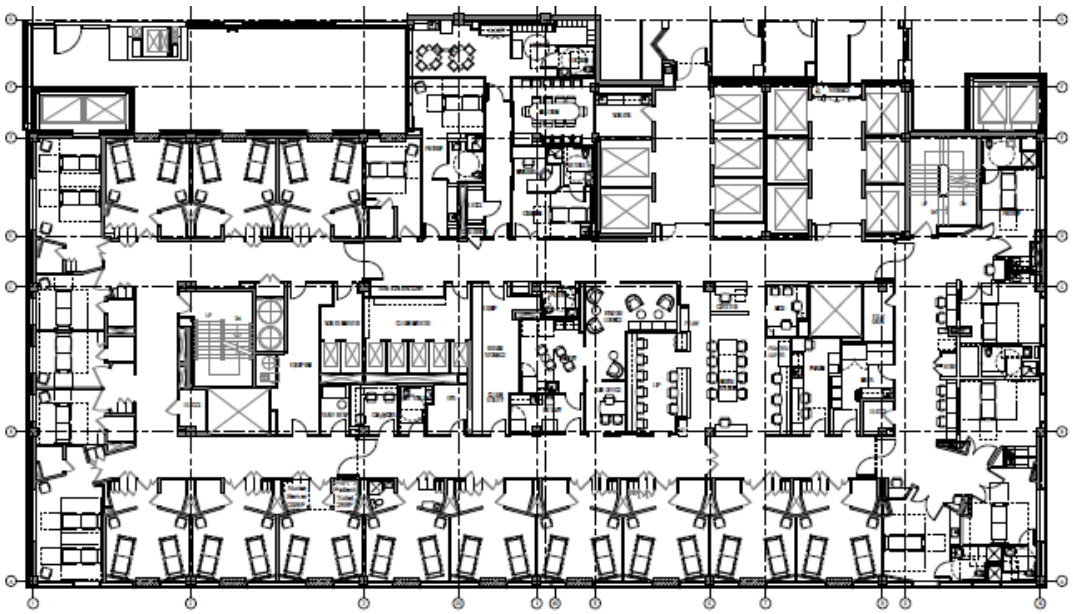


Figure 6-14. Stage 5 pilot site 3 schematic design plan
Source: © HOK Architects, New York.

While still early in the design phase, the project was limited by the existing structural grid, the building exterior envelope, plumbing, and the need to maintain most of the semi-private room/bathroom configuration as a result of negative revenue implications in moving to an all-private room layout. However, four private rooms had been established for a higher patient risk group requiring additional observation – the NOU (Neuro Observation Unit). The unit was also developed with consideration for the unique supply chain and logistics operation that included "clean master" and

"soiled master" elevators, separated from the elevators for staff, patients, and visitor transport.

Based upon feedback from prior pilots and scenarios, the test was facilitated by the researcher. This group tested falls, infection control, and medication safety. Risk categories were integrated and organized by decision type (e.g., unit layout versus material selection). Fifteen participants were present for the test. Two arrived later in the session (design-related participants) and two (infection prevention) left early.

6.5.4.2 Pilot Test Participants

Each site had a range of participant roles, many with expertise specific to one of the risk categories (e.g., pharmacists/nursing for medication safety, epidemiologists for infection control). Participant selection was left to the pilot test organization, but CHD provided suggestions for the types of people that might be considered. The first site had limited participation as a result of resource constraints, but several people were able to attend the session part-time (Figure 6-15).

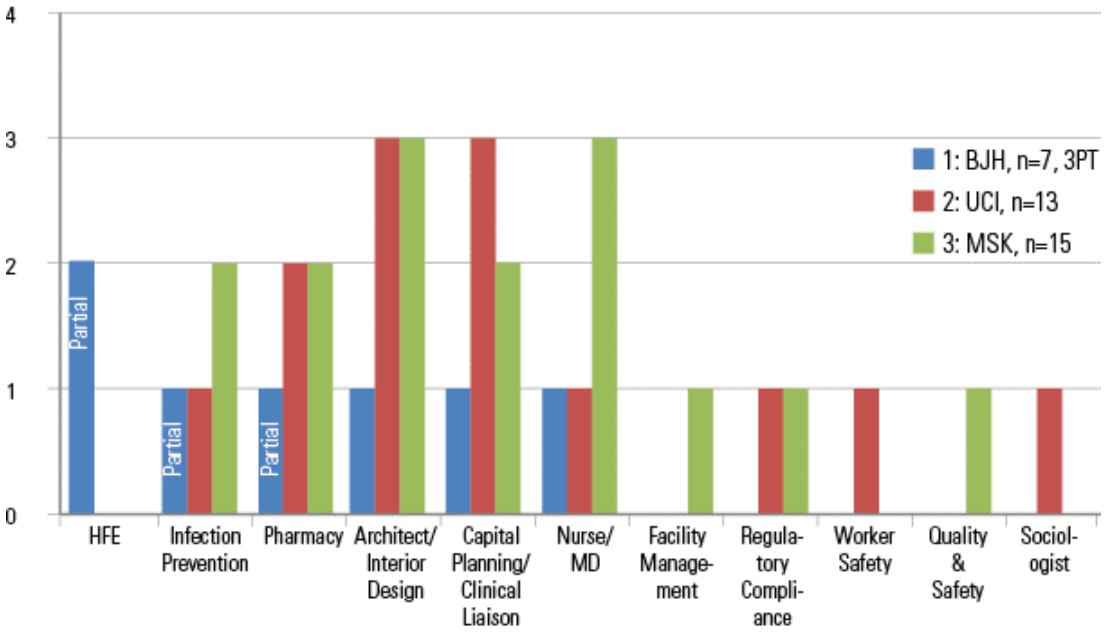


Figure 6-15. Stage 5 pilot site participant roles

6.5.4.3 Data Collection

6.5.4.3.1 Data collection flow

Each session included an orientation to the SRA project (remote before the pilot test or live), followed by a session where participants used the tool. Each session

was followed by completion of a survey and a focus group debrief. Each pilot site followed a similar process (Figure 6-16).

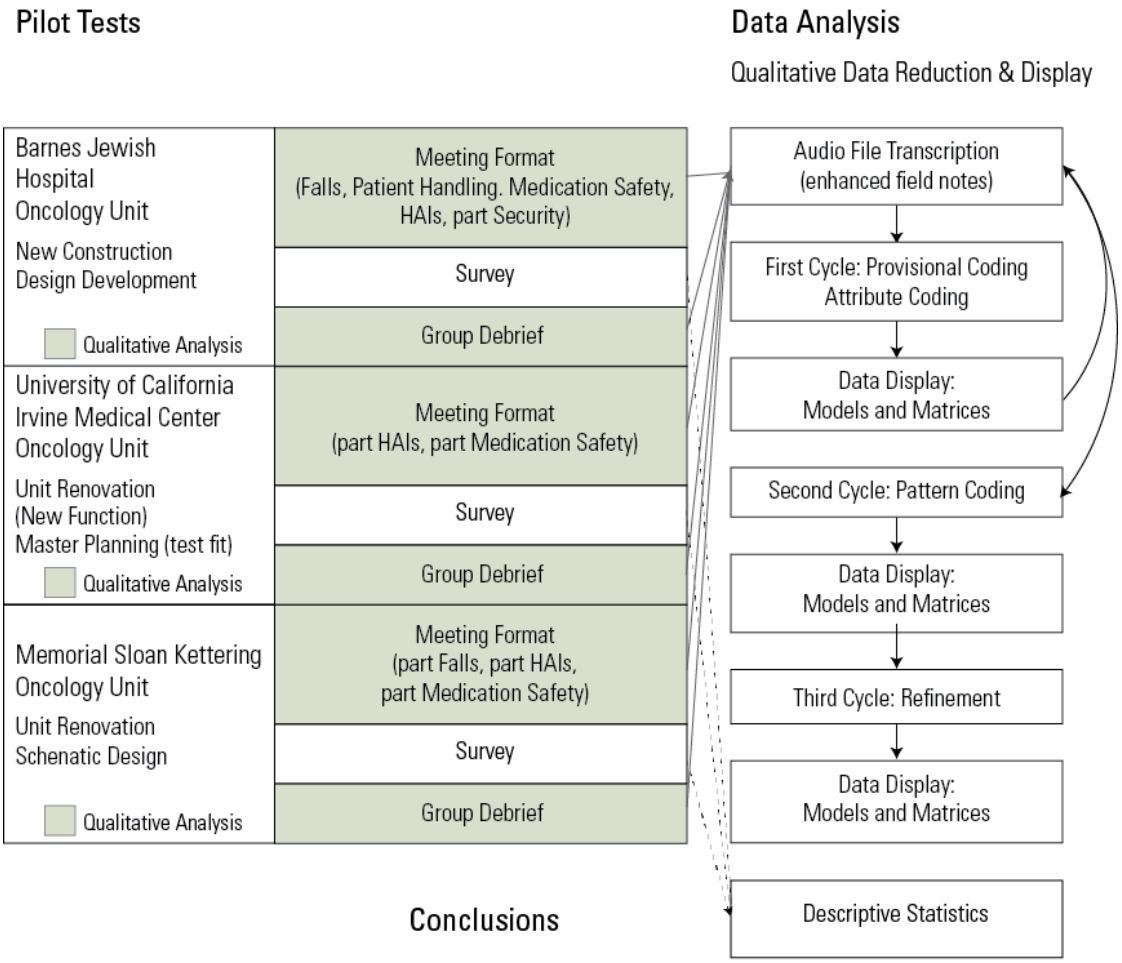


Figure 6-16. Data collection and analysis flow (Stage 5 - pilot sites)

6.5.4.3.2 Facilitation

The first two pilot sites self-facilitated use of the tool, tackling specific topic categories (e.g., falls, infection control). Sessions started with an orientation to the project by the design team, with drawings available for reference. The SRA tool was projected on the screen as an Excel file and a volunteer from the participating team completed the notes and decision fields during the group discussion. Based upon feedback from the first two sites, a facilitated discussion was employed at the third site, integrating topics according to levels of decision making (e.g., unit layout, room layout).

6.5.4.3.3 Pilot test recording

All sessions were recorded using digital audio devices (Philips DVT8000 Voice Tracer Meeting Recorder and Livescribe Echo pen). As with the hypothetical scenarios, the audio files supplemented field notes and were used to create a partial transcription that was further expanded during qualitative analysis coding (Richards 2006).

6.5.4.4 Role of the Researcher in Pilot Tests

In the first and second pilot test, I provided a project orientation to the assembled test team and conducted the focus group debrief. While the team tested the tool, I observed tool use and took field notes, providing additional information about the user interface (Excel manipulation) and clarifications on content sources (e.g., USP 1066 for medication safety). On four occasions, redirection was needed when the discussion was veering too far from the SRA content. There was also one instance where I actively prompted a discussion, based on a potential latent condition that was being introduced by one of the possible solutions. At the third pilot site, I actively facilitated the session by systematically moving through the content but was not part of the discussions surrounding decisions or possible solutions.

6.6 Preliminary Qualitative Data Analysis

Recordings and transcript templates were imported into NVivo (QSR International 2012). Transcript templates included a matrix of SRA considerations, consideration numbers, and any field notes. The recordings were used to further supplement field notes as a continued partial transcription. As the case study, all falls workgroups were analyzed. Additionally, three other non-falls "A" (meeting) modules were analyzed as a control to determine whether there were any differences in themes among groups. (The sixth "A" module, A3: Behavioral health/security, did not record and the field notes taken by a CHD staff member were not suited to PhD analysis.) All pilot site data were included in analysis.

Qualitative analysis followed the approach of grounded theory outlined by Corbin and Strauss (Corbin and Strauss 2014, Barbour 2008, Thornberg and Charmaz 2014). Pragmatic versions of GT recognize a preliminary focus and often start with some form of provisional (a priori) coding (Barbour 2008, Miles, Huberman, and Saldaña 2013). Coding was started following the expert workgroup sessions (Garfield

Center testing seminar), moving between an inductive and abductive approach that integrated domains of observations and ideas (Thornberg and Charmaz 2014). A system of multiple coders was not employed.

6.6.1 Provisional Coding

Provisional coding was established based upon my observations following the seminar – the context of the setting being tested, the types of discussions, how the tool was used for guidance, and tool usability. Provisional codes included categories such as the response, a duplicate or overlapping consideration, use as an audit vs. being proactive, use of the scenario, and facilitation. Provisional coding also included the categories of debrief questions: barriers, benefits, adoption, and implementation. The coding framework allowed flexibility for establishing new concepts (categories and subcategory nodes) through open coding, in which events/actions/interactions are compared with others for similarities and differences as discussed in Section 6.6.2. (Corbin and Strauss 2014).

6.6.2 Open Coding

Coding evolved without multiple coders but with oversight from a PhD advisor. During analysis, codes were expanded from the initial provisional coding and concepts evolved through open coding (Corbin and Strauss 2014), as shown in Table 6-5. In this phase, debriefing sessions were coded separately from in-use sessions.

Table 6-5. Sample evolution of open coding

Preliminary open coding	Evolved open coding
	Process
Scenarios	Scenarios
Confused - couldn't figure out	Confused - couldn't figure out
Demographics - data used	Demographics - data used
Function of space discussed	Function of space discussed
Not considered	Not considered
	Setting type helps
	Surrounding space
	Facilitation
	Facilitation-time check-other
	Researcher interaction
	Dominant personality leading
	Set stage
	Individual vs group process
Decisions	Decisions
Design change	Budget implication
	Design change

Preliminary open coding	Evolved open coding
Liability	Liability
	Not Applicable
	Not this phase
	Not this scenario
Personal experience	Not this space
Rationale check	Not enough evidence
	Not sure how done
Secondary safety risk	Secondary safety risk
	Standards (existing)
Tradeoff	Tradeoff
Yes discussion (or not)	Yes discussion (or not)
Answered already, but add	Answered already, but add
	Good for all - not just this
	Human behavior issue
	Explain how done
No discussion	No discussion
Operational-Clinical	Operational-Clinical
	Other implications (non SRA)
Guidance	Guidance – How Used
Audit vs. proactive	Audit vs. proactive
	Educational
Expert response	Expert response
No expertise response	No expertise response
Researcher interaction	One solution - multiple fixes
	Personal experience
	Potential differing views
	Priority not risk
Push dialogue	Push dialogue
	Rationale check
Revisit question	Revisit question
	Risk used
Facilitation (time check, other)	Stop VE
Tool Usability	Tool usability
Consideration	Consideration
	Different issue
Duplicate-overlap	Duplicate-overlap
	Skipped (unintentional)
	Too much in one
Unclear or not reading	Unclear or not reading
	Improvements
	Add complexity (skip, filter)
	Evaluate multiple options
	Group items
	Feature
	Location-type
	Phase-detail level
	Multiple stages
	Prioritize
Rationale unclear	Rationale unclear
Risk unclear	Risk unclear

As coding evolved, the new codes that had developed may have also been applicable to previously coded modules. However, prior to resolving the application of these new codes matrix queries were created and cluster analysis was conducted to review any patterns of similarities across workgroups and module settings (case levels) before further refinement or aggregation (Miles, Huberman, and Saldaña 2013).

6.6.3 Preliminary Cluster Analysis

An exploratory analysis of node coding for sources was conducted using NVivo cluster analysis. The debrief sessions and test session modules (use) were coded independently of each other during the open coding phase, and as a result the test sessions clustered together, separately from the debriefing sessions. Within use sessions, pilots tended to cluster together, as did the topics for hypothetical scenarios, although there were exceptions. There were fewer similarities in the debrief modules, although the pilots were still clustered as compared to the scenarios. This is partially represented in Table 6-6 highlighting the top 20 correlated sources.

Table 6-6. Preliminary Pearson correlation coefficient (coding similarity between sources)

Source A	Source B	PCC
Team 2: **Low-fidelity** *(C2_Falls-PH_2USE)*	Team 1: **Low-fidelity** *(C1_Falls-PH_1USE)*	0.71
TEAM 1: Low-fidelity *(C1_Falls-PH_1USE)*	**TEAM 1:** Meeting *(A_Falls-PH_1USE)*	0.69
TEAM 1: Low-fidelity *(C1_Falls-PH_1USE)*	**TEAM 1:** High-fidelity (*B1_Falls-PH_1USE)*	0.65
Real-world Pilot 3 *(MSK_USE)*	**Real-world** Pilot 1 *(BJC_USE)*	0.65
TEAM 1: High-fidelity *(B1_Falls-PH_1USE)*	**TEAM 1:** Meeting *(A_Falls-PH_1USE)*	0.59
TEAM 2: Low-fidelity *(C2_Falls-PH_2USE)*	**TEAM 2:** Meeting *(A_Falls-PH_2USE)*	0.59
Real-world Pilot 3 *(MSK_USE)*	Team 1: High-fidelity (*B1_Falls-PH_1USE)*	0.59
Team 1: High-fidelity (*B1_Falls-PH_1USE)*	Team 4: Meeting *(A_BH-Sec_4USE)*	0.59
Team 1: Low-fidelity *(C1_Falls-PH_1USE)*	Team 4: Meeting *(A_BH-Sec_4USE)*	0.59
Team 2: Low-fidelity *(C2_Falls-PH_2USE)*	Team 4: Meeting *(A_BH-Sec_4USE)*	0.59
Team 6: **Meeting** *(A_HAI-MS_6-USE)*	Team 5: **Meeting** *(A_HAI-MS_5-USE)*	0.57
Team 1: **Meeting** *(A_Falls-PH_1USE)*	Team 4: **Meeting** *(A_BH-Sec_4USE)*	0.57
Real-world Pilot 2 *(UCI_USE)*	**Real-world** Pilot 1 *(BJC_USE)*	0.55
Real-world Pilot 2 *(UCI_USE)*	**Real-world** Pilot 3 *(MSK_USE)*	0.55
Real-world Pilot 3 *(MSK_USE)*	Team 1: Meeting *(A_Falls-PH_1USE)*	0.55
Team 2: Low-fidelity *(C2_Falls-PH_2USE)*	Team 1: Meeting *(A_Falls-PH_1USE)*	0.54
Real-world Pilot 1 DB *(BJC_DB)*	Team 5: Meeting DB *(A_HAI-MS_5-DB)*	0.53
Team 6: **Meeting** *(A_HAI-MS_6-USE)*	Team 4: **Meeting** *(A_BH-Sec_4USE)*	0.53
Team 6: **Meeting** *(A_HAI-MS_6-USE)*	Team 1: **Meeting** *(A_Falls-PH_1USE)*	0.52
Real-world Pilot 2 *(UCI_USE)*	Team 1: Meeting *(B1_Falls-PH_1USE)*	0.52

PCC = Pearson Correlation Coefficient; DB = Debrief; **BOLD = setting correlation;** **COLORED CAPS = team correlation;** Topic correlation

During this phase of coding, the similarities of sources were not very high. However, there were some patterns relative to the setting types being similar in coding (e.g., low-fidelity to low-fidelity). As shown in Table 6-6, this was the case in eight of the top correlated sources. Topics were correlated as well, appearing together seven times. Teams (e.g., Team 1 to Team 1) were not correlated to each other as often in the same set of top 20 correlations. Furthermore, in considering the extensive number of nodes that had been generated, there had been noticeable growth under both the "Guidance" node and the "Yes Discussion" node. As a result, concept overlaps had developed (e.g., "Educational" under "Guidance" versus "Explain how done" under "Yes Discussion" versus "Educational" under "Debriefing"), as shown in Table 6-5. Overlaps were inconsistently coded under different node hierarchies. This may explain some of the lower correlation.

Matrix displays using NVivo were also created for both "Use" and "Debrief" modules, as in this phase, the sessions were coded with an independent node structure (Appendix K). There were common codes across many groups (both scenarios and pilots). There were several nodes where there was a prevalence of coding in one group and several where codes were only present in one group. This was indicative of the spread that needed to be resolved in interpreting meaning from the coding, but was also suggestive that modules could be aggregated in future analysis (e.g., high-fidelity, low-fidelity, pilot). There was also an implication that coding could be considered according to risk topic category (e.g., falls, HAI).

As a result, audio recordings (sources) were further coded as source classifications (i.e., meeting, high-fidelity, low-fidelity, pilot) to allow cross-case analysis by setting. Use session transcripts were also auto coded to the SRA consideration number. This allowed cross-case analysis by topic. There were a number of codes that were strictly tactical in nature (e.g., a redundant consideration) that would be used to clarify the tool itself but were not part of a larger theoretical construct.

6.6.4 Memoing and Defining Codes

In reviewing the growth in the number of nodes, a distinct pattern developed that was less about the particulars of the discussion and more about how knowledge was used and shared, as well as how users participated in the process. The second

iteration of coding was to further advance the synthesis of patterns (Miles, Huberman, and Saldaña 2013). This had a direct relationship to the literature review for design tools, and a second pattern coding was developed, based upon the coding of the initial literature review of design tools.

Memos (written records of analysis) were created to better define the new codes (Table 6-7) and understand the meaning behind the data (Miles, Huberman, and Saldaña 2013, Creswell 2012, Corbin and Strauss 2014). Prior coding was mapped to potential new coding as the starting point for the new model.

Table 6-7. Memos for new "in use" codes following review of open and axial coding

Nodes and child nodes			Sample memos
Design Culture	Existing Processes	Context	Length of time; repetition of mistakes; codes
		Design Climate	Multiple drivers vs actual needs (Liability; partial limits; tradeoffs)
		Design Value	Budget implication; cost benefit; stop VE; strategic priorities
		Steps/Tasks	Hand-offs over process cycle
	Users and Design	B-E Interaction	Behavioral vs. built environment; benefits for all; concurrent space and process definition
		Data Demographics	Metrics and demographics inform the discussion
		Process Management	Ownership of process – tactical vs. meaningful
		Silos	Too late; lack of collaboration - individual vs. group; specializations that don't talk; gaps to users
		Participatory Design	Dialogue; need to share expertise – multiple stakeholders; types of participants needed; embraced visions; understanding
Evidence Base	Managing Knowledge	Collection	Hierarchical classification – risk, priority; understanding; Not always 1:1
		Translation	How does this get solved/implemented in design; change agents
	Sharing Knowledge	Proactive	Open thought process; changes to design; reflection opportunities
		Reactive (POE)	Audit; checklist; feasible vs. priority; closed loop
	Using Knowledge	Information Range	Levels of evidence; evidence availability (rationale)
		Learning Styles	Ask questions, personal experience, reflect and reintroduce; tactile; visual
		Synthesis	Informed dialogue; Gathered/ interpreted; optimization vs. provision; people make decisions, not data
Guidance/Needs	Change	Communication-Feedback Loops	Iterative; in phases with how consideration is met; track history; tied to QC
		Filters-gates	Systematic; Evaluating options; high-level roadmap; macro to micro decisions
		Interface Regulations	Part of contractual or regulatory requirements to hold weight
		Meaning-Engagement	The extent to which there is constructive thought vs. a bureaucratic mentality
		Time	Making the best use of scarce resources: time

Nodes and child nodes		Sample memos
Tools	Content Clarity	Tactical – easy to understand
	Flexibility	Tactical – providing sorting capability
	Understanding	Tactical – Training and content knowledge
	Visual Legibility	Tactical – Display

6.6.5 Axial Coding

The memoing and definition was followed by refinement through axial coding, (Corbin and Strauss 2014). Axial coding further relates categories and subcategories, and in this study categories started to form around the framework established in the literature review about design culture, the evidence base, and guidance needs. This was a process of integrating and refining categories into the start of a theoretical construct, by reducing data from the multiple cases (including combining "use" and "debriefing" recordings) into relational categories (Corbin and Strauss 2014). While not always a 1:1 relationship, Figure 6-17 illustrates the reorganization and renaming of concepts being explored as they evolved from open to axial coding.

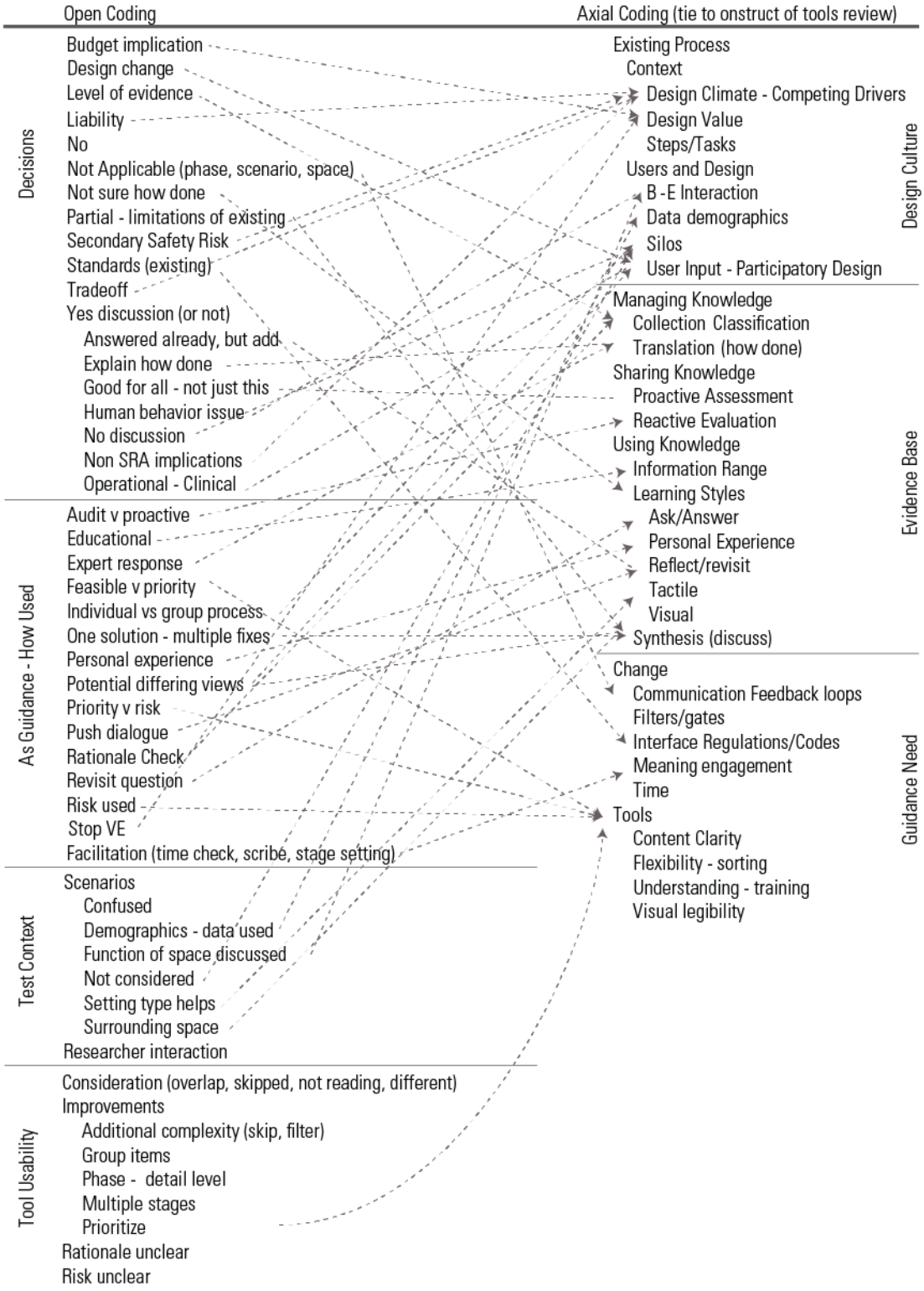


Figure 6-17. The evolution from open to axial coding

While the broad categories and child nodes (e.g., using knowledge, sharing knowledge, managing knowledge) align with the design tools literature review, the subcategories sometimes evolved out of additional levels of detail (Figure 6-18). For

example, in the design tools literature review learning styles was a single node, but in the coding of tool use different learning styles were indicated.

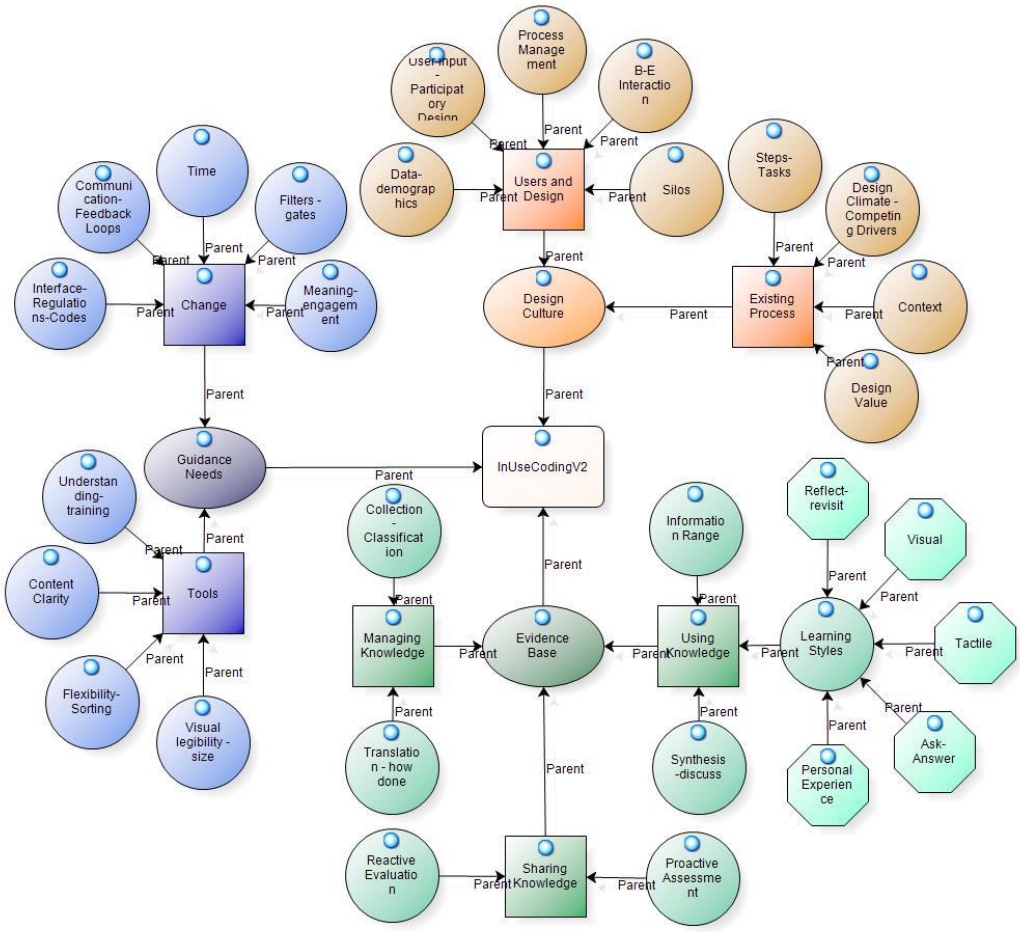


Figure 6-18. NVivo model following axial coding

6.6.6 Selective Coding and Preliminary Theoretical Model

Selective coding is the process of defining the central phenomena or major theme that unifies all others (Benaquisto 2008, Strauss and Corbin 1998). This major theme includes conditions, actions/interactions, and consequences, where the actions and interactions may respond to contextual shifts or bring about changes in the context framing the next action/interactional sequence in a larger context (Strauss and Corbin 1998). The main story is created (writing an initial sketch, using diagrams and notes) to evolve the theoretical scheme (Benaquisto 2008).

The initial selective coding reorganized the axial coding (shown in Figure 6-18) to focus on a theme – maximizing what we know. What had evolved out of the coding and comparative analysis was the benefit of both user and expert input into the

process, with the SRA becoming a participatory tool to engage in discussions. This leveraged a range of information (experiential to empirical), adapted to learning styles of participants, and resulted in a synthesis of solutions, both for specific safety topics (e.g., falls) and for integration of multiple topics that balanced multiple safety considerations across different topics within the SRA. While the structure of literature tools review was present, a visual reorganization began to further define those aspects of the evolving theme to maximize what we know (Figure 6-19).

Whereas the coding relationship of category and subcategory created a simple model of axial coding in Figure 6-18, many of the codes were interrelated (represented by dashed lines in Figure 6-19). Participatory design, for example, is linked to process management (how the SRA is led), understanding behavior-environment (B-E) interactions, the feedback loop, synthesis and discussion, and proactive assessment. Additional notes from memos were included in the diagram to more fully illustrate the concepts being developed. For example, the annotations reflected coding such as: what is the problem being solved and for whom (data/demographics); in theory it works like this, but in reality it works differently (B-E interaction); and bringing people together, getting the right people in the room, and gaining consensus (participatory design). Multiple forms of knowledge were reflected through the varied learning styles: let me see that (visual); now that I see that in 3D, move it (tactile); explain how that works (ask/answer); can we go back? (reflect/revisit); let me share my story (personal experience).

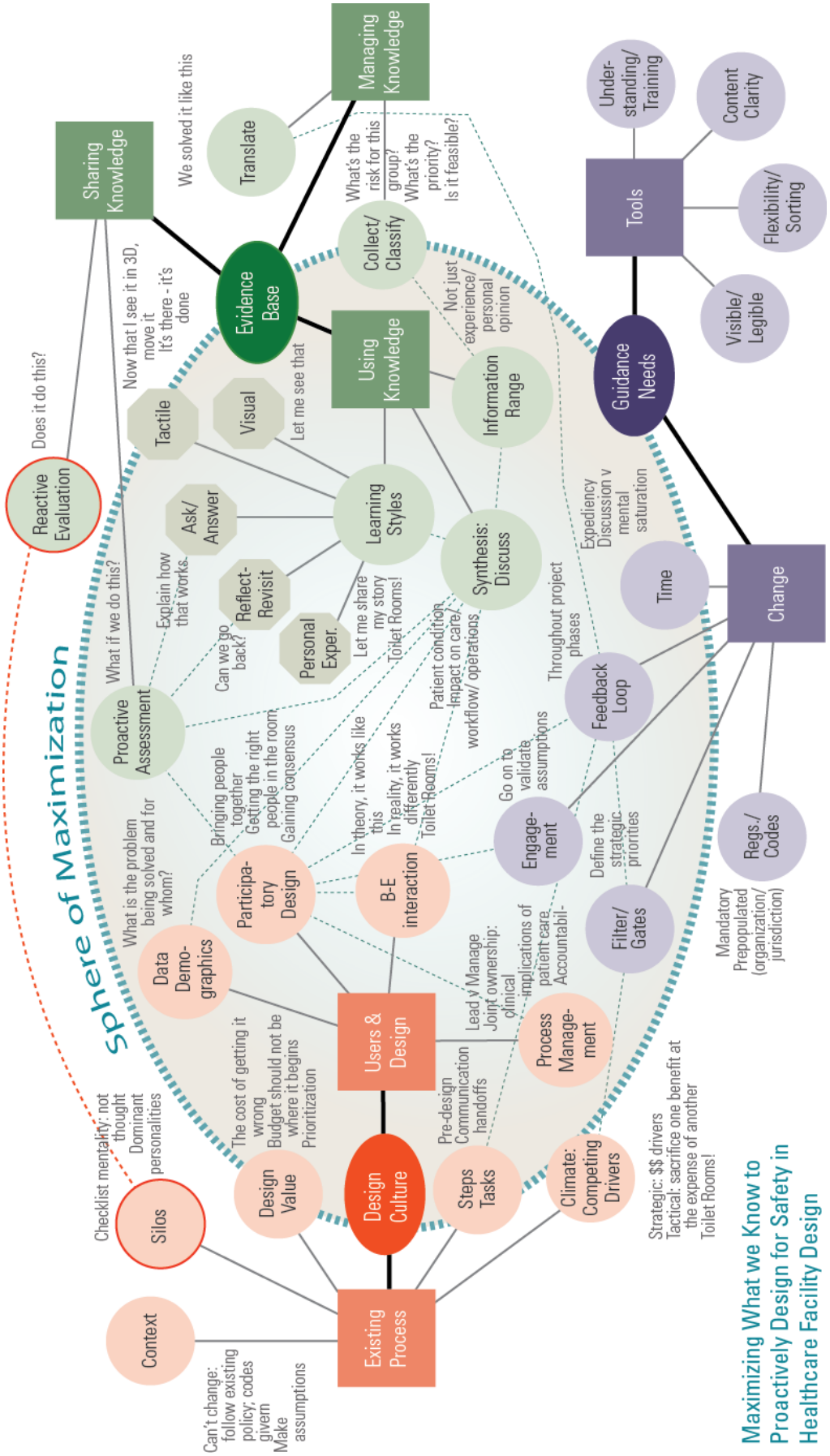


Figure 6-19. Preliminary central theme – Maximizing what we know

The evolving coding uncovered several important descriptive traits of what happened during testing. Design culture became less about existing processes and more about users and design. Change could be seen as a positive attribute of use with the potential for priority setting, engagement in the process, and feedback through the project life-cycle. Lastly, using multiple forms of available knowledge and devising proactive assessments of the problems to be solved allowed for synthesis in discussion. However, this initial central theme was more descriptive of what had happened rather than a theoretical construct to explain 'why' or 'how,' but participation and collaboration had become a primary driving concept to proactively consider safety events, which while preventable in many cases, should be anticipated in the course of providing care. The final phase of coding was to relate the coding to this core them - a theory of collaboration and consensus recognizing the value of multiple stakeholders, termed *Safety in Numbers? Anticipate to Participate to Integrate*. This is discussed in Chapter 7.

6.7 Quantitative Data Analysis

Quantitative analysis using SPSS 22.0 (IBM Corporation 2013a) included descriptive statistics, tests for normality, and comparison of means, to evaluate whether there were similarities or differences in self-evaluated perceptions of tool use. Because Shapiro Wilks tests for normality were violated in nearly all cases, comparing means by one-way analysis of variance (ANOVA) was inappropriate. As a result, probability distributions of data were compared with non-parametric tests for independent samples (Kruskal-Wallis H test) for the following:

- H_0: The probability distribution of the survey responses are the same across workgroups, pilots, or modules.
- H_a: At least two of the workgroups, pilots, or modules have probability distributions of survey responses that differ.

An alpha level of .05 was used for all statistical testing. Post hoc analysis was conducted for statistically significant results. To control for experimental type-1 error (the probability of rejecting at least one pair of hypotheses given all pairwise hypotheses are true), SPSS NPTESTS procedures adjust the p-values calculated and used for pairwise decisions. These are adjusted as $p_{adj} = pK(K-1)/2$ using ranks based on considering all samples rather than just the two involved in a given comparison, as

proposed for Kruskal-Wallis H testing in 1964 by Dunn (IBM Corporation 2013b). The results are presented in Chapter 7 with the final qualitative analysis.

6.8 Member Checking

Member checking (respondent validation) is often used in qualitative research to verify findings and meet the criterion of confirmability (Sandelowski 2008, Schwandt 2015), However, there is controversy about the method, as participants may not be in a position to validate or even recall what was said, and interpretation in the form of theories or phenomenological description may be inaccessible to participants (Sandelowski 2008). Schwandt (2015, 196) states a consensus that "*member checking is not profitably viewed as either an act of validation or refutation but is simply another way of generating data and insight.*" One approach is to embed validation by asking for clarification on what has been said or done during data collection (Sandelowski 2008). In one study a form of real-time member checking was conducted through a Likert-scale questionnaire at the end of each session (Ridner et al. 2012).

Member checking for this study took the form of the embedding understanding during data collection through dual methods, both the online surveys at the conclusion of each module as well as the subsequent debrief sessions (individual modules and the entire testing process). Each of these offered opportunities for clarifications and additional insight about the process. The debrief sessions initially were coded separately to allow a comparison to and supplement of the understanding of the "in use" coding.

Detailed notes (including transcribed participant quotes) were provided to at least one participant at each pilot site for review and comment. Member checking surrounding the interpretation of the theory relative to HF/E opportunities and integration was not conducted, as this was beyond the purview of participant engagement. This is consistent with another study that made a conscious decision to forego member checking, using the process itself to ground the data (Laws et al. 2009). According to the authors, as the goal was to "*code all responses and organise into a new higher order theoretical model, it was not expected that participants would be able to recognise their individual contributions or concerns. It was therefore not appropriate to seek 'validation' from individual participants*" (Laws et al. 2009, 4).

6.9 Conclusion

The chapter outlined the qualitative and quantitative methods as an approach to better understand prevailing attitudes about safety, with a particular focus on falls, the case study topic. A convergent mixed method approach (Figure 6-2) for this study was used to gather and analyze qualitative (coding derived from audio files) and quantitative (online surveys) data to evolve theory. This was conducted through several hypothetical scenarios tested by the expert workgroups (Stage 4) and three real-world settings (Stage 5). These methods were established to (1) tactically consider usability, feasibility, and relevance as pertains to designing for safety, and to (2) strategically understand the potential of the tool to foster collaboration and integration of varied viewpoints through GT. While the description of the qualitative methods included preliminary results of coding, the final results of both qualitative and quantitative analysis are reported in Chapter7.

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7 Results of SRA Testing: Constructing Theory

7.1 Chapter Overview

Chapter 6 reported the study design and methodological approach to data collection and analysis for Stages 4 and 5. The purpose of Chapter 7 is to report the results and synthesize the findings of the SRA process (Stage 6) as an emergent theory of HF/E to support safety in EBD. The relationship to prior research reviewed in Chapter 3 (tool development and use) is presented, while the relationship to participatory processes in HF/E is discussed in Chapter 9.

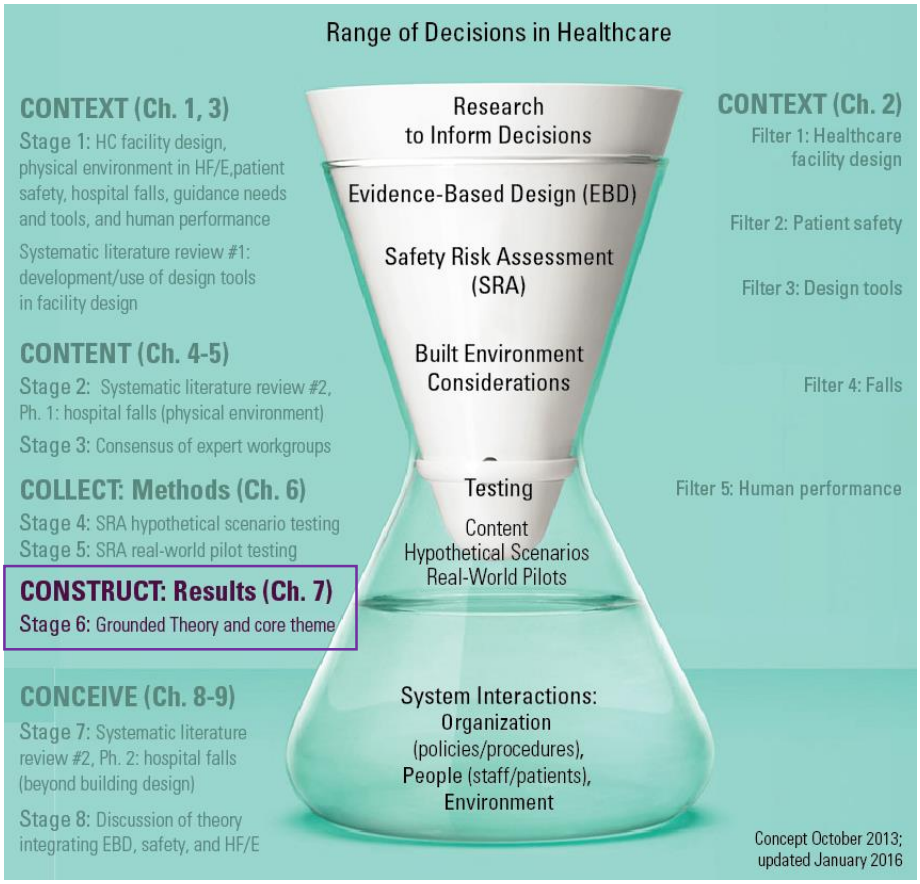

Figure 7-1. Chapter 7 signposting (construct)

7.2 Qualitative Summary

Throughout this chapter there are abbreviated references to the paired topics used to identify the hypothetical scenario teams (Table 7-1).

Table 7-1. Abbreviations for teams

Abbreviation	Topic/module
F/PH	Falls/Patient Handling
HAI/MS	Healthcare-Associated Infection/Medication Safety
BH/S	Behavioral Health/Security
PS	Pilot Site

To maintain anonymity, participant attributions are provided according to testing group: pilot site and consecutive participant number across all pilot sites (PS-#) or expert workgroup (Falls/Patient Handling [F/PH], HAI/Medication Safety [HAI/MS], and Behavioral Health/Security [BH/S]) and consecutive participant numbers across all seminar attendees (e.g., F/PH-#, HAI/MS-#, BH/S-#).

7.2.1 Central Theme: *Safety in Numbers? Anticipate to Integrate to Participate*

The emergent central theme from the analytical process discussed in Chapter 6 was Safety in Numbers? Anticipate to Participate to Integrate. This theme recognizes the value of a participatory process to advance safety, although not only in the sense of engaging a number of people but through collaboration and consensus-building. In other words, to optimize the design of the environment for safety, teams should *anticipate* adverse events and establish conditions to allow multiple end-users and stakeholders to *participate* in designing for safety where ideas emerge through collaborative discussion and converge on solutions that *integrate* considerations as teams build consensus. These three subthemes align with the stated research purpose and goals:

(1) Can the SRA effectively focus a discussion around design and safety for staff and patients?
(2) Does the SRA process foster collaboration and integration of different points of view?
(3) Can a systems perspective, beyond the environmental considerations, be introduced into the SRA process for HC facility design?

The emergent theoretical framework highlights group participation as compared to silos of a departmental user-group approach. This participatory process relies on views reflected through stakeholders representing diverse roles and expertise (recognizing that the number of participants alone is not a guarantee of success).

An NVivo model (Figure 7-2) was created to illustrate the node relationships representing the final core theme. The theme captured several existing paradigms faced by architects and owners identified in the tools literature review (Chapter 3), as well as insights into the evidence base (using, sharing, and managing knowledge) and guidance that gets synthesized into solutions to mitigate risk in HC facility design.

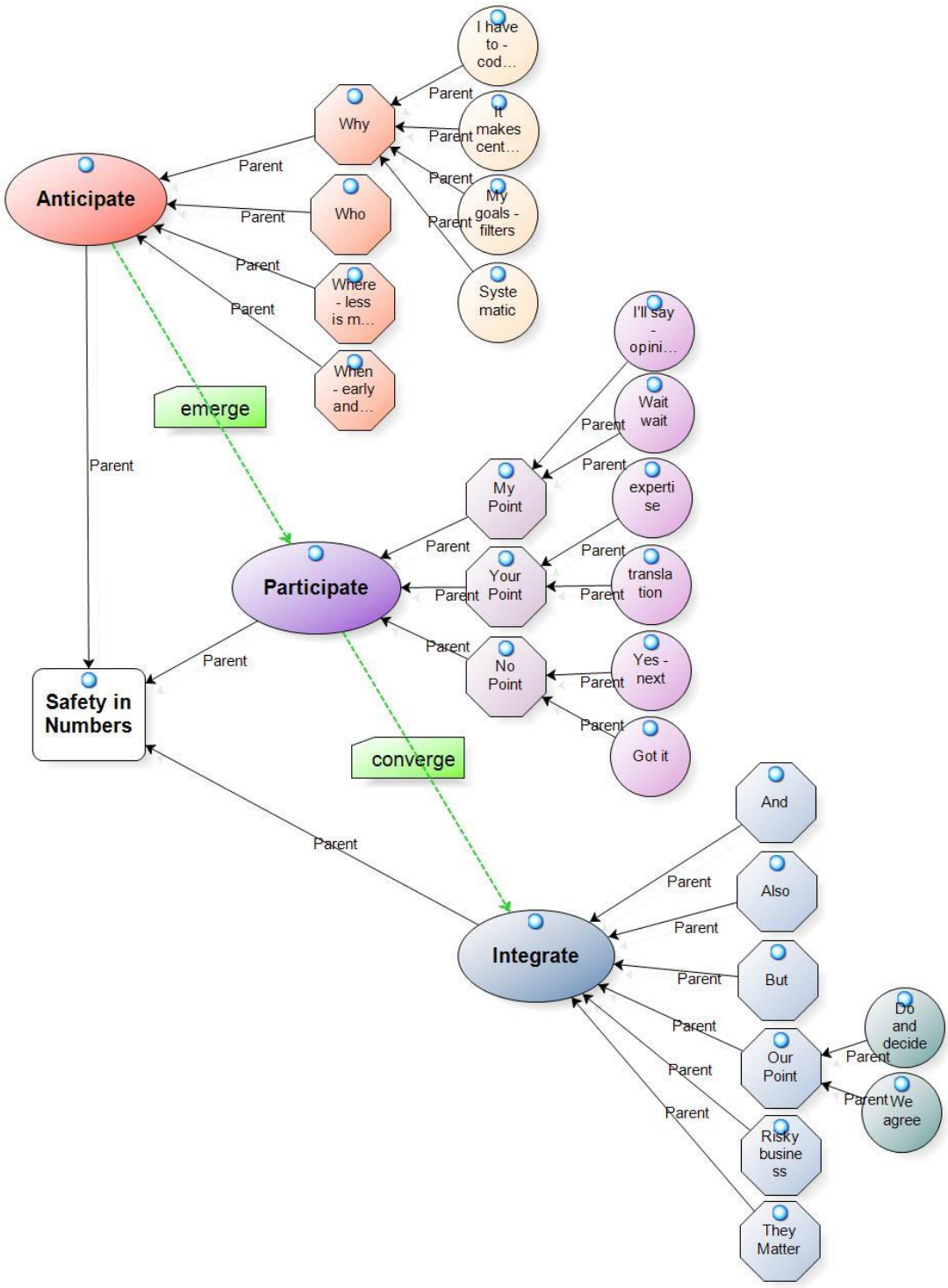

Figure 7-2. NVivo model: Safety in numbers? Anticpate to participate to integrate

7.2.2 Summary through Sample Quotes

To establish the context for the results presentation, a sample of illustrative quotes from node coding follows for each of the three primary subthemes, 'anticipate,' 'participate,' and 'integrate', which summarizes qualitative analysis (Table 7-2, Table 7-3, and Table 7-4). Additional quotes are provided in the narrative of the core theme that follows in Section 7.4.

Table 7-2. Summary quotes 'Anticipate'

Safety in numbers? Subtheme ANTICIPATE		
Section	Category	Sample Quote
7.3.1.1	When: Early/often	*"I look at this tool as before we really start the design… rather than us putting pencil to paper, this is a good tool to start the process;"* [PS-11] *"If we did it with the users before we started with schematic design . . . then we would do the design around what we agreed were the critical elements."* [PS-2]
7.3.1.2	Where: Less is more	"*You're not out there, actually in a prototype space. So you kind of have to imagine, so you bring all of that imagining with you."* [F/PH-11] *"I thought it was [most effective in] the low fidelity, where we could move stuff around and we didn't feel that – what I found was that in the high-fidelity room, where the things were fixed, I wanted to know why they were there, and I couldn't get over that."* [F/PH-7]
7.3.1.3	Who	*"It made us have the conversation very clearly."* [PS-29] . . . *"But that only works if the right people are in the room."* [PS-32] *"Correct. It only works with the right people in the room, but I like that it forced the discussion."* [PS-29]
7.3.1.4	Why: Systematic	*"I like the justification, or the rationale behind it. I think that really, kind of, sparks the thought of 'Why are we doing this?' And there is research that backs it up. So I think that was really a key thing to drive the discussion."* [PS-19]
	Why: Value	*"It [the design process] costs too much; it takes too much time; … and they [leadership] want an estimate first day that's within two percent of final project costs… once it's occupied and functional – that's the real cost."* [PS-14]
	Why: Prioritize	*"Do the exercise so that we can hear from everybody, what they're thinking, and then maybe use it as a tool in each meeting to say, 'Today we addressed this,' 'Remember we went back to our assessment and this is what we thought.'"* [PS-29] *"To help guide decisions."* [PS-30]
	Why: Regulatory	*"We have, for Joint Commission, things that are written up that have nothing to do with design, nothing we can do to fix it. It's really the people. Isn't that right?"* [PS-14] *"It's staff behavior."* [PS-19] *"But it seems like you could consider that, in this. It's good."* [PS-14]

Table 7-3. Summary quotes 'Participate'

Safety in numbers? Subtheme PARTICIPATE		
Section	Category	Sample Quote
7.3.2.1	My point	*"We always reach out to user groups, but sometime we just ask the question 'What are your needs?' but this organized and helped the user think through 'What <u>are</u> my needs?'" [PS-11]* *"In a different way, yeah." [PS-18]* "*The preference would be no curb and we'll deal with any water and mop it up…. To get a patient into that shower with any motor or sensory deficit…"* [PS-29] *"It's awful"* [PS-25]

Safety in numbers? Subtheme PARTICIPATE		
		"So a little bit of water and an extra towel is the preference…And the other thing I want to mention we can longer can disconnect patients from IVs for their showers, because of the CLABSI [central line associated blood stream infection], so we are very diligent about never disconnecting. In prior practice, we would free them up so they would be more comfortable taking a shower.[PS-29]
7.3.2.2	Your point	*"Well, this is not to mitigate the falls, this is to mitigate injury." [PS-4]* *"Yup, that's what that soft subfloor does [talking over each other]. [PS-1]* *"So the question is whether we're using that softer floor to mitigate the injury part." [PS-4]* *"And even if it could be around the perimeter of the bed, because that's where all the falls happen. That would even just make a big difference." [PS-7]* *"Have you tested that? Because we used to do that in epilepsy areas, like for neuro, and some, because of the cushion, some people were falling more because of give. …It's not with the cushion backing?" [PS-5]* *"On the top, it's VCT cheap tile. You would never know anything is underneath. It's still hard and firm on top. It's the subfloor." [PS-1] …* *"It distributes the, uh, force across the material, rather than, if I were to fall, and hit my elbow, it distributes that across so that you're less - it's really - yeah." [PS-7]*
7.3.3.3	No point	*"The way it stands now, there's nothing to evaluate against… The problem that we run into with the way it exist now, there could be a whole host of things that you could do to answer 'Yes,' but what if you only do one? Does that qualify for 'Yes?' What if you only do it a little bit? . . . It's a fine line with how much information you have to out in a question, to really be a guideline, to get a yes."* [F/PH-7] *"I like saying, 'Current design does not allow,' just to point out"* [F/PH-5] *"To show we thought about it"* [F/PH-7] *"Yeah, something. Now <u>they</u> have to think about it."* [F/PH-5]

Table 7-4. Summary quotes 'Integrate'

Safety in Numbers? Subtheme INTEGRATE		
Section	Category	Sample Quote
7.3.3.1	And	*"Well if you come in the room, from this one door, and the bathroom door is right there. It's not like it's hidden around a corner. You see it when you enter the room." [PS-5]* *"Well you're 80 years old, you've been narcotized, and you wake up in the middle of the night." [PS-6]*
7.3.3.2	Also	*"So a designer would be looking at this going 'So which rooms do I not have visibility? If we're going to add rooms here, do we have visibility at that point?' …"[F/PH-5]* *"… We say either another nursing station, or nursing, yes, on all four sides, at the center core." [F/PH-1]* *"So maybe catty-corner workstations to allow 360 visibility on all sides?" [F/PH-5]* *"Yeah." [F/PH-1]* *"And that would allow for a radius to turn, also. So our design recommendations to allow for both of those would be to cut those corners off the nurses station." [F/PH-5]*
7.3.3.3	But	*"Should I make a note about conflicting issues there? The slope for drainage versus the lips, or anything like that … It's tough."* [PS-1] *"Yeah. Friction versus the slope versus the water drainage. I think we all agree we don't have thresholds, but how big of a slope to keep water out of where, and the whole conversation is, 'Is it a one-drain bathroom versus a two-drain bathroom'… and the shower consideration"* [PS-2] *"And those weak patients think that little bitty slope is too much."* [PS-1] . . .

Safety in Numbers? Subtheme INTEGRATE		
		"Except we're not having the trench drain, we're having two separate drains… [PS-5] *"The drain we had was a long trough . . . They [infection control] were concerned it would sit in the trough, itself, and not get into the drain. . . . You're talking a little bit of water, but it's water, but it's moisture, but there's the potential for mold, as opposed to just a hole where it would just go down."* [PS-2]
7.3.3.4	Risky business	*… [Smooth transitions] that's high [priority]. Yeah, we've had falls because of that - bad falls."* [PS-29]
7.3.3.5	They matter	*"Knowing who the users of the room or the space are likely to be makes it easier to answer the questions."* [PS-12]
7.3.3.6	Our point	*"I think it's great to engage and build consensus of a whole group that are part of a design… and that's one of the toughest things for us, in our department, to build consensus. If everybody gave, you'd build a better product."* [PS-14]

7.2.3 Final Cluster Analysis

Following the emergence of the core theme, a final exploratory cluster analysis of coding was conducted in NVivo to review similarities of sources. While this type of analysis is not intended as a statistical method to draw conclusions, the final correlations (Table 7-5) were much higher as compared to the preliminary cluster analysis (Table 6-6).

Table 7-5. Final exploratory cluster analysis (top 20 using Pearson correlation coefficient)

Source A	Source B	PCC
TEAM 2: Low-fidelity *(C2_Falls-PH_2USE)*	**TEAM 2:** High-fidelity *(B2_Falls-PH_2USE)*	0.97
Team 1: Low-fidelity *(C1_Falls-PH_1USE)*	Team 2: Meeting *(A_Falls-PH_2USE)*	0.96
Team 1: Low-fidelity *(C1_Falls-PH_1USE)*	Team 2: High-fidelity *(B2_Falls-PH_2USE)*	0.96
Team 6: **Meeting** *(A_HAI-MS_6-USE)*	Team 5: **Meeting** *(A_HAI-MS_5-USE)*	0.95
Team 2: Low-fidelity *(C2_Falls-PH_2USE)*	Team 1: High-fidelity *(B1_Falls-PH_1USE)*	0.95
Team 2: **Low-fidelity** *(C2_Falls-PH_2USE)*	Team 1: **Low-fidelity** *(C1_Falls-PH_1USE)*	0.95
TEAM 1: High-fidelity *(B1_Falls-PH_1USE)*	**TEAM 1:** Meeting *(A_Falls-PH_1USE)*	0.94
Team 1: High-fidelity *(B1_Falls-PH_1USE)*	Team 2: Meeting *(A_Falls-PH_2USE)*	0.94
TEAM 2: High-fidelity *(B2_Falls-PH_2USE)*	**TEAM 2:** Meeting *(A_Falls-PH_2USE)*	0.94
Team 2: **High-fidelity** *(B2_Falls-PH_2USE)*	Team 1: **High-fidelity** *(B1_Falls-PH_1USE)*	0.94
TEAM 1: Low-fidelity *(C1_Falls-PH_1USE)*	**TEAM 1:** High-fidelity *(B1_Falls-PH_1USE)*	0.94
Team 2: Low-fidelity *(C2_Falls-PH_2USE)*	Team 1: Meeting *(A_Falls-PH_1USE)*	0.93
TEAM 2: Low-fidelity *(C2_Falls-PH_2USE)*	**TEAM 2:** Meeting *(A_Falls-PH_2USE)*	0.93
Team 2: **Meeting** *(A_Falls-PH_2USE)*	Team 1: **Meeting** *(A_Falls-PH_1USE)*	0.92
Team 2: High-fidelity *(B2_Falls-PH_2USE)*	Team 1: Meeting *(A_Falls-PH_1USE)*	0.92
TEAM 1: Low-fidelity *(C1_Falls-PH_1USE)*	**TEAM 1**: Meeting *(A_Falls-PH_1USE)*	0.91
TEAM 2: Low-fidelity DB *(C2_Falls-PH_2DB)*	**TEAM 2:** Meeting DB *(A_Falls-PH_2DB)*	0.83
Real-world Pilot 2 DB *(MSK_DB)*	**Real-world** Pilot 1 DB *(BJC_DB)*	0.76
Real-world Pilot 1 DB *(BJC_DB)*	Team 5: Meeting DB *(A_HAI-MS_5-DB)*	0.76
Pilot 2 DB *(MSK_DB)*	Team 5: Meeting DB *(A_HAI-MS_5-DB)*	0.70
PCC = Pearson Correlation Coefficient; DB = DB; **BOLD = setting correlation; COLORED CAPS = team correlation;** Topic correlation		

Whereas the preliminary coding had resulted in higher coding similarity between setting types (e.g., low-fidelity to low-fidelity), the final coding had a much higher rate of topic similarities between the coded sources (17 out of 20). There were also a higher number of similarities between the teams (e.g., Team 1 to Team 1). Within the top 20 correlations, this was almost an exact flip from the preliminary coding, with five similarities for setting types (as compared to eight) and seven similarities for team types (as compared to four).

Although final coding used the same code structure for both use and debrief session types, there was still a predominant overall clustering of use sessions separate from debrief sessions. (See Appendix K for a dendrogram visual representation.) There was minor overlap with the use sessions for pilot site 2, pilot site 3 (both in earlier stages of design), and the 'A' meeting modules for both medication safety teams (A5 and A6). However, while the debrief sessions were clustered, they were generally not highly correlated to one another. A comparison of coding presence was generated to understand the similarities and differences between Use and Debrief sessions (Table 7-6). Presence, as opposed to prevalence, is shown, as the number of considerations varies for each topic. As shown, there were only two codes that were exclusive to a test or debrief session. 'Where – less is more,' is a direct result of those comparing use of different settings during debriefing of hypothetical testing. 'Wait! Wait!' was captured during testing when a group returned to a consideration, but this was not explicitly noted by the participants during debriefing.

Table 7-6. Comparison of coding presence for use and debrief sessions

	A1	A2	A4	A5	A6	BJH	MSK	UCI	A1-DB	A2-DB	A4-DB	A5-DB	A6-DB	BJH-DB	MSK-DB	UCI-DB	All use	All debrief
Anticipate																		
When - early and often		•					•	•	•	•		•	•	•	•	•	•	•
Where - less is more										•	•	•						•
Why																		
I have to: Codes standards	•			•		•	•	•				•	•	•	•	•	•	•
It makes $ense: Value					•	•		•				•	•	•	•	•	•	•
My goals - filters	•			•	•	•	•	•		•	•	•	•	•	•	•	•	•
Systematic	•		•	•	•	•	•	•	•		•	•		•	•	•	•	•
Participate																		
My point																		
I'll say - opinion	•	•	•	•	•	•	•	•		•			•			•	•	•

	A1	A2	A4	A5	A6	BJH	MSK	UCI	A1-DB	A2-DB	A4-DB	A5-DB	A6-DB	BJH-DB	MSK-DB	UCI-DB	All use	All debrief
Wait! Wait!	•	•	•		•	•		•									•	
No point																		
Got it		•		•	•	•	•			•		•	•	•			•	•
Yes - next	•	•	•	•	•	•	•									•	•	•
Your point																		
Explain it	•	•	•	•	•	•	•	•				•					•	•
Translate it						•	•	•	•								•	•
Integrate																		
Also	•	•	•		•	•	•	•	•		•				•		•	•
And	•	•	•	•	•	•	•	•	•			•				•	•	•
But	•	•		•	•	•	•	•	•		•		•	•			•	•
Our point																		
Do and decide								•			•	•		•	•	•	•	•
We agree		•				•	•	•			•	•	•	•	•	•	•	•
Risky business				•	•	•	•						•				•	•
They matter	•	•		•	•	•	•	•	•		•						•	•

To better explain the model and pattern codes developed, narrative descriptions are included in Section 7.4 as a further representation of the central theme and testing observations (Miles, Huberman, and Saldaña 2013). The next section summarizes the quantitative results of the survey.

7.3 Quantitative Summary

7.3.1 Survey Results

Six questions were common to all participants testing the SRA tool. As an overall summary, bar charts to reflect the distribution of data (Figure 7-3).

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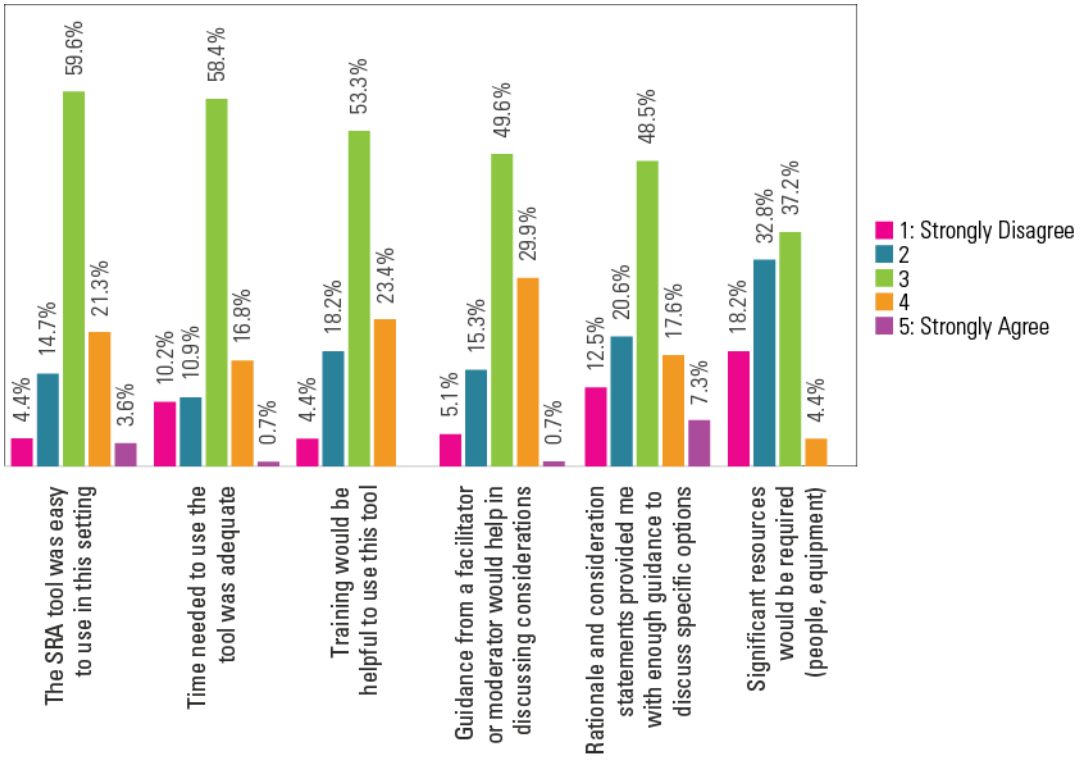

Figure 7-3. Bar charts for debrief survey questions (combined workgroups and pilot sites)

7.3.2 Kruskal-Wallis H tests

As previously discussed, probability distributions of data were compared with non-parametric tests for independent samples (Kruskal-Wallis H test) due to data characteristics. Comparisons were made according to:

- each team that tested the SRA (i.e., six workgroups and three pilot sites)
- the combined setting types (three module types for scenarios and the pilot sites combined as a "real-world" module)

The results are summarized in Table 7-7.

Table 7-7. Comparisons of all testing (independent-samples Kruskal-Wallis test)

	Teams (all)				Combined modules			
Null Hypothesis	Chi-Square	df	Asymp. Sig.	Decision	Chi-Square	df	Asymp. Sig.	Decision
"Easy to Use" is the same across column category "x"	13.247	8	0.104	Retain null	10.256	3	.017	**Reject null**
"Enough Time" is the same across column category "x"	23.038	8	0.003	**Reject null**	11.506	3	.009	**Reject null**
"Training" is the same across column category "x"	8.387	8	0.397	Retain null	1.366	3	.713	Retain null
"Guidance (person)" is the same across column category "x"	36.208	8	0	**Reject null**	18.553	3	.000	**Reject null**
"Guidance (rationale/ content)" is the same across column category "x"	39.379	8	0	**Reject null**	9.984	3	.019	**Reject null**
"Resources" is the same across column category "x"	10.272	8	0.246	Retain null	1.443	3	.696	Retain null

As shown, time and guidance were statistically different when analyzed for individual teams and setting types (combined modules). Ease of use was only statistically significant in settings. Post hoc pairwise testing determined the differences between both teams and settings, with statistically significant results summarized in Table 7-8.

Table 7-8. Comparisons of combined workgroups and pilot participants

Question	Sample 1-Sample 2	Test statistic	SE	Std. test statistic	Sig.	Adj. sig.
Easy to Use Setting	A to B: High-fidelity	-25.078	8.245	-3.041	.002	.014
Enough Time Settings	B: High-fidelity to Pilots	-36.829	8.928	-4.125	.000	.000
	A: Meeting to Pilots	-27.853	8.693	-3.204	.001	.008
Enough Time Teams	2 (F/PH) to UCI	45.000	13.871	3.244	.001	.042
	4 (BH/S) to UCI	46.677	13.400	3.483	.000	.018
	UCI to MSK	-48.398	13.621	-3.553	.000	.014
Guidance (person) Setting	B: High-fidelity to Pilots	-36.829	8.928	-4.125	.000	.000
	A: Meeting to Pilots	-27.853	8.693	-3.204	.001	.008
Guidance (person) Teams	2 (F/PH) to MSK	-62.407	24.072	-4.435	.000	.000
	BJH to MSK	-61.548	17.827	-3.452	.001	.020
	4 (BH/S) to MSK	-51.981	13.577	-3.829	.000	.005
	1 (F/PH) to MSK	-49.714	12.606	-3.944	.000	.003
	5 (HAI/MS) to MSK	-48.942	12.491	-3.918	.000	.003
	6 (HAI/MS) to MSK	-46.048	13.019	-3.537	.000	.015
Guidance (content/ rationale) Teams	2 (F/PH) to 6 (HAI/MS)	-44.891	13.226	-3.394	.001	.025
	2 (F/PH) to UCI	-46.385	14.412	-3.218	.001	.046
	2 (F/PH) to 4 (BH/S)	-46.621	13.924	-3.348	.001	.029
	2 (F/PH) to 5 (HAI/MS)	-48.767	12.854	-3.794	.000	.005
	2 (F/PH) to MSK	-76.237	14.710	-5.183	.000	.000
	3 (BH/s) to MSK	-65.517	14.231	-4.604	.000	.000
Guidance (content/ Rationale) Setting	A: Meeting to Pilots	--26.450	8.842	-2.992	.003	.017

As a mixed methods approach, additional statistically significant quantitative data are concurrently presented in Section 7.4 with the qualitative narrative, as described in Chapter 5.

7.4 Mixed Methods Narrative of the Core Theme

The following narratives include additional analysis of coding patterns related to these exploratory findings. Questions outlined by Strauss and Corbin (1998) and Scott (2004) were used to establish the story line of analysis. This includes:

- outlining the conditions when, where, and why the core theme occurs, as narrated in ‘anticipate’ (Section 7.4.1);
- identifying the actions and interactions through a review of how the core theme occurs, as narrated in ‘participate’ (Section 7.4.2); and
- understanding the consequences when the core theme occurs, as narrated in ‘integrate’ (Section 7.4.3).

The narrative focus is patient falls, as the qualitative analysis was predominantly conducted for falls/patient handling (F/PH) sources, the case study topic.

7.4.1 Anticipate (Conditions of the External Environment)

The analysis included in this section sets the stage for when, where, and why the SRA is used. It also presents who is engaged to understand participatory interactions and consequences that improve safety in design. Debrief sessions were the predominant source of coding related to anticipating the external environment. This is predicated on the awareness that adverse events will occur. The goal is to proactively consider the building as a setting that facilitates actions and behaviors to mitigate risk.

7.4.1.1 When: Early and Often

Feedback from debrief sessions during testing suggests the SRA process should occur during the earliest phases of design to support effective project planning: *"I look at this tool as before we really start the design. ... rather than us putting pencil to paper, this is a good tool to start the process"* [PS-11].

This feedback was heard most often at the pilot sites, who likely had a better sense of their own planning challenges in their project context: *"If you get too far into this, and then we're constrained by budget, and we went through the functional program and it was really dysfunctional, because we didn't consider these things"* [PS-14].

Participants also indicated early use would support prioritization of goals: *"If we did it with the users before we started with schematic design . . . then we would do the design around what we agreed were the critical elements*" [PS-2].

While including the SRA and multiple stakeholders as early as possible in planning, it could add cost. One team reflected:

> "It would be really helpful for us if we brought the architect and engineers while we're talking about the service delivery plan and the need for this project. Because if they understood why the hospital is building the project they would actually be armed with a lot more information that would help them design. And again, we don't do that because we think, 'Why would we invite designers to our business meetings?' . . ." [HAI/MS-18]

> "Having the architect and designer involved in the planning rationale maybe is important, but I get pushback for what it costs to have them there." [HAI/MS-20]

Participants testing the tool felt the process should reinforce decision-making through an iterative process over the course of the design, taking into account macro issues first and eventually moving to a greater level of detail.

> "I think part of the intent is that you might go back and use the tool multiple times. You might go through in schematic design and look at the question to do some prioritizing. We know we have an issue with falls. … These are the three things we want to address, and look at it and say, 'This assessment says that these are the things that are most related to high risk,' and let's talk about these conceptually. Then you start getting into the design; then you go back and say, 'have we looked at the visibility and the connection from the bed to the bathroom?' … So you go back and use it iteratively." [F/PH-1]

Additionally, the SRA process could be used as a communication device to align the understanding of priorities, goals, and objectives of the organization and project.

> "In all honesty, sometimes when you start a project, by the time you get to DD, you have different players. . . . Right now the medical planners we have on the project are very different than during concept planning. . . . having a tool like this to be consistent to make sure you're carrying through. . . . You increase your team as the phases go on, so that everyone knows [from this tool] why we're doing stuff." [PS-5]

Many commented on efficiency - the process itself needed to be streamlined for levels of detail that offered the right information at the right time. One example that emerged was addressing the need for patient handling at an early phase versus considering grab bars at a later phase. However, there was also an awareness of the need to balance a discussion of more detailed information that is often not considered until later in the process. A streamlined process is aligned with comments surrounding the efficient use of time. "*Time is of the essence… and it needs to be expedient for them to use*" [F/PH-6]. If not properly structured, "*Any time you give, you'll fill it*" [BH/S-32]. Time is further discussed as related to the setting (Section 7.4.1.2) and team (Section 7.4.1.3).

7.4.1.2 Where: Less is More

Settings affect how the SRA establishes participant interactions. Detail can act as a facilitator or barrier to thinking through new ideas. In Module A: Meeting Scenario, one participant felt *"You're not out there, actually in a prototype space. So you kind of have to imagine, so you bring all of that imagining with you"* [F/PH-11].

Another participant commented the most benefit was derived in Module C: Low-fidelity.

> "I thought it [the most benefit] was the low-fidelity, where we could move stuff around and we didn't feel that – what I found was that in the high-fidelity room, where the things were fixed, I wanted to know why they were there, and I couldn't get over that." [F/PH-7]

7.4.1.2.1 Easy to use

Consistent with qualitative data of bringing imagination to the process (i.e., requiring additional thought) participants felt Module A: Meeting was more difficult than the high-fidelity mock-up where many decisions had already been made. The Kruskal-Wallis H test for "Easy to Use" between the settings was significant χ^2 (3, N = 136) = 10.256, p = .017, with a mean rank score of 56.88 for A: Meeting; 81.96 for B: High-fidelity; 63.73 for C: Low-fidelity; and 72.79 for Pilots. The proportion of variability in the ranked "Easy to Use" scores was 0.69, indicating a strong relationship. (Effect size criteria based on rank-order data were defined by Cohen (1992) as strong [0.50], medium [0.30], and weak [0.10]). Post hoc tests were conducted to evaluate pairwise differences among the pilots. Statistically significant results were found only between A: Meeting and B: High-fidelity, p_{adj} = .014. There were no differences between the other combinations of settings. Response distributions are shown in Figure 7-4.

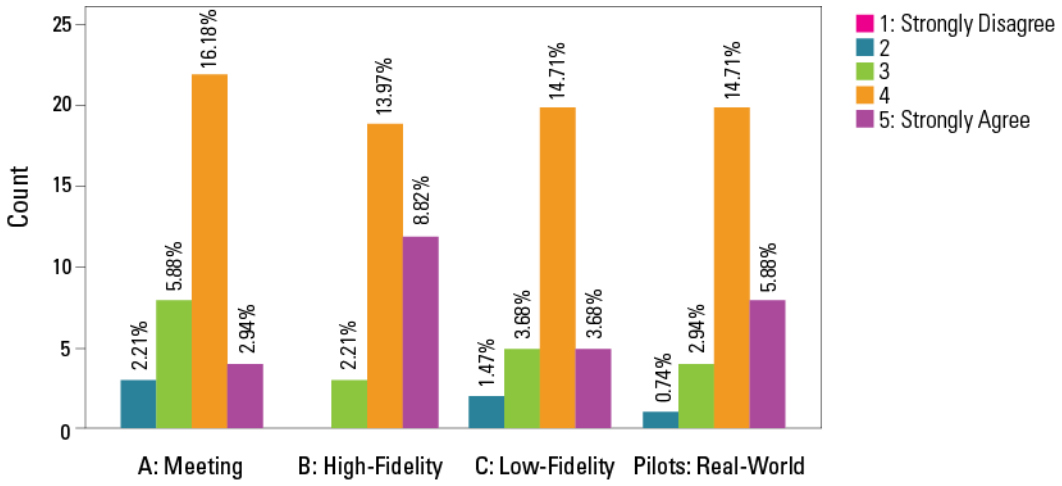

Figure 7-4. Easy to use by combined setting comparison

7.4.1.2.2 Setting and time

Quantitative results (Section 7.3) indicate the groups generally felt there was adequate time, with some variation according to the setting. As previously reported, the time used to discuss each consideration decreased with increased levels of detail provided (either through the setting or design phase), and this has a direct impact on actual and perceived time to conduct the SRA (Taylor, Quan, and Joseph 2015). In meeting settings (Module A and pilot sites) where there was no tangible setting for reference, there were more responses indicating a lack of time as compared to Module B: High-fidelity with the most detailed physical setting. While this might also be attributed to the novelty of testing in the hypothetical scenarios, statistical analysis did not reveal any perceived differences in time between the first and second use. However, there were differences between the first and last use in the hypothetical scenarios. This is discussed in Section 7.4.1.3.2.

7.4.1.3 Who (Teams)

As shown in Figure 6-9, there was a diverse group of experts for testing, described as a "dream team" by one group (HAI-MS, Team 5). This raises the importance of engaging the right team.

> "It made us have the conversation very clearly. . . ." [PS-29]
>
> "But that only works if the right people are in the room." [PS-32]
>
> "Correct. It only works with the right people in the room, but I like that it forced the discussion. . . . Because you know, the architect may assume." [PS-29]

During pilot testing, staff was recruited to represent pharmacy, nursing, and infection prevention. Participants found the SRA process differed from traditional inclusion and engaged these users in a different way. As one pilot site offered:

> "We always reach out to user groups, but sometimes we just ask the question, 'What are your needs?' but this organized and helped the user think through 'What are my needs?'" [PS-11]

> "In a different way, yeah." [PS-18]

7.4.1.3.1 Teams versus topics

While the final cluster analysis suggests a strong alignment for topics (Table 7-5), analysis suggests further implications for teams. Figure 7-5 visually represents presence of coding for the nodes across all individual 'Module A: Meeting' and real-world pilot site test use sessions (versus debriefs). The figure is organized by topic and as shown, there is not a presence of coding for any single topic as compared to others. As topics were paired during the hypothetical scenarios and the pilot sites reviewed multiple topics, this represents coding associated with a specific SRA consideration identified through a node classification (e.g., item #100 = falls). Presence, as opposed to prevalence, is shown, as the number of considerations varies for each topic.

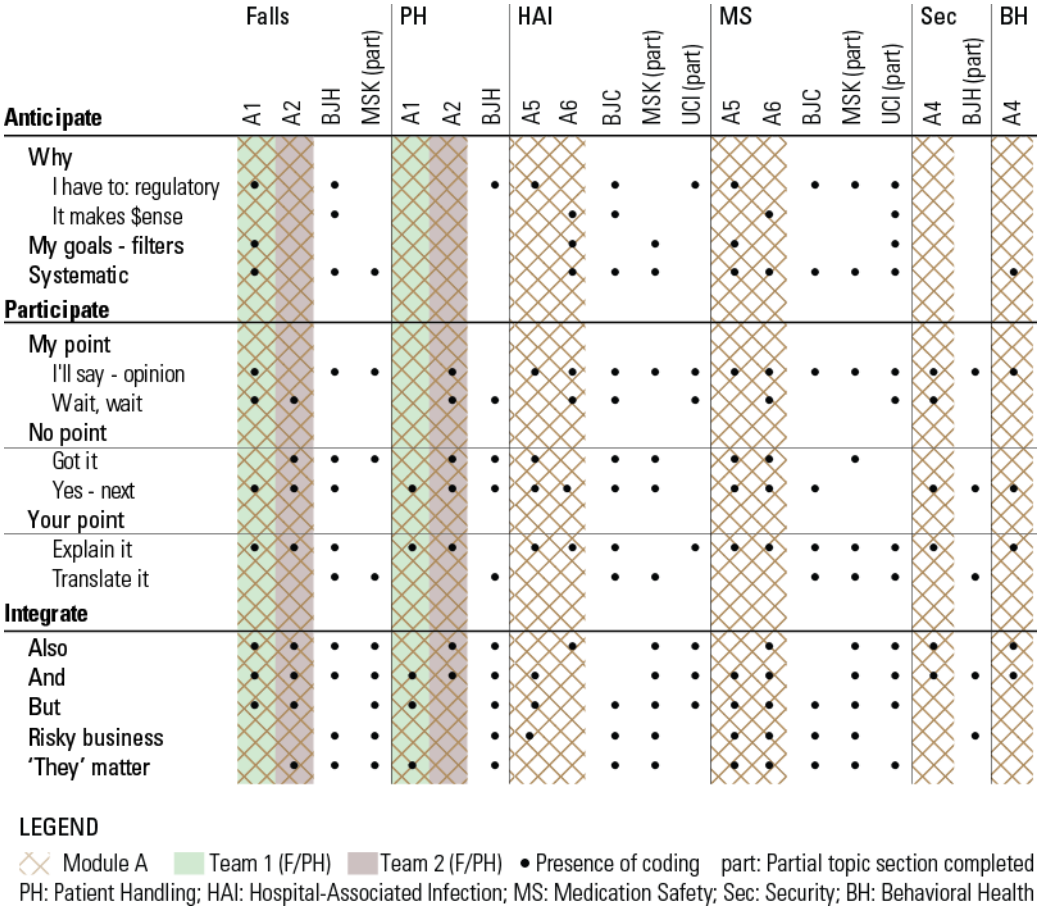

Figure 7-5. Coding presence across teams (Module A and pilot sites)

However, different teams within the same topic revealed different ways of thinking. For example, between the two teams reviewing falls and patient handling, there were noticeable differences in coding patterns. Table 7-9 reflects the general prevalence of coding for each team across all modules (A: Meeting, B: High-fidelity, C: Low-fidelity) and debrief sessions.

Table 7-9. Coding comparison - all F/PH modules (use and debrief)

Node	Team 1	Team 2
Anticipate		
When - early and often	●	●
Where - less is more	●	●●
Why		
I have to - codes standards	●	●
It makes $ense - value	●	
My goals - filters	●●	●●
Systematic	●	●
Participate		
My point		
I'll say - opinion	●●●	●
Wait! Wait!	●	●●

Node	Team 1	Team 2
No Point		
Got it	●●●	●●●●●●
Yes - next	●●	●●●●
Your point		
Explain it	●●●●	●●
Translate it	●	
Integrate		
Also	●●●	●
And	●●●	●●
But	●●●	●
Our point		
Do and decide	●	●
We agree	●	●
Risky business	●	●
They matter	●	●●

As shown, while both teams may have fallen subject to the silo mentality of little or no discussion during testing (No point), Team 2 seemed more likely to demonstrate this lack of discussion (further discussed in Section 7.4.2.3.2). A consistent difference between teams also occurred in the self-scoring for Guidance (Content/Rationale). Team 2 self-scored lower than nearly every other team (3, 4, 5, 6, UCI, MSK). This will be explored in Section 7.4.2.2.3. This may also be an indicator that the quality of discussions will be based upon the individuals selected to participate, rather than the content of the tool alone.

7.4.1.3.2 Teams and time

While the perceived time for use varied between settings, there was more variation when comparing results across the individual teams (Taylor, Quan, and Joseph 2015). Those teams engaging in a more proactive discussion (hence taking more time for each consideration) were more likely to indicate there was not enough time allocated. For example, the Kruskal-Wallis H test for "Enough Time" between the teams was significant χ^2 (8, N = 137) = 23.038, p = .003, with a mean rank score for Team 1 (F/PH), 76.83; for Team 2 (F/PH), 82.42; for Team 3 (BH/S), 60.87; for Team 4 (BH/S), 84.10; for Team 5 (HAI/MS), 65.76; for Team 6 (HAI/MS), 66.03; for BJH, 45.00; for UCI, 37.42; and for MSK, 85.82. The proportion of variability in the ranked "Enough Time" scores was 0.44, indicating a moderately strong relationship. Most of the statistically significant differences occurred between UCI (a team earliest in the design process and exhibiting the most discussion) and the teams

that exhibited the most silos in coding (Teams 2 and 4). The differences between UCI and MSK and Team 3 and MSK were also statistically significant, with pilot site MSK benefitting from a fully facilitated session.

Post hoc tests to evaluate pairwise differences among the teams indicated significant differences with UCI to Team 2 (F/PH), p_{adj} =.042, UCI to 4: BH/S, p_{adj} =.018, and UCI to MSK, p_{adj} =.000. There was also a significant difference between Team 3 (BH/S) and MSK, p_{adj} =.014. There were no other significant differences between the other team combinations, and while visually there appears to be a pattern associated with topics (i.e., Teams 5 and 6 for HAI/MS), there were no statistically significant differences when teams were grouped by topic (p=0.123). The distribution of responses in shown in Figure 7-6.

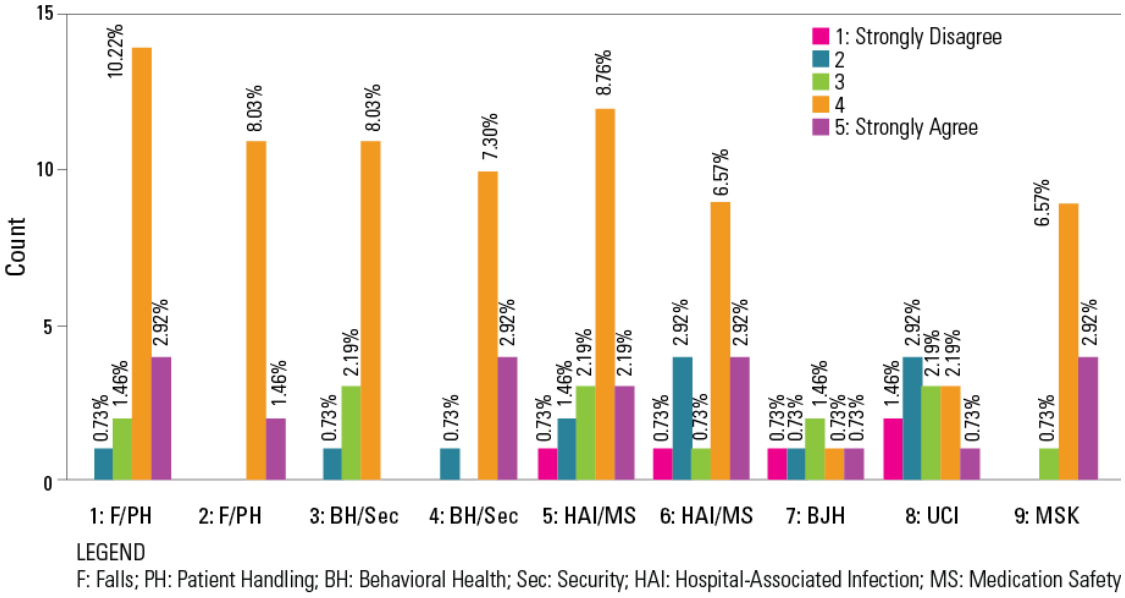

Figure 7-6. Enough time by all teams comparison

Additionally, as referenced in Section 7.4.1.2.2 for settings, there was a difference between perceived time for first and last use.

7.4.1.4 Why

In both the use and debrief sessions participants shared that the SRA could be used for several reasons to:

- enlist a systematic process instead of basing safety decisions on opinions (Section 7.4.1.4.1);
- define goals and set filters (Section 7.4.1.4.2);

- create financial return (directly through reimbursement or through whole-life cost analysis) (Section 7.4.1.4.3); or
- meet regulatory requirements (Section 7.4.1.4.4).

7.4.1.4.1 Systematic

During debrief sessions the level and type of evidence (beyond personal experience) was referenced as an important part of the process.

> "I like the justification, or the rationale behind it. I think that really, kind of, sparks the thought of 'Why are we doing this?' And there is research that backs it up. So I think that was really a key thing to drive the discussion." [PS-19]

And:

> "I like that fact that you're taking evidence from the industry and bringing it here into the tool, as opposed to all of us that bring our collective memories of things to the table, which I think we do a good job of, but it's a great way to make sure it's a systematic way that we're addressing key issues." [PS-29]

There were only few instances that a discussion addressed research findings themselves. During use, the evidence was sometimes called into question (often in infection control). This supported having someone knowledgeable in the topic area to advance the discussion when needed.

7.4.1.4.2 Goals and filters

During debrief sessions the SRA was seen as having potential for identifying strategic priorities for the organization. The focus on safety presents opportunities for targeted discussion and this might be used to inform general design meetings:

> "Do the exercise so that we can hear from everybody, what they're thinking, and then maybe use it as a tool in each meeting to say, 'Today we addressed this,' 'Remember we went back to our assessment and this is what we thought.'" [PS-29]

> "To help guide decisions." [PS-30]

> "Historically it's been about the department and their needs and this is really about the patient. … so it flips the paradigm of what we're all integrating. …" [PS-29]

> "And when you're all at the table talking about safety – that give and take, so what I think is safe might not – maybe pharmacy's need is more of a priority." [PS-26]

> "And then we should think about it. 'Which is the priority?'… Like our conversation about a wet floor versus the slant, the lip, we felt differently about it than what most people logically thought." [PS-29]

7.4.1.4.3 It makes $ense

Design solutions are often not considered in the context of the life-cycle of the facility. This sentiment was relayed during one pilot session debriefs. *"It costs too much; it takes too much time. . . . and they [leadership] want an estimate first day that's within 2 percent of final project costs. . . . Once it's occupied and functional – that's the real cost"* [PS-14].

The potential to quantify financial value was not expressed with respect to falls during use of the tool. It was more often referenced when discussing patient handling (the cost of a single staff injury providing the return) or more generally by participants in the infection control and medication safety groups when reflecting on "*the cost of getting it wrong*" [HAI/MS-18].

7.4.1.4.4 I have to

Just as falls risk assessments are mandated by accrediting bodies in the US, regulatory and accreditation requirements were often referenced during debrief sessions as a key to integration and implementation of the SRA. However, much of the regulatory and accreditation environment focuses on operations versus the supportive conditions that might optimize the system. This underlying theme was articulated by one participant.

> "We have, for Joint Commission, things that are written up that have nothing to do with design, nothing we can do to fix it. It's really the people. Isn't that right?" [PS-14]

> "It's staff behavior." [PS-19]

> "But it seems like you could consider that, in this. It's good." [PS-14]

However, compliance does not guarantee success or effective use: *"Sometimes it's easier to meet the prescriptive, but miss the intent"* [F/PH-5].

At a more detailed level, when individual considerations were aligned with a regulatory standard when discussing considerations, the conversation was often stopped short of any discussion. *"People of different heights? Not really. I've never seen that… Because the ADA really governs the heights of those"* [PS-3].

In another instance, the discussion never took place as the group felt a decision had been made by policy, rather than discuss whether the standard was still relevant. *"They would continue whatever is in their hospital. . . . They would follow policy"* [F/PH-6, others agreeing].

7.4.2 Participate (Actions/Interactions and How the SRA is Used)

The analysis included in this section sets the stage for understanding participatory engagement (how the SRA process is used). The SRA has the potential to allow multiple points of view to be expressed by creating a systematic platform for discussion. This discussion balances how people share knowledge and offers the opportunity to engage:

- end-users who can articulate the tacit knowledge of their work ('My point – I'll say'; 'My point – Wait! Wait!'),
- subject matter experts who can offer a wider view and educate the team ('Your point – explain that'), and
- design professionals to describe how an objective can be (or was) met spatially ('Your point – translate that').

However, silos are still prevalent, and the SRA process does not guarantee collaboration. This highlighted the need for prompting or facilitating the discussion.

7.4.2.1 My point

The subthemes 'I'll say' and 'Wait! Wait!' represent both participation and reflection and offered end-users of the space an opportunity to articulate tacit knowledge of the organizational operations and policies or share personal experience (e.g., 'at my facility'). The end-user perspective was most often represented by nurses during pilot testing, although some participants speculated on the patient perspective.

7.4.2.1.1 I'll say

Environmental hazards were most prevalent in both 'I'll say' and 'Wait! Wait!' subthemes. In 'I'll say' this was often concerning flooring conditions. For example,

with smooth flooring transitions to reduce falls, one non-clinician participant offered, *"One of the problems we're having in actual facilities where we've done this is that the shower water runs out and people end up putting towels on the floor"* [F/PH-2].

However, this comment addresses a single environmental hazard and may not address the complexity involved in the decision. In contrast, a discussion at one of the pilot sites highlighted the need to understand the interaction of the environment (the floor transition), the users (both patient condition/limitations and staff physical limitations), and organizational issues surrounding care policies (an IV staying in place).

> "The preference would be no curb and we'll deal with any water and mop it up. . . . To get a patient into that shower with any motor or sensory deficit—" [PS-29]
>
> "It's awful—" [PS-25]
>
> "So a little bit of water and an extra towel is the preference. . . . And the other thing I want to mention we can longer can disconnect patients from IVs for their showers, because of the CLABSI [central line associated blood stream infection], so we are very diligent about never disconnecting. In prior practice, we would free them up so they would be more comfortable taking a shower. [PS-29]

7.4.2.1.2 Wait! Wait!

The SRA process also allowed participants to reflect on what had been said and then return for clarification or closure after the group had moved. Many comments surrounded environmental hazards, but they also addressed visualization of patterning and contrast in flooring and walls. However, a lengthier probe surrounded the physical limitations of a patient and proximity of the bed to the toilet. In this instance what was initially a quick "Got it" turned into a more lengthy discussion. Participants articulated assumptions and elaborated on the reasoning for a possible solution that also integrated the considerations of the environment and the user. Tangential benefits of visibility and operability of patient-handling equipment were referenced, as well.

> "We have that." [F/PH-3]
>
> "Say 'done'." [F/PH-1]

"But with that, again, the position of the bed in the room, does it matter if you've got the - again I'm looking at the layout here." [F/PH-5]

"We also said we'd change the doors." [F/PH-4]

"So how close. Do we want to make a recommendation that when you place the bed, it's so close to the door to allow equipment to be moved around, but that might have impact on space arrangements on other things? . . ." [F/PH-5]

"We talked about, so when we talked about straight access to the bathroom, I presume we were talking about moving the door to the other wall." [F/PH-1]

"Between this dead space and the other wall that could be used for something." [F/PH-4]

"Which could be used for some other thing. I guess I'd like to have that be a sliding door, not a swinging door, because if it's a swing door, you tend to keep it closed and then if you're not using the lift, and you've got a walker, it's much harder to navigate and open the door, and get it out of the way, and everything else, where if it's a sliding door, you can slide the door." [F/PH-1]

"Keep it open." [F/PH-4]

"And direct visibility in helps." [F/PH-1]

"It's probably better for lift equipment also." [F/PH-6]

As illustrated in this example, reflection was often within a short period, but it occasionally would take place intermittently throughout the session as the design conversation evolved. At one of the pilot sites, the SRA was used to initiate a discussion about the number and location of isolation rooms and the number and location of medication rooms. Both of these discussions started as individual considerations but evolved over the course of the session, starting with one proposed solution and ending with other solutions after integrating considerations, discussing optimum workflows, and realizing the implications of typical staffing assignments for higher-acuity patients.

7.4.2.2 Your point

7.4.2.2.1 Explain that

In many cases, SRA content benefitted from subject matter expertise to adequately address the safety conditions (e.g., ergonomic analysis for patient handling). Expert workgroups sometimes offered a more robust view of what "could

be," based on their familiarity with approaches in multiple settings or through in-depth experiences from their own organizations. However, the benefit of expertise went beyond solving the problem. In many cases, the SRA became a venue where questions could be asked and explanations offered to educate others about how or why something works. The most prevalent coding surrounded patient physical limitations as well as patient visualization of the physical environment. At one pilot site, flooring characteristics were raised relative to the patient-floor interaction and movement.

> "Well, this is not to mitigate the falls, this is to mitigate injury." [PS-4]
>
> "Yup, that's what that soft subfloor does. [talking over each other] [PS-1]
>
> "So the question is whether we're using that softer floor to mitigate the injury part." [PS-4]
>
> "And even if it could be around the perimeter of the bed, because that's where all the falls happen. That would even just make a big difference." [PS-7]
>
> "Have you tested that?, because we used to do that in epilepsy areas, like for neuro, and some, because of the cushion, some people were falling more because of give. . . . It's not with the cushion backing?" [PS-5]
>
> "On the top, it's VCT cheap tile. You would never know anything is underneath. It's still hard and firm on top. It's the subfloor. . . ." [PS-1]
>
> "It distributes the, uh, force across the material, rather than, if I were to fall, and hit my elbow, it distributes that across so that you're less - it's really - yeah." [PS-7]
>
> At another pilot site, there was a question about identification of the bathroom:
>
> "So that is a safety tenet that it has to be clearly identifiable?" [PS-29]
>
> "Well, in Calkins—" [PS-25]
>
> [researcher explanation: visibility vs. proximity]
>
> "—The limitation of study, they didn't look, because it was done a while ago, there weren't that many rooms with a handrail in it, so that sample was one out of 26 or 23? So basically, the question as to whether or not having a handrail to the bathroom works is still a question that has only been intuitively answered. It's just our intuition. You usually can't have both. . . ." [PS-25]
>
> Competing drivers are furthered in Section 7.4.3.3.

7.4.2.2.2 Translate that

In conditions where the team is further along in a design process, design team members would also add expertise, but in the form of translation - explaining how a solution had been achieved (or was limited by existing conditions). This was not a re-evaluation of design but offered as a point of confirmation for other participants. In some cases, the solution was tangible (e.g., floor pattern) even though the discussion was rooted in a less tangible latent condition of a patient's visualization of perceived steps or holes in level surfaces at an individual level. *"[The floor will be] vinyl tile… The corridor is going to be one color, and then there's going to be a pattern in the room that's going to come out one foot. But it's not like contrast"* [PS-5].

In other cases, the explained solution might be more subjective, such as visibility and layout influencing staff observation. This acknowledged accommodations needed for work activities, such as charting/documenting within the patient view, to simultaneously allow patient visualization.

> "We really focused on the ability to have the nurse workstation. As you can see, in the [unit] where the yellow highlight is going, going north, up and down, if you can point out where we're adding workstations, so right here [pointing to a plan] for that bed, here, a bunch of them along that wall there, and we'll have the ability to see into two [rooms]." [PS-25]

> "Right, we also talked about glass so that you'd be able to see more than one bed. All of our other beds, it is really the traditional view, on that east wall of looking in the door and seeing the two heads of the bed." [PS-29]

7.4.2.2.3 Tell me more

As suggested by quantitative results, the level of expertise or translation may need to vary by topic, especially in the case of falls where research findings are multifactorial with complexity, confounders, and bundles of interventions that can lead to a less than clear direction for solutions (see Chapter 4). For example, the Kruskal-Wallis H test for "Guidance (content/rationale)" between the topic groups was significant χ^2 (2, N = 105) = 8.785, p = .012, with a mean rank score of 44.85 for Falls/Patient Handling (F/PH), 48.38 for Psychiatric Injury (BH)/Security, and 63.13 for Infection (HAI)/Medication Safety. (The distribution of responses is shown in Figure 7-7.) The proportion of variability in the ranked "Guidance (content/rationale)" scores was 0.71, indicating a very strong relationship. Post hoc testing indicated a

significant difference between F/PH and HAI/MS, p_{adj} = .017. There were no significant differences between F/PH and BH/S, p_{adj} = 1.00 and BH/S and HAI/MS, p_{adj} = .093.

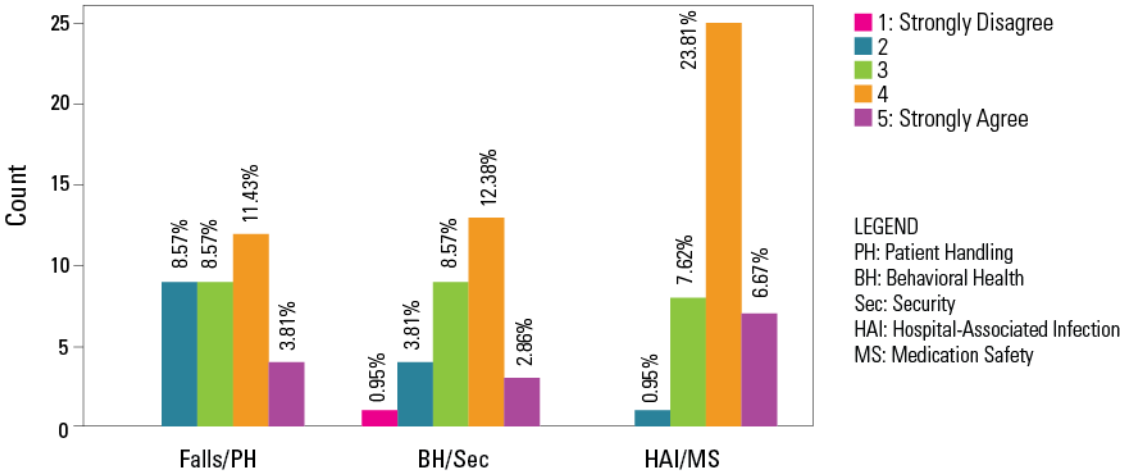

Figure 7-7. Guidance (content/rationale) by topic comparison

There were also statistically significant differences in Guidance (person), where MSK self-scored higher than nearly all other teams (1, 2, 4, 5, 6, BJH). Distributions are shown in Figure 7-8. These results reflect the perceived benefit according to those who had guidance during testing. The Kruskal-Wallis H test for "Guidance (person)" between the teams was significant χ^2 (8, N = 137) = 36.208, p = .000, with a mean rank score for Team 1 (F/PH), 59.50; for Team 2 (F/PH), 46.81; for Team 3 (BH/S), 84.30; for Team 4 (BH/S), 57.23; for Team 5 (HAI/MS), 60.27; for Team 6 (HAI/MS), 63.17; for BJH, 47.67; for UCI, 91.85; and for MSK, 109.21.

The proportion of variability in the ranked "Guidance (person)" scores was 0.43, indicating a moderately strong relationship. Post hoc tests were conducted to evaluate pairwise differences among the teams. Results indicated statistically significant differences between 1 (F/PH) to MSK, p_{adj} = .003; 2 (F/PH) and MSK, p_{adj} = .000; 4 BH/S) to MSK, p_{adj} = .005; 5 (HAI/MS) to MSK, p_{adj} = .003; and 6 (HAI/MS) to MSK, p_{adj} = .015; and BJH and MSK, p_{adj} = .020. (MSK was the only team that participated in a facilitated format.) There were no other statistically significant differences between teams.

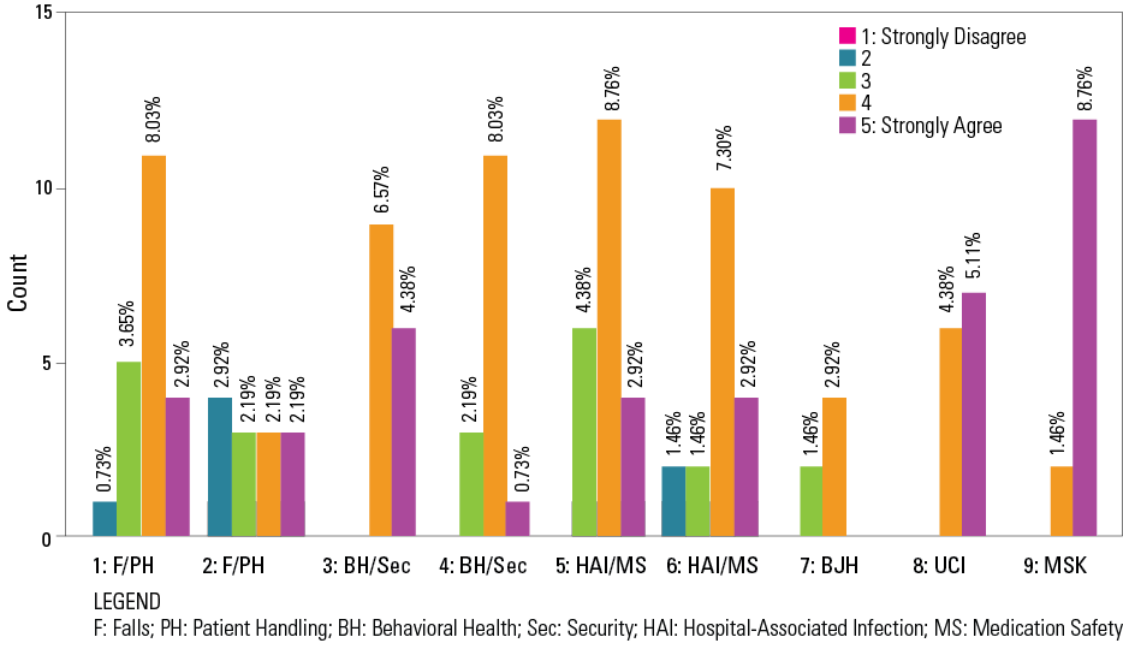

Figure 7-8. Guidance (person) by all teams comparison

7.4.2.3 No point

One prevalent theme occurring in all teams and settings was silos, where no particular point of view was articulated. In this case, considerations and decisions are advanced without discussion and without context. Unarticulated assumptions are being made about what is (or should be) included – items that *"in truth, you just kind of take for granted"* [PS-19] but in reality may be assumed differently by others.

7.4.2.3.1 Yes, next

A significant challenge encountered in testing the SRA was the potential for a checklist mentality, merely responding 'Yes' and moving on to the next consideration. In some cases this was illustrative of the traditional silos that exist in many HC facility design projects. In some cases this was enabled by dominant personalities that even in the face of discussion would move on to the next item. One participant pushed the group considering a hypothetical scenario to do more, recognizing that time could become a barrier. *"We already know all of these things are important, which is why they're in the SRA. … So we shouldn't just be saying 'yeah, that's important, and that's important"* [F/PH-5].

The group then responded with a brief discussion and proactive solution that provided an integrated solution for more than one problem (See Section 7.4.3).

7.4.2.3.2 Got it

While some workgroups and participants were able to use the SRA as a prompt for proactive discussion, others struggled with using the SRA as an audit tool for compliance. Rather than thinking about how to modify the design, some were focused on how to quantify responses:

> "The way it stands now, there's nothing to evaluate against… The problem that we run into with the way it exists now, there could be a whole host of things that you could do to answer 'yes," but what if you only do one? Does that qualify for 'yes?' What if you only do it a little bit?. . . It's a fine line with how much information you have to put in a question, to really be a guideline, to get a yes." [F/PH-7]

Others focused on evaluating the scenario plan or mock-up space, suggesting a lack of engagement and (perhaps) empowerment in the process.

> "I like saying, 'Current design does not allow,' just to point out—" [F/PH-5]
>
> "To show we thought about it." [F/PH-7]
>
> "Yeah, something. Now they have to think about it." [F/PH-5]

7.4.3 Integrate (Consequences)

The participation of multiple users and stakeholders can lead to better integrated solutions.

> "I like the concept of integration that has me thinking. Nothing you recommend is in isolation." [F/PH-5]
>
> "Right." [all]
>
> "So if you do move something here, and then we go through all the rest of the questions, then all of the sudden maybe here isn't such a good idea because something else touches it." [F/PH-5]
>
> "And then one of the other groups might go, 'Well you can't move that there; we already moved that cabinet out.'" [F/PH-4]

7.4.3.1 And

Integrated discussion ('And') builds on multiple points of view and has the potential to address system interactions that take into account the organization, people, and environment, as opposed to just meeting a requirement. According to one

participant, the discussion can connect non-users of the space (e.g., administration, architects) with an understanding of the operations. The node coding for 'and' was most prevalent for environmental hazards (flooring) and visibility (room and unit layout) and was most often associated with the larger workspace envelope and the ability for users to perceive physical conditions. The discussions often highlighted the need to understand patient conditions and limitations (Section 7.4.3.5) that were not always recognized or understood by participants:

> "Well, if you come in the room, from this one door, and the bathroom door is right there. It's not like it's hidden around a corner. You see it when you enter the room." [PS-5]

> "Well, you're 80 years old, you've been narcotized, and you wake up in the middle of the night." [PS-6]

Another group had a similar issue concerning bathroom visibility and highlighted the complexity of designing the environment and balancing needs of patient populations:

> "Well, if it's close, I don't know that you need to see it." [F/PH-14]

> "Well, but there's some research that says that the door should be on the same side as the headwall - over there - because it's closer, but the flip side of the research says it's better to see the door, so this is taking the position of seeing the door. . . ." [F/PH-12]

> "The falls research that it's drawing on is basically that if you've got an elderly population with a level of confusion, which may just be delirium and UTI-related, rather than a dementia process, and to actually be able to clearly see." [F/PH-10] (Agreement of the group)

> "Well, it's not just the elderly. … It's also if you're on a lot of drugs. You're coming out of surgery and you're kind of groggy. 'Oh, where's the bathroom?' and you see it." [F/PH-12]

7.4.3.2 Also

Through familiarity with the content, participants were able to identify where a proposed solution might solve other considerations or result in a solution seen as *"good patient-centered care"* [F/PH-14] (e.g., reducing noise).

For example, after one group (Module A1: Meeting) discussed the need to move beyond simple yes and no answers, a more proactive approach was considered

to address visibility at the individual level. The solution provided an integrated solution, simultaneously improving physical limitations of staff associated with patient handling activities (maneuverability of equipment).

> "So a designer would be looking at this going, 'So which rooms do I not have visibility? If we're going to add rooms here, do we have visibility at that point?' . . ." [F/PH-5]

> "We say either another nursing station, or nursing, yes, on all four sides, at the center core." [F/PH-1]

> "So maybe catty-corner workstations to allow 360 visibility on all sides?" [F/PH-5]

> "Yeah." [F/PH-1]

> "And that would allow for a radius to turn, also. So our design recommendations to allow for both of those would be to cut those corners off the nurses station." [F/PH-5]

> "Local nursing stations at the four corners." [F/PH-4]

> "That works out well." [F/PH-6]

7.4.3.3 But

The SRA process also allowed discussion surrounding competing drivers. These discussions sometimes involve budgets and existing structural constraints that limit optimized conditions.

> "We could technically change where the nurses stations are, have more multiples to avoid having to have the monitoring, right?" [F/PH-3]

> "Yes, but remember - there's a limited budget per bed and a lot of remote nursing station spaces will be expensive." [F/PH-1]

> "And there's some by the patient transport elevators that, no matter what you do, you're not going to see them." [F/PH-2]

At other times, solving one problem may have undesirable consequences. For example, a door could be positioned to allow visibility into a bathroom and straight tracking of a patient lift to the toilet, but the relocated door impinged on privacy. A decision needs to balance the priorities of the organization.

> "Rather than how it is here where the door is opening and there's a hallway and you switch it and now it's open to the whole room, and you have—" [F/PH-4]
>
> "On the other hand, research shows that most falls happen when people are getting out of bed at night and they're trying to find the bathroom, and if they can see directly into the bathroom, it's probably less, so—"[F/PH-1]
>
> "That's right." [F/PH-4]
>
> "—I would suggest the privacy issue isn't as important as the safety issue." [F/PH-1]

While discussions sometimes balanced a comfort or aesthetic issue against a safety issue (e.g., privacy versus visibility), a discussion may sometimes confront a competing safety issue. For falls, this often surrounded bathroom floor transitions (a trip hazard) versus wet floors (a slip hazard) and even infection control.

> "Yeah. Friction versus the slope versus the water drainage. I think we all agree we don't have thresholds, but how big of a slope to keep water out of where, and the whole conversation is, 'Is it a one-drain bathroom versus a two-drain bathroom'. . . and the shower consideration." [PS-2]
>
> "And those weak patients think that little bitty slope is too much. . . ." [PS-1]
>
> "Except we're not having the trench drain, we're having two separate drains. . . [PS-5]
>
> "The drain we had was a long trough. . . . They [infection control] were concerned it would sit in the trough, itself, and not get into the drain. . . . You're talking a little bit of water, but it's water, but it's moisture, but there's the potential for mold, as opposed to just a hole where it would just go down." [PS-2]

Lastly, at another pilot site:

> "And it's, there's so little space in the room. It's hard not to know where the bathroom is." [PS-29]
>
> "Well if you wake up—" [PS-25]
>
> "You can paint an orange door, then it would really attract attention. . . ." [PS-23]

"One thing you guys have done in prior renovations is to put a nightlight by the bathroom so there's a low light that streams down that's on all the time."[PS-26]

"Which I think works well." [PS-29]

There was additional explanation surrounding cognition and identification. The discussion continued with a statement that if a patient had a cognition deficit, they shouldn't be toileting alone. Toileting would be an assisted activity.

7.4.3.4 Risky Business

Participants often struggled with risk and alternatively discussed whether a consideration was either a priority or feasible. As one participant noted, just because a solution is not feasible does not mean the condition is without risk, and not acknowledging the difference is "*gaming the system"* [PS-26]. Even though priority was added as a category for evaluation in an effort to differentiate the two concepts, the groups still often merged priority and risk.

7.4.3.5 They Matter

As suggested by the testing results, when designing for safety it is important to understand the role of the patient as an active participant in the system. At a minimum, this includes an awareness of patient demographics (e.g., age, general medical conditions, co-morbidities) and any organizational challenges associated with outcomes (e.g., high falls rates, low satisfaction scores). Recognizing patient limitations can lead to different discussions about acceptable solutions (e.g., no-curb showers). According to one falls/patient handling group in the LDR mock-up, *"Knowing who the users of the room or the space are likely to be makes it easier to answer the questions"* [PS-12].

In another instance:

"That has to do with dementia interpretation of floor patterns, and Parkinson's, and that sort of thing." [F/PH-12]

"Are there stairs in that space? There are no stairs. It's not applicable." [F/PH-10]

"But if you have a change in flooring type it can be interpreted as a step. And certainly for someone with Parkinson's, it can stop them, because they don't know how to interpret the floor." [F/PH-12]

"So the goal might be, if they are going to renovate, to use a single pattern. . . " [F/PH-10]

"You can have flooring patterns, but they have to have meaning, and they shouldn't introduce a visual barrier." [F/PH-12]

7.4.3.6 Our Point

7.4.3.6.1 We agree

The pilot sites in particular felt the SRA process was a benefit to engagement of the stakeholders.

"I think it's great to engage and build consensus of a whole group that is part of a design. . . . and that's one of the toughest things for us in our department, to build consensus. If everybody gave, you'd build a better product." [PS-14]

This was echoed by another pilot site:

"It's nice to have the give and take… where each person brings something to the table and say something to help understand. … It's about sharing perspectives and opening our mind to other people's perspectives and then being able to find creative solutions to it… Discussing separately becomes like a game of telephone. You know, 'Well I think that the reason that those other people needed it was this,' 'Well that doesn't make sense – we need to do it this way.' OK, alright, we'll do it this way and it cycles around… It's nice to have everybody together to both hear the perspectives and also say, 'Oh that's why you guys do it.'" [PS-25]

According to a third pilot site:

"I wonder if it would be necessary for our leadership to experience this and understand the value of this, in order to make your effectiveness… I mean the value of this, to ensure it informs their decisions, to be able to have a collaborative discussion like this." [PS-8]

"That's culture change." [PS-14]

"Right. Yeah. But really, it is. We're saying we want to be an organization that considers patient safety, and quality, and patient satisfaction, staff safety, satisfaction, and I think this speaks directly to that and facilitates that." [PS-8]

Lastly, there is a need for the evolution and validation of conceived solutions. As one participant stated:

> "One challenge could be a tendency for people to think, 'Well, now we've answered all that.' It's truth - absolute truth,' versus 'this points in a direction' and now we have to validate some assumptions about how things are done, or maybe could be done, but haven't always been done that way." [PS-20]

7.4.3.6.2 Do and decide

With respect to who should facilitate the process, there was a range of opinions, but several felt it was important to distinguish between the tactical aspects of finishing the exercise versus the strategic aspect of balancing decisions. *"There is a difference between process and decisions. Managing the process could be part of the design. . . . Decision-making is always the Owner"* [PS-33].

A project manager might ensure the process is completed on time, with someone else becoming the point person for content, *"someone who understands all the different disciplines and how to get an answer"* [F/PH-7].

However, there were multiple views about ownership of the SRA process, some integrating points of view, others segregating expertise. One pilot site felt it should be led by the hospital and shared with (possibly managed by) the architect (like the ICRA [infection control, risk assessment]): "*We're talking about the clinical implication of all of these items on patient care*" [PS-29]. Others felt a need for joint ownership to facilitate decisions, set priorities, and establish accountability, as well as to "*curb the enthusiasm"* [F/PH-5] of participants who may not have a sense of balance between ideas and budget.

> "It should be a clinical person that oversees it and someone from the … a design person." [F/PH-6]

> "And they have to work together." [F/PH-1]

> "So it's like a two-person team – co-leaders." [F/PH-3]

> "Yeah, you've gotta have it on both sides." [F/PH-1]

Alternatively, there were discussions about whether the process should be segregated, as it would be faster for each person to fill out the considerations on their own, recognizing that someone would need to aggregate and interpret the responses. Others suggested that one or two people would consistently participate, with individual experts brought in for specific topics (e.g., falls, infection control). However, this can be a challenge if it is unclear who possesses the expertise or if only

one perspective is offered. As one participant suggested, *"And the topic, too. . . . So when I come to falls, I may have someone from risk management leading that"* [F/PH-5].

Another option was to include a facilitator - someone familiar with content of the tool to be able to navigate a team through the varying areas of concern without the bias of a stakeholder (see Section 7.4.2.2). Ultimately, "*You need a champion – someone who really wants to do this*" [F/PH-7].

7.5 Discussion

As described in Chapter 6, grounded theory approaches do not start with an a priori hypothesis but instead allows theory to emerge. In presenting this discussion, my argument is that the identified core theme establishes a theoretical framework of using the SRA in a process that responds to:

- the context of HC facility design (Filter 1 - Sections 2.2) – the existing process, implications for safety, and participation in design;
- the extant literature for design tool use (Chapter 3) – design culture, the evidence base, and guidance; and
- the stated purpose and goal of the study (Section 6.3) – a focused discussion on safety and a collaborative process.

This is one phase of the emerging theory development with further implications of the findings for a systems perspective presented in Chapter 9.

7.5.1 Anticipate

As shown through the narrative of Section 7.4.1, engaged participation using the SRA includes four "rights." Input and conditions of use should be:

1. at the right time (when),
2. in the right setting (where),
3. with the right mix of people (who), and
4. for the right reasons (why).

Using the tool early in the design process (pre-design, schematic design) allows teams to agree on critical elements of design, as explored in Section 7.4.1.1. Early use addresses obstacles identified as part of the existing HC facility design process. At this stage, decisions are traditionally based on industry rules of thumb for

budget, size, and operations (Sections 2.2.3) and a design culture replete with variations on prior solutions (Section 3.4.4.1.1) or "*the last best design"* [HAI/MS-23]. The SRA also supports a formalized negotiated consensus process identified as a guidance need (Section 3.4.4.3.2).

7.5.1.1 Right Time

As stated by participants during testing (Section 7.4.1.2), the SRA tool can be used to promote different types of discussion at different phases and offers the opportunity to validate assumptions through the project life-cycle. As demonstrated at pilot site 2, early phases allow teams to openly discuss possibilities without preconceived solutions. Ongoing use over the course of the project (a guidance need of Section 3.4.4.3.2) would support findings to use knowledge in the evidence base through formal processes to ensure goals are being met and to share information as part of a feed-forward process (Sections 3.4.4.2.1 and 3.4.4.2.2). Early and continued use also supports the need to move safety upstream in the design process to more effectively target the cost-influence curve (Figure 2-3).

Time to use the tool is correlated to the magnitude of decisions to be made, as shown through the three phases of development at the real-world pilot sites. The desire to streamline the process (Section 7.4.1.1) may be at the expense of gathering information in the appropriate window of opportunity. As identified in the tools literature review, an ongoing challenge is the situation of recognizing when information is relevant (Section 3.4.4.2.1).

7.5.1.2 Right Setting

It was evident from observing testing that there were limited conversations once a choice or judgement had been made. This observation is related to the right time (i.e., the phase of design) but also the right setting (through tangible artefacts that inherently establish bias). This was evidenced by the perception that there was "*less to decide*" in Module B: high-fidelity mock-ups (Section 7.4.1.2) and more limited forms of discussion during design development at pilot site 1 (Table 7-6). With each increasing round of what may be perceived as a finished product (e.g., a detailed design drawing, a high-fidelity mock-up), there is more reluctance to question prior decisions in which participants had not been involved.

7.5.1.3 Right People

The participatory process used with the SRA establishes a platform to challenge the status quo and integrate solutions through varying perspectives (Section 7.4.1.4). Results also indicate that the tool content benefits from incremental growth in familiarity (Section 7.4.1.2.2), and the diversity of stakeholders represented during testing supports discussion and the directional shift identified in the literature review to include higher levels of collaboration (Section 3.4.4.3.1). However, findings indicate that this participatory process relies on team composition and dynamics, which may have as much influence on collaboration as the topic content of the SRA tool. As reported in Section 7.4.1.3, variations across teams (as compared to individual topics) suggested silos associated with team-specific factors.

In the context of the case study topic, falls, the differences in teams may be associated with two primary factors. Firstly, an important consideration in understanding the potential team implication is that the expert panels assembled to test hypothetical scenarios did not work together, have an organizational context, or possess a deep understanding of the expertise brought to testing by each individual. Participants may have just met for the first time, or they may have been reintroduced from the prior seminar. While 57% of participants from content development for falls and patient handling returned for tool testing (Section 6.5.3.3), analysis of new and returning participants in the combined falls/patient handling teams indicate Team 1 had 75% returning participants, and Team 2 only had 33% returning participants (Figure 6-10). Some form of team building may enhance the team dynamic when starting use of the SRA. This was also articulated by participants in two different debrief sessions (one pilot site, one hypothetical scenario), who felt that you started to trust your colleagues' expertise, which led to less stress.

Secondly, the team differences observed during testing may be associated with a high attrition rate on Day 2 for Team 2, resulting in a lack of diverse expertise. As stated by two of three remaining members:

> "We lost all our people with any clinical background, which means - I mean, I've got my safe patient handling and a little bit of falls, but -" [F/PH-14]

> "Yeah, I think that was a disadvantage. They offered a lot. 'Well, I would approach the bed this way or that way.'" [F/PH-12]

"And the reasons were there, a lot, to talk about." [F/PH-14]

Participation may be especially important for the category of falls, where decisions are hampered by complexity of intrinsic and extrinsic conditions and a lack of clear and identifiable single built environment solutions (Chapter 4). Participants in the expert workgroups for falls and patient handling expressed that there are fewer experts in consulting and healthcare organizations that would have a comprehensive understanding of falls (and patient handling). The difference may also be partially attributed to the use of tacit and explicit knowledge. Infection control and medication safety, for example, have made strides in explicit translation of the built environment issues through regulation, as compared to falls, which may have more reliance on the tacit knowledge of what individuals know and share. For example, infection control has been included in the FGI *Guidelines for the Design and Construction of Health Care Facilities* since 1996, and medication safety has been promoted through the 2010 US Pharmacopeial Convention's National Formulary, *Chapter 1066: Physical Environments that Promote Safe Medication Use*.

7.5.1.4 Right Reasons

As explored in Section 7.4.1.4, benefits of using the tool included enlisting a systematic process, defining priorities, creating value, and supporting operationally-based regulatory requirements (i.e., The Joint Commission). Findings revealed value in the systematic EBD process of the SRA (Section 7.4.1.4.1), supporting the literature review where teams felt sharing knowledge through an evidence-based discussion would be valuable during design and that proactive approaches needed to be "built in" to a resilient process (Section 3.4.4.2.2). Priorities can be defined through early use (Section 7.4.1.4.2), supporting the literature that identified the potential for conflicting goals (Section 2.2) and the need to understand and support the project goals (Section 3.4.4.1.2).

The SRA also advances the value of making the right decision (Section 2.2.2) with respect to first and long-term costs. As found during testing, this proactive approach mitigates "*the cost of getting it wrong*" (Section 7.4.1.4.3). This addresses a shortfall within the existing design culture where facility design is not considered strategically with respect to the long-term impact of decisions (Section 3.4.4.1.1). However, while the SRA provides a level of definition and focus on safety, the nature

of a single use (the testing approach) may not fully reflect the real-world challenges of scope, schedule, and budget constraints identified in the overview of the HC facility design process (Section 2.2). Owners expect teams to develop solutions quickly, as articulated during the SRA testing process; a facility design project *"costs too much"* and *"takes too much time"* (Section 7.4.1.4.3).

Much of the accreditation environment focuses on operations and behavior versus the supportive factors of HC facility design that might optimize the system (Section 7.4.1.4.4). This represents less effective modifications identified by the ISMP (Section 4.5) and the blame and retrain mentality that is prevalent in healthcare (Section 1.3.4). This underlying theme articulated by one participant highlighted the potential for HF/E approaches (although not stated using HF/E terminology).

7.5.2 Participate

As discussed in Chapter 1, project budgets are established in early planning phases, often resulting in suboptimal solutions (Attaianese and Duca 2012, Gann, Salter, and Whyte 2003). User groups establish their real needs (Section 7.4.2.1), as compared to a typical process of completing room data forms that may be considered out of context and may not leverage the abilities, limitations, interpretation, and practice of users (Sections 2.2.3 and 3.4.4.1.1). As shown through the findings, the SRA also makes a significant contribution to support the evidence base identified in the literature review (Section 3.4.4.2) by establishing a proactive structured process to use, share, and manage knowledge.

Using knowledge (Section 3.4.4.2.1) includes accessing both tacit and explicit knowledge, which is enhanced by providing an explicit list of evidence-based considerations that are evaluated through the synthesis of tacit knowledge of expertise and experience (Section 7.4.2.2). In later design phases, this moves into a translation of how objectives were achieved (Section 7.4.2.2.2), serving to bridge the jargon/language barriers identified as a challenge for user participation (Section 3.4.4.1.2). The participatory process also addresses using knowledge in the evidence base by offering interaction that goes beyond written HF/E standards and availability of individual studies, offering a mechanism for incorporating the experience of real-world system interactions (Section 3.4.4.2.1). The results of testing suggest the gap between expectations and reality (Section 3.4.4.1.1) can be improved through the

participation of diverse stakeholders. The tool offers the structure to both generate awareness and improve discussions focused on safety. This was identified as a desired change in necessary guidance (Section 3.4.4.3).

However, results also indicate that collaborative discussion is not guaranteed solely by the *number* of participating stakeholders. There are limitations in identifying system interactions if organizations choose to use the tool as a checklist that merely elicits a set of siloed responses with "no point" (Section 7.4.2.3). Unfortunately, this aligns with the findings of the literature review that user participation does not ensure design success (Attaianese and Duca 2012). Testing suggests the SRA is a vehicle for a process that can inform and resolve this environment-behavior gap. Rather than relying on SRA considerations of the built environment alone, the SRA is a "tool for thinking" (Gann, Salter, and Whyte 2003), offering opportunities for incorporating the complex behavioral aspects of facility design identified as gaps in existing design paradigms that provide little guidance about the dynamic interactions that occur within a static built environment once occupied (Section 3.4.4.1.2).

7.5.3 Integrate

Integration addresses the opportunity for users to consider the complexity of human response to design (Section 3.4.4.3.1). The study findings suggest that diversity of participant roles allows solutions to be created and optimized from multiple points of view, potentially connecting non-users to the operations and organization (Section 7.4.3.1). The SRA allowed the integration of solutions that address more than one condition (Section 7.4.3.2) or required a tradeoff (Section 7.4.3.3). Managing knowledge through classification, translation, and evolution (Section 3.4.4.2.3) is also addressed through the participatory process established with the SRA, although this may need adjustments in implementation.

Unintended consequences, referenced as part of the existing design culture (Section 3.4.4.1.2), are more likely averted through a participatory structure, where stakeholders are actively engaged in decision-making through an integrated process of consensus (Section 7.4.3). A diverse group of stakeholders can effectively discuss the one-to-many challenge found in classifying EBD sources. The current classification system is aligned to building categories within topics, but even when not organized as

such (i.e., scenario testing), expert workgroups identified where one solution benefitted other conditions or resulted in potential tradeoffs.

The knowledge translation process of awareness, agreement, adoption, and adherence identified in Section 3.4.4.2.3 is substantially improved through the integrate theme. As revealed during testing, multiple stakeholders are made aware of the conditions, agree to possible solutions, and adopt an approach that is most suited to the project, taking into account complex considerations (Section 7.4.3.6). Unfortunately, risk was confused throughout testing, even when balanced with priority (Section 7.4.3.4). This is consistent with problems of measurement that do not take into account exposure (Section 3.4.4.1.1), as it is challenging for participants to identify the impact of particular interventions.

The options and implications for participation and influence are illustrated in Figure 7-9 with axes for group and individual leadership and more or less collaborative participation.

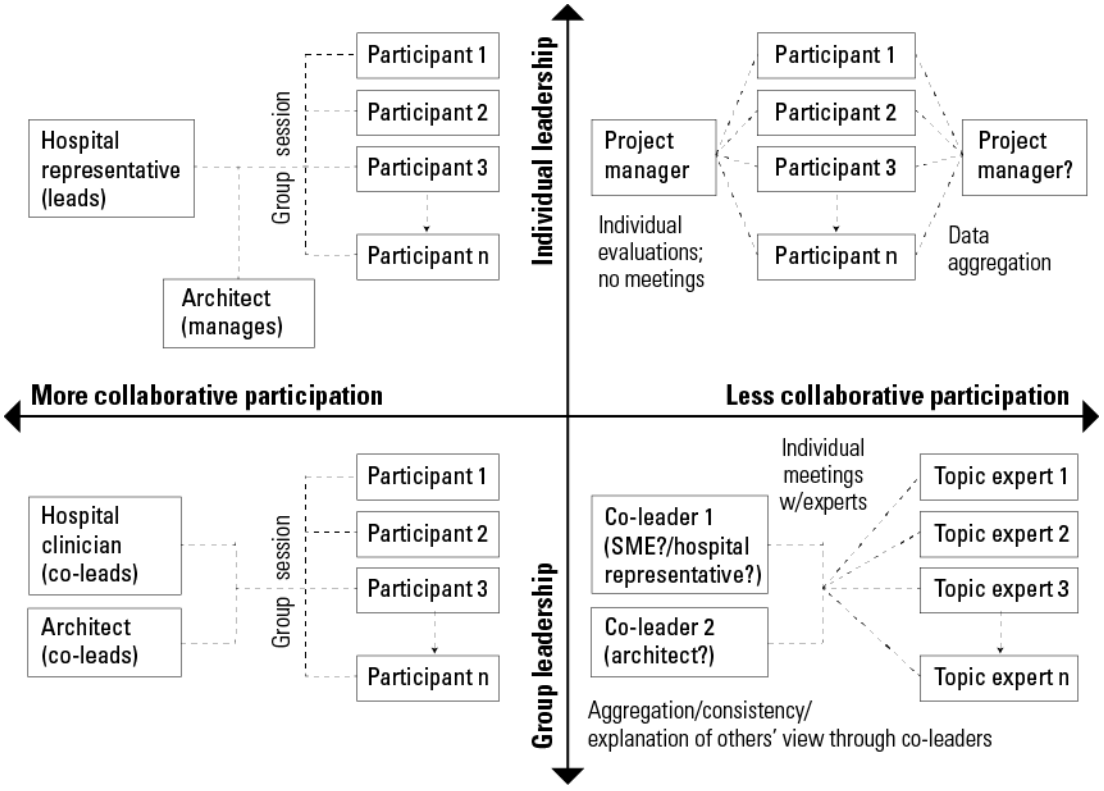

Figure 7-9. Four implementation options discussed for the SRA

While the implementation options vary according to an organization's stance on participation, the less collaborative process of data aggregation (the upper right quadrant of Figure 7-9) would likely not generate the same level of consensus. The

less collaborative process (the lower right quadrant) reflects current processes that have been identified as suboptimal. The more collaborative processes suggested by participants (left side quadrants) would provide a form of facilitation more reflective of the SRA benefits found in testing. This form of using the SRA centers on agreement through the problem-solving of multiple stakeholders presenting diverse viewpoints.

Based upon my observation and participation in the testing process, discussion is not inevitable and having people familiar with the content and intent has a significant effect on participation and the ability to navigate considerations. The caveat is that someone also needs to understand issues well enough to determine where an organic conversation is constructive to the process, rather than diverting the group. This may be a role for the HF/E specialist. A third-party facilitator may add value by being viewed as a neutral expert, as compared to a member of the team perceived as having an agenda (Section 2.2.3). As there is cost associated with outside facilitation, the benefits may be best recognized at certain phases of the project. For example, testing at pilot site 1 (design development) offered little more than an opportunity for observation of confirmatory discussion. However, earlier phases of master planning (pilot site 2) and schematic design (pilot site 3) offered opportunities to guide the discussion and prompt additional thinking. In some cases, there were more opportunities to educate and explain (evident during hypothetical scenarios with expert panels). In using more collaborative formats, questions could be facilitated in a judgement-free manner, prompting further group discussion. Lastly, with respect to integration, solutions were sometimes considered from a patient perspective, but the explicit patient view is missing (Section 7.4.3.5).

7.5.4 Limitations and Strengths

There are several limitations to the study. Firstly, during expert testing at the Garfield Center, participants felt there were gaps in the scenarios provided, including budget constraints for all but one of the scenarios This led to a common reaction that every consideration should be included, without much discussion. Additionally, some groups struggled with the nomenclature used for the first module termed *Board Room* to convey the meeting setting. Some took this to mean the meeting was literally with the Board of Directors, which had not been the intent and had not been described in

the narrative. This led to some discussion of hierarchies of information desired for a different kind of discussion than envisioned and created a longer start-up time.

There were also numerous last-minute cancellations that may have changed expert panel dynamics. As with any participatory process, dominant personalities can negatively affect balanced discussion, and some groups during scenario testing were hampered by single individuals directing the conversation. This was not the case where a stronger facilitator could balance the group dynamic, but in some instances the facilitator did not redirect the group. With respect to the pilot sites, each organization considered a different combination of topics, and the falls components were not undertaken at one of the pilot projects, making direct comparisons difficult. In all cases, the participants (or organizations) had self-selected to the testing process, so there is a strong potential for a positive bias – wanting to see the SRA work well. This may have been supplemented by the presence of researchers, who while most often were just observing, may have created a condition of participants wanting to please the researchers.

Another limitation in the falls category is that users can include both patients and staff. Traditionally, patients have rarely been included in earnest during design, and patient participation was not in the scope of the grant to develop and test the tool. The potential of a patient's direct experience of describing their own "work environment" would likely instill a different dynamic than existed with the expert workgroups who tested the tool using hypothetical scenarios from a more theoretical perspective. Patient participation in the design process is unusual due in part to the transient nature of their presence and in part to bias that they don't know what is needed in a healthcare facility. Recent trends to use patient advisory councils and focus groups during design are associated with a shift to patient-centered care and improving the patient experience. As with safety, the patient experience movement has been largely driven in the US as a result of reimbursement through HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems), a standardized national survey to measure and benchmark the patient perception of the hospital experience.

Despite these limitations, a significant strength of the study was related to integration of topics. Participants stated that they liked falls and patient handling being completed together, as it allowed the less experienced person to understand a

connection and could "*get people out of silos*." In other instances, there were overt statements in debrief sessions confirming the value of consensus found during testing, so often a challenge in HC facility design. To advance integration and synthesis, organizations will need to recognize that the restructuring of the process from individual user group meetings to a more collaborative process may require *initial* time and resources, both of which are typically in short supply during an HC facility design project. Unfortunately, this too is reflective of the design climate and challenges with design value discussed as part of the tools literature review. The value added is in the long view - the potential to arrive at optimal systems-based solutions more quickly through the collaborative problem-solving offered by the SRA.

7.6 Conclusions

The development of the central theme through GT, supplemented by quantitative analysis, offers perspective on the participatory process of the SRA. The central theme identifies the condition of using the SRA (the four "rights" – time, setting, people, and reasons) that should be anticipated to maximize participation value to better integrate solutions for safe HC facility design. The mixed methods analysis suggests that the SRA tool can be used in a variety of ways to focus teams on the issues of safety, and taken together, results suggest significant opportunity for a proactive process that focuses on safety to positively impact the approach to HC facility design. The process offers a decision-making forum that balances needs and priorities and provides an opportunity for stakeholders to learn from each other's perspectives. The use of knowledge is enhanced through the participation of experts and users who can challenge assumptions, share real-world experiences, and synthesize the types of information brought to the discussion. While the focus of analysis was falls/patient handling, the coding across safety topics suggests that the core theme may be generalizable to other safety topics as well. (Additional information specific to the grant is included in Appendix M.)

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8 Systematic Literature Review: Hospital Falls (Phase II)

8.1 Chapter Overview

Using the same sources cited in Chapter 4, a second phase of thematic analysis (Stage 7) was conducted to further categorize the range of interventions used to prevent hospital-based falls.

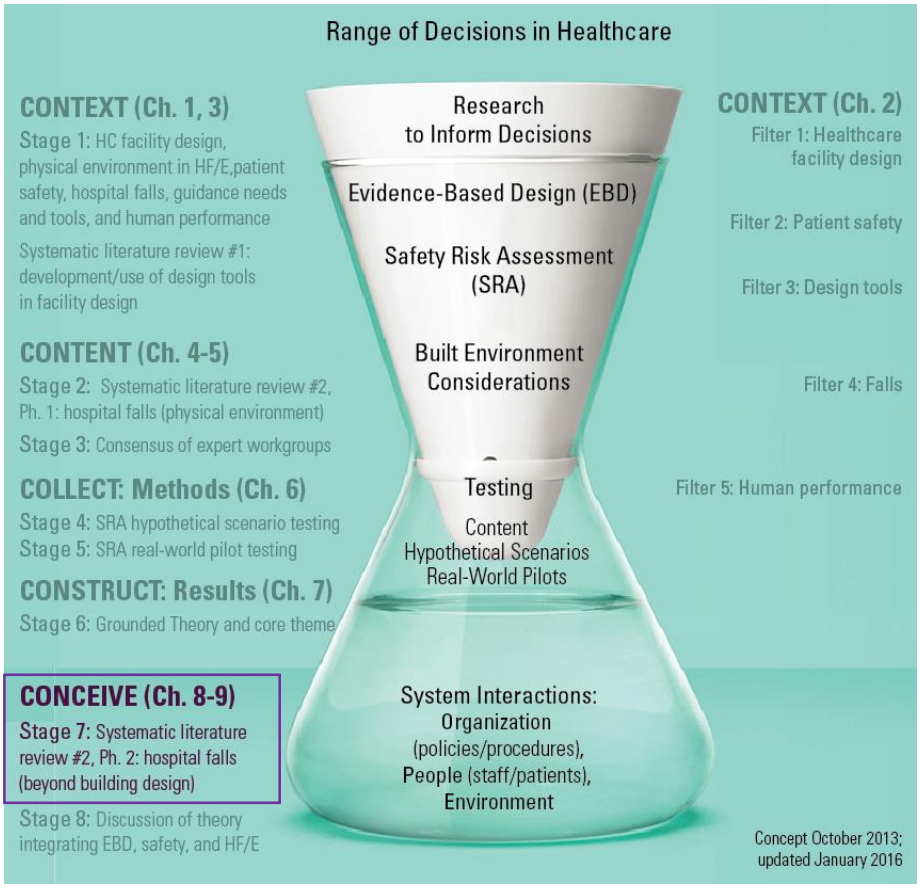

Figure 8-1. Chapter 8 signposting (conceive – Stage 7)

8.2 Aim and Objectives of the Stage 7 Literature Review

The aim in this second phase of literature review analysis was to more fully understand categories of the organization and people. As in Chapter 4 (categorizing considerations of the designed environment), individual interventions were documented according to their prevalence in studies and the context of the overall study appraisal from which they were drawn.

References for included studies are found in Table 4-3 and Figure 4-4 is presented again (as Figure 8-2) for ease of reference for this chapter.

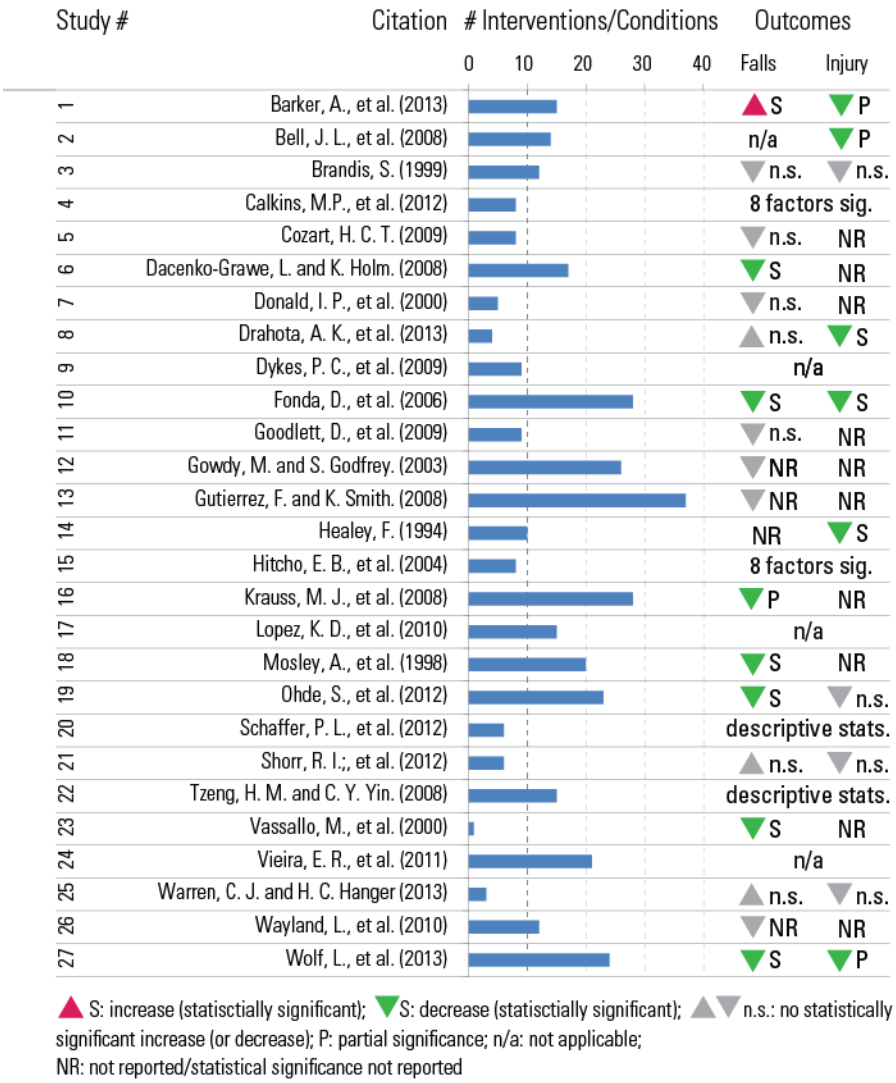

Figure 8-2. Hospital falls literature review studies (Figure 4-4 duplicated for reference)

8.3 Conditions of Implementation

Guidance offered by Popay et al. (2005) characterizes two components of narrative synthesis: effects of interventions and factors shaping the implementation of interventions. Recently, some systematic reviews for patient falls have started to identify implementation conditions related to the set of complex interventions to prevent falls (Hempel et al. 2013, Miake-Lye et al. 2013). While this was not the focus of this review, there were several factors (shaping the study or the culture of an organization) that may have influenced the study results. These were not interventions in and of themselves, and for the purposes of this review were identified as a reference in Figure 8-3.

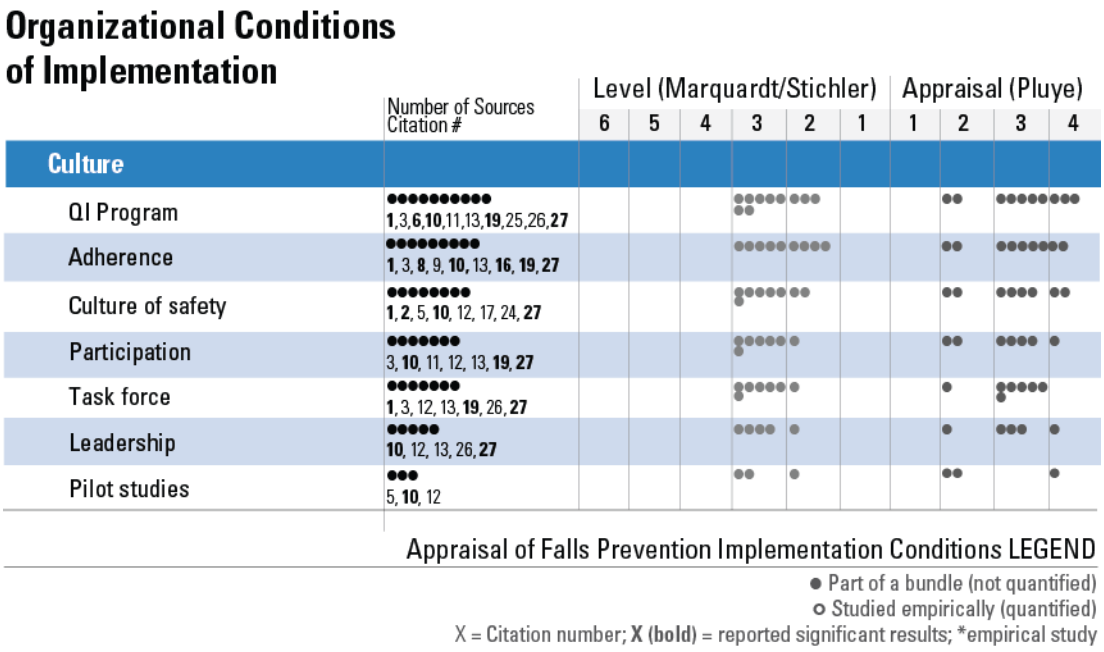

Figure 8-3. Organizational factors shaping falls prevention research

The most common condition (10 studies) was the organization's use of quality improvement initiatives, with half of these study authors reporting statistically significant results. Adherence with organizational policies and procedures was the next most-referenced condition and was a logical consideration given that "*even if a robust preventive program exists, effectiveness is unlikely if compliance is low*" (Ohde et al. 2012). However, adherence was a complex issue. Dykes et al. (2009) referenced that stakeholders often must add their own judgment, knowledge, and skills to execute the plan, and Ohde et al. (2012) acknowledged the confounding effect of the role of intervention itself versus adherence in implementing the intervention. Compliance included challenges associated with change and what may have been (or was perceived to be) additional work (Krauss et al. 2008, Fonda et al. 2006, Wolf et al. 2013); potential lax behaviors due to perceptions of increased safety (Drahota et al. 2013); understanding the correct application of the intervention or protocol (Gutierrez and Smith 2008, Barker et al. 2013); or measuring the adherence levels (Ohde et al. 2012, Brandis 1999, Krauss et al. 2008, Fonda et al. 2006, Gutierrez and Smith 2008).

A less defined condition was a "culture of safety" referenced in seven studies. Most of the remaining conditions, participation, leadership, and a task force, could be seen as engaging the stakeholders in the process, creating buy-in, and potentially increasing adherence. The two studies indicating the highest number of these

conditions of implementation (six of seven) also reported statistically significant outcomes (Wolf et al. 2013, Fonda et al. 2006).

8.4 Organization

8.4.1 Risk Factors (Correlates) of Falls

Organizational conditions included operations, policies, and procedures. There were few organizational conditions that were identified as site-specific correlates for falls (Table 4-5), but those cited included inadequate staffing such that patients were left unattended (Tzeng and Yin 2008). Counterintuitively, increased staffing levels were sometimes associated with higher rates of falls (Brandis 1999, Krauss et al. 2008). Turnover of staff and leadership was noted in one study (Wolf et al. 2013).

Maintenance issues related to the physical environment were commonly cited. This included contamination of the walking surface conditions from ice, rain, or urine (Wolf et al. 2013, Tzeng and Yin 2008, Vieira et al. 2011, Bell et al. 2008, Brandis 1999, Healey 1994, Hitcho et al. 2004, Mosley et al. 1998). Waxed floors were also noted as a contributing factor (Bell et al. 2008).

8.4.2 Organizational Interventions for Falls Prevention

Interestingly, despite a lack of identified organization-related correlates of falls, many interventions cited in papers included behavioral modifications associated with the policies and procedures of an organization defining what a caregiver or patient needs to do. Organizational interventions were numerous, resulting in subset themes: patient evaluation, communication, staffing, assistance policies, and maintenance (Figure 8-4).

Organization

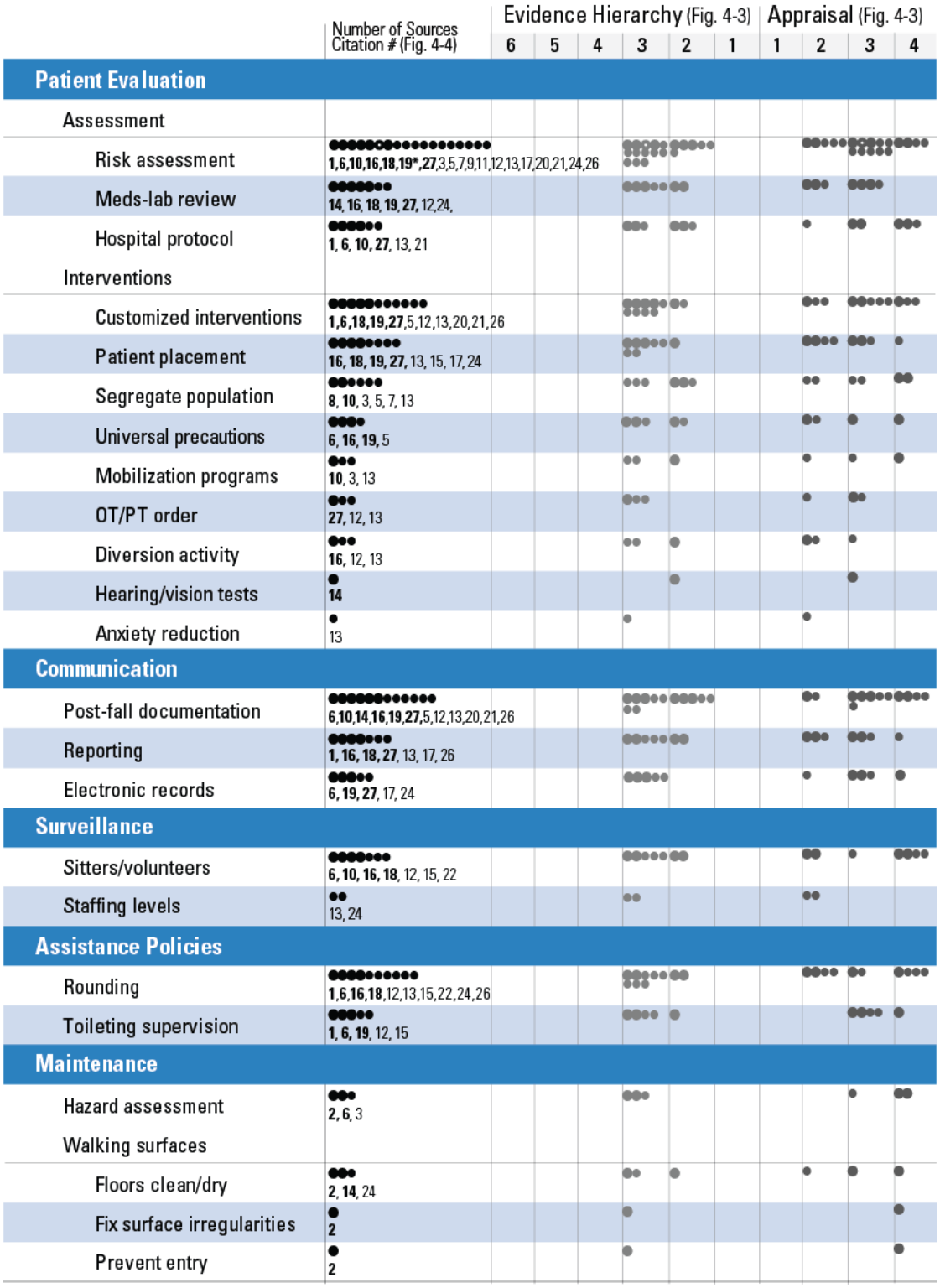

Figure 8-4. Organizational interventions to mitigate falls

8.4.2.1 Patient evaluations

Patient evaluations were the most common types of interventions within the organizational category. These included a combination of assessments and associated interventions. The most commonly cited evaluation was an overall patient falls risk assessment, which appeared in most intervention bundles (Figure 8-4). Where a risk assessment was not referenced, the studies were most often empirical flooring studies or descriptive correlational studies. However, in one correlational study (Hitcho et al. 2004), patients were categorized as high or low risk according to the risk assessment records. The authors found that 42.6% of patients who fell had been identified as low risk, implying that the predictive value of the risk assessment was inadequate. In a conflicting result, a QI study that included the development and statistical evaluation of a seven-item risk assessment was found to be highly predictive (Ohde et al. 2012). The studies including a risk assessment spanned a range in appraised quality, and seven of the 19 studies reported statistically significant results.

Other commonly referenced assessments included medication review (e.g., the effects of sedating medications) or conducting/reviewing lab tests (e.g., urine) to determine any medical conditions that might contribute to risk. While the studies incorporating this intervention were not the highest appraised quality, five of seven reported statistically significant results. Another referenced assessment was a hospital falls protocol, for example, the 6-PACK program described under a previously reported study (Barker et al. 2013). In most cases, the hospital protocol was not described in detail, making the concept difficult to assess.

With respect to interventions, a policy of customized interventions was cited in 11 studies, while universal protocols were cited in seven. Customized solutions typically included a set of options based on a score derived from the risk assessment. Most often, the set of targeted interventions were prescriptive, based on the risk level assessed (Dacenko-Grawe and Holm 2008, Gutierrez and Smith 2008, Ohde et al. 2012, Wayland et al. 2010, Wolf et al. 2013, Barker et al. 2013). In some cases, the nurse selects options based on professional expertise (Gowdy and Godfrey 2003, Schaffer et al. 2012), and in other cases, a hybrid solution was employed with prescribed solution sets supplemented by clinical judgment (Mosley et al. 1998, Shorr et al. 2012). In one case, a checklist was used to verify and score that the available safety equipment options were in place (Cozart 2009). Five of these studies reported

statistically significant results. Universal protocols, on the other hand, were those used for every patient and in some cases were a "base plan." These interventions were not consistent across studies and may have included lowering the bed height and bedrails (Ohde et al. 2012); assessing fall risk daily, educating patients and their families, and falls prevention signage (Krauss et al. 2008); providing non-skid footwear (Dacenko-Grawe and Holm 2008); or providing bed trapezes and ensuring the accessibility of bed controls (Cozart 2009). Three of the four studies recognizing a form of universal precaution reported statistically significant results, although given the variation of interventions the only conclusions that might be drawn is a benefit of defining a minimum standard to be instituted for falls prevention.

Patient placement near the nurses station was referenced in multiple studies (Figure 8-4), although one study addressed the operational reality that bed availability typically dictates room assignments with fall risk as a secondary consideration (Lopez et al. 2010). Another study reported data that more falls happen near the nurses station, perhaps as a result of highest-risk patients being placed in those rooms, while two rooms located near an office were documented with fewer falls, as the nurse was able to reach the patents quickly from his or her workspace (Wolf et al. 2013).

In some studies patient placement was considered through segregating populations (e.g., the elderly) such that the highest-risk patients were located in a specialty ward (Brandis 1999, Donald et al. 2000, Drahota et al. 2013, Fonda et al. 2006) or in a designated area of the unit with higher levels of observation or targeted interventions such as a falls-prevention room (Cozart 2009, Gutierrez and Smith 2008). Interventions with less evidence included mobilization programs to maintain strength (Brandis 1999, Fonda et al. 2006, Gutierrez and Smith 2008); orders for occupational or physio-therapy (Gowdy and Godfrey 2003, Gutierrez and Smith 2008, Wolf et al. 2013); diversion activities (e.g., music, TV) to prevent wandering (Gowdy and Godfrey 2003, Gutierrez and Smith 2008, Krauss et al. 2008); orders for hearing and vision tests (Healey 1994); and anxiety reduction through medication (Gutierrez and Smith 2008).

8.4.2.2 Communication

As shown in Figure 8-4, communication breakdowns, an organizational correlate of falls, was addressed through interventions such as reporting policies and post-fall follow-up documentation. Post-fall documentation was included in a dozen

of the reviewed papers, and the studies trended toward the higher levels of appraised quality. Half of the studies including this intervention reported statistically significant results. These interventions typically incorporated reporting circumstances and conditions immediately following fall events to define trends (often in addition to incident report), inform unit management, and provide feedback to staff. In some cases, this was captured in two phases: firstly, a systematic process to collect information from the post-fall huddle within 60 minutes and secondly, a more detailed investigation conducted by an advanced practice nurse with a resulting four-page form completed within 48 hours (Wolf et al. 2013). According to Wolf et al. (2013), this information was then also reported to risk management an included in their falls event report.

Few studies referenced patient feedback, but Kraus et al. (2008) referenced interviews with the nurse or patient, as well as a review of the physical conditions in the patient room. Other studies indicated staff expertise was solicited, for example, by asking for feedback as to whether and how the fall could have been prevented (Cozart 2009). In another study, the process was more formalized by conducting both a retrospective root cause analysis (RCA) and prospective failure mode and effects analysis (FMEA) (Gowdy and Godfrey 2003).

More generalized reporting policies were referenced as part of an intervention bundle in seven studies, with four of those reporting statistically significant study results. Policies included proper documentation of the care plan (Mosley et al. 1998); shift reporting to the immediate care team (Barker et al. 2013, Gutierrez and Smith 2008); and larger initiatives of reporting (monthly management meetings, risk management, etc.) to increase awareness and understanding (Wayland et al. 2010, Krauss et al. 2008). In one study (Wolf et al. 2013), ancillary staff was included in the process - occupational therapy staff posting activity communication in the patient room.

In five studies, electronic records were used to record falls and risk assessment information. However, in at least one of these instances, fall risk status and measures to prevent falls were not a mandatory entry and data were hidden within free text fields of the electronic record (Lopez et al. 2010). As a result, the paper chart became the most reliable data, but this was not always referenced. In other instances, the electronic records were used more proactively to provide real-time data to unit

management, including such information as contributing factors, the reason for getting up, the risk score and the implemented interventions, and follow-up at the time of the fall (Wolf et al. 2013).

8.4.2.3 Surveillance

One form of surveillance reported in the reviewed studies was engaging paid or volunteer sitters that were used as part of an intervention for any high-risk patient (Gowdy and Godfrey 2003, Hitcho et al. 2004, Krauss et al. 2008, Mosley et al. 1998, Tzeng and Yin 2008, Fonda et al. 2006) or in specific scenarios, such as alcohol withdrawal, mental challenge, or confusion (Dacenko-Grawe and Holm 2008, Mosley et al. 1998). Many of the studies using sitter programs demonstrated statistically significant results; however, as Tzeng and Yin (2008) suggested, sitter effectiveness for management and improvement of patient safety were challenging, as they were often not regular employees and not professionally trained.

Surveillance was more often assumed by caregivers, and staffing levels were cited in only two studies. While both studies were lower on the scale with respect to appraised quality, both identified statistically significant results with their program. In one study, the staffing level was two nurses to six patients, with one technical partner (Gutierrez and Smith 2008). The second study reported that patient perceptions included the need for more staff (Vieira et al. 2011). This conflicts with some of the identified risk factors, as the highest nurse-to-patient ratios were sometimes correlated to higher fall rates. (See Section 4.4.4.3.)

8.4.2.4 Assistance Policies

Providing patient assistance was cited as an intervention through policies of rounding for toileting supervision, as many falls are associated with elimination-related activities and occur when patients are unassisted in walking to the bathroom. Rounding was cited in 10 studies of varying appraised quality and was referenced in the context of frequent or timed rounding (sometimes specified as hourly) (Dacenko-Grawe and Holm 2008, Tzeng and Yin 2008) or as part of a frequent or timed toileting regime (Gutierrez and Smith 2008, Barker et al. 2013, Gowdy and Godfrey 2003, Hitcho et al. 2004, Krauss et al. 2008, Tzeng and Yin 2008, Vieira et al. 2011, Wayland et al. 2010). In one study, the authors identified patient assistance with toileting at least every four hours when awake, before bedtime, and before

administering sedation medication (Mosley et al. 1998). Beyond providing assistance to the bathroom, five studies in the middle to high range of appraised quality identified supervision of toileting activities until the patient was returned to bed (Barker et al. 2013, Dacenko-Grawe and Holm 2008, Gowdy and Godfrey 2003, Hitcho et al. 2004, Ohde et al. 2012). Three of these five studies reported statistically significant results.

8.4.2.5 Maintenance

Only a few studies referenced maintenance issues to address direct correlations of falls through hazard assessments (Bell et al. 2008, Brandis 1999, Dacenko-Grawe and Holm 2008); keeping floors clean and dry (Bell et al. 2008, Healey 1994, Vieira et al. 2011); preventing entry into spaces with hazardous/wet surface conditions (Bell et al. 2008); and repairing interior and exterior surface irregularities such as damaged tiles, loose or buckled mats and carpeting, and cracks or holes (Bell et al. 2008). The one study that referenced all of these (Bell et al. 2008) was focused on employee safety, although the interventions could easily apply to patients as well.

8.5 People

People engaged in mitigating the risk for falls include both patients and staff.

8.5.1 Risk Factors (Correlates) of Falls

The people-related intrinsic and extrinsic conditions that were correlates to falls are reported in Section 4.4.4.3. There were fewer interventions targeting the staff and patients, although many of the organizational interventions indirectly affect how someone is to act or perform (Figure 8-5).

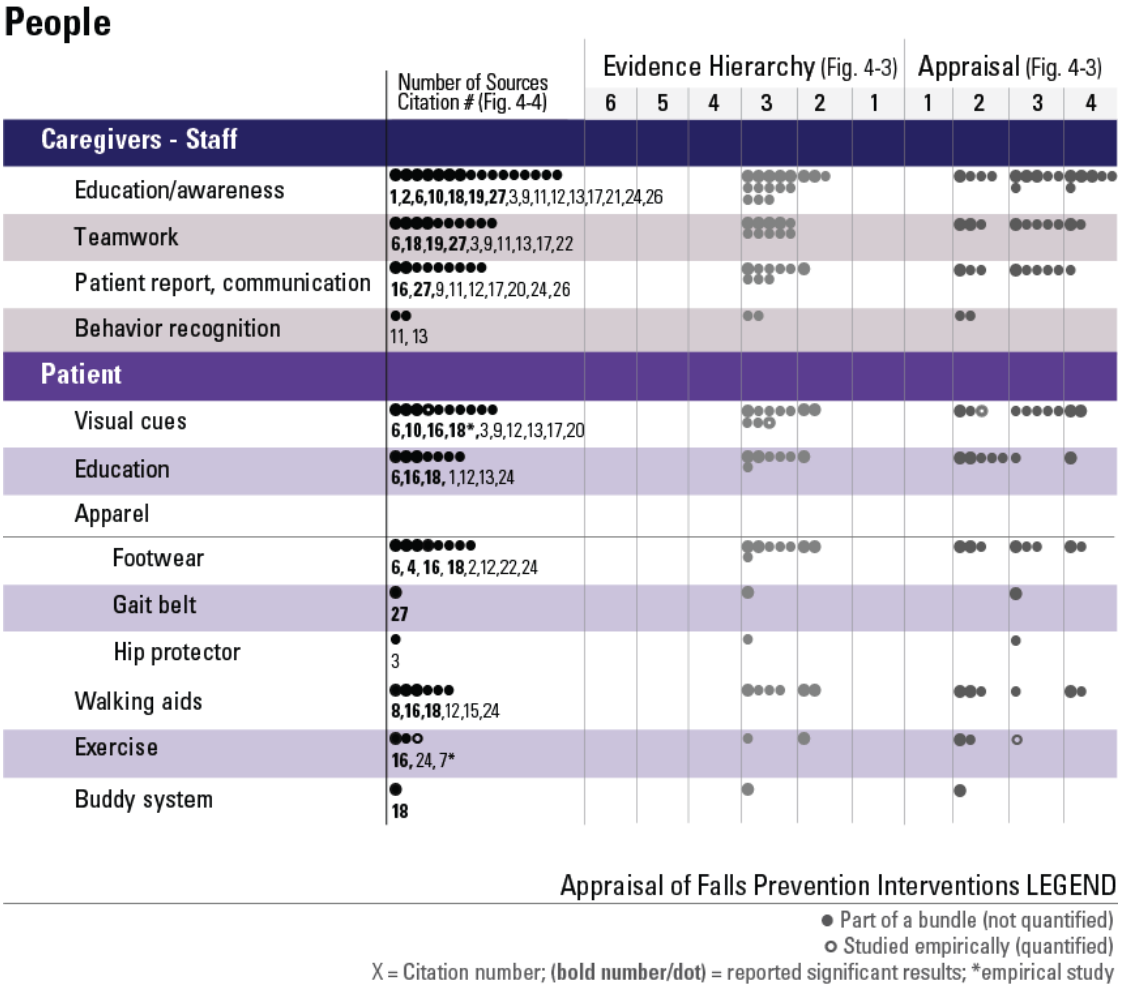

Figure 8-5. People-based interventions to mitigate falls

8.5.2 People-based Interventions for Falls Prevention

8.5.2.1 Caregivers—Staff

The most employed intervention related to staff was education and awareness, referenced in 17 studies, with statistically significant results in seven. Education programs had a range of foci such as general education to improve awareness, without specific detail provided (Bell et al. 2008, Gowdy and Godfrey 2003, Gutierrez and Smith 2008, Vieira et al. 2011). In one study, education was conducted one hour/week for four weeks during every shift (Mosley et al. 1998). In another, one hour of education was provided to all clinical staff annually (Ohde et al. 2012). Education was also focused on specific interventions or mandated falls protocol (e.g., low beds, armbands) and its effective implementation or meaning (Barker et al. 2013, Dacenko-Grawe and Holm 2008, Goodlett et al. 2009, Shorr et al. 2012, Wolf et al. 2013). Training was also employed. This included cross-training in falls prevention for

anyone spending any part of the day in patient care areas (Dacenko-Grawe and Holm 2008), individual nurse training followed by the signing of a competency checklist to signify commitment (Wolf et al. 2013), enhanced training for novice nurses pertaining to prevention, protocols, documentation, and safety equipment (Wayland et al. 2010, Gutierrez and Smith 2008), and evaluation of nursing knowledge of falls prevention (Lopez et al. 2010). There was also a range of delivery methods to enhance education and awareness, such as walking rounds to reinforce the fall prevention message (Barker et al. 2013, Shorr et al. 2012); written information via visual cues (also discussed in Section 4.4.4.4); reminder cards, newsletters, memos, brochures, or articles (Brandis 1999, Fonda et al. 2006, Wolf et al. 2013); and presentations (Brandis 1999, Goodlett et al. 2009).

Staff-related interventions also included improving teamwork, as referenced in 10 studies in the mid-range of appraised quality; however, as one author notes, *"while it is suggested that higher reductions occurred in areas where the multidisciplinary team enthusiastically embraced the project, it is unclear what aspect of the program was critical"* (Brandis 1999, 219). Teamwork was referenced as peers working together to provide surveillance (nurse to nurse) (Dykes et al. 2009); through shared accountability and assistance from ancillary staff with surveillance and response to patient calls (Dacenko-Grawe and Holm 2008, Dykes et al. 2009, Goodlett et al. 2009, Gutierrez and Smith 2008, Tzeng and Yin 2008, Bell et al. 2008); through collaborative and interdisciplinary consultation to determine the best solutions (Ohde et al. 2012, Wolf et al. 2013); or through family inclusion as a member of the team (Mosley et al. 1998). One study found complexities in the issue of teamwork, as caregivers and ancillary staff were either unsure how to help or fearful of not knowing the patient condition and resulting protocol (Dykes et al. 2009). Challenges in teamwork were reiterated in a focus group where participants expressed that nurse/nurse assistant partnerships were vital, but communication barriers hindered effectiveness (Lopez et al. 2010).

Better communication was desired by patients, family, and staff (Vieira et al. 2011). Verbal exchange was reported as the preferred method of communication, even with delays in reporting and the information inconsistency in the individuals giving and receiving (Dykes et al. 2009). Falls prevention status was often reported verbally at shift change (Krauss et al. 2008, Schaffer et al. 2012, Wayland et al. 2010);

however, the risk was evidenced in another study that cited unless there was a near-miss or injury, fall risk was rarely communicated (Lopez et al. 2010). In one study, communication with patients during every shift was referenced as a necessity, albeit a challenge due to information overload (Wolf et al. 2013).

Two studies referenced the ability to recognize patient behaviors. In one instance (Gutierrez and Smith 2008) it was stated that the falls prevention champions observed patient behaviors (presumably to educate unit staff). In the second (Goodlett et al. 2009), the authors declared the need to interpret patient behaviors leading to a fall, resulting in the necessity of consistent knowledgeable personnel (in this case, using video surveillance). In this study, monitoring staff were allowed to intervene and provide bedside assistance; speak through the call system; or alert caregivers of the need for immediate assistance or to other behaviors (such as restlessness or agitation) that might lead to unsafe behavior. Staff who monitored patients by video was also included in shift reporting (Goodlett et al. 2009).

8.5.2.2 Patients

The intervention most used for patients was visual cues (Figure 8-5). While visual cues were primarily for the benefit of staff, visual cues also serve as a risk reminder for patients and families. In most cases, colored wristbands were used (Dykes et al. 2009, Dacenko-Grawe and Holm 2008, Fonda et al. 2006, Gowdy and Godfrey 2003, Krauss et al. 2008, Mosley et al. 1998), but in some instances armbands were used (Brandis 1999, Gutierrez and Smith 2008, Lopez et al. 2010). There was no consistent standard for color, and studies reported green, orange, and neon pink were used.

Another frequently used intervention noted in eight studies was education programs to raise risk awareness and influence corresponding appropriate behavior. In some cases, education included instruction to call for assistance (Gutierrez and Smith 2008, Mosley et al. 1998), techniques on getting out of bed (Mosley et al. 1998), or familiarization with the environment (Mosley et al. 1998). Patient education was often delivered through discussion with the patient and family (Krauss et al. 2008, Mosley et al. 1998, Goodlett et al. 2009) or a form of written communication (e.g., instruction sheet, brochure) (Krauss et al. 2008, Gowdy and Godfrey 2003).

In one case, printed patient education materials were in multiple languages or supplemented by pictures for those who may be illiterate (Dacenko-Grawe and Holm 2008). While family was often included in patient education, one study found a lack of family awareness with respect to their role, also related to family presence in Section 4.4.4.4.1 (Vieira et al. 2011). According to the families participating in this study, education and communication were only necessary between staff and patients and should be enforced through regulations. Only three of the eight studies reporting patient education recorded statistically significant results.

Other patient-based interventions included worn items, such as non-slip footwear (Dacenko-Grawe and Holm 2008, Gowdy and Godfrey 2003, Healey 1994, Krauss et al. 2008, Mosley et al. 1998, Tzeng and Yin 2008, Vieira et al. 2011), gait belts (Wolf et al. 2013), or hip protectors (Brandis 1999). Non-slip footwear was also applicable to employees (Bell et al. 2008). Half of the studies reporting footwear as an intervention recorded statistically significant results.

Walking aids were referenced in six studies, half of which reported statistically significant results. This included a combination of providing access to assistive devices (Drahota et al. 2013, Gowdy and Godfrey 2003, Krauss et al. 2008, Mosley et al. 1998, Vieira et al. 2011) or bringing their own devices from home (Hitcho et al. 2004). In one study, the number of patients using assistive aids was reported between 68% and 76% (Drahota et al. 2013). Gowdy and Godfrey (2003) attributed much of the success in reducing the rate of falls to assistive walking devices, although this was not quantified.

One patient-related intervention referenced less frequently was exercise programs or occupational therapy to increase strength (Donald et al. 2000, Krauss et al. 2008, Vieira et al. 2011). A single empirical study (Donald et al. 2000) did not find statistically significant improvements in reducing falls, reducing length of stay, or increasing the likelihood of being discharged directly home. Another intervention cited in a single study included using a buddy system where roommates alerted the nurse that the other roommate was attempting to exit the bed (Mosley et al. 1998).

8.6 Discussion

It is clear from the number and prevalence of interventions, as well as the range of appraised quality, that there was no single or obvious prescriptive solution for the

organization, people, or environment. Even the most-used interventions may be misleading. Two of the top three referenced interventions, risk assessments and alarms, may also be some of the most controversial in more recent thinking regarding patient safety. As of June 2013, assessments are no longer a universal standard for accreditation under the UK National Institute for Health and Care Excellence (NICE) guidance (National Institute for Health and Care Excellence [NICE] 2013). Instead, the 2013 NICE guidelines suggest a multifactorial assessment and customized set of interventions for anyone 65 years or older or for those between 50 and 64 "at risk" if identified by a clinician because of an underlying condition. However, in the US assessments for falls are essentially required - upgraded from a National Patient Safety Goal in hospitals to a Provision of Care Standard in 2010 in the US by The Joint Commission as part of its accreditation standard (The Joint Commission 2009).

Alarms are also under increasing scrutiny due to cognitive overload and alarm fatigue. In 2013, The Joint Commission issued a sentinel event alert offering recommendations to reduce patient harm related to alarms. According to the alert, of 98 reported sentinel events between January 2009 and June 2012, 80 resulted in death, 13 in permanent loss of function, and five in unexpected additional care or extended stay (The Joint Commission 2013b). Additionally, the alert describes:

> The number of alarm signals per patient per day can reach several hundred depending on the unit within the hospital, translating to thousands of alarm signals on every unit and tens of thousands of alarm signals throughout the hospital every day. It is estimated that between 85 and 99% of alarm signals do not require clinical intervention, such as when alarm conditions are set too tight; default settings are not adjusted for the individual patient or for the patient population. (The Joint Commission 2013a, 1)

It is clear that alarms should be avoided if other solutions can address the same underlying causes.

Understanding the patient is important as well. Several studies referenced patient over-estimation of abilities, but the patient is rarely included in the review of safety events to provide his or her perspective, even though the patient may be the only "witness" to the event (Millman et al. 2011). However, the patient view needs to be considered in context as well. Recent studies have found that patients often believe that intended solutions were appropriate for "other people" without recognizing the importance of their own participation in prevention activities (Haines et al. 2014, Wolf

and Hignett 2015). Staff may have "*a tendency to perpetrate treatments on patients, not with them*" (Vieira 2011, 443).

8.6.1 SCOPE 2.0

In mitigating the risk for falls, design teams and healthcare organizations should consider the complexity of the system and consider the interactions and changeability between the organization, people, and the environment, with the environment conceived as a proactive forcing function (described in Chapter 4). Solutions require diverse perspectives and a well-grounded understanding of patient demographics and risk factors, falls data, organizational policies and procedures, work flows (staff and patient), and the furniture, technology and equipment that need to support a proposed layout and the design of the physical environment.

Figure 8-6 builds on SCOPE 1.0 presented in Chapter 4, adding identified interventions for organizational and people-based considerations. The ability to visualize all of the considerations simultaneously can generate discussions surrounding the potential interactions across ergonomic levels – a mesoergonomic approach.

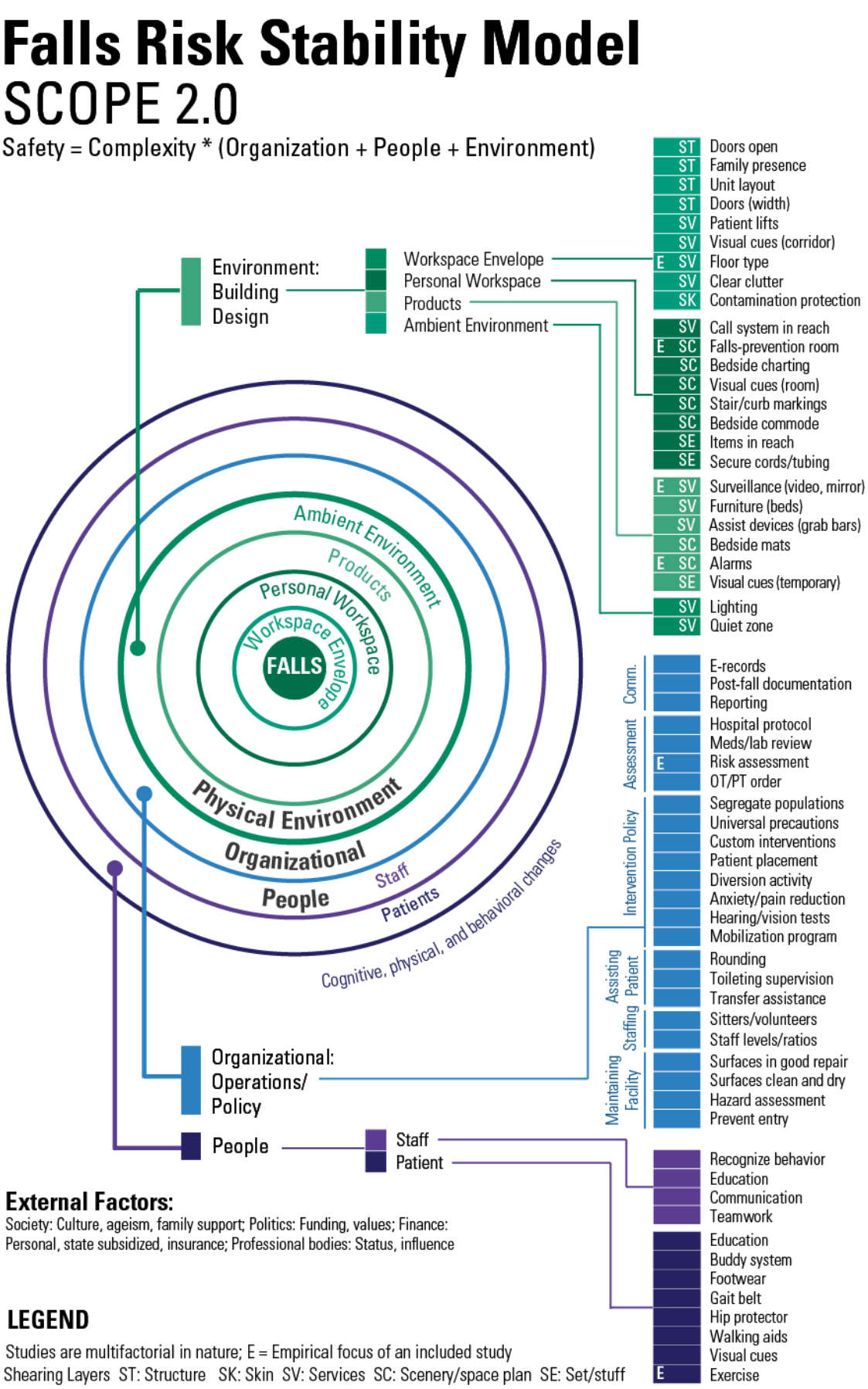

Figure 8-6. SCOPE 2.0 (based on SCOPE 1.0, phase 2 literature review)

8.6.2 Limitations

There are limitations common to both phases of the review. While falls are common adverse events in healthcare settings, there often is a lengthy period of time required in order to report significant change or maintenance of results. For example, a pilot cluster randomized control estimated that to achieve the same results with 80% power would take 33,480–52,840 patient days per arm, 8–12 clusters and 1,800–2,700 participants per arm, with a two-year follow-up (Drahota et al. 2013). This certainly raises some questions about small sample sizes and short durations, even in the best designed study.

Additionally, two independent reviewers did not conduct study selection, quality appraisal, or data extraction. One worked under the guidance of a doctoral advisor. A single outcome was not defined for the review (e.g., falls reduction) to create a more inclusive search that would provide insight on the interventions being used and/or tested. There are inherent limitations to any systematic review. The keywords and inclusion/exclusion criteria establish a focus that may preclude some relevant studies from the review, and in this instance interventions drawn from the literature in organization and people categories may be incomplete. Of the studies included, few were empirical studies of individual falls prevention interventions, although no single solutions are anticipated to solve the problem. Studies of single interventions may best be considered in the context of a larger defined bundle, as with Barker (2013). With respect to the limitations of the second phase, the identified conditions were not surveyed for consensus, as this was out of the scope of the grant with respect to participant commitment to the initiative and timing.

8.7 Conclusions

Stage 7 of the thesis furthered the systematic literature review of falls in healthcare settings presented in Chapter 4. Using the sources identified in Stage 2, findings were expanded beyond the scope of the SRA to identify additional multifactorial latent conditions contributing to the risk of falls – those related to the organization (policies and procedures) and people (both staff and patients). This literature review incorporated the previously referenced dual-method appraisal.

Each of the conditions was extracted (with related appraisal) and summarized in a format that provides a visual representation of patterns of intervention use. Two

of the top three referenced interventions, risk assessments and alarms, may also be some of the most controversial in more recent thinking regarding patient safety. This is evidenced by the latest clinical guidelines issued by NICE that no longer requires a 'scored' risk assessment for falls, but instead provides guidance for a multifactorial approach to risk (National Institute for Health and Care Excellence [NICE] 2013) and by a sentinel event alert issued to warn organizations of the risk of alarm fatigue that may result in a failure to respond in an appropriate or timely manner (The Joint Commission 2013b).

The resulting analysis builds upon the framework of Hignett's (2013) Dial-F systems model and incorporates a model of stability with respect to the built environment and highlighted the complexity of designing for patient safety and mitigating the risk of falls (Figure 8-6). As described in Chapter 4, the most permanent decisions, such as those affecting the building structure, should warrant the most time and discussion. However, as a system, other considerations cannot be ignored and should be used to inform decisions and understand implications of permanence of the physical environment. The participation of a diverse group of stakeholders who are familiar with the organizational, people-related, and environmental conditions is therefore essential when designing a healthcare facility. To fully optimize performance, HF/E expertise would benefit the design process to "*contribute to the design and evaluation of tasks, jobs, products, environments and systems in order to make them compatible with the needs, abilities and limitations of people*" (IEA 2015).

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9 Discussion

9.1 Introduction

Using the case study of falls, the thesis has explored the integration of EBD and HF/E in two parts. As presented in Chapters 4, 5, and 8, models for hospital falls mitigation were developed describing safety as the complexity of interactions with the organization, people, and environment (SCOPE), with building design at the core (Stages 2 and 7). Grounded theory was used to advance understanding for SRA use (Stage 6) through the core theme "Anticipate to Integrate to Participate," as presented in Chapter 7. This evaluated the SRA against the gaps and opportunities identified in Chapter 3 (design methods and tools literature review). As stated in Chapter 6, the thesis did not start with an a priori hypothesis. However, I had hoped that clear categories of built environment interactions would develop during testing and use of the SRA. This was not inherent in the data, and while findings reveal participation and integration as a core theme, findings also suggest several challenges to understanding real-world interactions.

This chapter, as the final stage of the thesis (Stage 8), provides an overview of the systems models (SCOPE 1.0, SCOPE 2.0) and the GT. The discussion conceives two theoretical approaches to bridge HF/E and EBD based on the two systematic literature reviews, explorations into additional literature (Dunne 2011), and data from SRA development. The first theoretical approach (Section 9.2) reframes the SCOPE of falls framework more definitively as an ergonomic design problem. The second theoretical approach (Section 9.3) proposes an HF/E framework to evolve the SRA to "*the implementation of ergonomics within a participative framework*" (Haines and Wilson 1998, 4).

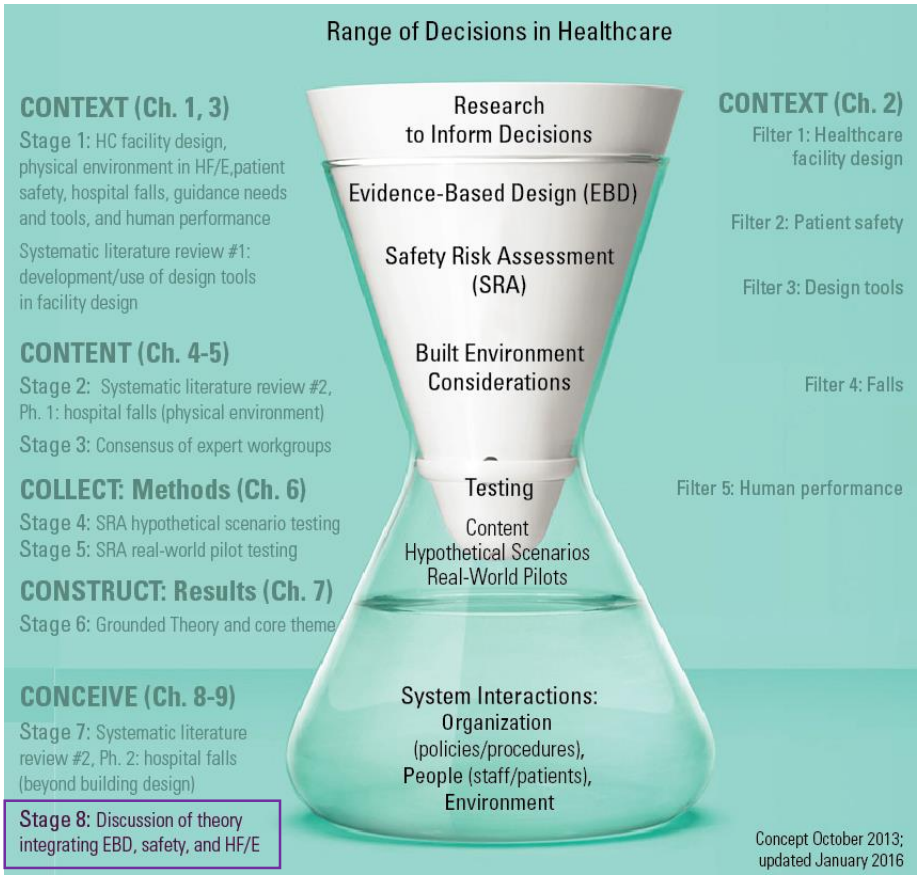

Figure 9-1: Chapter 9 signposting (conceive – Stage 8)

9.2 Aim 1: Systems Models for Falls in HC Facility Design

In this chapter, HF/E design principles bridge the EBD foundation of the SRA with HF/E considerations of organization, people, and the environment (Sections 9.2.2-9.2.4).

9.2.1 Overview: SCOPE 1.0 and 2.0

The SCOPE model was first conceived through extant research. Content was developed to understand the conditions of hospital falls (correlates and interventions) through a two-phase systematic literature review (Chapters 4 and 8) and consensus development for the SRA (Chapter 5). This established the EBD foundation for the study. HF/E was integrated by expanding Hignett's (2013) Dial-F systems model to describe building design and stability (SCOPE 1.0) with HF/E subsets that constitute the design of the physical environment defined (Chapter 4). The second phase of HF/E integration in EBD was achieved by elaborating the people and organizational considerations for hospital falls (Chapter 8, SCOPE 2.0).

9.2.2 Reframing Falls Thinking Using HF/E

As portrayed in Chapters 2, 4, and 8, people (the primary 'human' factor in design) possess an interrelated set of intrinsic conditions that both influence and are influenced by the built environment. The SCOPE framework is categorized in three broad categories of organization, people, or environment. These are potentially discrete units (McNeese et al. 1995) that may benefit from additional integration.

SRA testing illustrated the difficulty of solving falls as a design problem. For example, discussion during hypothetical scenarios and pilot tests included bathroom location (proximity versus identification), floor transitions (shower curbs or smooth transitions), and existing standards. As discussed in Sections 7.4.2.1.1, 7.4.2.2.1, 7.4.3.1, and 7.4.3.3, these are sometimes tradeoff decisions where supporting research is inadequate to address the 'lived-in' challenges raised by test participants. Because bathroom location influences the structural grid and overall unit size, a primary discussion for inpatient unit design is layout configuration: inboard (hallway side), outboard (window side), or nested toilets (between rooms on hallway and window side), as well as whether the bathroom is located on the headwall or footwall (Pati et al. 2009). As referenced in one pilot site (Section 7.4.2.2.1), there is an intuitive response to locate the bathroom as close as possible to the patient, without definitive research to support the decision. Visibility into the bathroom may mean a loss of patient privacy (Section 7.4.3.3), and in many conditions the desire for an identifiable bathroom is sacrificed for proximity and privacy.

Multiple views were also offered about bathroom/shower floor transitions and real-world implications, such as wiping water from the floor. In the case of a pilot site stating that clinical procedures would guide the decision of a curbless shower and nurses would wipe the floor, there was not a follow-on discussion of what design features would best support nurses in such a choice. The reverse was the case in the hypothetical scenario; introducing a curb to eliminate wet floors experienced in real-world projects was not discussed with respect to patient movement into the shower.

Grab bars or emergency pull cords may be placed according to code or manufacturer recommendations for accessibility, but without awareness of the physical limitations of movement or manipulation that might be experienced by an ill or aging patient, these may not be suitably located for use. Participants referenced this solely as a code issue. These examples illustrate that when framed as an

environmental condition, the interaction of active participants in the system is often lost. Introducing HF/E design principles is proposed to reframe the conversation into an ergonomic problem of design – fitting the environment to the user.

9.2.3 HF/E Design Principles: Body and Brain

Chapters 4, 5, and 8 discussed falls in the context of extant literature. Using the falls case study, Chapter 7 constructed theory in using the SRA as a design tool. In development and testing the considerations were framed through building design as a latent condition. To understand fit, however, it is important to understand the active participants (patients and staff). Designing for an unknown future user in a HC facility is complex and must consider general conditions of human performance (Section 2.6), behavior, and user characteristics.

Five HF/E healthcare design principles have been adapted from Carayon, Alvarado, and Hundt (2003) to establish a foundation to address user fit:

- Optimize opportunities for movement (Mv),
- Minimize manipulation time (Ma),
- Minimize need for human strength (St),
- Minimize perception time (Pe), and
- Minimize decision-making time (DM).

These were originally proposed for manufacturing (Helander and Willén 1999) and office environments (Kroemer and Kroemer 2001, Kroemer, Kroemer, and Kroemer-Elbert 2000). They can also be classified in two broad categories termed *body* and *brain* (Figure 2-7). Perception time and decision-making are both associated with the brain domain, while movement, manipulation, and strength are more closely aligned with body (although not mutually exclusive). These ergonomic design principles establish the HF/E framework to investigate systems relationships of the organization, people, and environment.

9.2.3.1 Body

9.2.3.1.1 Optimize opportunity for movement

The human body is not built to stay in the same position for lengthy periods and optimal design must balance the need for movement in patient care duties and sitting or standing for charting or other stationary activities (Kroemer and Kroemer

2001, Kroemer, Kroemer, and Kroemer-Elbert 2000, Carayon, Alvarado, and Hundt 2003). Equipment and materials should be conveniently located and easily accessible, with technology (e.g., cell phones, laptops) allowing for freedom of movement from workstations (Kroemer and Kroemer 2001, Kroemer, Kroemer, and Kroemer-Elbert 2000, Carayon, Alvarado, and Hundt 2003). In some instances the speed of movement needs to be considered. Response time is considered as a combination of reaction time (i.e., from signal onset to the beginning response) and movement time (i.e., the beginning response through to the completion of the response) (Sanders and McCormick 1993). This aspect of movement can also be related to decision-making.

According to these principles, designers should:

- support healthy/neutral postures that provide comfort without annoyance allowing flexibility in furniture (e.g., chairs, standing workstations, resilient flooring) (Kroemer and Kroemer 2001, Kroemer, Kroemer, and Kroemer-Elbert 2000, Carayon, Alvarado, and Hundt 2003, Wickens et al. 2014);
- place all things a user must operate with hands in front of the user, at elbow height, and within reach (Kroemer and Kroemer 2001, Kroemer, Kroemer, and Kroemer-Elbert 2000, Carayon, Alvarado, and Hundt 2003, Wickens et al. 2014); and
- locate visual displays within a normal line of sight and cone of easy eye rotation (Wickens et al. 2014).

Based upon SCOPE 2.0 (Figure 8-6), designing to mitigate falls within movement would include walking surfaces (floor materials and transitions, weather/contamination protection), tripping hazards (clutter, cords, equipment), understanding organizational policies for surface maintenance (cleaning, repair, accessibility of supplies), recognizing necessary movement aids for people (walking aids, footwear, bedside commodes), and facilitating the suitable reach of personal items.

9.2.3.1.2 Minimize manipulation time

Manipulation includes physical affordances and constraints to optimize use. Structural (static) and functional (dynamic) anthropometric data can help designers prevent awkward positions (i.e., heights, reach, grip, clearances) while recognizing

human variability (i.e., age, gender, ethnicity, occupation) (Wickens et al. 2014). However, dimensional characteristics (e.g., reach) do not guarantee the ability to lift or manipulate an object, and mechanical forces also must be taken into consideration (Wickens et al. 2014).

With respect to design, parts or equipment should be easy to move, easy to grip/grasp, and should not tangle, while materials should not be weak, easy to bend (unless intended), or likely to chip or crack (Helander and Willén 1999, Kroemer and Kroemer 2001, Carayon, Alvarado, and Hundt 2003). In addition, transfer of training (e.g., equipment use) should be considered so that previously acquired skills can be applied to new products or workstation layout to avoid confusion and loss of efficiency (Carayon, Alvarado, and Hundt 2003, Helander and Willén 1999).

Identified options (Wickens et al. 2014) include:

- designing for the extreme (e.g., clearance of the largest, reach of the smallest);
- designing for adjustability (e.g., seats);
- designing for the average (e.g., a registration counter); or
- designing for a percentile (e.g., the 5th or 95th to define upper and lower limits).

Based upon SCOPE 2.0 (Figure 8-6), designing to mitigate falls in manipulation would include ‘manipulating’ people, such as necessary space to support organizational policies of transfer assistance and wide doors to allow assisted ambulation (which could also be movement). Other considerations would include the manipulation of objects: call systems, doors (while attached to an IV or using a walking aid), and grab bars within a suitable reach (that if located to meet code may not be optimized for most users).

9.2.3.1.3 Minimize need for human strength

Strength is influenced by motivation and will (Kroemer 1999). It is most often associated with muscles in the arm, leg, or back and can be dynamic (e.g., lifting) or static (e.g., holding, gripping) (Sanders and McCormick 1993). A lack of strength can result in musculoskeletal injury or whole body fatigue (Wickens et al. 2014). According to Sanders and McCormick, strength shows an accelerated decline starting at age 51-55 (an 80% decrease from peak strength) with a 60% strength capacity (as

compared to peaks) by ages 71-75. This has implications for both patients and an aging workforce.

Biomechanical analysis is one approach for assessing dynamic capacity for infrequent manual handling tasks, while physiological approaches are often used for frequent tasks done over a period of time (Sanders and McCormick 1993). Psychophysical approaches take into account biomechanical and physiological stresses but also consider perceived stress (Sanders and McCormick 1993, Kroemer 1999). Designers should incorporate mechanical devices to reduce or eliminate the need for human strength (Kroemer and Kroemer 2001, Kroemer, Kroemer, and Kroemer-Elbert 2000, Carayon, Alvarado, and Hundt 2003).

Based upon SCOPE 2.0 (Figure 8-6), designing to mitigate falls in strength would include the room/bathroom configuration, toilet location in the bathroom, the use of grab bars to support weaker patients (also in manipulation for reachability), and the use of patent lifts to aid both patients (ambulation) and staff (at risk of falling from reflex reactions during assistance). Organizational policies for mobilization programs (and where that takes place) could influence design decisions (activities on unit hallways or in patient rooms, versus an occupational/physiotherapy area).

9.2.3.2 Brain

9.2.3.2.1 Minimize perception time

Information is collected by the senses (a bottom-up process of what is there through visual legibility, audibility, familiar representations) and is influenced by expectations that are a result of short- and long-term memory (a top-down process of what should be there through discriminating features, context, and redundancy) (Noyes, Garland, and Bruneasu 2004, Wickens et al. 2014). According to Carayon, Alvarado, and Hundt 2003 (2003) and Helander & Willén (1999), designers should:

- Understand that hidden or invisible parts are sometimes forgotten (e.g., small fonts on display monitors);
- Use visual discrimination such as size or color coding to form families of parts that belong together and enhance stimulus-response for reduced reaction time (e.g., red for alarms); and
- Recognize that touch (texture and size) can be a discriminating factor (e.g., sanded door knob finish to indicate no entry).

Based upon SCOPE 2.0 and the SCOPE matrix, designing to mitigate falls in perception would include fall alert visual cues inside and outside the patient room, the ability to leave doors open, lighting, decisions for technology to reduce noise (e.g., alarms, paging), and a recognition of patient conditions that result in an overestimation of abilities as well as changes to "normal" perception.

9.2.3.2.2 Minimize decision time

Decision-making is influenced by mental effort and attentiveness: selective, focused, and divided (Wickens et al. 2014, Noyes 2002). Wickens et al. (2014) describe the decision-making task as choosing from more than one alternative through information available relative to the options. Choice may be associated with uncertainty with no clear best option Wickens et al. (2014). As illustrated in Figure 2-7, this follows the delivery of perceptual information, which is interpreted through the working memory (impacted by capacity and time) (Wickens et al. 2014, Noyes 2002). It is documented that decision-making in context varies from decision-theory and choice behavior in controlled settings, but some cognitive task analysis methods have been developed to bridge this gap (Wilson and Sharples 2015).

As discussed in Section 2.6, mental models help organize the execution of a task, and task visibility is important in creating a mental model. According to Carayon, Alvarado, and Hundt 2003 (2003) and Helander and Willén (1999), designers should:

- Consider the user's mental model and recognize that diverse tasks result in different mental models to achieve different things with differing priorities (e.g., visibility, different alarm sounds);
- Minimize the number of (or collocate) components and related tools (also saving space) to reduce choice reaction time (e.g., code button at the bed);
- Locate work elements in sequential order with task items that belong together in close physical proximity (e.g., crash carts) to improve spatial compatibility and improve stimulus response;
- Incorporate visual, tactile, or auditory feedback to indicate that the task was completed (e.g., electronic sound for touchscreen functions).

Based upon SCOPE 2.0 (Figure 8-6), designing to mitigate falls in decision-making would mostly include considerations in an organizational context. From a

design perspective this would include organizational policies related to use of sitters (and family presence), falls documentation (and bedside charting), universal versus customized protocols, segregation of populations (and intent for patient placement). The display of patient education materials may also influence design. Design also should take into account unit layout and surveillance options as needed, especially as they pertain to workflow.

One study in the systematic review for falls included cognitive work analysis. The study design included observation, time motion analysis, focus groups, and surveys (including the NASA-TLX Workload Instrument) to understand the hidden work factors that impact patient falls (Lopez et al. 2010). Researchers found the physical environment was one of four work-process constraints that also included head data, temporal workload, and communication inconsistencies. As a result, staff employed workarounds, "*first order problem solving that adapts work to cope with inefficiencies* (Hollnagel, Braithwaite, and Wears 2013, 140). These included written and mental chunking schemas, bed alarms, informal querying of the previous care nurse, and informal video and audio surveillance (Lopez et al. 2010).

9.2.4 DEEP SCOPE (DEsigning with Ergonomic Principles)

As discussed in Section 9.2.2, the addition of the ergonomic design principles framework provides a way to synthesize findings into a systems-based model for ergonomic building design. DEEP SCOPE (Figure 9-2) builds upon the findings and expanded framework of the SCOPE 2.0 systems model presented in Figure 8-6 by incorporating design with ergonomic principles. The updated model adds HF/E design principles with a layer of color coding that supplements the three categories of organization, people, and environment.

As shown, there is a range of interventions that cross all of the HF/E design principles, as well as the subcomponents of the physical environment. The organizational considerations are marked by a prevalence of decision-making interventions, whether associated with communication, culture, patient assessment, or patient-based interventions. People-based interventions focus primarily on the patient and span a range of the HF/E design principles.

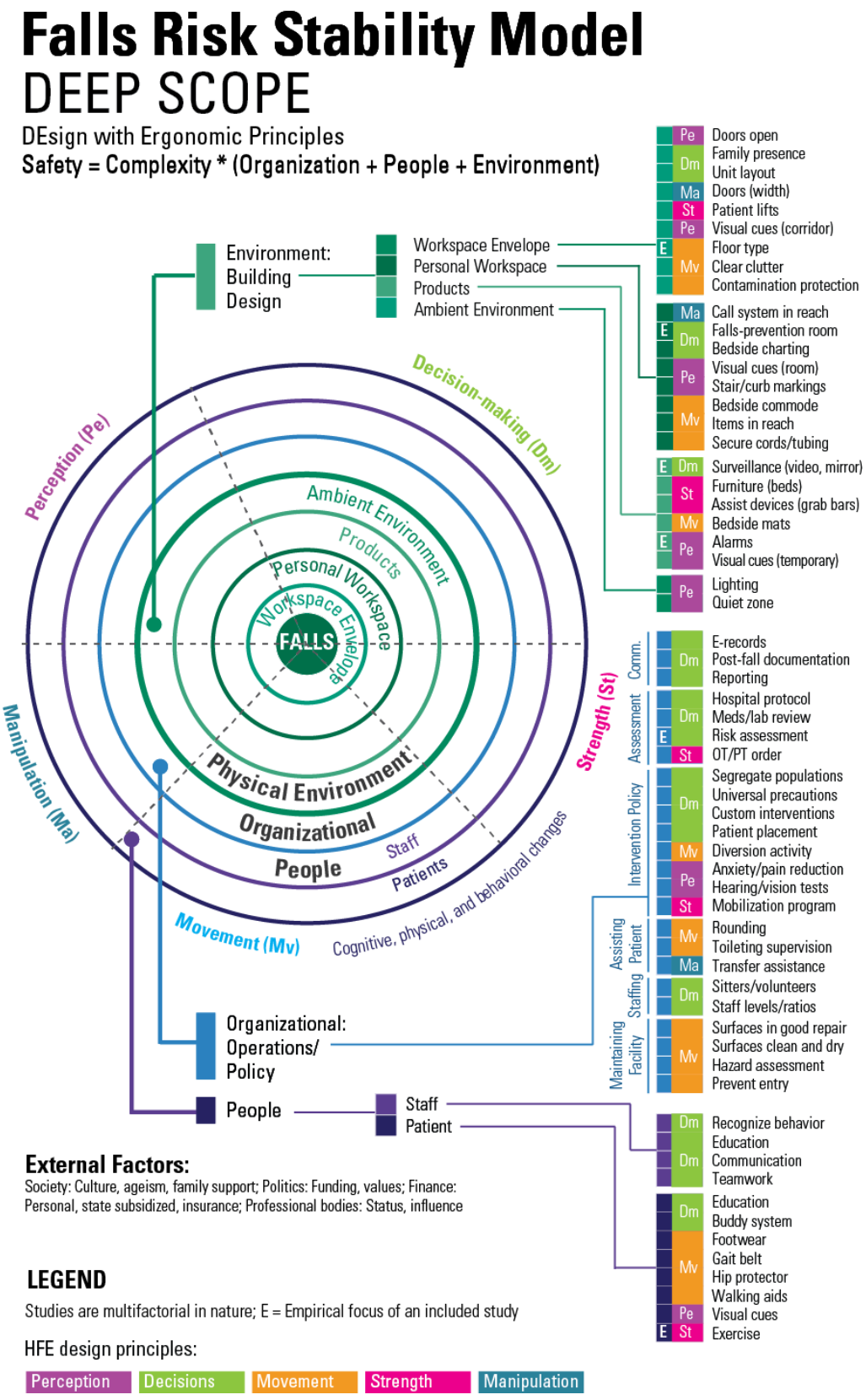

Figure 9-2. DEEP SCOPE (expanded from SCOPE 1.0 and SCOPE 2.0)

Figure 9-3 shows SCOPE evolution.

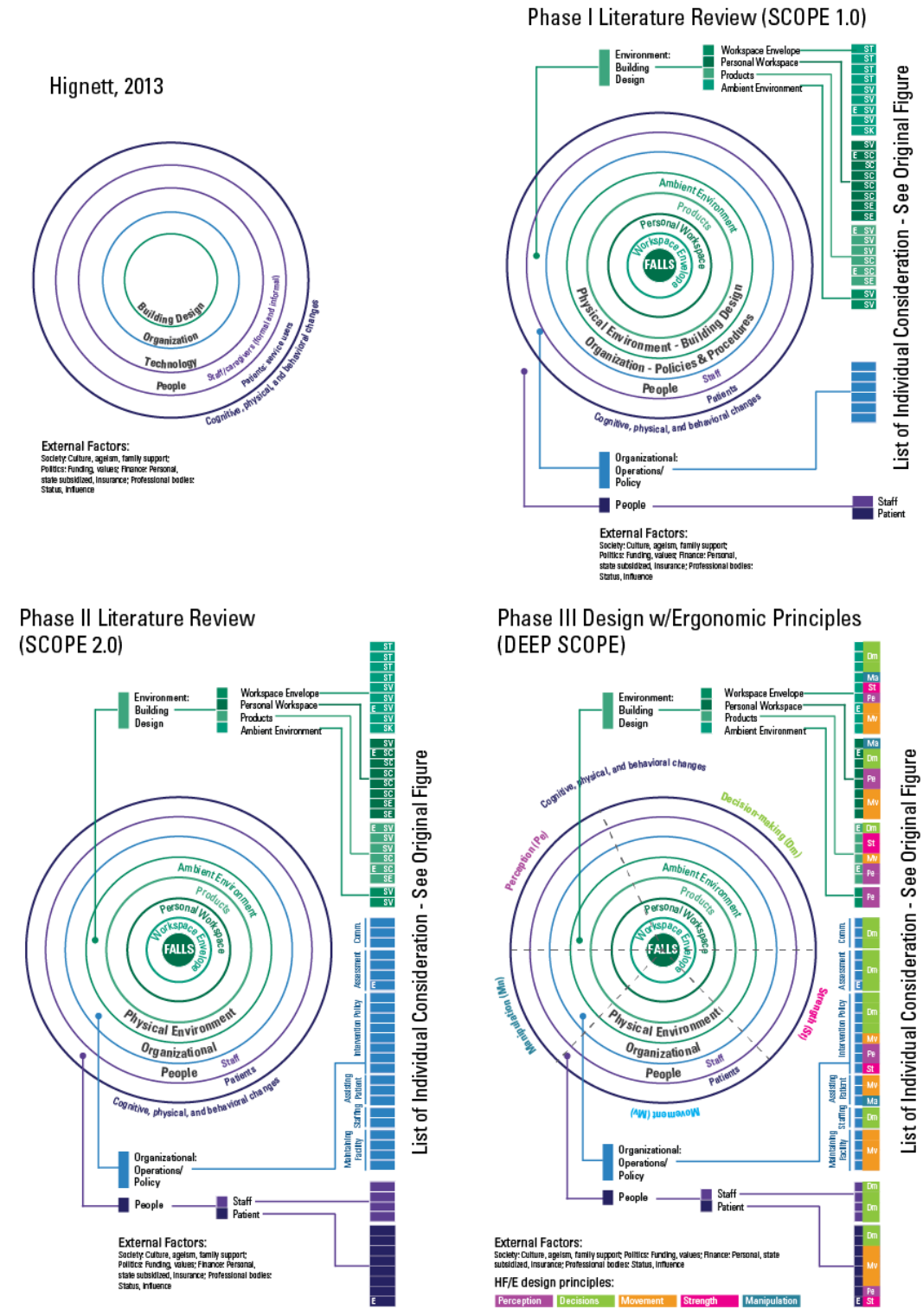

Figure 9-3. The evolution of the SCOPE model to design for safety from hospital falls

9.2.5 The DEEP SCOPE Matrix

A second visualization departing from the concentric circles of the Dial-F model (Hignett 2013) is provided in Figure 9-4.

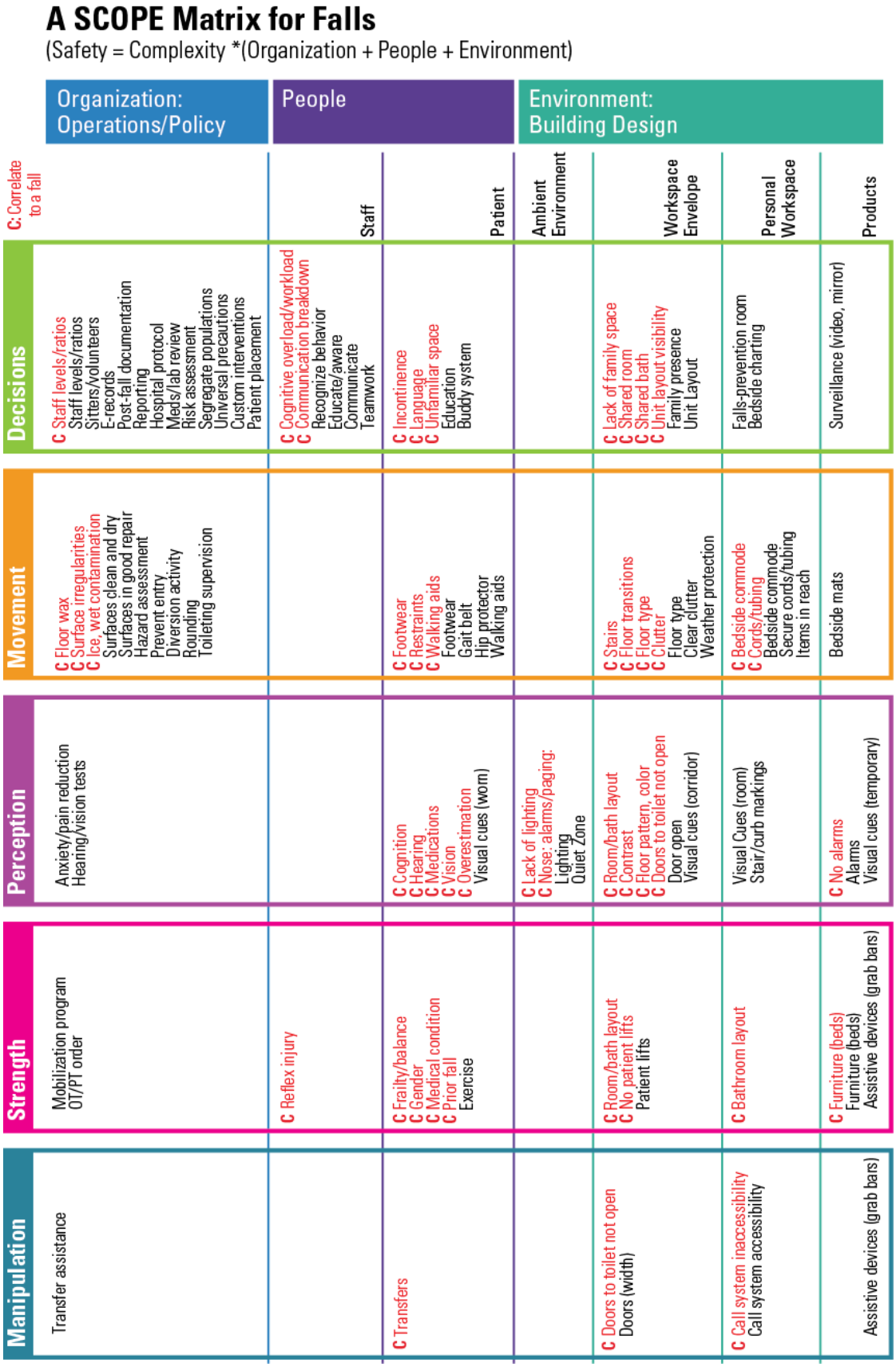

Figure 9-4. Falls risk and mitigation – the DEEP SCOPE matrix for falls

The DEEP SCOPE matrix includes the correlates of falls and might suggest the alignment of interventions that have been tested or used as part of a multifactorial bundle. (It also more easily allows an intervention to be placed with more than one principle, for example, grab bars that are used to support weak patients *and* placed to be reachable.)

9.2.6 The Model in Context of Prior Models

The understanding of falls is complex, as described throughout this thesis. The aim of the thesis was not to experimentally quantify the effect of specific interventions, but to theoretically explore how we think about the challenge of safety in HC facility design. As described in Section 2.3, the literature surrounding thinking for patient safety has evolved since the development of Reason's (1990) accident causation model often used as a basis for the role of the environment as a barrier to errors (Chapter 2). However, while this recognizes system influences, Reason posits a sequential approach that originates in imperfect decisions and line management deficiencies, further hampered by preconditions and unsafe acts that pass through a limited window of accident opportunity (Reason 1990).

According to Carayon et al. (2006), the strength of sequential thinking for accident causation is the etiology of accidents and adverse events with descriptions of contributing factors, while the lack of discussion of processes and guidance for system redesign is a weakness. As a result, guidance for system redesign was addressed through the SEIPS model (Carayon et al. 2006, Holden et al. 2013) where the work systems (including the internal and external environment) influence processes that subsequently influence outcomes. According to Carayon et al. (2006), the benefit of the SEIPS is focus on the system design and description and resulting effect on processes and outcomes. Its weaknesses include its framework - a descriptive model with no specific guidance as to the critical elements (Carayon et al. 2006). While there is reference to the use of plans and questions to determine the contribution of the environment to patient safety in the SEIPS model (Carayon et al. 2006), few papers citing SEIPS offer detail on the influence of the environment in their study. In my argument for the built environment as the stage for all activity, the SEIPS model does not optimize the proactive design process needed for safety in EBD projects.

The Dial-F systems model proposes building design as the most stable condition of the system and focuses on the patient as an active participant in care (Hignett 2013). While it makes this leap, it was not intended for HC facility design. These evolutions are important contributions, and each is logical in the context of an intended audience. What is missing from these approaches is both a hierarchy of decision-making for interactions with the environment and guidance for the conditions to be considered during a HC facility EBD process. The evolutions of SCOPE are intended to proactively advance safer HC facility design. The DEEP SCOPE theoretical framework establishes building design as an ergonomic problem by:

- defining stability and HF/E environment categories,
- identifying interventions in three interacting categories, and
- establishing connections to HF/E design principles.

9.3 Aim 2: Integrating HF/E methods and EBD in HC Facility Design

As discussed in the study findings in Chapter 7, the SRA provides opportunity for more effective decision-making through an understanding of the end-users of the system. The process also offers value by including a diversity of stakeholders in an interdisciplinary participatory process, as compared to traditional silos. This facilitates a process where different points of view can be expressed for optimum integration and priorities can be determined as part of a strategic decision-making process. This can also inform decisions surrounding tradeoffs and competing drivers. The proposed SRA process would leverage the subject matter expertise of the group, as well as an understanding of the system with respect to patient care and effective and efficient workflows across the organization. The process offers opportunities to engage users in HC facility design in a variety of ways: as users providing iterative feedback across stages of the project, as subject matter experts partnering with a facilitator, and as contributors that actively support a culture of safety and consensus within the organization.

The second theoretical approach of the thesis advances HF/E through a participative framework. Chapter 7 reported the core theme in context of findings of extant literature for use and development of design tools and addressing gaps in the existing design culture and use of the evidence base. This was conceived by identifying a participatory process as the means to integrate safety into EBD projects.

However, while user participation is widely recognized in design and EBD that promote use of an interdisciplinary design team, there is a lack of definition and adequate guidance (Chapter 2). As a result, additional literature searches were undertaken to explore participation (specifically participatory ergonomics) to support the evolving grounded theory resulting from data analysis of SRA testing (Section 7.4.3.6.1).

Data analysis through both SCOPE models and SRA testing suggests design solutions across HF/E levels:

- organizational and operational context (macroergonomics),
- specific solutions to address the users the design is to serve (microergonomics), and
- the interactions across these systems (mesoergonomics).

A framework of what I term participatory mesoergonomics is proposed in Sections 9.3.1 and 9.3.2. This includes SCOPE models and the SRA process to identify individual components (microergonomics), understand the organization and system (macroergonomics), and explore the interactions among other elements of a system as part of a mesoergonomic framework. I argue this could be supplemented by a range of PE practices to bridge the conceptual aspect of HC facility design and constructed reality that together optimizes human well-being and overall system performance. This leverages the EBD process of interdisciplinary teams, hypothesis generation, and testing.

9.3.1 From Participatory Ergonomics to Participatory Mesoergonomics

Introduced in Section 2.2, PE covers a broad range of ideas and practices. Vink et al. (1995) described an "ideal process" for PE that includes preparation, analysis of work, choice of solutions, implementation, and evaluation. Wickens et al. (2014) identify PE as the most common method for taking a macroergonomic approach. Wilson and Haines (1998) extended the concept of PE beyond workers to all stakeholders – anyone affected by the changes, subsequently validating a PE framework (PEF) (Haines et al. 2002). Recent research suggests the PEF (Haines et al. 2002) would benefit from tools and methods (Broberg, Andersen, and Seim 2011). The SRA can serve as a tool to support the PEF, engaging multiple stakeholders to solve mesoergonomic problems.

As described in Chapter 1, there is a need to broaden HF/E approaches in HC facility design to move beyond microergonomic solutions that are already constrained by early design decisions. The mesoergonomic framework for inquiry (Karsh, Waterson, and Holden 2014, Karsh et al. 2006) introduced in Chapter 1 includes factors of nested performance inputs: patient/provider (PP), work system/unit (WSU), organizational (O), and external environment (EE). These factors are added to the PEF of Haines et al. (2002) to result in the combined participatory mesoergonomics framework illustrated in Figure 9-5. This incorporates the grounded theory core theme subcategories (anticipate, participate, integrate) and proposes inputs of the SRA and SCOPE to advance an understanding of the designed environment within the mesoergonomic context.

SRA-HF/E Model
Participatory Mesoergonomics
Safety in Numbers: Anticipate, Participate, Integrate

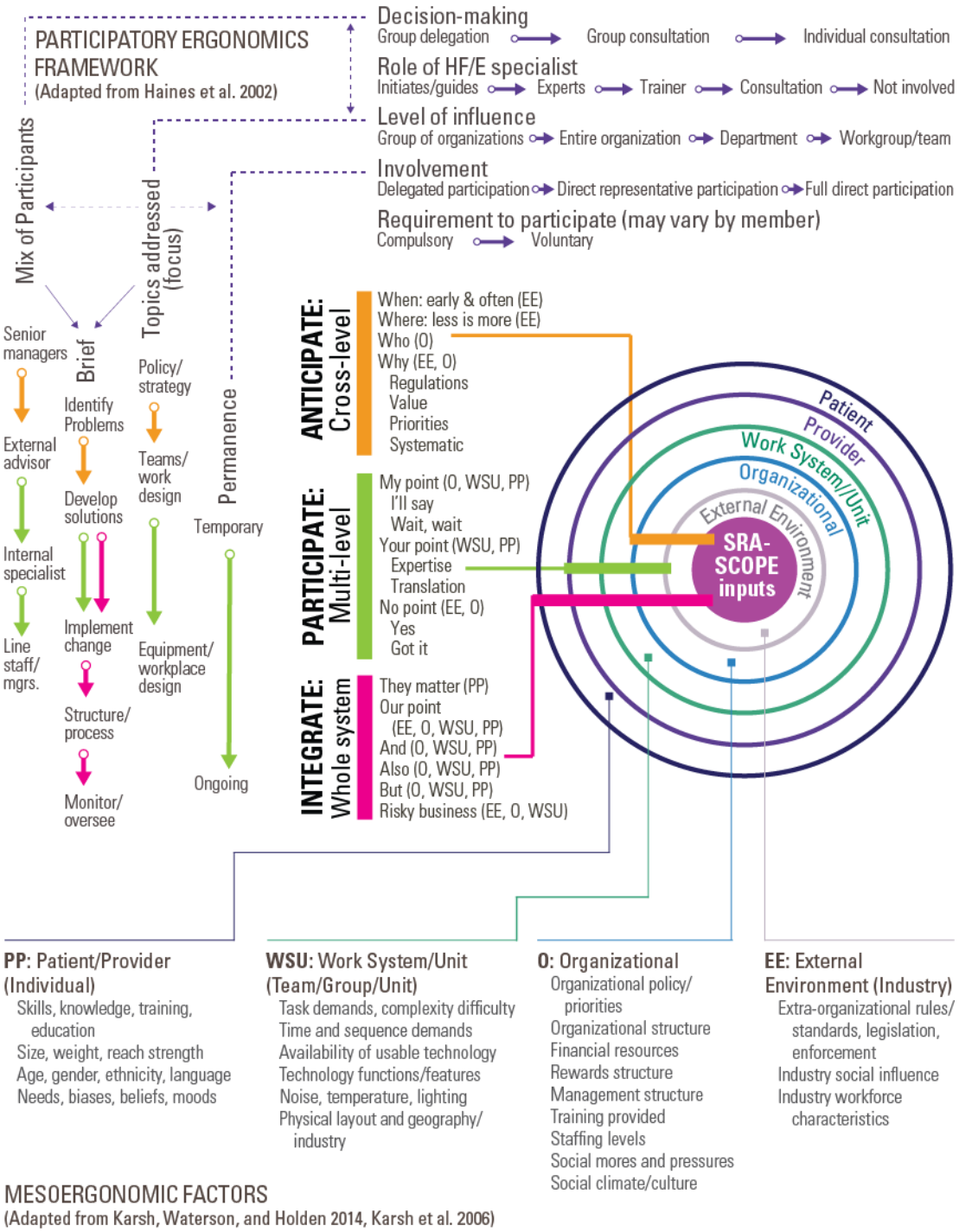

Figure 9-5. The SRA participatory mesoergonomics model

This model is intended as a framework to advance the SRA process. As a tool, the SRA is currently bound by built environment considerations. The SCOPE 2.0 model advances the understanding of considerations in other levels of the system. In the proposed participatory mesoergonomics model, the SRA toolkit and conditions identified in SCOPE provide the basis for a participatory process that can continue beyond the identification of solutions through the testing and evaluation of solutions. This would address the challenge of "*absolute truth*" raised during SRA testing and support the suggestion that the SRA is the first stage of a research process (Section 7.4.3.6.1).

9.3.2 Participatory Mesoergonomics to Anticipate, Participate, and Integrate

The participatory mesoergonomics framework advances grounded theory constructed in Chapter 7. It proposes that in using the SRA, organizations should *anticipate* adverse events and establish a proactive participatory approach for when the SRA will be used and by whom (through senior leadership commitment and organizational strategy). Multiple stakeholders should *participate* to provide a diversity of internal and external expertise and points of view (creating empowered teams to develop concept-based solutions in SRA sessions). Interdisciplinary teams should *integrate* the considerations to advance safety concepts, confirm solutions, and implement change (through SRA sessions and additional HF/E research methods to understand interactions). It is proposed that this will optimize the design for patient and staff conditions, workflow, and environment-behavior interactions.

Within the participatory mesoergonomics framework, 'Anticipate' has the potential for alignment with the mix of participants, engaging leadership and senior management to define priorities and goals for the safety considerations, as identified during SRA testing (Section 7.4.1.4, Section 7.5.1). This is further discussed in Section 9.3.2.1. The theme 'Participate' (Section 9.3.2.2) offers opportunities for a multi-level mesoergonomic approach that aligns design to organizational priorities, the work system/unit (e.g., tasks/sequence demands, ambient environments, physical layout), and the patient/provider (e.g., skills, physical demographics, beliefs). This leverages tacit knowledge of the system (Section 7.4.2.1) and subject matter expertise (Section 7.4.2.2). Lastly, the 'Integrate' theme crosses all mesoergonomic factors, highlighting the potential for a whole-system approach. Building on the two prior theme categories 'Anticipate' and 'Participate,' 'Integrate' continues the process of

solution development by converging on a solution derived from diverse points of view (Section 7.4.3.6), deciding on necessary tradeoffs (Section 7.4.3.3), and evaluating risk and feasibility (Section 7.4.3.4). This is described in Section 9.3.2.3.

9.3.2.1 Anticipate through Participatory Mesoergonomics

The SRA offers a structured process for safe design by proactively identifying design considerations, establishing the safety foci to be addressed at a strategic level, and anticipating a mix of stakeholders who will participate over the course of the project. This is a cross-level approach that must take into account the external environment and organizational factors.

When used early in the design process (Section 7.4.1.1), SRA testing confirms the tool as a process to systematically understand the built-environment conditions that contribute to risk (Section 7.4.1.4.1). The SRA provides structure for inventorying problems, the first stage of a typical PE process (Vink, Koningsveld, and Molenbroek 2006, Haines et al. 2002, Henning et al. 2009, Wilson 1995). As identified by participants during testing, organizational priority and cost-benefit need to guide the process (Section 7.4.1.1). This is consistent with findings from Wilson (1995) identifying that a large number of problems resulted in the need for prioritization reactive to costs and feasibility (as well as a balance to meet multiple user needs).

The dashed line linking the topics to be addressed and the level of influence are reminders that organizational policy and strategy can be included in the earliest phases of designing for safety, as identified by many of the participants during testing. It is important to align the goals and objectives of the organization and the individual participants in the process. In the PEF by Haines et al. (2002), the brief was identified as the second most important category, but in the use of the SRA this may be superseded by policy and strategy defining the topics to be addressed. This may be moderated by the use of a steering group (Vink, Koningsveld, and Molenbroek 2006, de Looze et al. 2001), an approach suggested (but not always used) in EBD (Section 2.2.3.2.2).

Design is a social interaction that considers both technical solutions and the organization of work (Garrigou et al. 1995). Empowerment increases the chance of success, leads to engagement as part of the decision-making process, and contributes to project ownership and higher satisfaction with results (Vink, Koningsveld, and

Molenbroek 2006, de Looze et al. 2001, Kujala 2003). However, not everyone can be involved. During the 'Anticipate' phase, stakeholders need to be identified by leadership and senior managers. As defined by Haines et al. (2002), individuals may unofficially represent a subset of the organization (e.g., nurses), while others may represent the organization's official proxy for the project (e.g., a clinical liaison responsible for ensuring open communication between staff and the project team). As described in Chapter 7, suggestions for participants were provided to the real-world pilot sites and the organizations' choices successfully included diverse views. Implementation methods (more or less collaborative in Figure 7-9) may vary. The participatory mesoergonomics model promotes the more collaborative process.

As indicated by the dashed line link (Figure 9-5), the participant mix should be considered with respect to decision-making authority. Authority may vary according to the culture of the organization, but there should be a clear understanding of whether the discussion will be elevated to a higher level before finalizing an approach. This ensures the participation is not just a "paper exercise" (Wilson 1995). During SRA testing, those with HF/E backgrounds were included as experts, but there are opportunities for leadership through testing and evaluating proposed SRA safety solutions. This will be discussed in Section 9.3.2.3.

Involvement in Figure 9-5 is most closely aligned with both the participant mix and the permanence of participation. At pilot site 3, it was communicated that there was a waiting list for participation, indicating that while participation might be compulsory at one level (representing a subset group of stakeholders), participation might be voluntary at another level (through expressed interest). Findings from SRA testing support the need for strong feed-forward communication (Section 7.4.1.2, Section 7.5.1), and this could be used for communication with others who do not have direct involvement (Section 7.4.1.1).

9.3.2.2 Participate through Participatory Mesoergonomics

Establishing the multi-level mesoergonomic approach in the 'Participate' category includes engaging a diverse group of stakeholders in the SRA that may include front-line staff (e.g., nurses, environmental services), internal specialists (e.g., infection preventionists, ergonomists), and external advisors not available within the organization (e.g., architects, ergonomists). This group is influential in development of the brief by proposing ideas and solutions through the collaborative discussion of

the SRA. Emerging ideas should also address work design to ensure solutions are consistent with the intended model of care. This represents a multi-level approach of the organizational, work system/unit, and provider inputs.

After identifying problems, teams develop solutions (Haines et al. 2002, Henning et al. 2009, Wilson 1995). In the context of the SRA, this was achieved through interdisciplinary discussion (Sections 7.4.2.1, 7.4.2.2, and 7.4.3). In a PE process, users continue from problem identification to solving problems through a range of HF/E methods. In solving problems, topics move from a strategy level to a teams and work design level, as well as the equipment and workplace design level (Haines and Wilson 1998). Garrigou (1995) notes that many PE studies use activity analysis to verify tacit knowledge. Methods to study activity analysis (e.g., link analysis, hierarchical task analysis) typically focus on existing processes and conditions. Activity analysis is less frequently used in EBD-related studies but can provide insight into the design of space. For example, one study used task analysis and link analysis to understand the design of soiled workrooms for clinical efficiency (Lu and Hignett 2009).

Participants can include consultants, internal specialists, and staff. Pilot site organizations designated participants, based on their role (e.g., a unit nurse manager), their expertise (e.g., an infection preventionist), and scope of the project. Based on the results of testing, it is important to assemble participants that can offer views on workflows, as well as provide subject matter expertise, without losing the ability to listen to others. Data from testing indicate the team is just as important as the SRA content (Section 7.4.1.3). It is not the number of people involved per se, but a balanced set of views that advance a proactive discussion. Lacking this dynamic, the process is less effective and trends toward a silo effect identified during testing and through the tools literature review (Section 7.4.2.3, Section 7.5.2, and Section 3.4.4.1).

Permanence of participation will vary. As ideas and solutions emerge and the project progresses, participant roles may be supplemented by additional temporary input (e.g., additional medical planners to develop detailed requirements, additional front-line staff to make certain selections). This may include individual consultations for decision-making at a localized level, as well as a tiered level of influence that looks at issues specific to a department or team (Haines et al. 2002). As identified by those testing the tool, instead of enlisting new members of the team in a silo, the SRA can be

used as a communication tool to continue alignment with the strategic and tactical goals of the project (Section 7.4.1). Ideally, senior leadership maintains a role as they delegate responsibility, fostering support and maintaining the high-level project priorities when difficult decisions are necessary or 'value engineering' is undertaken.

Some studies have identified the top-down and bottom-up combination. In one, top and middle management were involved during the introduction phase of PE, employees and designers during idea generation, and middle management and employees during idea selection (Vink, Imada, and Zink 2008). In another, management conceived the system design, while employees engaged in activity analysis (Garrigou et al. 1995). As participants testing the SRA suggested, engaging the architect/designer in the strategic goal-setting and decision-making process would be a preference to engender a better understanding amongst the project team as part of 'Anticipate' activities (Section 7.4.1.1).

9.3.2.3 Integrate through Participatory Mesoergonomics

Integration starts when participants form a team, recognize each other's experience and expertise as the basis of understanding interactions, and develop trust (Section 7.5.1). This is similar to the confidence identified by Haines and Wilson (1998). Chapter 7 reveals that this results in a collaborative decision-making process that incorporates workgroup views, while creating an understanding of priorities and tradeoffs.

As described in Section 7.4.3.6.1, there is a need to evaluate solutions and balance what was meant versus what was said (Gould and Lewis 1985), and what is performed versus what is described (Garrigou et al. 1995). There is also a challenge to determine the interactions with a future state that does not yet exist (Section 2.2.3.2). To achieve this goal, some have used boundary objects (models, mock-ups, photo journaling, games) to elicit user feedback on future work solutions (Broberg, Andersen, and Seim 2011, Reiling et al. 2004), while others have used simulation techniques (Garrigou et al. 1995) or field visits to other sites (Wilson 1995). Mock-ups and certain simulation methods are familiar to EBD design teams who may be seeking or proposing research, but the role of an HF/E specialist may frame activity in the HF/E context, especially where a method may be conceived differently, as in mock-ups (Appendix L). Integration of HF/E with design will likely need collaboration with the HC facility design team, perhaps creating the role of an

"ergotect" that synthesizes solutions, suggesting the more collaborative and group leadership process diagrammed in Figure 7-9.

As identified in the participatory mesoergonomics framework, there is a process of implementing and overseeing change. This was referenced throughout testing as a way to ensure that priority solutions were not being cut from the project for budget reasons (Section 7.4.1.1). According to Hall-Andersen and Broberg (2014), post-occupancy evaluation revealed that not all of the recommendations had been implemented as documented, despite their project including multiple disciplines and an ergonomist. The ergonomics guidelines document generated as part of the project was intended as a "closed" communication tool, but the document was judged as an "open" tool that was subject to design changes. A gap was created by the lack of continued participation (Hall-Andersen and Broberg 2014) highlighting the need for continuity throughout the project, transition planning, and occupancy to ensure a comprehensive understanding of the decisions and intent. Unfortunately, this is often a shortfall in the process, where the most permanent members during design, funded by capital sources, are released as the project completion nears.

9.3.3 Bridging an Understanding of HF/E in EBD

The typical design process and participation in design (Sections 2.2 and 3.4.4) differs from PE that studies ergonomics through a participatory framework using multiple methods and techniques (Haines and Wilson 1998, Wilson and Haines 1998). The proposed participatory mesoergonomics framework has the potential to advance thinking in both HF/E and EBD using the SRA as "*middleware*" that "*lubricates the connections among these differences to reduce friction in each transaction*" (Imada 2007, 93). Participatory mesoergonomics would engage teams in activities that have some level of familiarity and supplement concept and solution generation with further evaluation through HF/E approaches. An exploratory table is provided in Appendix L.

While PE was included as one of the methods that might be used to advance designing for patient safety in a prior seminar project (Joseph et al. 2011), it was not brought to the final seminar for review due to the perceived difficulty or "foreign" nature of the process. I believe this perception is due in part to a lack of understanding of the term *ergonomic* in the architecture profession (Section 1.1). As described in Chapter 1, the misconception of ergonomics and perceived boundaries of PE narrows

the focus solving ergonomic problems, and PE is confined to a staff process for work design and injury reduction (Haines and Wilson 1998, Hignett, Wilson, and Morris 2005, Wilson and Sharples 2015, Carayon 2011, van Eerd et al. 2010). However, adopting the position of Wilson and Haines (1998), PE extends beyond workers to all stakeholders. This reasonably includes the design team, as well as topic experts and the front-line staff, and management who work collaboratively toward mesoergonomic solutions that consider DEEP SCOPE in HC facility design. These solutions could be advanced by additional HF/E evaluation methods.

9.4 Conclusion

The SRA content is grounded in research and best practice, but is not intended solely as a compliance tool to meet requirements of US-based guidelines. There is significant worth in discussing EBD in HC facility design as a HF/E problem. This goes beyond work as imagined and offers opportunities to identify what may promote or impede desired behaviors for safety, rather than trying to modify behavior after the fact. This process of understanding the real "in use" characteristics of space can proactively inform decision-making through a *purposed* process that bridges the domains of EBD and HF/E. In summary, proposed use of the SRA to 'Anticipate to Participate to Integrate' for safety, with an understanding of HF/E conditions through the SRA and SCOPE models, can advance a participatory mesoergonomics framework for engaging stakeholders in solving mesoergonomic problems of safety.

10 Conclusion

10.1 Chapter Overview

This chapter summarizes the findings of the thesis through the aims identified in Chapter 1. The primary objective of the thesis was to advance proactive thinking in designing healthcare facilities for safety by constructing theory that bridges gaps between EBD and HF/E. This was pursued leveraging the development of the SRA for HC facility design and using the SRA topic of falls as a case study of exploration.

10.2 Crossing the Bridge: The Aims Answered

The context of HC facility design is both complicated and complex. Existing processes do not promote an end result of optimizing environments for safety. Using consensus-based methods to establish content for design considerations to mitigate the risk of falls, the research undertook a mixed methods approach to test the SRA in both hypothetical scenarios and real-world projects. An inductive and abductive approach was used with quantitative and qualitative data analysis to construct a core theme through grounded theory - *Safety in Numbers? Anticipate to Participate to Integrate*. This continued evolving into a theoretical participatory mesoergonomics framework for proactively considering safety in an EBD process. Through an extended systematic literature review to identify additional system considerations for falls (organization and people), extant literature was integrated with study findings and reframed thinking to advance the SCOPE of falls as an ergonomic problem, further bridging EBD and HF/E.

10.2.1 Aim 1: HF/E and the Built Environment

As stated in Chapter 1, the first aim of the thesis was to conceive a theoretical model for understanding the risks and interventions for hospital falls that addressed the relationship between HF/E and EBD. This theoretical model was developed leveraging content development for the SRA module on hospital falls.

The first framework, Safety as Complexity of the Organization, People, and Environment (SCOPE) evolved the definition of the HF/E environment using building design as the most stable element of the system and identifying built environment interventions to mitigate the risk of falls (SCOPE 1.0). Subsequent exploration added

non-building design interventions of the system such as organizational and people-based conditions (SCOPE 2.0). Lastly, HF/E design principles were incorporated to reframe thinking about design to mitigate the risk of hospital falls as an HF/E problem (DEEP SCOPE). A DEEP SCOPE matrix provided an alternate visual structure for the SCOPE model. DEEP SCOPE offers a new framework for proactively addressing falls during HC facility design by understanding the underlying HF/E design principles for the organization, people, and environment. Like its predecessors, the SEIPS and Dial-F models, the framework could also be used retrospectively as a comprehensive identification of conditions that contributed to adverse events (Carayon et al. 2006, Hignett, Youde, and Reid 2014).

10.2.2 Aim 2: Facility Design and HF/E

The second aim of the thesis was to construct theory for a proactive process for developing safety-related solutions using EBD and HF/E. This leveraged SRA testing to explore how the SRA is applied with falls as the primary case study topic. The second theoretical framework evolved from grounded theory constructed through SRA testing data suggesting design for safety as a participatory process to anticipate, participate, and integrate solutions in an EBD process. A participatory ergonomics framework was combined with a mesoergonomic framework of inquiry to advance participatory mesoergonomics where the SRA and SCOPE models are used as inputs over the course of an EBD project to achieve safety in design. This establishes a methodology purposed to designing ergonomic buildings, filling a practice gap identified by Attaianese and Duca (2012). This uses HF/E methods to support an EBD process that already promotes use of an interdisciplinary team and translation of research. It also advances EBD hypothesis generation and develops options for new research using HF/E methods.

10.3 Limitations and Strengths

There are several limitations of the research, although many of these limitations can also be seen as benefits. First, the thesis was completed part-time leveraging a pre-awarded grant. The grant scope established certain bounds of content development, testing, and timing. As the theory evolved through the thesis, there was not always an opportunity to inject or test new ideas, and there were times when the thesis needed to pause to meet the deadlines of the grant. However, these can also be

seen as strengths. As with any research project, there need to be established parameters, and the thesis research certainly could have led to many other tangents of exploration without the grant structure of scope and schedule. While there were certainly times it would have been desirable to further the evolving theory before continuing with the research (a more traditional grounded theory approach), the grant forced a pace to the surrounding work and also established a focus.

Second, the context of employment limits a certain level of theory implementation. For example, the physical ergonomic subsets cannot simply be introduced into the SRA, as the existing structure is based on previously devised architecturally-based categories used with other projects of the employer. HF/E considerations can't simply be added to the SRA, due to both the consensus process and a lack of funding to advance new material. However, the reputation of the employing organization provided a platform for participation that could not be achieved as a stand-alone thesis research project. A strength is that through the employer relationship, there is a higher likelihood that proposed theory can be gradually integrated into future projects.

Third, as testing occurred only as a one-time event in the real-world settings, the proposed theory does not recognize all of the constraints that might be found in implementing concepts for lengthy project life-cycles in healthcare. A significant concern was raised during testing about streamlining the SRA process. The proposed participatory mesoergonomics framework likely adds more *perceived* work. Additionally, the focus on falls may limit the generalizability of the proposed frameworks to other areas of safety, although data suggest otherwise. The volunteers and organizations that participated in developing and testing the SRA were biased to advance safety, and as a result, the proposed theory assumes a level of willingness and cooperation based in the conditions of development and testing.

An additional strength of the thesis is that the systematic and incremental development of theory based in both primary and secondary data can be used for further development of practice. An additional limitation is the knowledge gap between EBD and HF/E such that additional translation will be needed to realistically gain adoption. "Participatory mesoergonomics" *sounds* complicated and will not be immediately or intuitively accepted as a viable approach.

10.4 Contributions to Knowledge

A primary contribution to knowledge is that the larger context of the designed environment can be considered with an HF/E perspective. Recent HF/E papers start to distinguish between the physical environment of the work system and the external environment that can influence all work system elements (Carayon, Wetterneck, et al. 2013, Carayon, Karsh, et al. 2013), but the lack of specificity of the physical environment continues to leave gaps in fully integrated HF/E considerations in HC facility design. The contributions to knowledge exist on both practical and theoretical levels.

10.4.1 Theoretical Contributions

The thesis evolved theory to bridge the domains of HF/E and EBD through SCOPE and participatory mesoergonomics, as described in Sections 10.2.1 and 10.2.2. This work has been presented at several international conferences with published peer-reviewed proceedings. The built environment, as one factor in a system, has been advanced through the extensive literature review and the resulting incremental versions of SCOPE (Taylor and Hignett 2014b, Taylor, Hignett, and Joseph 2014, Taylor and Hignett 2015, in press, Taylor, Hignett, and Griffiths 2016c). Additionally, a method of evidence appraisal was created, advancing current thinking in evaluating EBD-related studies (Taylor and Hignett 2014a).

10.4.2 Practical Contributions

Through testing, the SRA toolkit has been shown to advance a practical integration of multiple safeties. It is the first tool of its kind to advance proactive thinking for safety in building design. The documentation of the process builds the knowledge base for tool development to support facility design (Taylor et al. 2014, Taylor, Quan, and Joseph 2015). Although constructed theory, the core theme of Anticipate, Participate, and Integrate, offers practical and relevant insight into incorporating safety into EBD projects (Taylor, Hignett, and Griffiths 2016a), and participatory mesoergonomics starts the understanding of HF/E through methods that may be familiar to design teams in a modified context (Taylor, Hignett, and Griffiths 2016b). Some of these findings have been shared anecdotally as part of ongoing dissemination through SRA workshops. Additionally, the framework of participatory mesoergonomics offers semi-structured options for research in EBD projects. Lastly,

requirements for a safety risk assessment were included in the 2014 version of US-based HC facility design guidelines, in part due to the concurrent development of the SRA toolkit through a consensus-based process.

10.5 Future Research

There are several avenues to continue research for the proposed theoretical models.

10.5.1 SCOPE: Safety = Complexity * (Operations + People + Environment)

The SCOPE model portrays the building as the most stable part of the system, but considers people as active participants, along with organizational operations, policies, and procedures. Other safety topics of the SRA have different conditions, some of which may be less applicable to the model, for example, a passive approach for ventilation systems and airborne transmission of pathogens or faucet configuration for sink splash and contact transmission. However, each safety would present opportunities for SCOPE, some of which have existing research to be translated to EBD (e.g., light/noise/distractions and medication safety; hand hygiene locations for infection). As a theoretical model based on the case study of falls, SCOPE could be developed for other safety topics to more fully integrate safety considerations for different topics, starting with the content for the SRA. This would address the generalizability of the framework.

Additionally, SCOPE could be used as a framework for falls auditing (Hignett, Youde, and Reid 2014) to capture information about the conditions of falls. This would need to take into account that most falls are unwitnessed and would address the challenge of patient perception of the event, as studied by Wolf and Hignett (2015). With the advent of ICD10 (Section 3.5), data may be more readily available for both prospective and retrospective approaches. A review of ICD10 coding categories for the environment/activities could be completed to understand how data collected through the latest reporting system might be used to support the model, as suggested by Edwards (2008).

10.5.2 Anticipate to Participate to Integrate

The results of the thesis research support a participatory process to design for safety. However, while gaining access to pilot sites (and during post-SRA

dissemination), questions have been raised about the additional time and cost of the SRA's participatory process. Speed to market has become an influential driver in HC facility design. A business case could be developed to look at the direct costs of a traditional process (individual user groups, change orders) as compared to the proposed use of the SRA. This might compare other emerging methods, such as design-build, integrated project delivery, P3, and Lean. This would estimate the cost-benefit of the long-term cost-avoidance associated with safety. Furthermore, the SRA toolkit could be expanded to include organizational and people-related considerations. Qualitative research could be conducted to capture positive adaptive behaviors (Safety-II) and generate HF/E-based questions to inform adaptive qualities of design.

10.5.3 Participatory Mesoergonomics

While a participatory process of Anticipate to Participate to Integrate is revealed for use of the SRA, the participatory mesoergonomics framework furthers evaluation and testing. Future work includes engaging a real-world team to undertake and test the participatory mesoergonomics framework for the life-cycle of a building project. To establish further guidance in participatory mesoergonomics, a taxonomy of HF/E methods should be developed for teams to fill gaps in EBD safety research using HF/E techniques (similar to Muller and Kuhn 1993). This would be employed to better understand the system and the underlying HF/E design principles, and can continue to inform the decision-making for the project.

10.6 Summary

In conclusion, the gap between EBD and HF/E can be bridged using safety (falls) as a proactive consideration during HC facility design using theoretical frameworks. The theoretical frameworks address:

(1) the definition of the physical environment and design considerations as an ergonomic problem (SCOPE);
(2) a participatory SRA process to proactively anticipate conditions of safety in HC facility design, engage diverse stakeholders to participate in proactive approaches, and foster discussion to integrate safe design solutions; and
(3) integration of the EBD process with HF/E methods to design, test, and evaluate concepts (participatory mesoergonomics) to account for complex interactions of the system.*Intentionally Blank*

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12 Appendices

12.1 Appendix A: Ch. 3 Search Terms

Table 12-1. Literature review search terms (design tools)

Search terms	MEDLINE (EBSCO)	Web of Science (Thomson Reuters	Avery Index (EBSCO)
(“Post-occupancy evaluation” OR “post occupancy evaluation”) AND health*	9	48	3
(evaluation or audit or performance or assessment) AND ("Built Environment" or "Physical environment" or "Health Facility Environment" or "Environment Design") AND (healthcare or "health care") AND (safety or risk)	153	256	1
proactive AND (risk or hazard) AND (("Built Environment" or "Physical environment" or "Health Facility Environment"))	2	3	0
Guidelines AND ("health care design" or "healthcare design")	10	17	0
(evaluation or audit) AND (facility or building or "built environment") AND health* AND safety AND proactive	3	13	0
(evaluation or audit) AND (facility or building or "built environment" or hospital) AND health* AND safety AND proactive	29	28	0
(quality OR evaluation OR audit) AND ("facility design") AND (facility or building or "built environment" or hospital) AND (health*) AND (tool)	34	27	0
("design quality") AND (building) AND (tool*)	157	40	5

12.2 Appendix B: Literature Review Tools

12.2.1 Tool Summaries

Table 12-2. Tool summary

Name	Type	Number of items		Open (free)	Current: In use	Test-pilot info	Appraisal by others/validity
		Broad Domains	Detail (total items)				
AEDET/ ASPECT exemplar	Scored Questionnaire	10	32/58 40/47	N/A	No longer mandated	Y	+/-, not exemplar
BPE	POE Balanced Scorecard	4	custom	N	Piloted following paper	N	N
BUDSET	Scored Audit Questionnaire	4 (18 subsets)	99	Y	Y	Y	Y
DQI	Scored Questionnaire	10		N	Y	Y	Y
EAT	Scored Audit Questionnaire	10	72		Y	Y	Y
MHS POE	POE – multiple tools	4	custom	+/-	Y	Y	N
MHS WC Checklist	Checklist	9	166	Y	Y	N	N
Physical Security Checklist	Scored Audit Checklist	16	62	?	Y	N	N
Sharing Knowledge	Manual	N/A	7 methods	N/A	Site no longer active	N	N
Usable Buildings Portfolio	Online Resource Listing	4		Y	?	Y	N

12.2.1.1 AEDET Evolution/ASPECT Exemplar Layer (University of Sheffield 2007)

The goal of the AEDET tool is to promote dialogue and summarize how well a healthcare building complies with best practice. ASPECT represents section C of AEDET Evolution with a focus on the latest known research to link design and outcomes. Both are organized across three broad categories (impact, build quality, and functionality) and 10 assessment criteria headings (character and innovation; citizen satisfaction; internal environment; urban and social integration; performance; engineering; construction; use; access; and space). These 10 categories and subsets align with the DQI tool.

The continued development through the 2007 study (University of Sheffield) intended to look at the extent to which research data could be supplemented by an

exemplar layer of healthcare projects and design features images, including guidance about the intended focus and intent of the image example. During development, it was recognized that not all statements could be easily matched with images or photographs. Four criteria were developed to select relevant statements that:

- could easily be matched with an image or images;
- if matched with images/ photographs, would highlight, without confusion, good design features;
- did not involve mathematical calculations; and
- were not about compliance with guidance or recommendations.

As a result, 32 of 58 AEDET statements and 40 of 47 ASPECT statements were matched to images and tested. The authors noted issues that required resolution such as image content, image quality, and copyright/permissions to publish the photographs and images. It seems the exemplar layer was never instituted in the final AEDET tool, and mandatory use of AEDET Evolution and ASPECT has ceased. Minimal information is available through archived webpages (http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Aboutus/Procurementandproposals/Publicprivatepartnership/Privatefinanceinitiative/InvestmentGuidanceRouteMap/DH_4132945).

12.2.1.2 BPE (Building Performance Evaluation) (Steinke, Webster, and Fontaine 2010)

The BPE was developed based on the balanced scorecard framework to provide feedback on "*both internal business processes and external outcomes to continuously improve strategic performance and results*" (Steinke, Webster, and Fontaine 2010, 71). The four scorecard categories included: service performance, related to patients; functional performance, related to staff; physical performance, related to physical design and technical performance; and financial performance, related to initial versus operating cost. At the time of the 2010 paper, the tool had not been piloted.

12.2.1.3 BUDSET (Birth Unit Design Spatial Evaluation Tool) (Foureur et al. 2011, Sheehy et al. 2011, Foureur et al. 2010)

The BUDSET was developed through a comprehensive literature review and qualitative process of interviews with experts. The tool was developed as part of a

larger project to establish the "optimality score" for units serving maternity patients. The tool included four broad domains with multiple subsets:

- Fear cascade (space: arrival; space: outside; space: reception; space: birthing rooms; sense of domesticity; privacy; noise control; universal precautions;
- Facility (physical support; birthing bath; ensuite facilities;
- Aesthetics (light; color; texture; indoor environment/airflow/smell; feminine symbols)
- Support (food and drink for woman; accommodation for companions and birth attendants)

12.2.1.4 The Design Quality Indicator (DQI) (Gann, Salter, and Whyte 2003)

Developed as an extension of the Rethinking Construction agenda, the DQI tool focused on explicitly measuring the quality of buildings. It grew into use across design phases. The current tool (http://www.dqi.org.uk/website/default.aspa) is managed through the private sector with a licensing fee. It incorporates the use of questionnaires that are used to generate discussion of key topics during workshop sessions that are facilitated by an accredited and experienced DQI Facilitator. The questionnaire provides an introduction describing the goals of the tool, which is organized in four sections: Section 1: demographics and aims; Section 2: functional issues with three subsections of use, access, and space; Section 3: impact issues in four subsections: form and materials, internal environment, urban and social integration, and character and innovation; and Section 4: build quality with three subsections: performance, engineering systems, and construction.

During development, the Steering Group agreed that there could be no single universal result from the analysis of design quality of a building, due to multiple viewpoints from a diversity of stakeholders. The tool was envisioned to be used by anyone and provided an opportunity for expression of intentions and views, creating a dialogue between all stakeholders. It was determined the questionnaire should take no longer than 20 minutes. During development, the research team struggled with balancing questions that were "*useful, clear and direct, but at the same time did not leave themselves open to the accusation that the tool was 'dumbing down' design quality*" (Gann, Salter, and Whyte 2003, 325).

12.2.1.5 EAT (Environmental Audit Tool) (Smith et al. 2012, Fleming, Fay, and Robinson 2011)

The EAT tool was created to provide assessment of an environment to facilitate daily living for people with dementia and was intended to allow facilities to determine where environmental improvements needed to be made. The tool consisted of 72 questions (mostly yes/no, some N/A) grouped into 10 subscales that emerged from a review of empirical research. These included: safety; size; visual access; reduction of unnecessary stimuli; highlighting of useful stimuli; provision for wandering and outdoor area; familiarity; privacy and community; community links; and domestic activities. "Yes" responses resulted in points and extra points were available for certain features. The tool could be used by anyone but required eight hours of training for inter-rater reliability. The score for each subscale was calculated by dividing the points scored by the maximum possible points, resulting in a percentage that gave equal weight to the subscales. The total score was the average of the 10 subscale percentages.

12.2.1.6 MHS POE (Part of the World-Class Toolkit) (Clemson University and NXT 2012)

The POE toolkit was created with a building-in-use model and was composed of data collections tools for: archival data requests; facility documentation; observations through a walk-though of the facility and technical readings such as light and noise; perception surveys for leadership and staff; and interviews protocols. More than 100 metrics were structured at the facility, unit, and/or room level and were used to assess building performance of inpatient units. While many of the measures cross space types, some were specific to the setting, such as inpatient area accommodations for visitors or length of stay. As a result, some areas required customized tailoring of the metrics to address specific unit designs and features. POE reports were housed in the World-Class Facilities website (www.facilities.health.mil), although access to the project tool required certified registration. The POE tool was based on the MHS guiding principles and strategies included in the World-Class Facilities Checklist, outlined below.

12.2.1.7 MHS World-Class Facilities Checklist (Part of the World-Class Toolkit)

The WC Facilities Checklist was primarily based on published research studies. It was initially developed by Georgia Tech and Noblis for TRICARE Management (for the MHS) as an interactive Excel spreadsheet (V2.2, 2009) that was converted to an online format in 2011. The checklist attempted to balance education and advice without dictating solutions. The checklist was based on nine MHS guiding principles (e.g., patient- and family-centered care; world-class quality and safety; community responsibility; good stewards of taxpayer money) and was organized by domain: basic infrastructure; leadership and culture; processes of care; performance; knowledge management; and community social responsibility. Within the basic infrastructure, 166 strategies were provided, 22 of which were mandatory. These could be sorted by phase, but not by guiding principle (e.g., quality and safety). Instead, the guiding principle and core domain were listed after a strategy was selected. Information included for each strategy (via drop-down menu) included: the guiding principle; core domain; research summary; design implications; images (in the form of plan diagrams, where applicable, to be used during design review); metrics (case examples of ROI; design review considerations; potential mock-up/prototype/simulations; post-occupancy information collections; focused research options); references; and comments. The strategy information could be downloaded into a PDF format. The checklist, as a whole, is no longer available as a download.

12.2.1.8 Physical Security Review Checklist (Mental Health) (MacAlister 2013)

While there are different types of security considerations in mental health units, (staff/patient relationship, procedural, physical), the tool focused on the physical design of the unit or facility to target the issue of elopement. The tool was developed by compiling elements of three existing sources: the Environmental Design Principles-Adult Medium Secure Units (UK Department of Health, 2009); the Mental Health Environment of Care Checklist for Locked Mental Health Units (US Veteran's Administration, 2011); and the Design Guide for the Built Environment of Behavioral Health Facilities (National Association of Psychiatric Health Systems, 2010). The final checklist included 16 categories with descriptive or question-based prompts: Site/Building Perimeter; Outdoor Areas – Fencing; Outdoor Areas – Gates; Outdoor Areas – Trees and Landscape; Outdoor Areas – Security Cameras and Alarms; Outdoor Areas – Furniture; Outdoor Areas – Elevated Courtyards; Areas

Surrounding the Unit; Unit Entry; Unit Entry – Secured Unit; Emergency Exits; Fire Alarm Pull Stations; Ceilings/Walls/Windows; Internal Unit Design; Seclusion Rooms; and Intake/Transport. There were 62 subset questions that linked the physical environment to the risk of elopement. The final report summarized the information into nine categories to reduce overlap. The tool was used to evaluate 53 units, located in three stand-alone facilities and 14 acute care hospitals in 10 Alberta cities and towns. Clinical management and/or staff, protective services, and maintenance staff were engaged to answer questions to support accurate completion of the checklist. Photographs were taken at each site and on each unit as part of the review process and to assist in producing accurate information.

One of the reference tools used in development, the VA Mental Health Environment of Care Checklist (MHEOCC), was created based on review of the Root Cause Analysis database maintained system-wide for VA facilities. This information was supplemented by expertise from the multidisciplinary VA team tasked to develop the checklist.

12.2.1.9 Sharing Knowledge (Bartholomew 2005)

The Sharing Knowledge manual summarized lessons learned and provided case studies that resulted from a two-year project (Learning from Experience) led by David Bartholomew Associates (DBA) and a subsequent study (Spreading the Word). The author stated, "*the manual is not a recipe book: knowledge sharing cannot be reduced to a set of instructions which, followed mechanically, can be relied on to work*" (Bartholomew 2005, 45). The manual provided an experiential evaluation of tools and techniques, such as foresight and hindsight; codifying knowledge; yellow pages; wikis; communities of practice; mentoring; and workspace design as they apply to knowledge sharing. These topics were illustrated with case studies based on work in nine professional practices, ranging in size from 30 to 7,000 employees.

There were no published papers about the development, but according to the Usable Buildings portfolio website, six pilots were undertaken in the earlier project. The study produced the Knowledge Sharing Toolkit. (The links to this site are no longer active.) The Knowledge Sharing Manual and related case studies were published on the Usable Buildings website (http://www.usablebuildings.co.uk) under Publications, although it was not part of the portfolio referenced below.

12.2.1.10 Usable Building Portfolio (Bordass and Leaman 2005)

The Usable Building portfolio of techniques was a listing of resources and tools falling into five categories that could be updated as future needs warranted. Different tools were identified as appropriate for different phases of the project life-cycle, including a process of "aftercare" that could extend several years into occupancy. While summary information about the tool was included, the tool itself was not included as part of the website. The website (http://www.usablebuildings.co.uk/fp/index.html) allowed sorting by: technique categories (audit, discussion, questionnaire [including DQI], process, and packages); phase; building sector (e.g., healthcare, defense); and development status (e.g., publication status and practical details such as availability of software or ease of use).

12.2.2 Tool Testing (Pilots)

12.2.2.1 AEDET Evolution/ASPECT Exemplar Layer (University of Sheffield 2007)

Testing of the Exemplar Layer included showing images of healthcare projects to two student groups of 12-15 graduate nurses and graduate architects. Sources for the images included: a professional photographer who took photos according to standards developed by the research team; the existing Department of Health portfolio; the NHS trusts; architects/designers; and trade literature. The testing was expected to show psychometric validity, as well as whether there was homogeneity between architects and nurses. Two one-day sessions were held, with each group of students following a pilot of the test methodology evaluated a year earlier. A feedback session was also conducted on the testing.

Following the sessions, the scores were coded and analyzed, and it was determined that the majority of images showed significant differences, a positive result meaning there was consensus on whether or not an image was highly scored. There was also a high degree of consistency between the two groups. However, the team also correlated the average scores of the architects and nurses within each statement to determine whether architects and nurses agree about which images should get the high or low scores against each statement. The overall correlation for AEDET Evolution statements was only 0.3 (37.5% highly correlated) but for ASPECT statements, 0.7 (70% highly correlated). The authors concluded that while overall agreement was high, the lower correlations associated with the AEDET Evolution suggested that the

tool was better suited for a mediated group trying to arrive at consensus than aggregated ratings given by individuals independently.

12.2.2.2 BUDSET (Birth Unit Design Spatial Evaluation Tool) (Foureur et al. 2011, Sheehy et al. 2011)

Testing included a quantitative study at five facilities with multiple researchers independently using the tool to evaluate design features in place. Results indicated the tool had an acceptable intra-class correlation coefficient (internal validity) for half of the 18 subset categories. Content validity was also tested through a mixed methods study at two locations (12 participants), with a survey and interviews used to assess agreement with BUDSET items. Findings indicated variances between the survey and interview data. Surveys indicated strong content validity for facility and support domains, and interview analysis found support for birthing room design elements in the fear cascade and aesthetic constructs. Facility and support elements were highly relevant to optimal birthing rooms. The results are currently being used to refine the tool.

12.2.2.3 DQI (Gann, Salter, and Whyte 2003, Whyte and Gann 2003)

Pilot testing of the DQI included the design teams, and where possible, potential users of the building. The sample used for pilot testing the DQI included five sites representing a range of building types and project phases from the programming through to completion. Testing was intended to prompt feedback about the questions, sections, subsections, weighting mechanism, and overall DQI concept. It was through this two-year development and testing process that the tool evolved into what was termed *a tool for thinking*.

Each pilot started with a presentation explaining the tool. Participants were then asked to fill in the questionnaire with feedback gathered through interviews or group discussion in a semi-structured format. A questionnaire was also used to capture feedback on how the pilot tool performed. When the tool was used in the early phases, there were questions about whether responses should be aspirational or judgmental. According to Gann:

> The pilots indicated that it was difficult to determine ex ante what the implications of using the tool would be for different projects. In each project, there were tensions and debates about the quality of design within the project

> team. In the initial phase, it was found that the tool allowed for direct comparison between different actors involved in the building design. (Gann, Salter, and Whyte 2003, 328)

Following this first phase, an interim phase, without major sponsorship, included development of a business plan for launching and running the beta testing process, development of an interactive web-based version, and full deployment of the tool, along with the development of case studies. The case studies included further testing developed as a 1.5-hour session. The facilitators spent 15 minutes familiarizing the participants with a presentation of DQI aims and objectives, followed by a 30-minute period to complete the questionnaire. This was followed by group feedback on the participant understanding of the tool, the benefits obtained from using it, and its envisioned uses. During this interim phase it was determined that organizations participating in the Phase Two testing would need to contribute a fee to cover some of the testing costs.

The second phase development and beta testing was sponsored by the Department of Trade and Industry, the Commission for Architecture and the Built Environment (CABE), and Rethinking Construction. Phase Two of beta testing was planned to expand industrial deployment of the tool across additional building sectors. This phase included a prioritization of issues for each section of the tool. This "trailblazer" phase started with 44 organizations with six projects each, but the goal was for 100 organizations, with six projects each (600 pilots), using 12,000 respondents. At the time of published paper (Whyte and Gann 2003), 72 organizations had been recruited and the testing was in progress. During the second phase, the DQI team also worked with the developers of other tools for evaluating design within particular sectors of the industry (such as AEDET) in order to create an industrywide consensus on design evaluation.

The task of moving the DQI from a paper-based tool to an online format included the need for strategic decision-making about the nature of the DQI and structure of the process. A review conference that included 80 users and most Phase Two pilot organizations included four break-out groups following presentations of case studies and development work. Participants felt a need to structure a process to use the tool and define a minimum set of activities. Large projects would be more complex than small projects, but certain steps would always occur.

The decision was made to include a printable version of the tool and to give the facilitator a leading role, with choice over how to structure the process and present the results to users. In the online version, the facilitator entered the project details and context information, followed by the creation of the assessment page, which bound the purchased key to the assessment, ensuring the key could only be used once. Different users had access to different levels of information on the site. The questions that made up the online questionnaire were generated from a database, populated from a spreadsheet that enabled the tense of questions to be correctly displayed, according to the project phase. The authors noted that developing the tool involved a widening number of stakeholders who represented an increasing number of opinions, with resolution becoming increasingly problematic.

12.2.2.4 EAT (Environmental Audit Tool) (Smith et al. 2012)

The purpose of the EAT study was validation, rather than pilot testing. Fifty-six units were selected for the validation testing through a randomized process from a pool of 89 facilities that had been screened for eligibility in a prior study. During the process, results indicated strong concurrent validity and inter-rater reliability when compared with to two other validated tools. The authors state that the EAT's procedure was perceived by researchers as more simple and less time-consuming to complete and score.

12.2.2.5 MHS POE (Clemson University and NXT 2012)

The MHS POE toolkit was piloted at two facilities. The pilots yielded substantial results using a variety of tools and revealed a more effective process when conducted by an interdisciplinary team. At the second site, there was a greater patient and family involvement; refinement of the performance dimensions (from 20 to 10); the introduction of four outcome categories to focus results; and increased participation by the project architects in order to evaluate performance compared to the design intent. The four outcome categories included positive experience (behavioral assessment); operational efficiency (functional assessment); clinical effectiveness (quality of care/safety assessment); and healthy environment and sustainability (technical assessment). Future work recommended as a result of the pilot included suggestions for areas of focus and weight; modules that could be customized (added or subtracted) by category; and a more complete technical

assessment of the building. It was also suggested to continue with the eight-step process, refining and streamlining the subset activities where possible. No detailed information was published about the development of the POE checklist.

12.2.3 Published Critique

Two tools, the DQI and AEDET Evolution/ASPECT (based on the DQI) were critiqued. With respect to the DQI, Markus (2003) raised issues of validity, reliability, and consistency. He also suggested some "semantic ambiguity" - whether design was intended as a noun or verb and how respondents interpreted the statements as a result.

Both the DQI and AEDET Evolution/ASPECT tools used statements evaluated by respondents on a six-point Likert scale. An importance rating was also captured relative to sets of statements. However, while the tool promoted a balance of subjectivity with objectivity, what was gathered was a subjective response to objective or subjective statements. There was no consideration for the balance of the numbers of respondents in varying groups. Additionally, the numeric system captured subjective data that were represented graphically, but were lacking further analysis to provide rigor (e.g., factor analysis, cluster analysis or the relationships of rating to relative importance) (Markus 2003). The scoring to identify perceptions of success and importance was criticized by Markus as lacking transparency. He stated, "*the numerical paraphernalia (scoring, weighting algorithms, etc.) can and should be abandoned*" and the evaluative components "*enriched*" if the true aim is discussion (Markus 2003, 402).

With respect to AEDET Evolution, one paper appraised the tool as "*epistemologically confined, narrow and problematic*" due to its theoretical perspective that ignored the "wicked and messy" nature of design (O'Keeffe, Thomson, and Dainty 2012, 3). The authors raised the same issues relative to the subjective ratings of both subjective and objective questions. They argued scores are "*always mediated by the interpretative views of such participants*" (4) and therefore were not the most effective method to influence design quality. The authors of the exemplar layer study (University of Sheffield 2007) suggested that given the poor correlations found in use of the AEDET evolution tool, the questions should be re-evaluated. They speculated that during development, pressure to minimize the number of statements to reduce survey time may have contributed to a "false economy" reducing the validity of results.

12.3 Appendix C: Ch. 4/8 Search Terms

Table 12-3. Literature review search terms (hospital falls)

Search terms	MEDLINE	Wed of Science	CINAHL
("Built Environment" or "Physical environment" or "Health Facility Environment" or "Environment Design" or Hospital) AND fall* AND ("LOW BED" OR "BED WIDTH" OR TOILET*) NOT (home* or resident* or community*) NOT "nursing home"	45	50	30
("Built Environment" or "Physical environment" or "Health Facility Environment" or "Environment Design" or Hospital) AND fall* AND (flooring or floor covering or floor surface) NOT (home* or resident* or community*) NOT "nursing home"	21	109	10
falls AND intervention AND hospital AND environment	163	156	70
"Interior Design and Furnishings" or floor* OR "equipment design" or bed* or toilet* AND ("Patient safety" or "safety management" or "safety culture") AND "risk factor*" or "risk assessment" or "risk management" AND ("Built Environment" or "Physical environment" or "Health Facility Environment" or "Environment Design" or Hospital) AND (prevention or intervention*) AND fall* NOT (resident Or home OR community) NOT "nursing home"	49	44	32
("Patient safety" or "safety management" or "safety culture") AND "risk factor*" or "risk assessment" or "risk management" AND ("Built Environment" or "Physical environment" or "Health Facility Environment" or "Environment Design" or Hospital) AND (prevention or intervention*) AND fall* NOT (resident Or home OR community) NOT "nursing home"	145	156	158

12.4 Appendix D: Grant Review and Systematic Review Sources

A non-systematic narrative literature review for falls was conducted (as described in the Preface) in the autumn of 2012, prior to the PhD enrollment. A number of citations drawn from The Center's database of more than 2,000 EBD references were not used, as they were not specific to falls (i.e., the searching mechanism was not as robust as a scholarly database). Since at that time, the master database only included citations through 2008, another search was conducted at an academic library, using the library search function for e-resources in multiple databases such as MedLine, ProQuest, Social Science Citation Index, etc.). This search was conducted using combinations of terms including falls; slips, trips, and falls; hospital/physical environment/built environment; and patient safety. The focus for returned results (although not exclusive) was papers published after 2008 to supplement the CHD citations. Some papers published prior to 2008 were included as an original source, as opposed to a secondary reference in a newer source.

A final search was conducted to find sources related to regulatory publications, NHS reports, and Pennsylvania Patient Safety Authority Advisories – resources typically not included in scholarly databases. Many of the resulting papers were not relevant (e.g., electronic reporting of falls) or duplicates (i.e., the same study reported in a different journal under a different lead author), but several additional reports were included. The final set of sources used for content development comprised 96 references, some of which provide good background information to set context, but were not necessarily used in the definition of built environment conditions. The following table highlights the overlaps in sources and reviews.

Table 12-4. Overlaps in sources (grant and thesis)

Citation and legend	Traditional review (2012)	Systematic review (2013, 2015)	Choi (2011)	Gulwadi (2008)	Spoelstra (2012)	Hempel (2013)	Miake-Lye (2013)
Barker, A., Kamar, J., Tyndall, T., & Hill, K. (2013). Reducing serious fall-related injuries in acute hospitals: are low-low beds a critical success factor? J Adv Nurs, 69(1), 112-121.	NYP	x					
Bell, J. L., Collins, J. W., Wolf, L., Gronqvist, R., Chiou, S., Chang, W. R., . . . Evanoff, B. (2008). Evaluation of a comprehensive slip, trip and fall prevention programme for hospital employees. Ergonomics, 51(12), 1906-1925.	•	x					

Citation and legend	Traditional review (2012)	Systematic review (2013, 2015)	Choi (2011)	Gulwadi (2008)	Spoelstra (2012)	Hempel (2013)	Miake-Lye (2013)
Brandis, S. (1999). A collaborative occupational therapy and nursing approach to falls prevention in hospital inpatients. Journal of Quality in Clinical Practice, 19(4), 215–221.			x	x			x
Calkins, M.P., Biddle, S., & Biesan, O. (2012). Contribution of the designed environment to fall risk in hospitals (pp. 1-95). Concord, CA: The Center for Health Design.	●	x					
Cozart, H. C. T. (2009). Environmental effects on incidence of falls in the hospitalized elderly. (PhD Dissertation), Texas Woman's University, Denton, TX.						**	
Dacenko-Grawe, L., & Holm, K. (2008). Evidence-based practice: a falls prevention program that continues to work. Medsurg Nurs, 17(4), 223-227.		x			o	o	
Donald, I. P., Pitt, K., Armstrong, E., & Shuttleworth, H. (2000). Preventing falls on an elderly care rehabilitation ward. Clin Rehabil, 14(2), 178-185.	●		**				
Drahota, A. K., Ward, D., Udell, J. E., Soilemezi, D., Ogollah, R., Higgins, B., . . . Severs, M. (2013). Pilot cluster randomised controlled trial of flooring to reduce injuries from falls in wards for older people. Age Ageing.	NYP	x					
Dykes, P. C., Carroll, D. L., Hurley, A. C., Benoit, A., & Middleton, B. (2009). Why do patients in acute care hospitals fall? Can falls be prevented? J Nurs Adm, 39(6), 299-304.		x			o	o	o
Fonda, D., Cook, J., Sandler, V., & Bailey, M. (2006). Sustained reduction in serious fall-related injuries in older people in hospital. Med J Aust, 184(8), 379-382.			**				**
Goodlett, D., Robinson, C., Carson, P., & Landry, L. (2009). Focusing on video surveillance to reduce falls. Nursing, 39(2), 20-21.		x				o	
Gowdy, M., & Godfrey, S. (2003). Using tools to assess and prevent inpatient falls. Jt Comm J Qual Saf, 29(7), 363-368.						**	
Gutierrez, F., & Smith, K. (2008). Reducing falls in a Definitive Observation Unit: an evidence-based practice institute consortium project. Crit Care Nurs Q, 31(2), 127-139.	●	x				o	
Healey, F. (1994). Does flooring type affect risk of injury in older in-patients? Nurs Times, 90(27), 40-41.	●	x	o	o			o
Hitcho, E. B., Krauss, M. J., Birge, S., Claiborne Dunagan, W., Fischer, I., Johnson, S., … Fraser, V. J. (2004). Characteristics and circumstances of falls in a hospital setting: a prospective analysis. J Gen Intern Med, 19(7), 732–9.			x	x			
Krauss, M. J., Tutlam, N., Costantinou, E., Johnson, S., Jackson, D., & Fraser, V. J. (2008). Intervention to prevent falls on the medical service in a teaching hospital. Infect Control Hosp Epidemiol, 29(6), 539-545.	●	x	o			o	o

Citation and legend	Traditional review (2012)	Systematic review (2013, 2015)	Choi (2011)	Gulwadi (2008)	Spoelstra (2012)	Hempel (2013)	Miake-Lye (2013)
Lopez, K. D., Gerling, G. J., Cary, M. P., & Kanak, M. F. (2010). Cognitive work analysis to evaluate the problem of patient falls in an inpatient setting. J Am Med Inform Assoc, 17(3), 313-321.		x					
Mosley, A., Galindo-Ciocon, D., Peak, N., & West, M. J. (1998). Initiation and evaluation of a research-based fall prevention program. J Nurs Care Qual, 13(2), 38-44.						**	
Ohde, S., Terai, M., Oizumi, A., Takahashi, O., Deshpande, G. A., Takekata, M… Fukui, T. (2012). The effectiveness of a multidisciplinary QI activity for accidental fall prevention: staff compliance is critical. BMC Health Serv Res, 12, 197.		x					
Schaffer, P. L., Daraiseh, N. M., Daum, L., Mendez, E., Lin, L., & Huth, M. M. (2012). Pediatric inpatient falls and injuries: a descriptive analysis of risk factors. J Spec Pediatr Nurs, 17(1), 10-18	●	x					
Shorr, R. I., Chandler, A. M., Mion, L. C., Waters, T. M., Liu, M., Daniels, M. J. . Miller, S. T. (2012). Effects of an intervention to increase bed alarm use to prevent falls in hospitalized patients: a cluster randomized trial. Ann Intern Med, 157(10), 692-699.						**	
Tzeng, H. M., & Yin, C. Y. (2008). The extrinsic risk factors for inpatient falls in hospital patient rooms. J Nurs Care Qual, 23(3), 233-241.	●	x					
Vassallo, M., Azeem, T., Pirwani, M. F., Sharma, J. C., & Allen, S. C. (2000). An epidemiological study of falls on integrated general medical wards. Int J Clin Pract, 54(10), 654-657.	●		**				
Vieira, E. R., Berean, C., Paches, D., Costa, L., Decombas-Deschamps, N., Caveny, P., . . . Ballash, L. (2011). Risks and suggestions to prevent falls in geriatric rehabilitation: a participatory approach. BMJ Qual Saf, 20(5), 440-448.	●	x					
Warren, C. J., & Hanger, H. C. (2013). Fall and fracture rates following a change from carpet to vinyl floor coverings in a geriatric rehabilitation hospital. A longitudinal, observational study. Clin Rehabil, 27(3), 258-263.	NYP	x					
Wayland, L., Holt, L., Sewell, S., Bird, J., & Edelman, L. (2010). Reducing the patient fall rate in a rural health system. J Healthc Qual, 32(2), 9-14; quiz 14-15.						**	
Wolf, L., Costantinou, E., Limbaugh, C., Rensing, K., Gabbart, P., & Matt, P. (2013). Fall prevention for inpatient oncology using lean and rapid improvement event techniques. HERD, 7(1), 85-101.	NYP	x					

italics from bibliography search with source indicated to the right

● - included in traditional review (AHRQ grant); x – systematic search; o –systematic search and published literature review; ** - published literature review only; NYP – not yet published

12.5 Appendix E: Ch. 4/8 Study Characteristics (Populations, Timeframes, Setting Type)

Table 12-5. Study characteristics (populations, sample size, timeframes, setting type)

	First author (year)	Population/age NR = not reported; int.= intervention	n/gender NR = not reported; pt.= patient;	Time period	Setting/unit Types/areas
1	Barker et al. (2013)	All admitted inpatients in high risk wards; Mean age: 59.2-64.75 (high risk ward)	356,158 Study pop: 52-57% F	01/99-12/09 (11 yrs.)	Acute hospital: high risk med-surg wards (4 at start, 7 in final yr.)
2	Bell (2008)	All employees; STF claim rates sig. greater > 45	16,900; mean of 835, 2803, 3045 each yr./ hospital;412 falls STF claims, 88% F	01/96-12/05 (10 yrs.)	3 non-profit hospitals: Entries, sidewalks, stairs, ramps, OR areas, ED, nurse stations, pharmacy, histology lab, halls, kitchen/ cafeteria areas, pt. rooms, bathrooms, instrument decontamination areas, engr. shops, morgue; parking, bus stops
3	Brandis (1999)	all incident forms reporting a patient fall; Age: 77%>60; 40%>80	Pre: 270 falls/ 201 pts; Post: 258 falls/ 190 pts	Pre (4/95-3/96); Post (4/97-3/98); 1 yr. ea.	acute care hospital (500 beds)
4	Calkins (2012)	inpatients; Age: 53-79 (avg 65)	995 falls; 670 pt. rooms; Gender: NR	1 yr. data, where possible	12 hospitals, 27 units: 11 Gen. med/surg; 6 Neuro med/surg; 1 Post-op/surgical med/surg; 5 Cardiac med/surg; 2 Oncology med/surg; 1 Rehab; 1 Palliative
5	Cozart (2009)	Admitted military veterans, 50+ yrs., LOS: 7+ days; high fall risk (MFS> 45); Study: 60-69; 4 fallers: 61, 65, 76, 77	64; 97% M	3-4Q 2008 (6 m)	VA hospital; 350-bed capacity: 8 intervention rms, 8 control rms; study unit combined 2 specialized services: neuro/ rehab; 2 rms in each group private; 6 rms each - semi private (2 beds)
6	Dacenko-Grawe (2008)	Inpatients; Age NR	854 fallers; Gender NR	10/02-09/06 (4 yrs.)	Suburban 325-bed acute care teaching hospital: 9 units: Surgical Intensive Care; Coronary Care Unit; Surgical cardiac; Medical cardiac; 2 med/surg; Pediatrics; maternal/child
7	Donald (2000)	All inpatients admitted for rehab asked to consent; Mean age: 81+	54 consecutive pts; Vinyl: 18 F, 8 M; Carpet: 26 F, 2 M	02/96-09/96 (9 m)	community hospital: Elderly care rehabilitation ward
8	Drahota (2013)	All admitted adults in the study area were eligible, no exclusions Age means: Pre int.:84; Pre Control: 80; Post int.: 81.1; Post Control: 80.6	226 participants; Pre: Int.: 53; Control: 69; Post: Int.: 225; Control: 223; Gender: Pre: Int.: 49 F (92.5%); Control: 69 F (100%); Post: Int.: 153 F (68%); Control: 202 F (90.6%); Pre: Int: 4 M; Control: 0 M; Post: Int 72 M; Control: 19 M	04/10-08/11; Pre: 2-5 m; Int.: 12–13 m	8 sites: elderly care wards (allocated 1:1)
9	Dykes (2009)	Nurses, nurse assistants Median age: Nurse: 39; Nurse asst.: 49	Participants: 23 Nurse: 91% F; 19 Nurse asst: 79% F		4 acute hospitals: 2 urban academic medical centers, 2 suburban teaching hospitals

	First author (year)	Population/age NR = not reported; int.= intervention	n/gender NR = not reported; pt.= patient;	Time period	Setting/unit Types/areas
10	Fonda (2006)	All admissions; Mean age Yr. 1: 82.4 (range:45–105); Mean age yr. 3: 82.4 (53–103)	1905/ 2260/ 2056 admits annually; Gender: Yr. 1: 63.6% F; yr. 3: 62.6% F	01/01-12/03 (3 yrs.)	4 wards (Aged Care Services ward; acute care of elderly, geriatric evaluation/mgmt., restorative care); 96-120 beds
11	Goodlet (2009)	High risk fall inpatients (hist. data): cog. dysfunction/ disregard of safety instruction; older; excluded: suicide precaution, requiring restraints; Age: NR	417 pts admitted (camera rooms) Gender: NR	1 yr.	34-bed internal medicine unit
12	Gowdy (2003)	geriatric psychiatric unit (GPU) Age: NR	NR	06/00-1Q/03 (2.75 yrs.)	457-bed, not-for-profit community hospital: GPU = 10 beds
13	Gutierrez (2008)	Cardiac/ high acuity med-surg telemetry; sig. fewer dementia inpatients by project end; Age: NR	NR	Ph1 05-06/07; Ph2 06-09/07: 3 m	Definitive Observation Unit (DOU); Specialty Adult; Focused Environment (SAFE) unit within DOU
14	Healey (2004)	Elderly wards Median age carpet: 84; Median age vinyl: 86	Random sample - 213 fall reports: Carpet 27; Vinyl 186 Gender: Carpet: 16 F, 11 M; Vinyl: 86 F, 100 M	4 yrs.	3 acute admission wards, 5 rehab wards, 1 acute admission ward for pts in need of joint assessment
15	Hitcho (2004)	Included: falls in medicine, cardio, neuro, ortho, surgery, oncology, and women/ infants services Excluded: psychiatry; falls during physical therapy sessions Mean age: 63.4 yrs. (range 17 to 96)	183 fallers; 168 (92%) fell 1x, 13 (7%) 2x; 2 (1%) fell 3x; 200 falls Gender: 97 F (53.0%)	10/02-01/03 (3 m)	1,300-bed urban academic hospital
16	Krauss (2008)	Nursing staff and medicine patients Mean Age: Int.:65.5; Control floor: 65.5	100 staff; Nurses 56; Pt care techs 35; unit secretaries 9 Gender: Int.: 28 F, 20 M, Control: 36 F; 34 M	Pre: 7/04-3/05; Int: 4/05-12/05; (9 m ea. pre/int.)	1300 bed urban tertiary-care academic hospital: 2 of 9 general medicine floors served as intervention floors, 2 similar floors served as controls.
17	Lopez (2010)	Nurses, nurse assistants; Ages: 18-30: 25; 31-40: 25; 41-50: 44); >50: 6	100 (RNs, NAs, and unit clerks) Gender: NR		572-bed academic medical center: 26-bed, general neuro unit (stroke/ epileptic pts)
18	Mosley (1998)	All inpatient units; Age: NR	Ph. 1 pre and post: NR; Ph. 2:16 falls in "L" (Ph. 2); Gender: NR	2 yrs. each pre/ post; pilot '93-'94	extended care units (4 nursing home care units, 1 spinal cord injury unit, 2 intermediate care units); acute medical and surgical: 4 medical, 2 surgical, 3 CC; 5 psychiatric units
19	Ohde (2012)	Adult inpatients; excluded: maternity, prevent. health screening inpatients, ICU, LOS < 24 hours; Mean ages: 53.9 - 55.8	71396 pts; 16829 pts (23.6%) at risk for falls; Gender: 47.7% - 48.9% M	07/04-12/10 (6.5 yrs.)	520-bed community-based, tertiary-level, teaching hospital
20	Schaffer (2012)	All inpatients with fall events reported;	53 falls; Gender: 22 F; 31 M	6 m	530-bed quaternary-care pediatric academic medical center(US Midwest); 1 of a multisite study

	First author (year)	Population/age NR = not reported; int.= intervention	n/gender NR = not reported; pt.= patient;	Time period	Setting/unit Types/areas
		Median age: 9; 13 falls < 3 yrs. 40 falls > 3 yrs.			
21	Shorr (2012)	inpatients in general medical, surgical, specialty units; Control (baseline; study): 59.3; 59.1; Int. (baseline; study): 60.1; 59.6	27,672 pts Gender: Control baseline: 53.7% F; study 53.8% F; Int. baseline: 55.7% F; study F 54.7%	09/05-04/06 (8 m); 05/06-10/07 (18 m)	16 nursing units (8 control, 8 int); urban community hospital; 349 beds; control nursing units: neuro, oncology, transplant, and 5 general M/S; intervention nursing units: stroke, transplant, ortho, step-down, surgical oncology, 3 general M/S.
22	Tzeng (2008)	inpatient fall incident reports; Mean age: 58.6	104 fall reports; Gender: NR	1/05-12/06 (2 yrs.)	1 unit - 32-bed acute medical (Michigan medical center)
23	Vassallo (2000)	Inpatients (matched for age and sex) Faller mean ages: Ward A: 56.6; B: 72.4; C: 71.4	1,609 pts: Ward A-678; B-439; C-492 Gender by ward: A: 342 M, 336 F; Falls: 11 F, 7 M; B: 226 M, 213 F; Falls: 6 F, 8 M; C: 262 M, 230 F; Falls: 13 F, 18 M	4 m	3 acute medical wards chosen for different structural design
24	Vieira (2011)	inpatients (65+), staff, family; Age: NR	10 pts; 12 staff (no roles); 6 family Gender: NR	Falls data 01/06-12/08 (3 yrs.)	2 geriatric rehab units (A and B); gathered information from Unit A; 35 beds each; same patient components/environment conditions
25	Warren (2013)	All inpatients; Age: Carpet: 81.3; Vinyl: 81.6	4,641; Gender: Carpet: 1017 M, 1509 F Vinyl: 930 M, 1185 F	11/07-12/09 (12 m ea. pre/ post)	6 wards (129 beds); geriatric rehabilitation hospital
26	Wayland (2010)	all inpatients; Age: 60s	NR	07/08-09/08 (3 m)	148 bed community rural hospital
27	Wolf (2013)	Oncology inpatients; Age: NR	150 nurses, pts NR	pre: 01/10–04/11; post:08/11-12/12 (16 m ea. pre/post)	academic medical center; 3 longitudinal oncology units; few rooms within sight of the nurses station

12.6 Appendix F: Ch. 4/8 Study Characteristics (Interventions and Outcomes)

Table 12-6. Study characteristics (interventions and outcomes)

	First author (year)	Interventions	General outcomes	Falls*	Injury*	Serious/major injury*
				*Rates stated as per 1,000 patient days/occupied bed days, unless reported as bed days (BD); NR = not reported; Intervention = int.		
1	Barker et al. (2013)	Intervention of low-low beds in three phases w/fall risk assessment; 'falls alert' sign; pt. supervision in bathroom; walking aids w/I reach; toileting regime bed/chair alarm	Statistical significance in ratio w/1 low-low bed: 3 standard beds; Serious injury: 67% 80+; Serious injury: 62% F	3,946 falls total; Pre: 4.63/1,000; Post: 7.66/1,000	1,005 fall injuries; Pre: 0.03/1,000 Post: 0.18/ 1,000	60 serious (55 fractures, 5 sd. hematoma
2	Bell (2008)	Hazard assessments, changes to housekeeping procedures/products, STF preventive products/procedures, awareness campaigns, ice/snow removal, flooring changes, slip-resistant footwear for some employees	STF workers' compensation claims rate declined by 58% from the pre-int. (1996–1999) to post (2003–2005)	Pre: 1.66/100 FTE; Post: 0.76/100 FTE		
3	Brandis (1999)	Decision tree: green arm band; Green bed sign at the bed head (similar to nil by mouth signs); Hip protector pads (prior fallers); storage of hip pads on wards for easy access; Document Falls Management Plan; decision tree added to ward manuals; Instructional posters in wards.	Reduction following fall program targeted at age 65+; increase of 11 falls in the 65-79 age; decrease of 40 falls in the 80+ age group	Pre: 1.74/1,000; Post: 1.61/1,000	138 injurious; multiple injuries 32 patients; 8 fractures (3%) to 3 (1%); pre 70%; post 55.5%	
4	Calkins (2012)	Correlates (risk factors) vs interventions: evaluation of 40 environmental characteristics	Strong relationships for fewer falls related to: Private bathroom; bathroom door open (vs managing opening a door); footwall bathroom footwall; toilet on sidewall in bathroom vs across from entry; 2 grab bars each side of toilet; family area in room; flooring w/no, small or large pattern; VCT/ ceramic tile vs. linoleum; fewer alarms/ paging	1.7-6.5/1,000?	NR	NR
5	Cozart (2009)	Falls prevention room (FPR): low position beds, bed alarms, bedside commode, non-skid socks/slippers/quick-drying non-skid shower slippers, hipsters, lighting at all times, bed trapeze, fall prevention poster, exit side rail up for support/foot rail down all times, bevel edge floor cushions/mats, non-skid shower mats	No statistical significance between control and int. rooms; short study period	3% overall, 6% (combined unit), 6% (study participants); 1 fall int. unit, 3 control	NR	NR

	First author (year)	Interventions	General outcomes	Falls*	Injury*	Serious/major injury*
				*Rates stated as per 1,000 patient days/occupied bed days, unless reported as bed days (BD); NR = not reported; Intervention = int.		
6	Dacenko -Grawe (2008)	Risk assessment; non-skid footwear; pt./family education; magnetized signs (1 of 7 languages) on whiteboards; orange bracelet; orange autumn leaf on door (fall); accompanied to bathroom/bed; portable bed monitor; post fall documentation; hourly rounding; include ancillary staff	Falls declined 50% over a 3-year period without rebound after fall prevention protocol	2002: 4.04/1,000; 2003: 3.45/1,000; 2004: 2.98/1,000; 2005: 2.39/1,000; 2006: 2.27/1,000	NR	NR
7	Donald (2000)	Carpet vs vinyl floor in bed areas; 2 modes of exercise (conventional and additional)	No evidence to support flooring or exercise in preventing falls; strong trend towards vinyl being superior over carpet.	Carpet: 10; Vinyl: 1 Conventional exercise: 7; Add. exercise: 4	NR	NR
8	Drahota (2013)	Intervention: 8.3-mm thick flooring; control: 2-mm standard in situ flooring	More falls in the int. group (n = 31 fallers; 13.8% of admissions) than in the control group (n = 22 fallers; 9.9% of admissions); incident rate for falls only slightly higher in the int. group; uncertain estimated effect of int. is a 7% increase in falls; fewer injuries	Int: 7.81/1,000 ; Control: 7.17/1,000 ; Int.: 13.78%; Control: 9.87%	Int.: 1.78/1,000; Control 3.04/1,000; Int.: 22.9% Control: 42.4%	no moderate/ major injuries in int.; 6 in control
9	Dykes (2009)	N/A (qualitative study)	Knowledge/ communication and capability/ actions; environmental mods and ‘‘common sense’’ actions (uncluttered room; clear path to bathroom; assistive devices nearby); visual cues (fall precaution signs, colored wristbands, bed alarms); visual cues especially important to the NAs w/absence or delay of pt. report; balance - futility of signs w/too many (become immune), too generic/not actionable	N/A	N/A	N/A
10	Fonda (2006)	Multi-strategy approach phased in over 3 months: data gathering, risk screening with appropriate int., practice changes, env./ equipment changes, staff education	Staff compliance completing falls risk assessment tool increased 42% to 70%; 60% of staff indicated they changed their work practices to prevent falls	Pre: 12.5/1,000 Yr. 1: 11.3/ 1,000 Yr. 2: 10.1/1,000; 19% reduction		0.73/1,000 0.39/1,000 0.17/1,000 ; 77% reduction

	First author (year)	Interventions	General outcomes	Falls*	Injury*	Serious/major injury*
				*Rates stated as per 1,000 patient days/occupied bed days, unless reported as bed days (BD); NR = not reported; Intervention = int.		
11	Goodlet (2009)	Video surveillance cameras when staffing could not be increased	One fall (no injury) occurred in int. rooms - failure of the monitoring staff to respond (patient's behavior misinterpreted); patient/family care plan/camera guidelines; notification of video surveillance in camera rooms to alert visitors; fall risk assessment to identify appropriate patients for camera rooms; staff-education/ awareness; cross-train staff; cost analysis	1 fall; 6% reduction; 0.68/1,000	No injury	
12	Gowdy (2003)	Development of risk assessment tool w/ phased customized intervention/proactive audits (FMEA) to improve program	Pre: GPU = 58% of falls - 67/1,000; Post: 35% of falls - 23.3 /1,000 (1Q 2003)	6.1/1,000 2.6/1,000; 43% decrease	NR	NR
13	Gutierrez (2008)	Strategies from literature to reduce falls embedded into care in SAFE unit (3 semi-private rooms located at the end of a hallway w/satellite nursing station); also current fall protocol, high-fall-risk order sets, SAFE unit order sets, post-fall order sets, quiet zone, recliners in hallway, low beds w/bed alarm; diversion equipment, doors/curtains open; portable PCs for charting near patients	Many process outcomes did not improve; staff knowledge of falls increased for fall prevention protocol, Morse scoring, int. for fall prevention; unit culture changed to active fall prevention	Pre 3 Qs: falls steadily rose from 3.00/1,000 to 4.87/1,000 pt. days; Ph1: 3.59/1,000; Ph2: 1.37/1,000	NR	NR
14	Healey (2004)	Exist units floored in vinyl w/carpeted sitting rooms; 1 acute admission ward (pts needing joint assessment) carpeted except for 2 pt. rooms and toilet room); Carpet varied, all washable w/ single vs looped fibers/thin underlay	Patients who fall on carpet are less likely to be injured than those who fall on vinyl; 17 falls on vinyl slippery by urinary incontinence; further research required to determine if carpet is associated with reduced fall risk	N/A	Carpet: 17% sustained injuries; Vinyl: 46% sustained injuries	NR

	First author (year)	Interventions	General outcomes	Falls*	Injury*	Serious/major injury*
				*Rates stated as per 1,000 patient days/occupied bed days, unless reported as bed days (BD); NR = not reported; Intervention = int.		
15	Hitcho (2004)	Correlates (risk factors) vs interventions	Females, elimination factors sig. risk factors for injury; Int. used inconsistently before/at the time of fall; Side rails: 4%, 0-1 side-rails raised, 67% 2-3 side-rails raised, 10% 4 side-rails up (restraint); Call light used 3% just prior to fall; 24% not using call felt help not needed; 8% (most slips) w/floor wet due to urine/ water; 8% tripping over/ misuse/malfunction of furniture/equip; 19% in bathroom (assistant outside waiting); 30% alone after assist to bedside commode; Injury ages: <50: No injury: 24.3%; moderate injury 24.2%; serious injury (SI): 14.3%; SI the same in 60-69/70-79/>80: 28.6%	2002: 3.29/1,000; study period: 107 falls w/no injury 3.38/1,000	33.9% minor Injury (62) 42% first fall w/injury (183);	8% moderate/ severe Injury (14)
16	Krauss (2008)	Nursing education for fall prevention during study period; all high risk pts.: green armband, green fall prevention sign (bed/door), mobility needs posted, shift change verbal reports; fall prevention teaching (patient/family); toileting schedule/safety rounds (2 hours/day, 4 hours/night); med review/education; PT/OT order; w/optional strategies (e.g., bed alarms, low bed, floor mat, place near nurses station, family sit w/pt.); differences from usual: mobility needs, toileting schedule, med review, OT/PT, walking aids if used at home	Nursing knowledge and use of prevention strategies increased. Fall rates decreased for 5 months after the educational int., but reduction not sustained.	Int.: 57 falls (48 patients fell; 39 fell 1x, and 9 fell 2x); Control: 78 falls (70 patients fell; 62 fell 1x, and 8 fell 2x		
17	Lopez (2010)	Cognitive work analysis: constraints in work processes and the work environment (physical, organizational systems/culture, individual, and technical) imposed on acute care nurses that may increase the likelihood of patient falls; identify nurse workarounds to deal with constraints	4 workarounds for systemic design flaws (work processes/physical work environment vs safety culture/nursing knowledge): written/mental chunking, bed alarms, informal queries of prior care nurse, informal video/audio surveillance; unit layout removed nurse from physical proximity w/o direct patient visibility (only 3/17 rooms); difficult to prevent when away to chart, prep meds, access equipment			

	First author (year)	Interventions	General outcomes	Falls*	Injury*	Serious/major injury*
				*Rates stated as per 1,000 patient days/occupied bed days, unless reported as bed days (BD); NR = not reported; Intervention = int.		
18	Mosley (1998)	Risk assessment; Individualized /measurable interventions.: "Risk for Fall" stickers on the chart/bed; green dot on care plan/ bracelet; green door sign if fell in hospital; pt. education; low bed; split rail - bottom down; call light in reach; dim night light; toileting rounds (4 hrs./day); confused/at-risk near nurse; ID hypotension; call for assistance; buddy system; non-skid slippers; clear path; family/sitters; instructional posters; med review	Pilot: 8% decrease; 13 units (72%) experienced a reduction in the number of falls; additional 35 % decrease in 6 months following study	Pre: 7.07/1,000; Post: 6.33/1,000	NR	NR
19	Ohde (2012)	fall risk assessment tool; int. protocol; environmental safety int.; staff education; multidisciplinary healthcare staff compliance monitoring and feedback mechanisms	25% reduction over five years; staff compliance rate of implementing an appropriate int. increased from 85.9% to 95.3% over the study; most dramatic reduction from 2006 to 2009.	2004: 2.13/1,000 2010: 1.53/1,000	NR	NR
20	Schaffer (2012)	Correlates vs int.: identified patient characteristics and environmental factors related to falls and injuries	58.5% resulted in injury; of injured children, 83% developmentally appropriate	53 falls; 0.84/1,000	24 of 31 (77.4%)	7 of 31 (22.6%)
21	Shorr (2012)	Cluster RCT for utility of bed alarm systems for falls prevention in hospitals - aimed at increasing use of bed alarms by nurses to estimate effectiveness.	No difference in change in fall rates per 1,000 patient-days or injurious fall rates; int. for increased bed alarm use did increase alarm use w/no statistically or clinically significant effect on fall events or restraint use.	Baseline (statistics sim.): Control: 192 falls (5.11/1,000); Int. :182 falls (5.76/1,000); Study period: Control: 359 pts/408 falls (4.56/1,000); Int.: 282 pts/315 falls (5.62/1,000)	Study period: Control: 111 (27.2%) injuries (94 minor, 6 moderate, 5 NR); Int.: 77 (24.4%) injuries (59 minor, 7 moderate, 10 NR)	Control: 5 major, 1 death; Int.: 1 major
22	Tzeng (2008)	Correlates vs int.: incident reports, perspectives of nurses, attendants; 16 extrinsic factors from incident reports; 4 patient room design/settings; 3 hospital equipment; 9 manpower; nurse-patient communication most cited	71 falls (77.2%) reported/assumed unwitnessed; 21 (22.8%) witnessed by family/staff; 15 (15.8%) repeat falls; 14 (13.5%) medication-related; env. factors: distance/path bed to bathroom; bed height; insufficient light at night; insufficient room space for unused equipment; poor bed maintenance; ceiling lift/bed pressure alarm not used regularly; bedside commode/portable lift systems not readily available	1Q 2005-4Q 2006: 4.40/1,000 (national comp. fall rate = 4.19)	21 (20.2%) some form of injury (level NR)	NR

	First author (year)	Interventions	General outcomes	Falls*	Injury*	Serious/major injury*
				*Rates stated as per 1,000 patient days/occupied bed days, unless reported as bed days (BD); NR = not reported; Intervention = int.		
23	Vassallo (2000)	Natural experiment: 2 nuclear wards (85% visible from 1 or 2 nurse stations); 1 longitudinal ward (only 20% beds visible from nursing)	Longitudinal unit - most falls, fall positive days, and fallers; higher cumulative risk of falls/ fall positive days; significant independent risk factor when controlled for age, sex, diagnostic variation between units (no diagnostic category predisposing to falls); extrinsic classification (A 11.1%, B 7.1%, C 6.4%)	63 falls events (3.23%); 52 patients	NR	NR
24	Vieira (2011)	Correlates vs int.: Increase understanding of complex issues considering the perspectives of patients, staff and family members	Staff mentioned the most risk factors during the interviews (possibly related to staff education/ frequent discussion w/peers); each group perceived some risks/ overlooked others. Family members said little - shorter interviews w/ less content/ depth; concern that patients at increased risk of falling after discharge when family is primary caregiver	256/310 falls on units A/B (study units); 7 and 8/1,000	NR	NR
25	Warren (2013)	Floor covering changed from 5 mm carpet tiles to vinyl	Non-significant trend to lower fall rates on carpet in the stroke group/general ward. Significantly higher rate of falls on carpet in secure psychiatric ward; no sig. difference between rates when grouped together	Pre: 19.5/1,000 BD Post: 19.6 falls/1,000 BD		Carpet: 15 fractures; Vinyl: 11 fractures
26	Wayland (2010)	Toileting rounds; walking reports at shift change; run charts in fall prevention posters; additional training; documentation of pt./family engagement; room signage "Yield"; relative fall risk ID from incident analysis; fall investigation presented at Fall Prevention mtgs (education/discussion)	Patients w/highest number of falls are in their sixties, have had limited prior contact with the facility, are early in their admission, have a high Braden Scale and a high Fall Risk Score of 10–13; Following int., steadily reduced patient falls for last 3- month period	01/08-06/08: 4.5/1,000; 07/08: 4.37/1,000; 08/08: 1.29/1,000; 09/08: 0/1,000	NR	NR
27	Wolf (2013)	Rapid improvement event: standardized assessment, int. (algorithm) based on condition (low bed, floor mat, PT/OT order, gait belt, bedside commode, bed/chair alarm; lab reviews); post-fall investigation	22% decrease in total fall rate; 37% decrease in falls with injury rate were achieved in the 16-month post-int. period.	All falls: Pre: 227; Post 197; Baseline (pre): 5.93/1,000 Post RIE: 4.61/1,000	Minor injury: Pre: 62, Post: 39; Baseline (pre): 2.01/1,000 Post-RIE: 1.26/1,000	serious injury: Pre: 15; Post:15; Baseline (pre): 0.39/1,000; Post RIE: 0.35/1,000

12.7 Appendix G: Comparison of Falls Considerations

Table 12-7. Comparison of considerations (traditional and systematic review)

Systematic Review (2013, 2015)			Traditional Review (2012)
Topic	Risk	Intervention	SRA Consideration
Unit Layout	x	x	Do nurse seating locations allow for direct accessibility to the room with visibility of patient head?
		x	Do charting areas include visibility to the patient?
		x	Does the unit shape and configuration allow visibility to all patient rooms, including with a normal walking pattern?
Room layout: Toilet location	x		Is the bathroom visible from the bed? (*see also doors open*)
Room layout: Toilet distance	x		Is the bathroom located in close proximity to the bed?
Visual Cues (corridors)		x	Has space been provided for fall alert signage at the door and/or the patient bed?
Floor type	x	x	Are flooring and subflooring materials selected to mitigate injury in the event of a fall?
	x		Are paths of travel clearly visible (e.g., not confused by patterns, high-gloss finish, and obstructions)?
	x	x	Are smooth transitions between flooring used?
	x	x	Are walking surfaces designed to be clear of surface irregularities?
	x	x	Are rugs and carpeting secured to the floor?
Space for family	x	x	Is there space for families to be present in the patient room to encourage communication with caregivers about falls and increase the level of patient surveillance?
Clear clutter		x	Does the room layout provide clear and unobstructed paths of travel?
Doors Open	x	x	Is the bathroom visible from the bed?
	x		Is space provided on the opening side of the patient toilet room door to facilitate the use of equipment and/or assistive devices?
Doors (width)		x	*Included in Patient Handling*
Patient Lifts		x	Are lifts being used to assist staff in performing transfer of patients?
Contamination protection (wet)		x	Is the entrance protected from weather?
		x	Are floors slip-resistant in potential wet areas (e.g., bathrooms, entrances, kitchens) and on ramps and stairs?
		x	Are floors protected from spills and wet conditions?
Call system accessibility	x	x	Are call buttons within easy reach of the bed, patient chair, and bathroom activities?
Visual cues (room)		x	*See Visual Cues (Corridor)*
Items in reach		x	*Not included*
Bedside commode	x	x	Has toilet accessibility been considered (e.g., height)?
		x	Is the bathroom located in close proximity to the bed?
Falls-prevention room			*Not included*
Bedside charting	x	x	*See unit layout (visibility)*
Stair/curb markings	x	x	*Not included*
Alarms	x	x	Are bed/chair alarms in use to alert staff to potential exit and fall risk?

Systematic Review (2013, 2015)			Traditional Review (2012)
Furniture (beds)	x	x	Have beds been selected to afford low height positions?
Furniture (rails, brakes, stability)	x	x	Are bedrails/restraints present - with use minimized *(too operational?)*
	x		Does furniture have components that could trap patients (e.g., lap trays)?
Surveillance		x	If direct proximity is not possible, is visual patient monitoring available (e.g., video surveillance)?
Bedside mats		*x*	*Operational versus design consideration*
Visual cues (temporary)		*x*	*Operational versus design consideration*
Availability of assistive devices (grab bars)	x	x	Are additional grab bars and handrails mounted in the bathroom to allow varying support heights? Are grab bars located on either side of the toilet to support patients getting up and down toileting? Are grab bars and handrails located to support patients while ambulating to the toilet?
Cords, tubing	x	x	*See also clutter*
Lighting	x	x	Is low-level lighting available in nighttime/dark conditions?
		x	Has lighting been designed to eliminate abrupt changes in light levels?
Noise/Quiet Zone	x		Is noise controlled through the use of wireless communication systems (e.g., paging, alarms, etc.)?
Not corroborated – indirect solution to reduce noise	-	-	Is noise controlled through the design (e.g., material selection?
Not corroborated	-	-	Is contrast designed to differentiate between the floors and walls and minimize transitions between colors and/or materials?
Not corroborated	-	-	Have fall risks from procedure tables been considered?
Not corroborated	-	-	Has ergonomic design been considered in furniture selection? (fatigue)
Not corroborated	-	-	Has lighting been designed to allow flexibility to adjust levels between the surgical operating area and other areas of the room?

12.8 Appendix H: Content for SRA Testing Following Delphi Process (Falls)

Table 12-8. Final SRA content for testing

Building category	Environment latent condition	Rationale	Design consideration question/statement
Room Layout	Visibility	*Rationale: Bathroom locations visible from the bed, with the door open, resulted in fewer falls.*	Is the bathroom door clearly identifiable from the bed?
Unit Layout	Visibility	*Rationale: Numerous studies suggest locating higher risk patients closest to the nurse station. While this may be seen as operational, the design can support improved visibility and proximity through the specific location of nurse stations (e.g., decentralized); the location of charting (e.g., bedside); visibility of the patient head; visibility from the corridors with a normal walking pattern, and supplementing the layout with technology when needed to provide improved visibility.*	Does the unit layout allow staff to easily see the patient head in all rooms from work stations or a routine circulation pattern (i.e., no hidden rooms in the corners)?
Unit Layout	Visibility	"	Does the design maximize the ability of staff to view patients?
Unit Layout	Visibility	"	If direct visibility is not possible, is additional patient monitoring available (e.g., video surveillance, alarms)
FFE	Accessibility	*Rationale: Research papers often cite the call button within reach of the patient as an intervention to reduce falls, although specific locations are not referenced.*	Are all call button/systems accessible and usable?
FFE	Accessibility	*Rationale: Numerous studies reference visual cues so that staff and visitors are alerted to a fall risk condition. This includes signage at the door and sometimes at the patient headwall.*	Is there space for safety alert signage (e.g., fall risk, isolation precaution) at the patient room entrance and/or the patient bed?
Building Envelope	Environmental hazards (e.g., slippery floors)	*Rationale: Canopies can protect entrances from inclement weather, while walk-off mats wide enough to cover the door width and long enough to capture several steps can reduce the tracking of contamination into the building. Umbrella bags can provide temporary measures to reduce floor contamination, but should not become obstructions in the path of travel*	Is the entrance protected from weather?
Room Layout	Environmental hazards (e.g., slippery floors)	*Rationale: While clutter may appear to be an operational issue of housekeeping, it is influenced by the room and unit layout. A layout designed without space for necessary equipment and related cords may inherently create obstacles for staff and patients. Inadequate storage facilities, either within the room or unit, can lead to unused equipment being left out, potentially in the paths of travel.*	Does the room layout provide clear and unobstructed paths of travel?

Building category	Environment latent condition	Rationale	Design consideration question/statement
Room Layout	Environmental hazards (e.g., slippery floors)	*Rationale: A recent study found that rooms with18" of space on the opening side of the door had a lower rate of falls.*	Is space provided on the opening side of the patient toilet room door to facilitate the use of equipment and/or assistive devices?
FFE	Environmental hazards (e.g., slippery floors)	*Rationale: Studies find the use of bedrails and restraints do not contribute to a reduced rate of falls and may contribute to an increased risk of falls, although some studies indicate this intervention is in place as part of a multi-factorial falls reduction program.*	Is the use of unnecessary restraints minimized (including the use of bilateral full-length bedrails)?
FFE	Environmental hazards (e.g., slippery floors)	*Rationale: Chair lap trays have been cited as a risk factor, defined as restraints despite their intended purpose. (They may be attached to chairs to prevent people getting up without assistance.)*	Does furniture selection/specification support independent mobility?
Interior Material (Finishes)	Environmental hazards (e.g., slippery floors)	*Rationale: Research indicates that changes in floor surfaces and their transitions can be a contributing factor for falls.*	Are there smooth transitions in walking surfaces or between flooring types to avoid surface irregularities leading to trips?"
Interior Material (Finishes)	Environmental hazards (e.g., slippery floors)	*Rationale: Research indicates that flooring patterns and high gloss floor finishes may contribute to falls, possibly by obscuring objects or creating confusion about the floor surface. High gloss finishes also contribute to decreased mobility (due to fear of falling) resulting in decrease leg strength, further contributing to falls.*	Do selection/ specification of floor materials and pattering accurately convey the floor conditions (level floor vs. stair/threshold)?
Interior Material (Finishes)	Environmental hazards (e.g., slippery floors)	*Rationale: Contrast between surfaces for visual acuity is identified as a factor that influences a risk for falls. A suggested intervention includes contrast between floors and walls*	Is contrast designed to differentiate between the floors and walls and minimize transitions between colors and/or materials?
Interior Material (Finishes)	Environmental hazards (e.g., slippery floors)	*Rationale: Loose carpets or improperly placed mats have been indicated as a contribute to falls*	Are rugs and carpeting secured to the floor?
FFE	Ergonomics	*Rationale: While research has not confirmed the benefit of handrails from the patient bed to bathroom, expert opinions support their use. They should support patient weight while ambulating and many suggest visibility ay night. Handrails in the bathroom and shower are often at awkward heights that require excessive bending and/or reaching. Some experts propose that the addition of grab bars at a secondary height is useful to address a varied population.*	Are grab bars and handrails located to support patients while ambulating to the toilet?
FFE	Ergonomics	*Rationale: Research indicates that grab bars on both sides of the toilet helps the patient with the required push up force, in lieu of trying to use the sink.*	Are grab bars located on either side of the toilet to support patients getting up and down toileting?
FFE	Ergonomics	*Rationale: Numerous studies indicate that beds with adjustable heights that can be used in a low position with brakes contribute to reduced falls.*	Have beds been selected to afford low height positions and brakes?

Building category	Environment latent condition	Rationale	Design consideration question/statement
Interior Material (Finishes)	Ergonomics	*Rationale: Research shows that softer underlays (e.g., wood versus concrete) underlays may contribute to a reduction in injuries associated with patient falls through energy absorption. Certain materials may contribute more or less to the risk of falls as well.*	Are flooring and subflooring materials selected to mitigate injury in the event of a fall?
Room Layout	Family friendly environment	*Rationale: Research indicates that organizations that engage families through education and/or surveillance of patients have a lower rate of falls*	Is there space for families to be present in the patient room to encourage communication with caregivers about falls and increase the level of patient surveillance?
Lighting	Light quality/ Levels	*Rationale: Few studies evaluate specific lighting levels, but it is often cited as both a hazard (improper lighting) and an intervention. Unevenness of lighting in hallways and abrupt changes are referenced as conditions that may create disorientation or confusion.*	Has lighting been designed to eliminate abrupt changes in light levels?
Lighting	Light quality/ Levels	*Rationale: Few studies evaluate specific lighting levels, but it is often cited as both a hazard (improper lighting) and an intervention. Given the prevalence of night-time falls and falls en route to toileting, most implemented strategies suggest ensuring visibility to the patient bathroom at night.*	Is low-level lighting available in nighttime/dark conditions?
Acoustic environment	Noise	*Rationale: Some studies indicate a relationship between sleep quality and falls. Noise reduction can improve sleep.*	Are call and communication systems designed to minimize public noise?
Room Layout	Proximity	*Rationale: Research concerning the location of the bathroom on the headwall versus the footwall is limited and inconclusive, although a recent study found lower fall rates when the bathroom was on the footwall. Conflicting needs should be considered including the ease of the patient path to the bathroom, the visibility for the patient, and the visibility for staff (to see when a patient is trying to walk to the bathroom).*	Is the bathroom located in close proximity to the bed?

Questions were transformed into statements, and rationale statements were reviewed for consistency with the final statement prior to testing.

12.9 Appendix I: Ethics Approval and Informed Consent

12.9.1 Loughborough University Ethics Approvals

Ethics Approvals (Human Participants) Sub-Committee

Loughborough University

Ethical Clearance Checklist

Has the Investigator read the 'Guidance for completion of Ethical Clearance Checklist' before starting this form?	Yes

Project Details

1. Project Title: Bench to Board to Bedside:Bridging Built Environment Research, Architectural Design, and Human Factors to Inform a Proactive Safety Risk Assessment for Healthcare Environments

Applicant(s) Details

2. Name of Applicant 1: Ellen Taylor	10. Name of Applicant 2: Dr Sue Hignett
3. Status: PGR student	11. Status: Staff
4. School/Department: Loughborough Design School.	12. School/Department: Loughborough Design School.
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7b. Telephone number: +1 267 939 3847.	15b. Telephone number: 223003.
8. Supervisor: No	16. Supervisor: Yes
9. Responsible Investigator: No	17. Responsible Investigator: Yes

Participants

Positions of Authority

18. Are researchers in a position of direct authority with regard to participants (e.g. academic staff using student participants, sports coaches using his/her athletes in training)?	No

Vulnerable groups

19. Will participants be knowingly recruited from one or more of the following vulnerable groups?	
Children under 18 years of age	No
Persons incapable of making an informed decision for themselves	No
Pregnant women	No
Prisoners/Detained persons	No
Other vulnerable group Please specify: Click here to enter text	No
If you have selected No to all of Question 19, please go to Question 23.	
20. Will participants be chaperoned by more than one investigator at all times?	Choose an item
21. Will at least one investigator of the same sex as the participant(s) be present throughout the investigation?	Choose an item
22. Will participants be visited at home?	Choose an item

Researcher Safety

23. Will the researcher be alone with participants at any time?	No
If Yes, please answer the following questions:	
23a. Will the researcher inform anyone else of when they will be alone with participants?	Choose an item
23b. Has the researcher read the 'guidelines for lone working' and will abide by the recommendations within?	Choose an item

Methodology and Procedures

24. Please indicate whether the proposed study:

Involves taking bodily samples (please refer to published guidelines)	No
Involves using samples previously collected with consent for further research	No
Involves procedures which are likely to cause physical, psychological, social or emotional distress to participants	No
Is designed to be challenging physically or psychologically in any way (includes any study involving physical exercise)	No
Exposes participants to risks or distress greater than those encountered in their normal lifestyle	No
Involves collection of body secretions by invasive methods	No

Prescribes intake of compounds additional to daily diet or other dietary manipulation/supplementation	No
Involves pharmaceutical drugs	No
Involves use of radiation	No
Involves use of hazardous materials	No
Assists/alters the process of conception in any way	No
Involves methods of contraception	No
Involves genetic engineering	No

Involves testing new equipment	No

Observation/Recording

25a. Does the study involve observation and/or recording of participants?	Yes
If **Yes**:	
25b. Will those being observed and/or recorded be informed that the observation and/or recording will take place?	Yes

Consent and Deception

26. Will participants give informed consent freely?	Yes

Informed consent

27. Will participants be fully informed of the objectives of the study and all details disclosed (preferably at the start of the study but, where this would interfere with the study, at the end)?	Yes
28. Will participants be fully informed of the use of the data collected (including, where applicable, any intellectual property arising from the research)?	Yes

29. For children under the age of 18 or participants who are incapable of making an informed decision for themselves:	
a. Will consent be obtained (either in writing or by some other means)?	N/A
b. Will consent be obtained from parents or other suitable person?	N/A
c. Will they be informed that they have the right to withdraw regardless of parental/guardian consent?	N/A
d. For studies conducted in schools, will approval be gained in advance from the Head-teacher and/or the Director of Education of the appropriate Local Education Authority?	N/A
e. For detained persons, members of the armed forces, employees, students and other persons judged to be under duress, will care be	N/A

taken over gaining freely informed consent?	

Deception

30. Does the study involve deception of participants (i.e. withholding of information or the misleading of participants) which could potentially harm or exploit participants?	No
If **Yes:**	
31. Is deception an unavoidable part of the study?	Choose an item
32. Will participants be de-briefed and the true object of the research revealed at the earliest stage upon completion of the study?	Choose an item
33. Has consideration been given on the way that participants will react to the withholding of information or deliberate deception?	Choose an item

Withdrawal

34. Will participants be informed of their right to withdraw from the investigation at any time and to require their own data to be destroyed?	Yes

Storage of Data and Confidentiality

35. Will all information on participants be treated as confidential and not identifiable unless agreed otherwise in advance, and subject to the requirements of law?	Yes
36. Will storage of data comply with the Data Protection Act 1998?	Yes
37. Will any video/audio recording of participants be kept in a secure place and not released for any use by third parties?	Yes
38. Will video/audio recordings be destroyed within ten years of the completion of the investigation?	Yes
39. Will full details regarding the storage and disposal of any human tissue samples be communicated to the participants?	N/A
40. Will research involve the sharing of data or confidential information beyond the initial consent given?	No
41. Will the research involve administrative or secure data that requires permission from the appropriate authorities before use?	No

Incentives

42. Will incentives be offered to the investigator to conduct the study?	No
43. Will incentives by offered to potential participants as an	No

inducement to participate in the study?	

Work Outside of the United Kingdom

44. Is your research being conducted outside of the United Kingdom?	Yes
If **Yes**:	
45. Has a risk assessment been carried out to ensure the safety of the researcher whilst working outside of the United Kingdom?	Yes
46. Have you considered the appropriateness of your research in the country you are travelling to?	Yes
47. Is there an increased risk to yourself or the participants in your research study?	No
48. Have you obtained any necessary ethical permission needed in the country you are travelling to?	Yes

Information and Declarations

Checklist Application Only:
If you have completed the checklist to the best of your knowledge, and not selected any answers marked with an * or †, your investigation is deemed to conform with the ethical checkpoints. Please sign the declaration and lodge the completed checklist with your Head of Department/School or his/her nominee.

Checklist with Additional Information to the Secretary:
If you have completed the checklist and have only selected answers which require additional information to be submitted with the checklist (indicated by a †), please ensure that all the information is provided in detail below and send this signed checklist to the Secretary of the Sub-Committee.

Checklist with Generic Protocols Included:
If you have completed the checklist and you have selected one or more answers in which you wish to use a Generic Protocol (indicated by #), please include the Generic Protocol reference number in the space below, along with a brief summary of how it will be used. Please ensure you are on the list of approved investigators for the Generic Protocol before including it on the checklist. The completed checklist should be lodged with your Head of Department/School or his/her nominee.

Full Application needed:
If on completion of the checklist you have selected one or more answers which require the submission of a full proposal (indicated by a *), please download the relevant form from the Sub-Committee's web page. **A signed copy of this Checklist should accompany the full**

submission to the Sub-Committee.

Space for Information on Generic Proposals and/or Additional Information as requested:

Click here to enter text.

For completion by Supervisor

Please tick the appropriate boxes. The study should not begin until all boxes are ticked.

☒ The student has read the University's Code of Practice on investigations involving human participants

☒ The topic merits further research

☒ The student has the skills to carry out the research or are being trained in the requires skills by the Supervisor

☒ The participant information sheet or leaflet is appropriate

☒ The procedures for recruitment and obtaining informed consent are appropriate

Comments from supervisor:

.

Signature of Applicant:

Signature of Supervisor (if applicable): .

Signature of Head of School/Department or his/her nominee: .

Date: . 18/10/13

12.9.2 Sample Informed Consent (verbal delivery by PowerPoint)

Informed Consent:

You are invited to take part in a research study to support an AHRQ seminar grant to support facility design for patient safety. The purpose of this study is to identify the underlying built environment conditions that contribute to safe healthcare facility design. Our goal today is to evaluate the content and use of a draft decision-making tool to support safe healthcare facility design. We expect to gather information from a variety of perspectives that will allow us to refine the tool before completion. The findings of the testing phase will be used in 1) the further development the SRA tool for use in healthcare facility design; 2) an annual AHRQ grant report, 3) a PhD dissertation and 4) additional public outreach including magazine articles, peer-reviewed papers, and conferences. The outcome of the project will include the finalization of a Safety Risk Assessment tool that will support a requirement for a Safety Risk Assessment, or SRA, in the in the 2014 FGI Guidelines for the Design and Construction of Healthcare Facilities

The session today will start with our research team observing your use of the SRA tool. After using the tool, each of you will be asked to fill out a brief survey to evaluate your thoughts on using the tool. You may refuse to answer any questions that you don't wish to answer. A focus group will be conducted following completion of the surveys to capture additional perceptions.

The session will be recorded for analysis following testing at multiple sites.

Is it okay to proceed with our session using the SRA tool today?

All research studies have some degree of risk or discomfort. In this case, the time burden and confidentiality of feedback is anticipated as a minimal risk. Through the structured agenda, we have tried to ensure an effective use of your time today and any individual responses will be reported anonymously.

There is no direct benefit to you from being in this study, although your project may benefit from the discussions today and your participation will contribute to the overall advancement of patient safety in the area of healthcare facility design.

You will receive no reimbursement for participation and your organization is not incurring any of our direct or indirect costs.

You do not have to agree to continue participation, and you may change your mind at any time during today's session. If you have any questions or complaints about this study, you can contact the principal investigator, Dr. Anjali Joseph.

Pease sign and return non-disclosure agreement

Module A: Using the Safety Risk Assessment (SRA) for a unit renovation in the context of a traditional meeting

The Context

Hospital of Good Faith is a non-profit general medical and surgical hospital with 315 beds. The hospital has recently vacated one of their inpatient units, relocating those rehab services to a new specialty facility where brain-injury, spinal-cord-injury, trauma and stroke units will help promote the recovery of individuals who have functional deficits resulting from injury or illness. The leadership is planning the retrofit of this floor, but is undecided as to whether the new inpatient unit should be planned for med-surg, neurology, or ICU. As a result, they are interested in flexibility and wish to pursue a universal room concept. There are many unanswered questions. With the threat of reimbursement declines due to value-based purchasing, there has been an increased focus on non-reimbursed safety events, but the Quality, Patient Safety & Effectiveness Department has been targeting other performance improvement and safety initiatives, as well.

Your Charge

You are not designing the new layout, but need to guide the hospital in deciding what considerations need to be included in the project program related to safety improvements for the renovation of this single unit. While the existing infrastructure must remain (i.e. column grid and plumbing), there may be some infrastructure-related modifications (e.g. additional sinks) you might suggest. The existing patient rooms vary in size, ranging from 13'-4" – 14'-6" wide and approximately 25' deep. The existing patient area corridors are 8' wide.

Because the unit you are considering may be used for multiple service lines, nurse staffing may range from a 1:1 ratio up to a 6:1 ratio. It is hoped the unit will fit 24 beds. The budget will be established after recommendations are considered.

What you know

General Information and Statistics

Admissions:	23,824
Inpatient surgeries:	6,136
Outpatient Surgeries:	10,022
Outpatient visits:	280,473
Emergency room visits:	68,891
Births:	2,016

Employed Staff (Full Time)

Physicians and dentists*:	40
Registered nurses:	575
Licensed practical nurses:	6
Faculty Personnel:	NA

Employed Staff (Part Time)

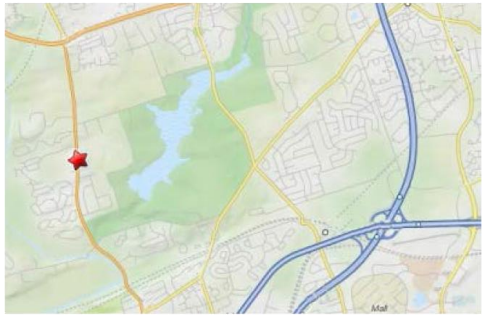
Physicians and dentists*:	22
Registered nurses:	331
Licensed practical nurses:	3
Faculty Personnel:	NA

* At many hospitals, physicians and dentists are not on staff but paid as faculty by a medical school or other arrangements.

Source:http://health.usnews.com/best-hospitals

Location

Located on the East Coast, the suburban community hospital is located between two major urban hubs. The facility is in close proximity to a primary interstate highway and is bound on one side by a park and reservoir.



The facility is served by a loop road with drop-off points at a main lobby, an outpatient center, and the ED.

Demographics

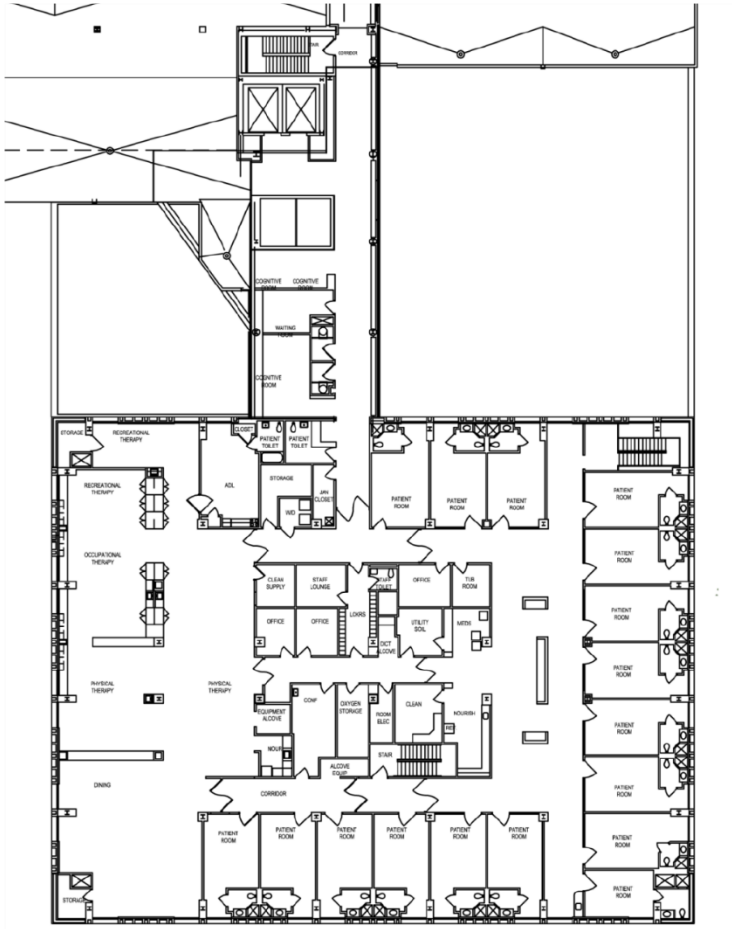
The total population of the hospital's service area increased to approximately 446,900 residents in 2013 from 438,700 residents in 2000. The population is projected to increase slightly by 2018 to 448,300 residents. Just under one-quarter of residents are between the ages of 0-17 (22%), nearly one-third are 18-44 (32%), more than three in ten are 45-64 -64 (31%), and 15% are 65 or older. When comparing with 2000, the service area saw a decrease in the percentage of younger residents, including those ages 0-17 and ages 18-44, and an increase in the percentage of older residents, including those ages 45-64 and those age 65 and older. The trend toward an aging population in the service area is expected to continue through 2018. Approximately 49% of the service area's population is male and 51% is female. In this area, 85% of residents identify as White, 5% identify as Latino (most Puerto Rican), 4% identify as Black, 4% identify as Asian (most Indian), and 2% identify as an "other" race/ethnicity and most speak English at home (89%).

Obesity related conditions include heart disease, stroke and diabetes. Heart disease is the second leading cause of death in the service area. More than one-quarter (26.9%) of adults in the service area are obese and one-third (33.7%) of adults are overweight. The percentage of adults in the service area who are obese has increased since 2010 from 21.8% to 26.9% in 2012. One in ten (10.9%) adults in the service area has been diagnosed with diabetes; this percentage represents approximately 38,200 adults and is similar to the statewide percentages. In the service area, one-third of children are overweight (14.6%) or obese (16.9%).

Nearly one in six (15.4%) adults in the service area has been diagnosed with a mental health condition; this percentage represents 53,700 adults. Of those with a mental health condition, more than one-third (37.5%) are not receiving treatment for the condition. One in eight (13.0%) older adults in the service area has signs of clinical depression, and approximately 28,700 adults (8.3%) are in recovery for a substance abuse problem.

The Existing Plan

The unit under consideration is located on the second floor of the Medical-Surgical Main Wing (lower right of block diagram). The unitplan is shown on the next page.


COGNITIVE ROOM
COGNITIVE ROOM
WAITING ROOM
COGNITIVE ROOM
STORAGE
RECREATIONAL THERAPY
CLOSET
PATIENT TOILET
PATIENT TOILET
RECREATIONAL THERAPY
ADL
STORAGE
JAN. CLOSET
INFO
PATIENT ROOM
PATIENT ROOM
PATIENT ROOM
PATIENT ROOM
OCCUPATIONAL THERAPY
CLEAN SUPPLY
STAFF LOUNGE
LOUNGE
OFFICE
OFFICE
OFFICE
OFFICE
UTILITY SOIL
SOIL CLOSET
TV/R ROOM
MEDIA
PHYSICAL THERAPY
PHYSICAL THERAPY
EQUIPMENT ALCOVE
CONF
OXYGEN STORAGE
ROOM ELEC
CLEAN
NOURISH
STAIR
MOUT
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DINING
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Publicly reported outcomes measures: include errors, accidents, and injuries

Healthcare Associated Infections details

Measure	# Infections Reported (A)	Days or Procedures	Predicted # Infections (B)	Standardized Infection Ratio (SIR) (A/B)	Evaluation
Central line-associated blood stream infections (CLABSI)	7	5510 Central Line days (CLD)	8.916	0.785	No Different than U.S. National Benchmark
Catheter-associated urinary tract infections (CAUTI)	27	6969 Catheter days	10.586	2.551	Worse than the U.S. National Benchmark
Surgical site infection from colon surgery (SSI: Colon)	2	98 procedures	2.983	0.670	No Different than U.S. National Benchmark
Surgical site infection from abdominal hysterectomy (SSI: Hysterectomy)	1	187 procedures	1.649	0.606	No Different than U.S. National Benchmark
Methicillin-resistant staphylococcus aureus (or MRSA) blood infections	1	28659	1.199	0.834	No Different than U.S. National Benchmark
Clostridium difficile (or C.diff.) infections	33	27118 patient days	20.966	1.574	Worse than the U.S. National Benchmark

Standardized infection ratio (SIR) national benchmark = 1; Lower SIRs are better. A score of (0) is best.
Source: http://www.medicare.gov/hospitalcompare Data collection period: 4/1/2012-3/31/2013

Other Hospital Acquired Conditions

Measure	This hospital	worst	average	best	source
Foreign Object Retained After Surgery	0.000	0.389	0.03	0	CMS HAC
Air Embolism	0.000	0.103	0.00	0	CMS HAC
Pressure Ulcer - Stages 3 and 4	0.120	0.907	0.10	0	CMS HAC
Falls and Trauma	0.419	2.005	0.48	0	CMS HAC
Death Among Surgical Inpatients with Serious Treatable Complications	98.25	163.08	113.56	54.89	CMS AHRQ PSI
Collapsed Lung Due to Medical Treatment	0.34	0.75	0.34	0.07	CMS AHRQ PSI
Breathing Failure After Surgery	13.16	21.27	11.66	4.99	CMS AHRQ PSI
Postoperative PE/DVT	5.17	11.88	4.53	0.97	CMS AHRQ PSI
Wounds Split Open After Surgery	0.86	2.73	0.96	0.17	CMS AHRQ PSI
Accidental Cuts or Tears From Medical Treatment	1.63	4.2	2.00	0.38	CMS AHRQ PSI

Source: http://www.hospitalsafetyscore.org; time period: 07/01/10 - 06/30/12

Other process measures to protect patients from errors, accidents, and injuries.

Measure	This hospital	worst	average	best	Data Source
Computerized Prescriber Order Entry (CPOE)	5	5	46.25	100	2013 Leapfrog
ICU Physician Staffing	15	5	28.19	100	2013 Leapfrog
Leadership Structures and Systems	120.00	0	110.42	120	2013 Leapfrog
Culture Measurement, Feedback and Intervention	20.00	0	17.78	20	2013 Leapfrog
Teamwork Training and Skill Building	12.00	0	34.20	40	2013 Leapfrog
Identification and Mitigation of Risks and Hazards	65.45	0	108.73	120	2013 Leapfrog
Nursing Workforce	38.10	0	90.73	100	2013 Leapfrog
Medication Reconciliation	18.67	0	31.79	35	2013 Leapfrog
Hand Hygiene	24.00	0	27.27	30	2013 Leapfrog
Care of the Ventilated Patient	13.33	0	18.16	20	2013 Leapfrog
Patients Received Antibiotic within 1 Hour Prior to Surgical Incision	99	0	98.43	100	CMSHC
Patients Received the Right Antibiotic	98	0	98.49	100	CMSHC
Antibiotic Discontinued After 24 hrs	99	0	97.33	100	CMSHC
Urinary Catheter Removed on Postop. Day 1 or 2	100	0	95.00	100	CMSHC
Surgery Patients Received Appropriate Treatment to Prevent Blood Clots at the Right Time	99	0	97.34	100	CMSHC

Source: http://www.hospitalsafetyscore.org citing 2013 Leapfrog Hospital Survey (01/01/12 - 12/31/12) and CMS Hospital Compare (CMSHC) (10/01/11 - 09/30/12)

HCAHPS Summary

	This facility	State average	National average
Patients who reported that their nurses "Always" communicated well	82%	74%	78%
Patients who reported that their doctors "Always" communicated well	78%	78%	81%
Patients who reported that they "Always" received help as soon as they wanted	71%	61%	67%
Patients who reported that their pain was "Always" well controlled	71%	68%	71%
Patients who reported that staff "Always" explained about medicines before giving it to them	65%	61%	64%
Patients who reported that their room and bathroom were "Always" clean	71%	70%	73%
Patients who reported that the area around their room was "Always" quiet at night	49%	51%	61%
Patients who reported that YES, they were given information about what to do during their recovery at home	86%	83%	85%
Patients who gave their hospital a rating of 9 or 10 on a scale from 0 (lowest) to 10 (highest)	77%	67%	70%
Patients who reported YES, they would definitely recommend the hospital	83%	70%	71%

Source: http://www.medicare.gov/hospitalcompare

Module B1: Using the Safety Risk Assessment (SRA) in a high fidelity mock-up

The Context

Founder's Goodwill Hospital is a large urban academic medical center. Its aging infrastructure prompted the decision for major facility replacements (e.g. inpatient tower) several years ago, but the financial crisis and uncertainty surrounding healthcare reform delayed plans until leadership agreed to move ahead in early 2014. However, the delay has meant another five years before the new inpatient project will be occupied. Accordingly, leadership has deemed that an investment to address safety issues in one of the existing units is required as an interim solution. The unit, treating oncology patients, was selected for several reasons. For example, this cohort has higher risks for falls (primarily associated with anemia, fatigue and weakness stemming from treatment) and self-harm (due to pain or the conditions of a life-threatening illness that lead to an increase in suicidal thoughts). However, the cohort also contributes to risk of staff injury associated with moving debilitated patients, as well as security and medication safety issues that are inherent to narcotics and the extensive medication regimen required. As many of these patient are immune-compromised, infection control is also a top priority. The existing unit has 34 private-room beds and the renovation budget is $3M, approximately $88,000 per bed.

Your Charge

You will be meeting in a mock-up of the existing patient room, which was refurbished 10 years ago, but does not include many of today's standard features. Using the mock-up you will identify the features you think need to be included, recognizing there may be significant trade-offs due to budget constraints. As a result, you should do your best to come to consensus on the top priorities for your areas of consideration. You may want to take into account the additional information provided here. The session will be recorded and you are encouraged to "think aloud" for any changes you think should be considered. The bed count cannot be reduced.

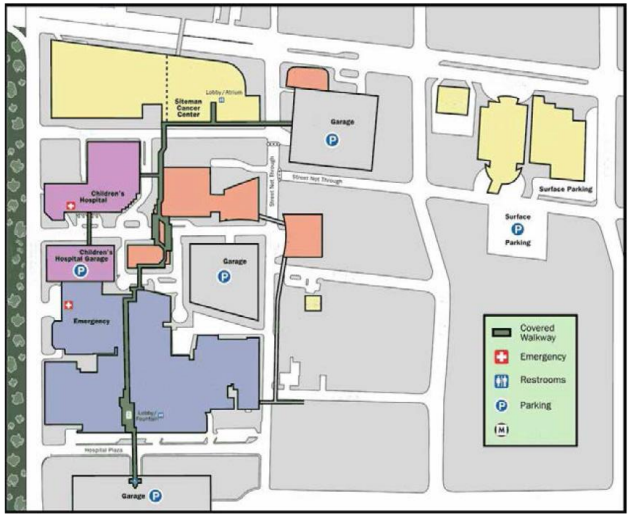
What you know

General Information and Statistics

Licensed Beds:	1,315
Inpatient Admissions:	54,738
Inpatient Surgeries:	19,173
Outpatient Visits:	689,089
Outpatient Surgeries:	21,926
ED Visits:	84,920
Staffing (Full Time)	
Registered nurses:	2,708 (FT); 864 (PT)
Licensed practical nurses:	45 (FT); 19 (PT)
Attending Physicians:	1,762
Residents/Fellows:	809

Location

The medical center occupies 3 city blocks and typical of many urban hospitals, access is through several lobbies, manned by security, with the requirement of staff credentials or a visitor pass.



Demographics

The 2013 population estimate for the county is 1,001,444, virtually unchanged from 2010 census data. Census data also indicate 5.7% of the population is less than 5 years of age, while 22.7% are under 18. Those over age 65 comprise 15.7% of the population. Approximately 47% of the service area's population is male and 53% is female. In this area, 70.5% of residents identify as White, 23.6% identify as Black, 3.8% identify as Asian, and 2.7% identify as Latino. A small percentage indicates two or more races. The poverty rate is 12%. (http://quickfacts.census.gov/)

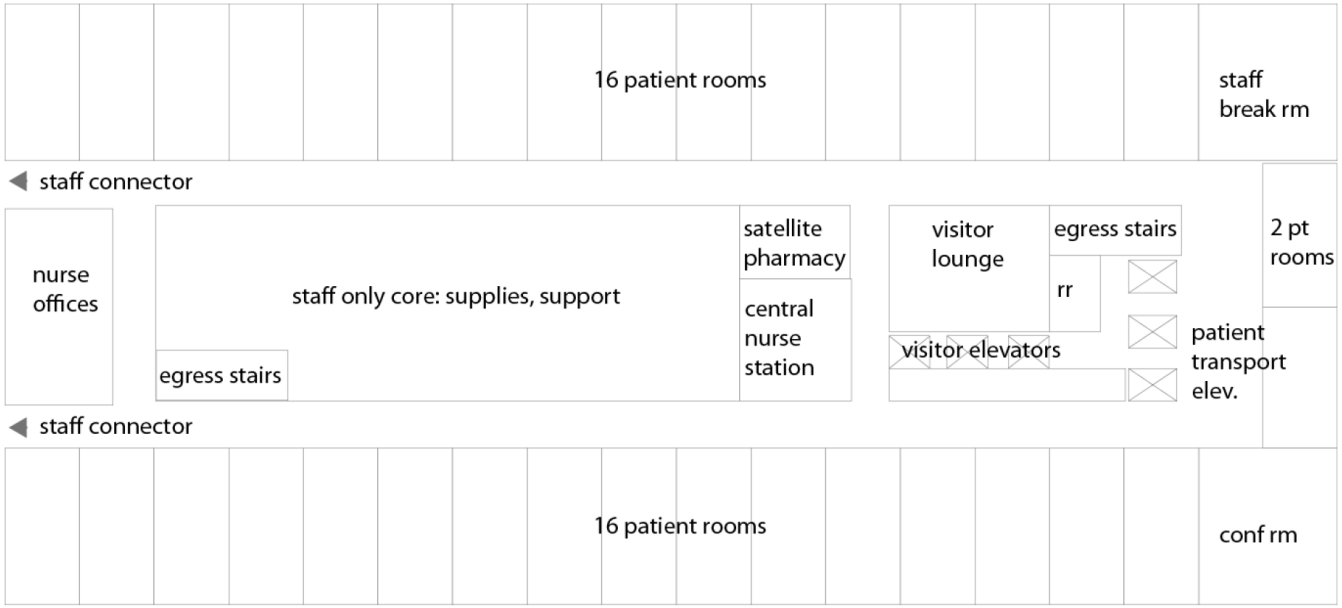
The three leading causes of death in the county were heart disease, cancer, and stroke. In the county, 33.9% of adults were overweight and 29.8% were obese. In the service area, 28% of adults have diabetes.

In this area, approximately 9.5% of persons aged 12 or older were classified as having a substance use disorder and among adults aged 18 or older, 6.9 percent experienced a major depressive episode in the past year, similar to the rates in the state and nation (http://www.samhsa.gov/data). While this unit has not recently experienced a suicide, it should be recognized that studies indicate that the incidence of suicide in cancer patients can be equal to the incidence in the general population or up to 2 to 10 times as frequent.

Fall rates for this unit are 5.93/1,000 patient days, and falls with injury are 2.01/1,000 patients, but were recently reduced to 4.6 and 1.26, respectively, following a rapid improvement recent organized by the unit nurses and performance improvement engineers.

The Oncology Unit

The oncology unit is a 1950s vintage layout with a central nurse station adjacent to the visitor elevators. A satellite pharmacy was located in the unit after becoming the oncology unit. However, there is no additional medication room.


16 patient rooms
staff break rm
staff connector
nurse offices
staff only core: supplies, support
satellite pharmacy
central nurse station
egress stairs
visitor lounge
egress stairs
rr
visitor elevators
patient transport elev.
2 pt rooms
staff connector
16 patient rooms
conf rm

Publicly reported outcomes measures: include errors, accidents, and injuries

Healthcare Associated Infections details

Measure	# Infections Reported (A)	Days or Procedures	Predicted # Infections (B)	Standardized Infection Ratio (SIR) (A/B)	Evaluation
Central line-associated blood stream infections (CLABSI)	20	26427 Central Line days (CLD)	56.33	0.355	Better than U.S. National Benchmark
Catheter-associated urinary tract infections (CAUTI)	118	29654 Catheter days	76.866	1.535	Worse than U.S. National Benchmark
Surgical site infection from colon surgery (SSI: Colon)	14	726 procedures	25.29	0.553	Better than U.S. National Benchmark
Surgical site infection from abdominal hysterectomy (SSI: Hysterectomy)	4	772 procedures	7.458	0.536	No Different than U.S. National Benchmark
Methicillin-resistant staphylococcus aureus (or MRSA) blood infections	9	83351	7.272	1.238	No Different than U.S. National Benchmark
Clostridium difficile (or C.diff.) infections	75	80579 patient days	56.305	1.332	Worse than U.S. National Benchmark

Standardized infection ratio (SIR) national benchmark = 1; Lower SIRs are better. A score of (0) is best.
Source: http://www.medicare.gov/hospitalcompare Data collection period: 4/1/2012-3/31/2013

Other Hospital Acquired Conditions

Measure	This hospital	worst	average	best	source
Foreign Object Retained After Surgery	0.000	0.389	0.03	0	CMS HAC
Air Embolism	0.050	0.103	0.00	0	CMS HAC
Pressure Ulcer - Stages 3 and 4	0.301	0.907	0.10	0	CMS HAC
Falls and Trauma	0.401	2.005	0.48	0	CMS HAC
Death Among Surgical Inpatients with Serious Treatable Complications	105.53	163.08	113.56	54.89	CMS AHRQ PSI
Collapsed Lung Due to Medical Treatment	0.41	0.75	0.34	0.07	CMS AHRQ PSI
Breathing Failure After Surgery	14.84	21.27	11.66	4.99	CMS AHRQ PSI
Postoperative PE/DVT	10.04	11.88	4.53	0.97	CMS AHRQ PSI
Wounds Split Open After Surgery	1.85	2.73	0.96	0.17	CMS AHRQ PSI
Accidental Cuts or Tears From Medical Treatment	0.77	4.2	2.00	0.38	CMS AHRQ PSI

Source: http://www.hospitalsafetyscore.org; time period: 07/01/09 - 06/30/11

Other process measures to protect patients from errors, accidents, and injuries.

Measure	This hospital	worst	average	best	Data Source
Computerized Prescriber Order Entry (CPOE)	65	5	46.25	100	2013 Leapfrog
ICU Physician Staffing	5	5	28.19	100	2013 Leapfrog
Leadership Structures and Systems	No report	0	110.42	120	2013 Leapfrog
Culture Measurement, Feedback and Intervention	"	0	17.78	20	2013 Leapfrog Hospital Survey
Teamwork Training and Skill Building	"	0	34.20	40	2013 Leapfrog
Identification and Mitigation of Risks and Hazards	"	0	108.73	120	2013 Leapfrog
Nursing Workforce	"	0	90.73	100	2013 Leapfrog
Medication Reconciliation	"	0	31.79	35	2013 Leapfrog
Hand Hygiene	"	0	27.27	30	2013 Leapfrog
Care of the Ventilated Patient	"	0	18.16	20	2013 Leapfrog
Patients Received Antibiotic within 1 Hour Prior to Surgical Incision	96	0	98.43	100	CMSHC
Patients Received the Right Antibiotic	98	0	98.49	100	CMSHC
Antibiotic Discontinued After 24 hrs	97	0	97.33	100	CMSHC
Urinary Catheter was Removed on Postoperative Day 1 or 2	89	0	95.00	100	CMSHC
Surgery Patients Received Appropriate Treatment to Prevent Blood Clots at the Right Time	98	0	97.34	100	CMSHC

Source: http://www.hospitalsafetyscore.org citing 2013 Leapfrog Hospital Survey (01/01/12 - 12/31/12) and CMS Hospital Compare (CMSHC) (10/01/11 - 09/30/12)

HCAHPS Summary

	This facility	State average	National average
Patients who reported that their nurses "Always" communicated well	80%	79%	78%
Patients who reported that their doctors "Always" communicated well	83%	82%	81%
Patients who reported that they "Always" received help as soon as they wanted	62%	67%	67%
Patients who reported that their pain was "Always" well controlled	71%	70%	71%
Patients who reported that staff "Always" explained about medicines before giving it to them	66%	63%	64%
Patients who reported that their room and bathroom were "Always" clean	67%	72%	73%
Patients who reported that the area around their room was "Always" quiet at night	54%	61%	61%
Patients who reported that YES, they were given information about what to do during their recovery at home	91%	86%	85%
Patients who gave their hospital a rating of 9 or 10 on a scale from 0 (lowest) to 10 (highest)	74%	70%	70%
Patients who reported YES, they would definitely recommend the hospital	78%	70%	71%

Source: http://www.medicare.gov/hospitalcompare

Module B2: Using the Safety Risk Assessment (SRA) for an LDR project using a high fidelity mock-up

The context

Desert Health is a small rural healthcare provider, serving a population of more than 53,000 people in an 1,800 square mile area. Their primary facility is a 59-bed acute primary care hospital built in 1976, but they also have a 120-bed continuing care center, with subacute care, skilled nursing, and transitional care. Services include a wide range inpatient and outpatient diagnostic, treatment and rehabilitation services, home health and hospice services, and a variety of community outreach services. Outpatient behavioral health services were added in 1997. Maternity services were brought on as a new service line in 2003. Recently, the organization has received designation as a federally qualified health center. As a result of public funding, a federal grant, and the generous donation of a single individual, Desert Health plans to renovate and moderately expand the maternity services center from four LDRP beds to six LDR beds. Currently, the organization has 50% market share with an 80% occupancy rate. There is an overflow condition 33% of the time. The expansion was validated by a market demand report commissioned by the donor. The ALOS is 1.9 days, consistent with the national average.

Your charge

You have been offered the opportunity to visit another facility's high-fidelity mockup of their LDR room. As your group has little experience in the area of designing and constructing a new facility, you would like to use this as a brainstorming opportunity for your team. Using the high-fidelity mockup you are visiting, you will be developing your own ideas surrounding safety in your LDR room design. The architect has provided a preliminary diagram for your facility, and you may want to reference this for additional considerations outside of the room. The session will be recorded and you are encouraged to "think aloud" for any changes you think should be considered.

What you know

General Information and Statistics

Patient days M/S:	8,787
Patient days OB/GYN:	1,047
Patient days ICU:	988
Patient days swing beds:	764
Patient days newborn:	688
Behavioral health visits:	7,650
Emergency room visits (existing):	24,959

Staff

Physicians and dentists:	90
Nurses, all specialties:	N/A
Other employees:	600

Location

The facility is in a remote location, 75 miles from the county hospital, and 40 miles away from the nearest inpatient facility. The county map shows the facility location in context of other providers.

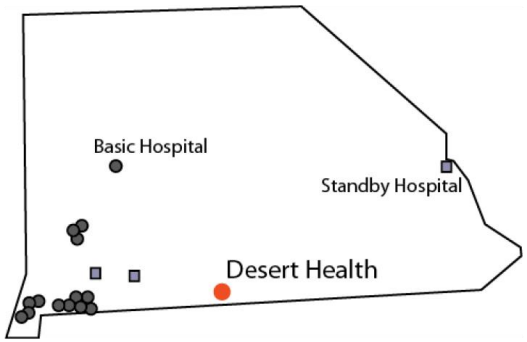


Figure 1: County Map of Hospitals

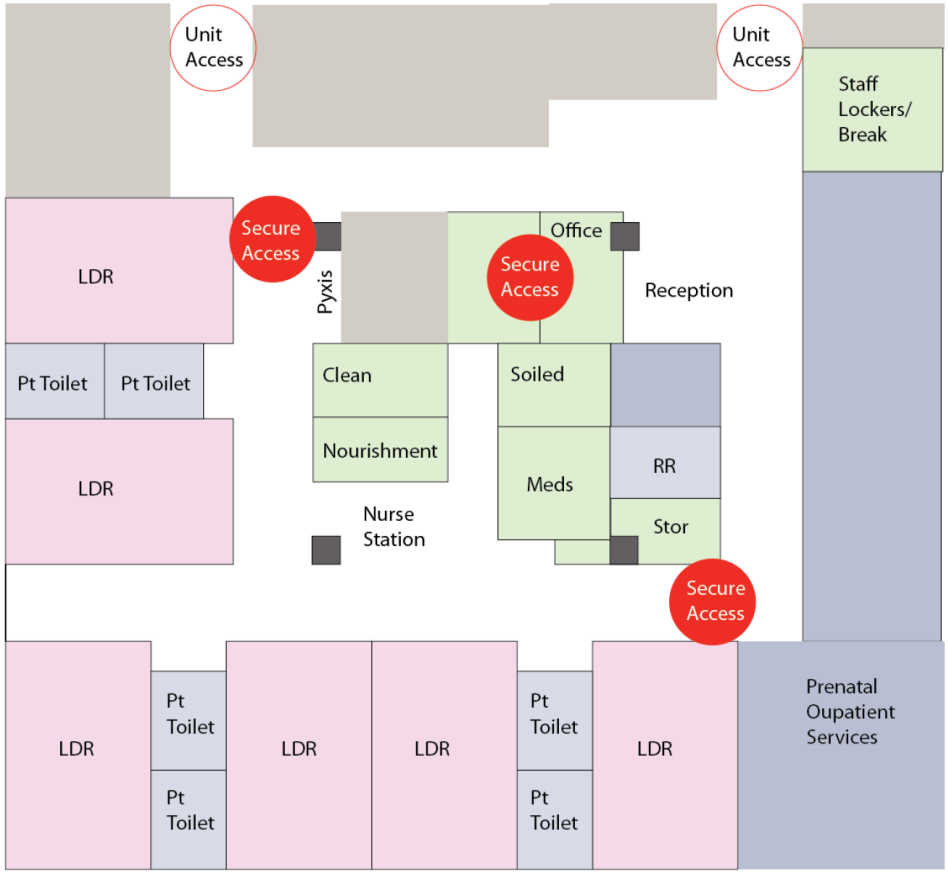
Figure 2: Aerial View of Desert Health

Demographics

The age distribution in the area skews younger than the average state or US population. Eighty-eight percent of the population served by Desert Health is under 64 years of age. The demographics of the area show a population segmentation of 23% between ages 1-18, 60% between ages 19-44, 5% between 45-64, and 12% are 65 years and older. This 19-44 age group had historically been more likely to be under insured or uninsured, resulting in excessive costs for charity care and unfortunately, bad debt. In 2011, the organization absorbed $4 million in costs for unreimbursed care. According to census data, 65% identify as White, 5% as African American, 20% as Hispanic/Latino, 2% Asian, 8% Other, with 5% identifying two or more categories. More than 40% of the population does not have a high school degree.

Twenty percent of the population served by the provider is considered to be living in poverty, compared to 14% statewide and 12% nationwide. The median household income is significantly below the state average. There is an absence of large employers in the area, other than Desert Health itself. Care is therefore often sought through the emergency room or during a catastrophic event when the cost to deliver the care is more expensive.

The Birthing Unit Diagram



Publicly reported outcomes measures: include errors, accidents, and injuries

Healthcare Associated Infections details

Measure	#Infections Reported (A)	Days or Procedures	Predicted # Infections (B)	Standardized Infection Ratio (SIR) (A/B)	Evaluation
Central line-associated blood stream infections (CLABSI)	0	321 Central Line days (CLD)	0.610	N/A (predicted infections < 1)	N/A
Catheter-associated urinary tract infections (CAUTI)	3	602 Catheter days	1.204	2.492	No Different than U.S. National Benchmark
Surgical site infection from colon surgery (SSI: Colon)	0	22 procedures	0.575	N/A (predicted infections < 1)	N/A
Surgical site infection from abdominal hysterectomy (SSI: Hysterectomy)	0	14 procedures	0.132	N/A (predicted infections < 1)	N/A
Methicillin-resistant staphylococcus aureus (or MRSA) blood infections	0	3117	0.112	N/A (predicted infections < 1)	N/A
Clostridium difficile (or C.diff.) infections	2	2916 patient days	1.272	1.572	No Different than U.S. National Benchmark

Standardized infection ratio (SIR) national benchmark = 1; Lower SIRs are better. A score of (0) is best.
Source: http://www.medicare.gov/hospitalcompare Data collection period: 4/1/2012-3/31/2013

Other Hospital Acquired Conditions

Measure	This hospital	worst	average	best	source
Foreign Object Retained After Surgery	0.000	0.389	0.03	0	CMS HAC
Air Embolism	0.000	0.103	0.00	0	CMS HAC
Pressure Ulcer - Stages 3 and 4	0.000	0.907	0.10	0	CMS HAC
Falls and Trauma	0.000	2.005	0.48	0	CMS HAC
Death Among Surgical Inpatients with Serious Treatable Complications	N/A	163.08	113.56	54.89	CMS AHRQ PSI
Collapsed Lung Due to Medical Treatment	0.38	0.75	0.34	0.07	CMS AHRQ PSI
Breathing Failure After Surgery	14.78	21.27	11.66	4.99	CMS AHRQ PSI
Postoperative PE/DVT	4.29	11.88	4.53	0.97	CMS AHRQ PSI
Wounds Split Open After Surgery	1.84	2.73	0.96	0.17	CMS AHRQ PSI
Accidental Cuts or Tears From Medical Treatment	1.58	4.2	2.00	0.38	CMS AHRQ PSI

Source: http://www.hospitalsafetyscore.org Time period: 07/01/10 - 06/30/12

Other process measures to protect patients from errors, accidents, and injuries.

Measure	This hospital	worst	average	best	Data Source
Computerized Prescriber Order Entry (CPOE)	20	5	46.25	100	2013 Leapfrog
ICU Physician Staffing	N/A	5	28.19	100	2013 Leapfrog
Leadership Structures and Systems	Did not report	0	110.42	120	2013 Leapfrog
Culture Measurement, Feedback and Intervention	"	0	17.78	20	2013 Leapfrog
Teamwork Training and Skill Building	"	0	34.20	40	2013 Leapfrog
Identification and Mitigation of Risks and Hazards	"	0	108.73	120	2013 Leapfrog
Nursing Workforce	"	0	90.73	100	2013 Leapfrog
Medication Reconciliation	"	0	31.79	35	2013 Leapfrog
Hand Hygiene	"	0	27.27	30	2013 Leapfrog
Care of the Ventilated Patient	"	0	18.16	20	2013 Leapfrog
Patients Received Antibiotic within 1 Hour Prior to Surgical Incision	95	0	98.43	100	CMSHC
Patients Received the Right Antibiotic	87	0	98.49	100	CMSHC
Antibiotic Discontinued After 24 hrs	89	0	97.33	100	CMSHC
Urinary Catheter was Removed on Postoperative Day 1 or 2	87	0	95.00	100	CMSHC
Surgery Patients Received Appropriate Treatment to Prevent Blood Clots at the Right Time	93	0	97.34	100	CMSHC

Source: http://www.hospitalsafetyscore.org citing 2013 Leapfrog Hospital Survey (01/01/12 - 12/31/12) and CMS Hospital Compare (CMSHC) (10/01/11 - 09/30/12)

HCAHPS Summary

	This facility	State average	National average
Patients who reported that their nurses "Always" communicated well	74%	74%	78%
Patients who reported that their doctors "Always" communicated well	72%	78%	81%
Patients who reported that they "Always" received help as soon as they wanted	62%	61%	67%
Patients who reported that their pain was "Always" well controlled	66%	68%	71%
Patients who reported that staff "Always" explained about medicines before giving it to them	60%	61%	64%
Patients who reported that their room and bathroom were "Always" clean	67%	70%	73%
Patients who reported that the area around their room was "Always" quiet at night	59%	51%	61%
Patients who reported that YES, they were given information about what to do during their recovery at home	82%	83%	85%
Patients who gave their hospital a rating of 9 or 10 on a scale from 0 (lowest) to 10 (highest)	69%	67%	70%
Patients who reported YES, they would definitely recommend the hospital	63%	70%	71%

Source: http://www.medicare.gov/hospitalcompare

Module C: Using the Safety Risk Assessment (SRA) for an ED renovation using a low fidelity mock-up and block schematic diagrams

The context

Intercare Health is a large not-for-profit health plan, serving millions of members across the country. The organization provides inpatient and outpatient care and physician group practice maximizes their ability to care for patients. Through an organized delivery system, Intercare provides as many services as possible under one roof. The organization has established standards for several room types (e.g. inpatient rooms, treatment rooms) that are used across medical centers and freestanding emergency centers. The organization has had an extensive program of building and renovation, but the construction of a new medical center has prompted the consideration of a new standard for an ED treatment room. The six-story, 435,000 SF, 264 bed "green" replacement hospital will include 10 operating rooms, an emergency department with 40 treatment rooms and a NICU. The 275,000 SF medical support building will house 116 offices for primary care and specialty physicians, an outpatient procedure suite with six rooms, a pharmacy, a laboratory and radiology services.

Your charge

Using a low-fidelity mockup of foam core, cardboard, plywood, some furnishings, and placeholder paper items (e.g. gel dispenser), you will be providing guidance for this early ED treatment room design concept, as it pertains to safety of the built environment. However, safety issues should be considered in the context of two options for a unit layout, as shown in Figures 1 and 2 and you may make recommendations related to the selection of Option 1 or 2. The session will be recorded and you are encouraged to "think aloud" for any changes you think should be considered. Larger format plans will be with the mock-up.

What you know

General Information and Statistics

System Hospitals:	38
System Medical Offices/OP sites:	618
Total discharges (existing):	13,781
Patient days (existing):	56,441
Emergency room visits (existing):	68,388
System Employed Staff	
Physicians and dentists:	16,942
Nurses, all specialties:	48,701
Other employees:	174,259
Existing facility staff	
RN	373
LPN/VN Nurses	71
Other Personnel	501

Location

The new medical center will be part of a mixed use/retail development on 63 acres in an urbanized industrial area, with direct access from an Interstate highway. Surface parking for more than 2,000 cars will be provided initially, with structured parking planned for the future. About 97 percent of current members (265,000) in the County live within 10 miles of the site.

The hospital will be built to current seismic standards, as the area is within a seismic hazard zone, subject to both liquefaction and ground-shaking amplification due to soil type. The nearby fault has historically ruptured about every 140 years for its previous five large earthquakes. It has been 145 years since the last major earthquake (Magnitude 7). Nearly three million people live along this Fault.

Demographics

The 2013 population estimate for the county is 1,578,891, a 4.5% increase from 2010 census data. Census data also indicate 6.3% of the population is under 5 years of age, while 22.1% are under 18. Those over age 65 comprise 11.8% of the population. Approximately 49% of the service area's population is male and 51% is female. In this area, 52% of residents identify as White, 23% identify as Latino, 13% identify as Black, 28% identify as Asian, and 2% identify as an "other" race/ethnicity. Many indicate two or more races. The poverty rate is 13.5%.

The three leading causes of death in the county were heart disease, cancer, and stroke. For males, heart disease, cancer, and unintentional injuries were the three leading causes of death. Among those 1-24 year, homicide, unintentional injuries, and suicide were the leading causes of death. In the county, 30.5% of adults were overweight and 22.7% were obese. African Americans had the highest prevalence of obesity (42.4%) more than 2.4 times the rate among Whites. Among children, one-third of males (33.2%) and one-quarter of females (25.2%) were overweight. In the service area, 7.8% of adults have diabetes.

Approximately 8.9% of adults had experienced psychological distress in the past year in the county. Among adolescents, 14.1% had received psychological counseling in the past year. Women were much more likely to report psychological distress than men, and younger adults (below 40 years) were over twice as likely to experience psychological distress as older adults. Nearly one in five adults reported the need to see a professional for mental health issues in the past year. Among those who needed professional help for their mental health, four in ten

did not receive help. Among those who saw any provider for their mental health, 41.4% saw a mental health provider, 33.2% both a mental health and primary care provider, and 25.4% saw a primary care provider. In the county, emergency department (ED) visits for mental disorders also varied by subgroup and location, with the most common primary diagnoses including drug abuse, neurotic disorders, nonorganic psychoses, and alcohol dependence. Rates of ED visits for mental disorders were highest among males 45-54 years and females 15-24 years. The highest suicide rate was noted among the male elderly people 85 years or older.

The ED

On average, patients currently spend 5 hrs 16 minutes before being admitted to the hospital, consistent with the state average. The national average is 4 hrs 35 minutes. Transfer time (boarding time) averages 51 minutes, significantly less than the state average of 2 hrs 3 minutes and the national average of 1 hr 37 minutes (source; http://projects.propublica.org/emergency/hospital/).

There are two layout options being considered, as shown on the following pages.

Figure 1: Block diagram option 1

Figure 2: Block diagram option 2

Publicly reported outcomes measures: include errors, accidents, and injuries

Healthcare Associated Infections details

Measure	# Infections Reported (A)	Days or Procedures	Predicted # Infections (B)	Standardized Infection Ratio (SIR) (A/B)	Evaluation
Central line-associated blood stream infections (CLABSI)	3	3921 Central Line days (CLD)	6.373	0.471	No Different than U.S. National Benchmark
Catheter-associated urinary tract infections (CAUTI)	7	4736 Catheter days	5.848	1.197	No Different than U.S. National Benchmark
Surgical site infection from colon surgery (SSI: Colon)	3	122 procedures	3.673	0.817	No Different than U.S. National Benchmark
Surgical site infection from abdominal hysterectomy (SSI: Hysterectomy)	2	56 procedures	0.451	N/A (predicted infections < 1)	N/A
Methicillin-resistant staphylococcus aureus (or MRSA) blood infections	1	14931	0.666	N/A (predicted infections < 1)	N/A
Clostridium difficile (or C.diff.) infections	15	13938 patient days	11.016	1.362	No Different than U.S. National Benchmark

Standardized infection ratio (SIR) national benchmark = 1; Lower SIRs are better. A score of (0) is best.
Source: http://www.medicare.gov/hospitalcompare Data collection period: 4/1/2012-3/31/2013

Other Hospital Acquired Conditions

Measure	This hospital	worst	average	best	source
Foreign Object Retained After Surgery	0.000	0.389	0.03	0	CMS HAC
Air Embolism	0.000	0.103	0.00	0	CMS HAC
Pressure Ulcer - Stages 3 and 4	0.000	0.907	0.10	0	CMS HAC
Falls and Trauma	0.000	2.005	0.48	0	CMS HAC
Death Among Surgical Inpatients with Serious Treatable Complications	123.68	163.08	113.56	54.89	CMS AHRQ PSI
Collapsed Lung Due to Medical Treatment	0.39	0.75	0.34	0.07	CMS AHRQ PSI
Breathing Failure After Surgery	10.09	21.27	11.66	4.99	CMS AHRQ PSI
Postoperative PE/DVT	1.33	11.88	4.53	0.97	CMS AHRQ PSI
Wounds Split Open After Surgery	1.85	2.73	0.96	0.17	CMS AHRQ PSI
Accidental Cuts or Tears From Medical Treatment	1.61	4.2	2.00	0.38	CMS AHRQ PSI

Source: http://www.hospitalsafetyscore.org; time period: 07/01/09 - 06/30/11

Other process measures to protect patients from errors, accidents, and injuries.

Measure	This hospital	worst	average	best	Data Source
Computerized Prescriber Order Entry (CPOE)	100	5	46.25	100	2013 Leapfrog
ICU Physician Staffing	5	5	28.19	100	2013 Leapfrog
Leadership Structures and Systems	111.43	0	110.42	120	2013 Leapfrog
Culture Measurement, Feedback and Intervention	20.00	0	17.78	20	2013 Leapfrog
Teamwork Training and Skill Building	40	0	34.20	40	2013 Leapfrog
Identification and Mitigation of Risks and Hazards	109.09	0	108.73	120	2013 Leapfrog
Nursing Workforce	100	0	90.73	100	2013 Leapfrog
Medication Reconciliation	35	0	31.79	35	2013 Leapfrog
Hand Hygiene	30	0	27.27	30	2013 Leapfrog
Care of the Ventilated Patient	18.33	0	18.16	20	2013 Leapfrog
Patients Received Antibiotic within 1 Hour Prior to Surgical Incision	100	0	98.43	100	CMSHC
Patients Received the Right Antibiotic	99	0	98.49	100	CMSHC
Antibiotic Discontinued After 24 hrs	98	0	97.33	100	CMSHC
Urinary Catheter was Removed on Postoperative Day 1 or 2	99	0	95.00	100	CMSHC
Surgery Patients Received Appropriate Treatment to Prevent Blood Clots at the Right Time	100	0	97.34	100	CMSHC

Source: http://www.hospitalsafetyscore.org citing 2013 Leapfrog Hospital Survey (01/01/12 - 12/31/12) and CMS Hospital Compare (CMSHC) (10/01/11 - 09/30/12)

HCAHPS Summary

	This facility	State average	National average
Patients who reported that their nurses "Always" communicated well	74%	74%	78%
Patients who reported that their doctors "Always" communicated well	79%	78%	81%
Patients who reported that they "Always" received help as soon as they wanted	63%	61%	67%
Patients who reported that their pain was "Always" well controlled	70%	68%	71%
Patients who reported that staff "Always" explained about medicines before giving it to them	61%	61%	64%
Patients who reported that their room and bathroom were "Always" clean	70%	70%	73%
Patients who reported that the area around their room was "Always" quiet at night	47%	51%	61%
Patients who reported that YES, they were given information about what to do during their recovery at home	84%	83%	85%
Patients who gave their hospital a rating of 9 or 10 on a scale from 0 (lowest) to 10 (highest)	67%	67%	70%
Patients who reported YES, they would definitely recommend the hospital	70%	70%	71%

Source: http://www.medicare.gov/hospitalcompare

12.11 Appendix K: Chapter 7 Early Matrix Queries and Final Dendrogram

Table 12-9. Matrix display of "use" following open and axial coding

	A_BHSec_4USE	A_Falls-PH_1USE	A_Falls-PH_2USE	A_HAI-MS_5-USE	A_HAI-MS_6-USE	B1_Falls-PH_1USE	B2_Falls-PH_2USE	C1_Falls-PH_1USE	C2_Falls-PH_2USE	BJC_USE	MSK_USE	UCI_USE
Decisions												
Budget implication			*	*	*	**				*	*	*
Design change-decision	*	*	*			**	*	*	*	*	*	*
Level of evidence				*	*					*	*	*
Liability		*										
No										*		
Not Applicable												
not this phase		*	*					*	*		*	
not this scenario	*			*	*		*					
not this space	*	*	*	*		*	*	*	*	*	*	*
Not sure how done	*			*						*	*	
Partial - limitations of existing										*	*	*
Secondary safety risk	*	*				*		*		*		*
Standards (existing)		*								*	*	*
Tradeoff	*	*				*		*	*	*	*	*
Yes Discussion (or not)												
Answered already, but add	*		*	*	*	*	*		*	*	*	*
Explain how done										**	*	*
Good for all - not just this	**											
Human behavior issue		*			*	*		*		*	*	**
No discussion	***	*	**	**	***	*		*	*	****	*	*
Non SRA implications	*	*	*	*	*	*	*	*	*	*	*	*
Operational-Clinical	*	*	*	*	*	*	*	*		**	***	***
Guidance – how used												
Audit v proactive			*	*			***		*	*		
Educational	*	*	*	*	*	*	*	*	*	**	*	*
Expert response		*		*		*		*	*	*	*	*
Feasible v priority											*	
individual vs group process					*					*		
One solution - multiple fixes	*	*				*				*	*	
Organic												*
Personal experience	*	*		*	*	*		*	*	*	*	*
Potential differing views		*				*						
Priority v risk				*		*	*			*	*	
Push dialogue		*		*	*					*	*	
Rationale check							*			*		*
Revisit question	*	*	*		*		*	*	*	*		*
Risk used		*			*		*			*	*	
Stop VE				*								
Process - Garfield												

	A_BHSec_4USE	A_Falls-PH_1USE	A_Falls-PH_2USE	A_HAI-MS_5-USE	A_HAI-MS_6-USE	B1_Falls-PH_1USE	B2_Falls-PH_2USE	C1_Falls-PH_1USE	C2_Falls-PH_2USE	BJC_USE	MSK_USE	UCI_USE
Facilitation												
Facilitation-time check-other	*	*	*	*	*			*	*			
Scribe-dominant personality leading (neg)					**		*					
Set stage		*	*	*	*			*	*			
Scenarios												
Confused - couldn't figure out			*				*		**			
Demographics-data used	*	*	*	*	*	*						
Function of space discussed			*					*				
Not considered	*		*						*			
Setting type helps						*	*	*				
Surrounding space							*					
Researcher interaction	*	*	*	*	*			*	**	*	*	*
Tool Usability												
Consideration												
Different issue	*	*		*	*	*	*	*	*	*	*	
Duplicate-overlap	*	**	*	*	*	*	*	**	*	*	*	*
Skipped (unintentional)			*						*	*		
Too much in one		*	*				*			*	*	
Unclear or not reading	**	*	*	*	*	*	*	*	*	*	*	
Improvements												
Additional complexity (skip, filter)			*									
Adjust columns										*		
Evaluate multiple options			*									
Group items												
Feature			*				*			*		
Location-type	*											
Phase-detail level		*	*									
Multiple stages			*	*								
Need definitions	*	*	*		*		*					
Prioritize			*		*							
Rationale unclear				*						*		*
Risk unclear		*	*							*		
What is really being answered				*						*		

Table 12-10. Matrix display of "debrief" following open and axial coding

	A_BH-Sec_4DB	A_Falls-PH_1DB	A_Falls-PH_2DB	A_HAI-MS_5-DB	A_HAI-MS_6-DB	B1_Falls-PH_1DB	B2_Falls-PH_2DB	C1_Falls-PH_1DB	C2_Falls-PH_2DB	Day2_Falls-PH_DB1	Day2_Falls-PH_DB2	BJC_DB	MSK_DB	UCI_DB
Debriefing														
Adoption														
Management (Champion)														
Design team	*			*							*	*		*
Facilitator	*									*	*			
Multiple				*						*			*	
Owner	*			*									*	*
Record keeper	*										*		*	
Regulatory				*						*				
Strategic alignment				*	*					*		*		
Usability														
Flexible tool - filters	*	*	*					*	*	*	*			
Formatting-tool								*		*		*		
Pre-populate stds/regs														*
Barriers														
Audit v feasibility											*			
Checklist misuse			*	*			*	*			*			
Content clarity	*	*		*	*	*					*			
Micro-macro	*	*	*	*					*	*	*			
Operations disconnects				*										*
Redundancy	*			*		*							*	
Scenarios														
Blue sky		*	*		*	*	*				*			
Data	*	*						*						
Drawings		*						*						
Setting		*			*		*	*	*	*	*			
Time														
Balance													*	
Process	*			*		*	*					*		*
Visual legibility - size										*				*
Benefits														
Consensus														*
Cost-benefit			*	*	*					*		*	*	
Culture enabler						*							*	*
Education		*		*		*	*			*			*	*
Historical record									*		*	*		
Interactive-integration								*			*			
Liability - protection				*										
Other safety issues to consider													*	
Proactive thinking	*	*	*	*		*	*				*	*	*	*

	A_BH-Sec_4DB	A_Falls-PH_1DB	A_Falls-PH_2DB	A_HAI-MS_5-DB	A_HAI-MS_6-DB	B1_Falls-PH_1DB	B2_Falls-PH_2DB	C1_Falls-PH_1DB	C2_Falls-PH_2DB	Day2_Falls-PH_DB1	Day2_Falls-PH_DB2	BJC_DB	MSK_DB	UCI_DB
QC process-phases		*	*	*	*	*			*	*		*	*	*
Solutions	*					*	*		*	*			*	*
Staff safety													*	
Systematic	*		*	*			*			*	*	*	*	*
Work-users				*			*	*				*	*	*
Implementation														
Cost of tool										*				
How applied														
Meaning-engagement				*	*		*					*		*
Prioritize						*	*				*			*
Risk					*	*								
Y-N-M					*	*	*							
Integration-process	*			*	*	*					*	*		*
Contractual													*	*
Design decision-specific													*	
Early phases													*	*
Revamp user groups													*	
Supplement research														*
People														
Diversity	*	*		*	*	*			*	*		*	*	*
Expertise		*			*	*				*		*	*	*
Personality				*										*
Trade-off/conflict	*							*					*	
Understanding-training	*				*		*			*		*		*

A cluster analysis of sources visualizes node coding similarities for all testing sessions in a dendrogram (below). Dendrograms (tree diagrams) represent hierarchical clustering that evaluates pairs of items for commonalities. In this type of visual representation, each subtree (or clade) and items to the right (or bottom if vertically displayed) are the most similar (highly correlated). Greater branch height indicates bigger differences (Saraf and Patil 2014, Divjak and Fieller 2014, Burns and Burns 2008).

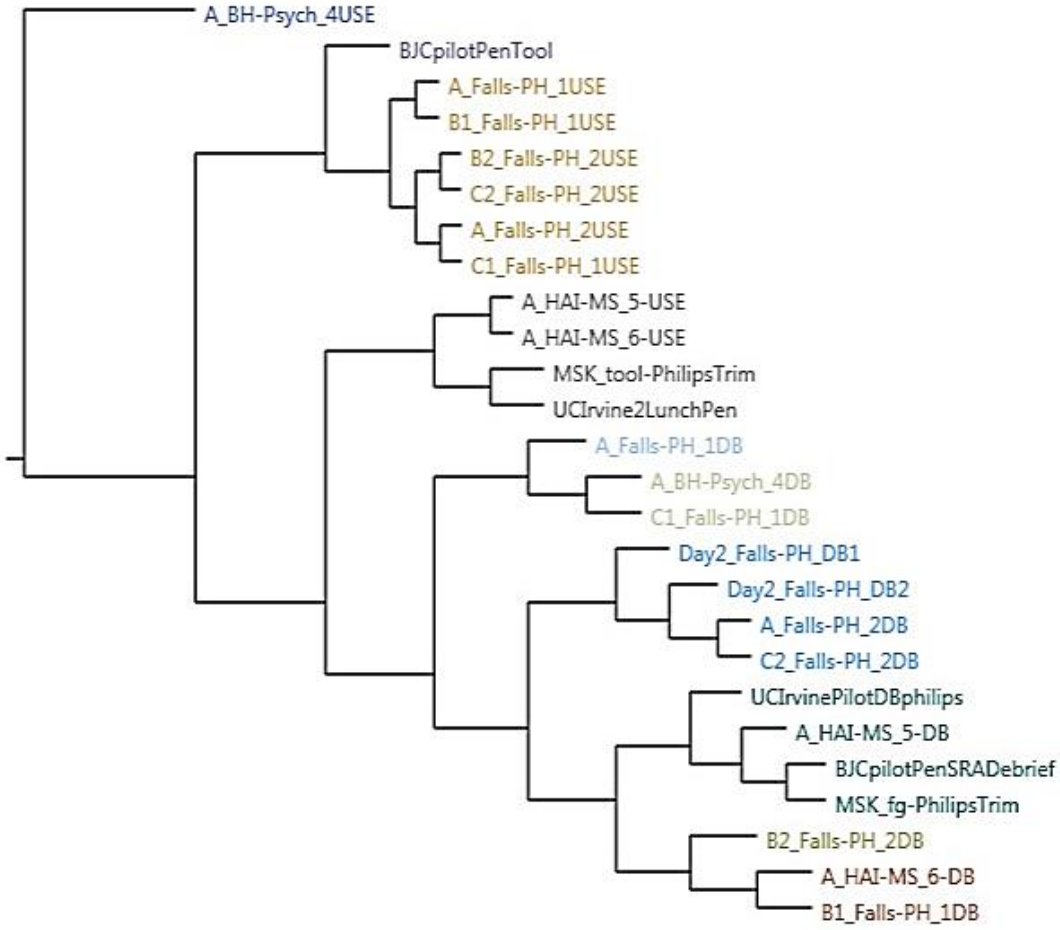


Figure 12-1. Final Dendrogram Cluster Analysis

12.12 Appendix L: Comparing and Exploring HF/E Methods for Safety in EBD (Falls)

As the basis for outlining opportunities, a table was been created to compare methods referenced in architecture (American Institute of Architects 2001, Groat and Wang 2013), EBD (Hamilton and Shepley 2010, 2009, Cama 2009), and HF/E texts (Wilson and Sharples 2015, Carayon, Xie, and Kianfar 2014, Stanton et al. 2013, Wickens et al. 2014). Rather than developing a definitive list of all available methods and techniques (for example, task analysis alone may include more than 100 techniques (Stanton et al. 2013), the goal was to illustrate:

- methods that might be more prevalent (or only exist) in one domain versus another (e.g., post-occupancy evolution in architecture/EBD, heuristics in HF/E);
- methods that might be familiar to multiple stakeholders but with different descriptions, techniques, or approaches (e.g., simulation and modeling – both prototypes and mock-ups and mathematical modeling); and
- opportunities where HF/E methods could capture additional data that might inform safety in HC facility design (e.g., cognitive work analysis).

The results (Table 12-11) are further discussed through several examples that follow to highlight the application to the case study topic, falls.

Table 12-11. Research methods across fields

Strategy/ description Method/technique	Groat & Wang, 2013	AIA, 2009; Architect's Handbook, 2013	Cama, 2009	Hamilton & Shepley, 2010	EBD for HC Facilities, 2009	Wickens et al., 2014	Wilson & Sharples, 2015	Stanton et al., 2013	Carayon, 2011
Interpretive, retrospective									
Literature Review	•	•	•	•		•	•		
Contextual, inferential, recollective, lessons learned	•			•	•				
Client data, archival data, data mining, accident/incident analysis			•	•		•	•		
Public databases				•		•	•		
Case studies	•		•	•	•	•			
Pre-/post-occupancy evaluation	•	•	•	•	•				
Qualitative									
Interviews, focus groups, surveys	•		•	•			•	•	

Observation	●		●					●	
Content analysis	●		●				●		
Ethnography	●						●		
Descriptive correlational									
Relationship studies, causal comparative studies w/ surveys, sorting, observation	●		●	●	●	●	●		
Method study (observation, link analysis, layout analysis, flow, mapping/spaghetti diagrams); may include video	●			●	●	●	●	●	●
Experimental/ quasi-experimental: Use of a treatment/ independent variable, measured outcomes with a comparison or control group to establish causality	●			●		●	●		
Simulation and modeling:									
Prototyping/live simulation (trial with prototype interface), mock-ups	●		●	●	●	●		●	●
Mathematical model (e.g., computer simulation, spreadsheet, isovist)	●	●	●	●	●	●	●	●	●
Logical argumentation: chain of logic linking research to design; typologies	●	●							
User/System Performance									
QI/PI: Lean (eliminate waste), 6σ (reduce errors/defects): process flow charts, value stream mapping			●		●				●
Work system data analysis (cognitive work analysis, critical decision method); performance measures (work rate, waste, errors); time analysis; task/activity analysis							●	●	●
Stakeholder analysis (personas, scenarios)			●				●		
Design participatory processes, inter-disciplinary teams									
User groups; consultant types, construction, researcher, public			●	●					
Co-design, role playing, design decision groups, cooperative evaluation, living labs							●		
Participatory ergonomics						●	●		●
Other descriptive information (people, equipment, environments)									
Physical (anthropometry), physiological (sway, posture, gait), environment (temp, light, sound) measurements, perceptual/cognitive assessment (visual acuity, response times, psychophysics, task analysis)						●	●		
Social and organizational measures (network or sentiment analysis)							●		●
Demands/effects on people									
Physical response (exertion), psychological response, posture/activity analysis, physiological measures (heart rate), fatigue/stress measures							●		
Job/work attitude measures							●		
Heuristic evaluation						●	●	●	●
Risk management (Failure Mode Effect Analysis (FMEA), hazard or fault tree analysis)								●	●

12.12.1.1 Mock-ups

One method in particular is common to all domains, but may be conceived differently. In architecture, mock-ups have become more commonplace in healthcare design, but the US Army Technical Manuals from 1990 portray a different picture, indicating that mock-ups would only be used if requested or required by Headquarters Department of the Army or the contracting officer to satisfy a specific need (HQDA 1990). In the traditional process, the use of mock-ups (ranging from exterior facades to interior spaces) was not well documented in peer-reviewed literature. However, they were portrayed in the industry in different ways. According to some, because mock-ups are expensive, they were used when introducing new concepts or technology as a "*selling*" tool or a way to "*discover that great ideas don't fly*" (Roper and Payant 2014, 232). According to others in the industry, mock-ups were seen as multi-functional: to evaluate the design through use of a survey, to conduct analysis by zones (clinician, patient, family), and to highlight issues of constructability (Bell 2007). In recent examples, some organizations considered further simulations of common activities or even "live" environments followed by individual user feedback processes (Peavey, Zoss, and Watkins 2012).

Supplementing this traditional approach, HF/E methods of mock-up evaluation add rigor. For example, Hignett, Lu, and Fray (2010) described mock-ups through two case studies using a five-step protocol that included:

(1) Defining an example to test;
(2) Observing task activities using Hierarchical Task Analysis (HTA) and Link Analysis (LA) to develop a test scenario;
(3) Conducting Functional Space Experiments (FSEs) with the test scenario to determine spatial requirements;
(4) Taking additional information into account, for example, storage, family space and circulation, regulations, standards, etc.; and
(5) Using steps 1-4 to review and test spatial requirements following changes in working practices and the introduction of new equipment/technology.

The data were collected with multi-directional filming and analyzed frame by frame to plot the movements between the nurses and other components in the space. In this study, patients were included in the second stage of the protocol – observation.

In another study (Mughal et al. 2001), researchers used nurses to evaluate modifications that had been suggested on paper in a brainstorming session prior to the construction of the mock-up of an ICU room. Researchers included nurses of two heights to evaluate the impact of stature and thereby recognize some of the limitations of users. As an experimental repeated-measures design, the normal condition served as a control to two modified designs and two groups of subjects (height). Additionally, by incorporating simulated tasks, the researchers were able to identify that instances of positive changes for one component may have created negative impacts for another. Feedback was solicited through six questions pertaining to ergonomic conditions such as awkwardness of using equipment or the physical effort required to move equipment.

Lastly, Andersen and Broberg (2014) described the use of four mock-ups as a participatory ergonomics approach to explore both design concepts and specific work conditions in hospital facilities. The videotaped process included two parts: an introduction, where the participants and the facilitators discussed work processes and the challenges that might be faced in the proposed room layouts, and testing, where participants enacted scenarios of future work practices, while participants and facilitators discussed the implications for work flow and made suggestions for improvement. According to the authors, "*the participants were not actively focusing the sessions towards ergonomics evaluations; instead their focus was on testing the physical layout of the rooms*" (Andersen & Broberg, 2014, p. 798). The authors indicated a potential for improving the ergonomic aspect of evaluation by strengthening the facilitator's role to direct the sessions around work conditions.

12.12.1.2 Additional Methods

The following case study examples (summarized in Table 12-12) are provided to support both the HF/E design principles framework, as well as the participatory mesoergonomic framework of anticipate, participate, and integrate, in particular to inform and validate assumptions developed through participatory ergonomics in the earliest stages of design.

Table 12-12. Case study examples to support HF/E methods and design principles

	Heuristics	Simulation/ modelling (prototypes/ mock-ups)	Experimental/ quasi-experimental	Descriptive correlation (relationship studies)	Descriptive correlation (methods studies such as CWA, LA)	Qualitative	Archival data
Decision-making					(Lopez et al. 2010, Lu and Hignett 2009, Mansfield et al. 2010)	(Wolf and Hignett 2015)	(Choi, Noblis, and Georgia Tech 2011)
Perception			(Barker et al. 2013)	(Lockhart et al. 2002)		(Lockhart et al. 2002)	(Hignett, Sands, and Griffiths 2011)
Movement	(Fink, Pak, and Battisto 2010)	(Fink, Pak, and Battisto 2010, Mullick 2013, Pati et al. 2015, Cloutier et al. in press)					
Strength			(Spritzer et al. 2015, Barker et al. 2013)				(Hignett, Sands, and Griffiths 2011)
Manipulation	(Fink, Pak, and Battisto 2010)	(Fink, Pak, and Battisto 2010, Mullick 2013, Pati et al. 2015, Cloutier et al. in press)					

12.12.1.2.1 Anticipate: Perception - Cognition

Understanding the patient condition is essential to affecting successful design solutions to prevent falls. For example, Hignett, Sands, and Griffiths (2011) evaluated the differences between frailty and confusion in patient falls using a retrospective analysis of accident reports. The authors found that fewer confused patients fell in the

toilet/bathroom and were significantly more likely to have falls associated with bedrail use. The authors suggested that confused patients may have been unable to find the toilet. This type of analysis is most applicable to the 'Anticipate' category of the participatory mesoergonomics theme that considers cross-level aspects such as patient conditions that teams should anticipate are present in the system.

12.12.1.2.2 Anticipate: Strength - Frailty

The Hignett, Sands, and Griffiths retrospective analysis (2011) also found that significantly more than the expected number of frail patients fell in the toilet/bathroom and significantly fewer than the expected number of frail patients fell at the bed/chair. It was hypothesized, in part, that the availability of bedrails may have become a mobility aid to a goal-oriented frail patient while exiting the bed (Hignett, Sands, and Griffiths 2011). While these studies did not evaluate comparative travel distance to the bathroom, it intuitively follows that a shorter distance to the toilet would benefit a frail patient. This type of analysis underscores the benefit of a holistic understanding of the patient condition as a way to supplement what is traditionally expressed numerically as ratio-per-patient days. This study type is most applicable to the 'Anticipate' category of the participatory mesoergonomics theme that considers cross-level aspects of patient conditions that teams should anticipate as part of the system.

12.12.1.2.3 Participate: Manipulation (and Movement) – Usability

While not focused solely on patient falls, one study undertook the development of heuristics to evaluate environmental design and usability of patient bathrooms (Fink, Pak, and Battisto 2010). Recognizing the benefit of heuristics in product design, the authors translated findings from a grounded theory approach into a tool that could be used in facility design by both architects and human factors experts. According to the authors, the methods included a participatory process where the "primary users" (defined as nurses) were first interviewed for opinions about patient bathrooms and then asked for feedback on a bathroom prototype (i.e., mock-up) after conducting several typical tasks. Nurses took turns role-playing a patient.

The participants reported fall risks in categories such as surfaces, heights, location, and safety but also highlighted the importance of space needed for adequate assistance in toileting, as well as the appropriate locations of grab bars (i.e., within easy reach). While not intended as a precise tool, the authors stated the benefits of the

final tool were a method to identify major usability flaws at any point in the design process. This type of heuristic development is most suited for the 'Participate' category of the participatory mesoergonomics theme that considers the multi-level conditions of personal workspace and workspace envelope.

A shortcoming of studies that incorporated mock-ups is the lack of participation by patients or potential patients who have physical or cognitive limitations that often go unrecognized by healthy individuals. For example, in a recent project post-occupancy evaluation conducted by myself and another researcher, a staff member relayed that nurses had been engaged in determining the layout details for a patient room bathroom. This included a wall that angled away from the toilet to allow staff assistance in patient toileting. Nurses role-playing patients had no problems reaching for the adjacent toilet paper roll, but once the facility was open, it was discovered that the angled wall put the toilet paper out of reach of most patients who were older or in a stage of recovery that limited their range of motion. (This is also a challenge in using anthropometric tables, which in the US have traditionally been based on measurements of health military personnel who may not represent the norm.)

An exception to this critique is a non-healthcare-based study (Mullick 2013) that evaluated the universal design for accessibility in residential bathrooms. For this study (funded by the National Institute on Disability and Rehabilitation Research) the 32 research participants included wheelchair users, mobility-impaired people not using wheelchairs, people affected by multiple sclerosis, children, young adults, pregnant women, overweight people, and elderly people. Each participant was asked to simulate the performance of several activities of daily living (fully clothed) and provide feedback following the task. Each participant was also filmed with overhead cameras for further analysis.

12.12.1.2.4 Participate: Movement – Biomechanics

While including patients in simulated mock-ups is rare, there is (perhaps) hope that patient participation will become more common. In a recent study (Pati et al. 2015 [under peer review], Cloutier et al. in press), a multi-disciplinary team was led by architects and mechanical engineers with experience in biomechanics, healthcare engineering, ergonomics, and kinematics and dynamics of mechanical systems. The team devised a scripted protocol in a mock-up and investigated falls in 30 subjects 70

years or older. The study used motion capture technology, conventional digital video capture, marker labeling in Cortex, COM tracking, and jerk calculation/potential fall identification. The engineering team worked with designers on the research team to translate the findings into implications for design. According to Pati (2015 [under peer rview]), bathroom location (left or right side of the bed) was predictive of potential falls inside the bathroom but significance was lost when posture variables were added to the model. However, significant bathroom postures identified by the research team included turning, grabbing, pulling, and pushing, which might have an implication for design. These study types are most applicable to the 'Participate' category of the participatory mesoergonomics theme that considers the multi-level conditions of patients and their personal workspace and workspace envelope.

12.12.1.2.5 Participate: Perception (and Movement) - Sensory

Using a mixed methods design, researchers evaluated how sensory changes with age affected falls through subjective assessments of floor slipperiness and associated friction demand characteristics (Lockhart et al. 2002). The authors reported that sensory changes in the elderly increased the likelihood of slips and falls. Although tasks were conducted in a laboratory setting, the study illustrated the potential to include patients during design research for a facility project by understanding the dynamics that exist between intrinsic conditions (i.e., age groups), subjective assessments (i.e., accuracy of evaluating hazardous conditions), and biomechanical parameters of walking and responses to falling (e.g., sensory organization, muscle control). These study types are most applicable to the 'Participate' category of the participatory mesoergonomics theme that considers the multi-level conditions of patients and their personal workspace and workspace envelope.

12.12.1.2.6 Participate: Decision-Making - Cognition

The patient perspective might also be more fully incorporated into designing for safety. In a prospective qualitative study conducted on an oncology unit, Wolf and Hignett (2015) found a gap between the patient and nurse perceptions for patient fall risk. The authors established interview questions from industry experts and a modified perception of participatory ergonomics survey and analyzed data with a qualitative approach and evolved themes surrounding space and the environment, assistance

(including call buttons), and information. While patients may not have fully understood the risk factors for falls and falls with injury, they were able to offer opinions about the interventions used to prevent falls. While the study did not include any patients with significant cognitive deficits, the authors found that each patient felt the risk was not for them but others. Another study found similar results reporting that only 12% of fallers surveyed felt they were at risk for falling (Sonnad et al. 2014). The authors found the perceptions were driven by the presence of helpful nurses, being careful and able to walk, and the limited amount of time spent out of bed, limiting risk.

This study type is most applicable to the 'Participate' category of the participatory mesoergonomics theme that considers the multi-level conditions of patients and their work systems and can also shed light on the decision-making process used by patients when they are in what they consider to be a protected environment.

12.12.1.2.7 Integrate: Decision-Making – Work Demands

As referenced in Chapter 9, CWA was included in one study of the systematic literature review (Lopez et al. 2010). The text-based description presented in the paper was somewhat useful for designers, but because a unit floor plan was included in the study publication, additional information could be drawn from the findings. For example, the use of a centralized nurse station, albeit located in the middle of an "L" configuration, required charting to be distant from the patient. The remote location of support functions (e.g., supplies, medication) required nurses to move to distant locations within the unit. The combination of human factors methods with a visualization of the plan illustrates how a comprehensive systems approach can be used to study the complex problem of falls and can be used proactively to better understand the potential of a new design or renovation.

Other observational methods that may help understand work and work flow to support the prevention of falls includes task analysis, which has been used in the past to provide building design and layout information. For example, one study used link analysis to document movements of staff while accounting for the complexity of their tasks within a space. This could be used at a unit level as well (Lu and Hignett 2009). This study also included an annotated plan to allow a visual and spatial representation of the study findings, as compared to a node diagram that might be more typically seen in an engineering context.

However, task analysis and cognitive work analysis can be labor intensive. For example, Lu observed seven days of activity. In some cases, multiple video cameras are used and recordings are reviewed and coded following data collection. Wrist-mounted Bluetooth RFID detectors may allow ubiquitous use of technology in task analysis. In one study (Mansfield et al. 2010), RFID data uploaded automatically to software and provided a graphic representation of the space with locations and links between each RFID tag. The dataset offered combined data or individual subsets. These study types are most applicable to the 'Integrate' category of the participatory mesoergonomics theme that considers the whole system.

12.12.1.2.8 Integrate: Strength - Multiple Hazards

Patient lift devices are often studied as supportive equipment to minimize staff musculoskeletal injury associated with manual handling. From a falls perspective, lifts serve a dual purpose, as many patients need assistance in ambulating (often to the bathroom) and toileting. The weight of a patient inherently places risk for staff in this caregiving activity. However, a recent study investigated the use of patient lifts in an epileptic unit to reduce falls associated with seizure-related collapses in epilepsy patients (Spritzer et al. 2015). The authors found the lifts were the first intervention to have a significant impact on reducing falls out of many interventions that had already been tested previously on an incremental basis. This quasi-experimental pre- and post-study highlights the benefit of anticipating the patient condition and incorporating solutions that can address multiple safety conditions (staff injury of manual handling and patient falls). It also illustrates the advantage of incremental change that might be evaluated as part of a multifactorial bundle to start the process of assessing the efficacy of individual components. (This phased approach was also used in the Barker et al. study included in the falls literature review (2013) that evaluated incremental changes for use of low-low beds as part of the 6-PACK protocol). These types of studies might be conducted during a design process to inform a decision, especially if the team knows how to prepare for the outcomes of accepting or rejecting the null hypothesis.

This study type is exemplary of the 'Integrate' category of the participatory mesoergonomics theme that considers the whole system, including multiple hazards (staff manual handling and patient falls).

12.13 Appendix M: Final Grant Report

Final Progress Report

1. TITLE PAGE
Grant Number: 5R13HS021824-03

FAIN: R13HS021824

Principal Investigator: Anjali Joseph

Project Title: Developing and disseminating a Patient Safety Risk Assessment (PSRA) toolkit

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Contents

2. STRUCTURED ABSTRACT
Purpose: This three-year project aimed at developing and disseminating a Safety Risk Assessment (SRA) tool for proactively identifying and eliminating healthcare built environment latent conditions that impact patient and worker safety.

Scope: The SRA tool covers six safety areas – infection control, medication safety, falls, patient handling, behavioral health, and security – as required by the 2014 FGI *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*.

Methods: The tool content was developed through a Delphi process and Nominal Group Technique, including literature review, surveys, and a workgroup seminar with over 100 experts. An Excel format was developed and tested with expert workgroups and at three hospitals. The tool was optimized to include a supporting user guide based on testing and was disseminated through a one-day seminar (an education module including presentations, panel discussion, and workgroup sessions) at the Planning Design & Construction Summit, educational sessions, webinars, articles, and other venues.

Results: The SRA toolkit includes a Safe Design Roadmap, risk data, and design considerations for six safety areas, and research references. Design considerations are supported by rationale statements that include

research citations and various tags for sorting and filtering. A user guide provides background and recommendations for toolkit implementation. Feedback from attendees indicated success of all three seminars in tool development and dissemination.

Keywords: Safety, Risk assessment, Healthcare design, Healthcare-associated infections, Patient falls, Medication safety, Patient handling, Behavioral health/psychiatric injury, Security

3. PURPOSE

This project's aim over the course of three years was to develop and disseminate a proactive patient safety risk assessment (PSRA) toolkit, which was expanded to cover staff safety after feedback from industry experts. The SRA toolkit serves as a supplement to the FGI *Guidelines for Design and Construction of Hospitals and Outpatient Facilities* to significantly strengthen the focus on patient safety, as well as staff safety, in the design of healthcare environments. The four aims for the three-year project and the corresponding specific aims for each year are listed in the table below.

Overall aims for three-year period 2012-2015	**Aims for the first year 2012-2013**	**Aims for the second year 2013-2014**	**Aims for the third year 2014-2015**
• Develop an online SRA toolkit that can be used to conduct a proactive patient safety risk assessment during the healthcare facility design process	• Develop the structure and format for the SRA tool including consensus on key hazards and latent conditions to be considered and the degree of risk associated with different environmental design features	• Test and refine the SRA tool • Pilot test the SRA or relevant parts of it with three healthcare organizations	• Develop online SRA tool • Develop a framework for measuring SRA tool impacts on design and healthcare outcomes
• Develop white papers and guidelines to support the use of the SRA and to detail the process for implementing it across the facility life cycle		• Develop information to guide use of the SRA and integrate components into an SRA toolbox	• Develop supporting guides and white papers • Develop education and training modules for SRA
• Further develop a Safe Design Roadmap for healthcare CEOs and integrate with the SRA toolkit		• Further develop the Safe Design Roadmap to provide the overarching structure for conducting the SRA throughout the design process	
• Create an education platform to promulgate successful SRA activities			• Develop case study documentation from SRA pilot tests

One aim, creating an online tool, was modified over the course of the project. A decision was made to develop the SRA in Excel and PDF formats (accessible online) based on high cost estimates from similar online tool development projects. The functionality suggested by testers to render a functional tool incorporates complexity in programming and implementation and requires resources beyond the seminar grant award.

In the first year (2012-2013), appropriate content, structure, and format of the tool was developed through literature reviews, surveys, and focus groups; additional feedback was gathered from the expert attendees at the face-to-face seminar in Washington, DC on June 5-6, 2013.

In the second year (2013-2014), an Excel tool format was developed to effectively integrate various parts of the toolkit such as the Safe Design Roadmap and the SRA risk components. The SRA tool was pilot tested at three

healthcare organizations, as well as by workgroup experts at the face-to-face seminar at Kaiser Permanente's Garfield Innovation Center in San Leandro, CA. The feedback from these different sources was invaluable to the team in modifying the tool and developing a suggested process for using the tool during the healthcare facility design process.

In the third year (2014-2015), the SRA tool in Excel and PDF format was further improved based on pilot testing results and feedback. A user guide was developed in PowerPoint to serve as guidance, as well as a training module that can be accessed via an on-demand webinar. The finalized toolkit, supporting user guide, and lessons learned from testers were disseminated through national conference workshops and other venues.

4. SCOPE

Improving safety is one of the most urgent issues facing healthcare. As one key component of the healthcare system, the physical environment interacts with other factors (e.g., organizational culture, operation) in complex ways impacting the risk of adverse events. However, although the body of relevant research is growing, safety considerations often are not adequately addressed during the healthcare facility design process. The lack of easy-to-use methodologies and tools integrating safety considerations into the healthcare design process is a major barrier in applying relevant research in safe design practice.

An umbrella safety risk assessment (SRA) has been included as a requirement in the 2014 FGI *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*. However, the Guidelines are not prescriptive as to the method for implementing the SRA in practice. To make the safety considerations more acceptable, actionable, and easily incorporated in practice, efforts focused on developing a reliable and well-designed SRA tool with supporting implementation materials and training modules. The proactive SRA tool covers six key safety areas: infection control, medication safety, falls, patient handling, behavioral health, and security as defined by the FGI Guidelines. It will be a significant step forward in enhancing patient and staff safety through reducing adverse physical environment latent conditions that are built into facilities during the planning, design, and construction of healthcare facilities.

The three-year project has made significant progress and accomplished these goals:

1) Final Excel and PDF SRA tool after multiple rounds of testing and revision;
2) General consensus on the SRA content and format, achieved through multiple rounds of surveys, Delphi process, pilot testing, and national seminars;
3) Continuous engagement of more than 100 industry experts, as well as national organizations, who may help with the dissemination and implementation of the tool in practice;
4) Generation of interest among healthcare organizations in using the tool in actual design projects; and
5) Creation of an education module for implementation of the SRA process.

5. METHODS

Advisory council

An 11-member advisory committee was organized at the beginning of the project to provide advice and feedback through periodical conference calls (see Appendix for a list of committee members).

Content development

Consensus around safety risk assessment items included in the six topic areas of the proactive SRA tool was achieved through a series of steps in a Delphi process and modified Nominal Group Technique using literature analysis, surveys, and the Year 1 seminar.

Literature review

A narrative literature review was conducted as the first step of the Delphi process to explore all physical environment design elements relevant to six safety issues, in healthcare settings, especially in acute care settings (i.e., healthcare-associated infections, patient falls and immobility, medication errors, patient handling and movement, behavioral health, and security). Relevant sources were found through searching CHD's Knowledge Repository database as well as other databases such as PubMed and Google Scholar. Additionally, reference lists of articles as well as other data sources such as industry reports were reviewed. A detailed literature analysis table was created for each safety topic area, including environmental variables, safety outcomes, metrics, study design, samples, and research findings. Latent conditions were identified based on each research article. A mind-map was then created for each topic area to better understand the conceptual relationships between the variables and outcomes and to help develop built environment latent condition questions. Next, the FGI Guidelines was

cross-referenced with the latent condition questions to determine what was required and what was suggested in appendix language of the Guidelines. Additions and revisions were made to the list of latent condition questions based on industry standards (e.g., guidelines, standards, reports) as well as expert opinion. The result of the literature review was a draft list of safety-related latent condition questions and associated rationale organized in six topic areas with the sources and Guidelines relationship marked as research, consensus, opinion and FGI Guidelines - body or appendix.

Surveys

At the same time, six groups of industry experts were recruited and led by designated workgroup leaders. Each workgroup included 10-20 individuals who were knowledgeable in a particular topic area (e.g., medication safety) but with diverse backgrounds (e.g., representatives from design, nursing, facility management, human factors, etc.). A Delphi process was established for gathering data. As described in Hsu and Sanford's 2007 paper, *The Delphi technique: Making sense of consensus*, the technique is widely used and accepted and aims to reach a consensus of expert opinion on specific real-world issues through multiple iterations of questionnaires. The workgroup members were informed about the purpose of the project and the Delphi process. The first iteration included initial content development from the literature reviews. This was followed by two online surveys for each workgroup to achieve consensus on the latent condition questions to be included in the SRA tool for a specific topic area. Both surveys were conducted through the online tool, Survey Monkey. The initial invitation and follow-up reminders were sent through email.

In survey #1, workgroup members were asked to:

- evaluate each latent condition (LC) question
- indicate whether it should be included as an item in the SRA tool
- decide whether the wording of the question was acceptable
- provide suggestions regarding the wording of the question.

Reminder emails were sent to ensure members responded to the survey. Based on survey results, the LC questions with at least 70% consensus on both inclusion and wording (i.e., "yes" answers) were considered approved and not to be included in subsequent survey and seminar discussion. The LC questions with less than 70% consensus on inclusion and/or wording were revised and included in the second survey. Several questions were removed from further consideration because more than 70% respondents indicated that the questions should not be included.

In survey #2, respondents were asked to evaluate each revised question and vote on its inclusion in the SRA tool and its wording. The results of survey #2 were analyzed in the same way as survey #1. The LC questions with less than 70% consensus on inclusion and/or wording were revised and included in the seminar discussion. The numbers of approved questions after the two surveys are listed in the Results section of this report.

Year 1 seminar: Consensus

To further build consensus around SRA items and other aspects of the SRA tool, a "Designing for Safety Seminar" was held in Washington, DC on June 5-6, 2013. A total of nearly 70 industry experts and other professionals participated in the seminar, which included presentations by safety experts, a panel discussion, and workgroup discussions.

During workgroup discussions, participants in each group reviewed the remaining LC questions (those without consensus on inclusion and/or wording after two surveys) and, one by one, made comments and revisions using a round robin process, and cast votes for inclusion and/or wording. The comments, suggestions and revised questions as well as voting results were recorded on flip charts and 22"x34" spreadsheets. The results were also revisited at the end of the second day to make final adjustments.

In another brainstorming session, participants were re-organized into six groups (each with representatives from different workgroups) to discuss how the SRA tool might be used in the healthcare design process (e.g., process of adoption, implementation, and impact on workflow [see figures below for results from this discussion]). As a result of the seminar discussion, consensus was reached on almost all of the LC questions, even though a small number of questions still needed further revision and evaluation.

A post-seminar online survey was conducted to evaluate the perceived effectiveness of the seminar.

Refine the tool content
The research team finalized the SRA content developed in 2013-2014 through additional workgroup calls, survey results, and cross-examination of design considerations in the six individual safety topic areas.

- Cross-examination of latent conditions (i.e., design considerations). Since the six workgroups worked separately on the design considerations during the Delphi process in Year 1, there was potential for duplicates or conflicts between design considerations in different topic areas. To address this issue, a master spreadsheet was created of all design considerations in the six areas. The design considerations were listed on both the top row and the left column. Using this matrix each design consideration was evaluated in relationship to all other design considerations in the SRA. The design considerations were evaluated for inter-relationships, duplication, or conflicts. A few duplicates and conflicts were identified and addressed.
- Completion of HAI-related latent conditions (i.e., design considerations). As the result of the 2013 seminar, all design considerations were approved, except for 13 HAI-related questions. (The Year 1 progress report provides additional detail.) After the seminar, the research team worked with HAI workgroup leaders to find a solution for these considerations. The workgroup leaders proposed to 1) combine eight heating, ventilation, and air conditioning (HVAC) design considerations into one question, 2) revise the wording of two design considerations, and 3) delete three design considerations. Following the Delphi process, the proposed revisions were included in a third survey for workgroup approval. The workgroup reached consensus (70% threshold) in the survey. The HAI considerations were then finalized.

Tool format development
Initially, the tool was envisioned as an online tool that could be accessed and used via an internet browser. Later, it was determined that an alternative platform would be used to avoid the high cost of web design associated with the full level of functionality desired, as well as data security issues expressed by several healthcare provider organizations. Various formats were tested (Word, fillable (interactive) PDF, and an Excel spreadsheet) and after conducting a survey with workgroup members and informally polling individuals who attended a presentation at the PDC Summit in 2014, the research team decided to use the Excel spreadsheet format. The Excel format allows for additional sorting functions and more user-friendly hyperlinking to move through different parts of the tool.

On-site pilot test for the SRA tool
Three pilot tests were planned to evaluate the tool interface and content in real-world settings. The original plan was to include individual projects in the earliest design phases from 1) a large national system, 2) a regional system, and 3) a community-based facility. However, following attempts to recruit project sites, a convenience sample was chosen, primarily based on personal relationships between potential project contacts and the research team members. While they represent regional diversity – the Midwest, West Coast, and East Coast, they all represent more advanced/academic systems, which may reflect the ability of a larger organization to absorb a “lesser-known” process into the project.

The projects represented three different design phases: master planning following a “test fit” exercise (pilot 2), schematic design (pilot 3), and design development (pilot 1). Interestingly, each project had a program related to oncology – an area of high-risk and vulnerability due to the medical condition and treatment of patients. Two of the three projects (pilots 2 and 3) represented renovations, reflecting constraints posed by the existing infrastructure.

The first two pilot tests allowed the project team to “drive” the Excel-based tool. While this was straightforward in pilot site 1 where most design decisions had already been made, it was less effective in site 2, where very few decisions had been established and the team was not fully conversant in the considerations included in the tool. Pilot 3 incorporated a facilitated discussion by a CHD team researcher to guide the team as an alternative approach.

Year 2 seminar: Usability
Development of the content and process of the seminar
The second Designing for Safety Seminar was held on May13-14, 2014 at Kaiser Permanente’s (KP’s) Garfield Innovation Center in San Leandro, CA. The Garfield Center is a 37,000-square-foot “living laboratory” warehouse with simulated spaces for testing that include an entire medical-surgical unit complex, various patient rooms, an operating room, emergency bay, family waiting room, interventional radiology suite, and more. Here, the entire care process can be analyzed, questioned, tested, and refined under one roof. The Garfield Center was the

location for the Year 2 Designing for Safety Seminar, given the focus on testing and validating the SRA tool in the context of a facility design project.

The main purpose of the seminar was to further test use of the tool under a variety of simulated design conditions (i.e., A - typical office meeting room discussion, B – simulated high-fidelity mock-up, and C – low-fidelity mock-up) and construction project scenarios (i.e., A – retrofit of an existing inpatient unit, B – LDR unit expansion / oncology unit renovation, C – ED renovation). A second goal of the seminar was to brainstorm strategies for disseminating the SRA.

Several KP staff actively participated in the seminar planning process, which lasted from September 2013 to May 2014. On-site and virtual visits to the Garfield Center and multiple conference calls were conducted for coordination on the agenda and logistics of the seminar. The existing high-fidelity mock-up patient rooms and labor and delivery and recovery rooms (LDR) at Garfield were used to serve as the setting for the high-fidelity mock-up scenarios. Two low-fidelity ED rooms were constructed using wood panels with support structures, equipment temporarily borrowed from other spaces, and cardboard boxes with pictures of typical ED furniture, fixtures and equipment.

Seminar agenda & approach

Participants from the Year 1 seminar and additional experts were invited to attend the Year 2 seminar via email. Six workgroups were created. Each workgroup consisted of seven to eight individuals from multiple subject matter areas. For example, individuals with expertise in patient handling were paired with individuals with expertise in falls. Each workgroup was assigned to one of three pairs of SRA topic area sections (e.g., Falls/Patient Handling, Behavior health/Security, HAI/Medication safety). Thus, there were two workgroups working on a pair of SRA topic areas. The meeting attendees were invited to attend a 30-minute call prior to the on-site seminar to orient them to the intent and structure of the meeting. The simulated scenarios that the groups would work through were also provided to attendees prior to the meeting.

The seminar began with informative presentations by industry experts in the Garfield Center's central meeting space, followed by simulation workshop sessions in various locations (e.g., meeting spaces, mock-ups) in the Garfield Center. Six workgroups rotated through five 90-minute workshop sessions: three use scenarios (A, B, C, as described earlier), one brainstorming session about education and dissemination tactics/ideas (D), and one session for cumulative debriefing back in the central meeting space. Because of the limited mock-up spaces, the sequences of scenarios/brainstorming session varied across different groups. Each group focused on the same two SRA components across the three scenarios to help evaluate usage of same tool at different design conditions and project scenarios.

Group	SRA components	Session 1	Session 2	Session 3	Session 4	Session 5
1	Falls/ Pt Handling	A	B	D	C	Debrief
2	Falls/ Pt Handling	A	B	D	C	Debrief
3	Psych/ Security	A	C	B	D	Debrief
4	Psych/ Security	A	C	B	D	Debrief
5	HAI/ Med Safety	A	D	C	B	Debrief
6	HAI/ Med Safety	A	D	C	B	Debrief

Note; A. Board room—Unit renovation; B. High-fidelity—Oncology unit/LDR; C. Low-fidelity—ED renovation (two identical spaces); D. Brainstorm education and marketing tactics/ideas

The workgroup sessions were facilitated by a professional moderator and seven KP staff members trained in meeting moderation. A CHD staff member was assigned to each of the different scenarios as observer and note taker. In each use scenario session, participants spent the first five minutes reviewing the project scenario, a five- to seven-page description, including context, task, and general information of the construction project, location, demographics, floor plans, and safety risk data. They then went through the considerations and rationale for two assigned SRA components (each for 35 minutes) and decided whether to incorporate the considerations (i.e., yes, no, maybe, or not applicable [NA]) in the assigned scenario project. Following the exercise, a round robin process was used in which every group member was encouraged to provide opinions and feedback about the process. One group member in each group was elected to "own" the work product for each session and record the decisions and discussion notes on pre-printed sheets. After the completion of two SRA components, the group was asked to complete an online survey on their mobile devices about the tool usability. Paper surveys were provided as an option but were not chosen by participants. The session was then summarized with a 10-

minute group debrief during which participants provided feedback about the format and content of the SRA tool. CHD members documented the discussion points throughout the session.

The brainstorming session was conducted using a modified nominal group technique. Participants first were asked to respond to specific questions by writing down ideas on Post-it notes without discussion. They then presented ideas and grouped them into logical categories or themes on flip charts, discussed the ideas, and finally distilled their ideas to form several key conclusions/recommendations.

The 30-minute cumulative debrief was held after a "gallery walk" of the flip chart sheets showing results of previous sessions. Representatives from workgroups shared the common views of group members regarding the best practices for using the tool and the ways of informing people about the existence and proper use of the SRA tool.

Safe Design Roadmap
The Safe Design Roadmap was envisioned as a tool that would enable CEOs and leadership team to implement key strategies to ensure that their facility design project was strongly focused on patient safety. The tool would help to ensure that an organization's safety and quality improvement efforts were integrated with the facility design process. The first version of the tool was shared with experts at the Designing for Safety seminar conducted at Virtua Health in 2011 with funding from AHRQ (Grant 1R13HS020322-01A1). While the tool was well received at the time, attendees felt it was too detailed for C-suite decision makers, and had inadequate detail for architects and other design team members. Further, attendees indicated that they would like the tool to be more actionable.

Using this feedback, an effort was made to further develop the Safe Design Roadmap as a high-level tool to support the more detailed considerations of the six risk areas. Interviews were conducted with C-suite decision makers at three different healthcare organizations to obtain their feedback on the tools relevance and usability. The individuals interviewed were:

- Barry Rabner, President and Chief Executive Officer at Princeton Healthcare System
- Tejas Gandhi, Chief Administrative Officer at The Medical Center of Central Georgia (now Navicent Health) and
- Gerald Bracht, Chief Administrative Officer at Palomar Medical Center

Some key themes from the conversation included:

- Important to make the message more clear upfront – how a brick and mortar strategy could impact patient, staff, and organizational outcomes
- Provide examples of how healthcare organizations have used the tool
- Provide examples of return on investment
- Make the tool actionable. Reference was made to the American Hospital Association's *Second Curve Road Map for Health Care* tool as a possible model.
- Make the language simpler and remove unfamiliar jargon (e.g., latent conditions)

As a result, the tool was simplified and restructured. The new Safe Design Roadmap was modeled on the AHA's *Second Curve Road Map for Health Care* such that it could potentially be included as a module in the AHA tool in the future. The tool is designed as a self-evaluation tool that a decision maker could use to evaluate how ready they were to undertake a facility design project focused on safety. The Safe Design Roadmap self-assessment tool is organized around four broad phases of the facility life cycle. The user is asked to indicate their level of agreement (0 = no agreement to 4 = complete agreement) with the statements under each phase. The four phases of the facility life cycle and number of statements under each phase are:

- Strategic & Operational Planning (15 statements). This phase reflects the organization's high-priority strategies, supported by a concept of operation achieved through the creation of operational planning and performance improvement projects to realize patient and staff safety goals.
- Programming & Design (9 statements). During the program and design phase, the concept of operations is translated into the amount of space required and then the design of the facility itself. Designs are submitted in an iterative fashion, beginning with more general designs, such as block adjacency drawings (e.g., radiology is located next to the emergency department), to the specific, such as hardware specifications and furnishing material selection.

- Construction & Commissioning (8 statements). Construction, which sometimes begins before the design is finished, includes the clearing of the site and all activities involved in actually building the facility, including the placement of some built-in equipment and furniture. During the commissioning phase, the building is outfitted with all additional equipment, furniture, medical and administrative supplies, and other essential healthcare materials.
- Sustainment (7 statements). This phase begins with occupancy of the building and includes all the routine maintenance and repair activities necessary to keep the building in good working order over the life of the building.

The Safe Design Roadmap is integrated into the SRA toolbox and users have the option of using the roadmap prior to using the SRA components or proceeding directly to the specific SRA components.

Content and format finalization
The research team made the following revisions to the design considerations and rationale in the six individual safety topic areas based on feedback and lessons learned from pilot testing at three design projects and the workgroup testing at the Year 2 seminar (i.e., the Garfield Center).

- Reduce duplication and clarify similarities among design considerations. During pilot testing, it was found that a small amount of duplication existed among design considerations both within one safety area and across different areas. Similar design considerations were combined. As a result, the total number of design considerations was reduced from 210 to 191 (see table below). We believe that this may improve the usability of the toolkit.
- Provide a hyperlink among design considerations in different safety areas that are relevant to each other (e.g., two design considerations in “falls” and “patient handling” sections but both addressing patient handling equipment). This was intended to explicitly indicate connections among design considerations included in different safety areas.
- Provide research citations and clarify linkage between rationale and design considerations. The rationale statement for each design consideration was revised to indicate the level of research support for the design considerations with citations (so that users might optionally further examine the relevant literature to make informed decisions) and to clarify the thought process behind the design considerations.
- Indicate multiple building categories for one design consideration. If one design consideration was related to multiple building categories (e.g., relevant to unit layout and room layout), it is tagged with one building category (e.g., unit layout) with a note that it was also relevant to the other categories (e.g., room layout).

In addition, multiple revisions were made to streamline the tool format.

- One copyright page and one page were added acknowledging the contribution of all team members and volunteers.
- Based on feedback from pilot testing, the columns in the checklist were rearranged to facilitate decision making. For example, the rationale column was removed and the rationale was included as comments automatically shown when users moved their mouse on the design consideration cells in the Excel tool.
- Users were asked to record their evaluation about each design consideration (i.e., estimated risk, priority, and cost magnitude). Decision on whether to implement a particular design consideration (e.g., yes, maybe, no), which was included in the earlier versions, was removed in the final version.
- The “underlying conditions” included in the previous versions of the tool were replaced by “building categories” that were universal to all six safety areas. This was because the “underlying conditions” were not universally termed and defined in different topic areas and this inconsistency might cause confusion.
- A list of research references in supporting design considerations.

In addition to the Excel SRA tool, a hyperlinked PDF version (including same content but limited sorting and other functions) was also created for easy access by some users. Both formats are through the CHD website (www.healthdesign.org) with the PDF version also accessible through the FGI website (www.fgiguidelines.org).

Develop a user guide
A user guide was developed by the CHD team based on recommendations from pilot sites and industry experts around the use of the SRA tool. PowerPoint was chosen as the format to keep the guide as concise and easy-to-follow as possible. Visual materials were included to meet the preferences of the main users of the tool.

Organize a national seminar for tool dissemination and education

A one-day Designing for Safety Seminar was held on March 15, 2015 at Henry B. Gonzales Convention Center in San Antonio, TX in conjunction with the Healthcare Facility Planning, Design, and Construction Summit (PDC Summit) as one of the pre-conference workshops. The purpose of the seminar was to educate facility design stakeholders on the purpose, uses, and benefits of the SRA and provide training to facilitate adoption and implementation.

Development of the content and process of the seminar
The PDC Summit was selected for tool dissemination because the annual conference has been a major healthcare design and construction event attracting around 3,000 healthcare facilities administrators, designers, and building contractors. The project team worked closely with the conference organizer to set up the logistics of the seminar, created content (e.g., presentations, plans, and other materials for the hypothetical building project), and invited workshop participants and pilot testers to serve on the faculty for the seminar.

A total of 31 individuals with no previous exposure to the SRA tool registered and attended for a fee regularly charged by the conference for pre-conference workshops. In addition, 23 participants, who included project team members and industry experts returning from the Year 1 and 2 seminars and pilot test sites, were allowed to attend at no charge. This was the first time that the Year 1 and 2 participants were able to see the toolkit as a whole. The 54 session attendees included 15 building contractors (30%), 16 healthcare administrators (32%), 14 designers (28%), and five government representatives (10%), from federal and state health departments.
A pre-seminar survey was sent to all registered attendees in order for the team to better understand the specific expectations, interests, and goals of attendees. Twenty-two (71%) attendees responded to the survey. The survey results were used to make adjustments including seating arrangements to ensure each group (table) represented multi-disciplinary stakeholders with various interests and goals. A 17-page SRA scenario description was developed for seminar attendees to practice using the SRA tool. The scenario description included general project background, budget, existing floor plans, demographics, outcome measures, and space requirements. These were printed for use during seminar group discussion. Attendees were also invited to bring their own building projects to the seminar.

Seminar agenda & approach
Both lecture-style presentations and hands-on interactive approaches were used in the Year 3 seminar. The seminar began with an overview of the SRA tool development including the background, process, structure, and usability of the tool. This was followed by a panel discussion where representatives from the three pilot testing sites shared their experience and insights around using the tool. The attendees were then divided into five groups to work with faculty members as teams to go through the process of using the SRA tool on a hypothetical construction project. The participants were instructed to first read the scenario description and floor plans, identify two to three SRA components to evaluate for the hypothetical project, and then use the printed copies of the SRA tool as well as the Excel format to address safety considerations during design and construction decision-making processes. The seminar concluded with a debrief with attendees sharing their opinions and the project team describing next steps in tool dissemination. After the seminar, an online satisfaction survey was sent to all participants including attendees and faculty members.

An online survey was conducted immediately after the seminar to gauge the effectiveness of the workshop in meeting expectations and to obtain feedback from participants. The survey included 12 questions that covered different aspects of the workshop. Respondents were asked to give either a “yes/no” answer or a rating on a Likert scale from 1 (very poor) to 5 (very good). Respondents were also instructed to provide feedback in an open comment box. Results are available in the Year 3 report.

6. RESULTS

Delphi process result (including Year 1 seminar)
As a result of the Delphi process, consensus was reached on most of the Latent Conditions questions (see the table below). A small number of questions still required further revision and evaluation.

Topic area	First draft	Survey # 1 result	Survey #2 result	Seminar result
HAI	49 questions	• 13 respondents • 11 questions with 70% agreement on inclusion and wording • 20 questions with agreement on inclusion but not on wording → Survey #2	• 12 respondents • 9 more questions with 70% agreement on inclusion and wording	• 8 participants • 12 more questions with consensus on inclusion and wording

		• 16 with 30-70% agreement on inclusion → Survey #2 • 2 questions deleted • 1 question combined with another	• 12 questions with agreement on inclusion but not on wording → Seminar • 13 with 30-70% agreement on inclusion → Seminar • 1 question deleted	• 13 questions to be further revised, some will be combined • Total 32 questions with 12 more to be revised
Patient handling & movement	22 questions	• 13 respondents • 9 questions with 70% agreement on inclusion and wording • 12 questions with agreement on inclusion but not on wording → Survey #2 • 1 with 30-70% agreement on inclusion → Survey #2 • 1 added based on comments	• 14 respondents • 8 more questions with 70% agreement on inclusion and wording • 5 questions with agreement on inclusion but not on wording → Seminar • 1 question deleted	• 8 participants • 4 more questions with consensus on inclusion and wording • 1 deleted • Total 21 questions
Medication safety	31 questions	• 15 respondents • 12 questions with 70% agreement on inclusion and wording • 13 questions with agreement on inclusion but not on wording → Survey #2 • 6 with 30-70% agreement on inclusion → Survey #2 • 1 added based on comments	• 13 respondents • 11 more questions with 70% agreement on inclusion and wording • 4 questions with agreement on inclusion but not on wording → Seminar • 4 with 30-70% agreement on inclusion → Seminar • 1 question added	• 8 participants • 7 more questions with 70% agreement on inclusion and wording • 3 deleted • Total 30 questions
Security	50 questions	• 9 respondents • 44 questions with 70% agreement on inclusion and wording • 5 questions with agreement on inclusion but not on wording → Survey #2 • 1 with 30-70% agreement on inclusion → Survey #2 • 1 added based on comments	• 10 respondents • 3 more questions with 70% agreement on inclusion and wording • 2 questions with agreement on inclusion but not on wording → Seminar • 1 with 30-70% agreement on inclusion → Seminar	• 6 participants • 2 questions to be further revised • 1 deleted • Total 47 questions with 2 more to be revised
Falls & immobility	36 questions	• 12 respondents • 20 questions with 70% agreement on inclusion and wording • 10 questions with agreement on inclusion but not on wording → Survey #2 • 6 with 30-70% agreement on inclusion → Survey #2	• 15 respondents • 4 more questions with 70% agreement on inclusion and wording • 6 questions with agreement on inclusion but not on wording → Seminar • 3 with 30-70% agreement on inclusion →Seminar	• 8 participants • 8 more questions with 70% agreement on inclusion and wording • 1 deleted • Total 32 questions
Behavioral health	59 questions	• 9 respondents • 21 questions with 70% agreement on inclusion and wording • 24 questions with agreement on inclusion but not on wording → Survey #2 • 10 with 30-70% agreement on inclusion → Survey #2 • 3 questions deleted	• 11 respondents • 19 more questions with 70% agreement on inclusion and wording • 7 questions with agreement on inclusion but not on wording → Seminar • 9 with 30-70% agreement on inclusion →Seminar • 1 deleted	• 5 participants • 14 more questions with 70% agreement on inclusion and wording • 2 deleted • Total 54 questions

Pilot testing results

SRA Pilot Site Case Study #1 – Barnes Jewish Healthcare (March 2014)

Project/Site: Washington University Medical Center Campus Renewal Project
New oncology inpatient unit – relocation from existing tower

Design Phase: Design development

Participating Architect: HOK (San Francisco office)

Participant Roles: Architecture, Human Factors, Nursing, Ergonomics, Pharmacy (medication safety only), Capital Planning, Infection Control (left early); the organization had limited capacity to invite all experts and for all participants to attend the full session.

Familiarity with Project: Two participants involved in content development (falls)

10

	(25 minutes); observation of use (170 minutes); survey and feedback session (45 minutes); a working lunch was planned
Modules Attempted:	1. Infection Control 2. Medication Safety
Time Use:	The group did not select a target time for completion of a module and the goal was to see how far they could get, given the early design phase. Additional time was needed during discussions to incorporate larger-scale design and strategic issues. Although the first module (infection control) had not been completed after 70 minutes, the group self-selected to move to a second module (medication safety) for the balance of the time – 100 minutes. The discussion for both topics was much more organic than merely following a list, and the group did not always use the tool sequentially.
Lessons Learned:	1. It was difficult to get the text large enough on the screen; the only two visible columns were the consideration and notes (i.e., no item number, rationale). This was still too small for some. 2. Even though re-ordered following the first pilot and seminar, the considerations were not reviewed sequentially due to the nature of an early design phase discussion with many larger-scale issues to consider. As a more organic design discussion, notes were often taken in any available cell, and time was needed to determine if there was a related consideration they should be taking into account. 3. Although priority and cost magnitude columns were added to facilitate the decision-making, these columns were not used; the risk estimate was not referenced. 4. The rationale was rarely used by the group, but when referenced (requiring the column to be unhidden), it did not clarify the question. (The scribe regularly checked the rationale.) 5. There were a number of important discussions pertaining to strategic decisions that arose from the SRA. These included the appropriateness of the unit type, the number and location of isolation rooms as balanced with workflow and policy issues, the desire for single or multiple medication rooms, and the visibility of medication preparation. 6. With a sociologist present, there were several discussions about the need to conduct workflow observations and work with front-line staff. There were numerous references to behavior-based considerations. 7. The group felt they could have spent more time in a single sitting without losing focus. They felt there was benefit to the diversity of the participants being present for the full session. 8. There was a perceived return on investment for the time committed (expense) to the process by nearly a dozen people. 9. The group agreed they would have been more effective had the session been facilitated to organize broad categories of consideration, perhaps with an introduction of the five top areas of concern. *Post-Pilot: Pilot site 3 should follow a facilitation model.* 10. The group wished they had been able to spend time with the tool before use, but even without prior review they felt it was a good way to establish a focus and ensure nothing was overlooked. It also served to confirm any assumptions that were being made but may not have been overtly stated.

Pilot site #3 is scheduled for August 12, 2014 and will be conducted as a facilitated workshop. Preliminary details are included below.

SRA Pilot Site Case Study #3 – Memorial Sloan Kettering (August 2014)

Project/Site:	MSK Oncology Unit Renovation (New York, NY) Inpatient Unit Renovation – demographic includes neuro and ortho oncology patients; structure and HVAC shafts to remain

Format and Timing:	User-led from Excel tool on screen, design drawings available on table (3 hours): onsite orientation (30 minutes); observation of use (105 minutes); survey and feedback session (45 minutes); no official break
Modules Attempted:	1. Infection Control 2. Falls 3. Patient Handling 4. Medication Safety 5. Security (partial)
Time Use:	The group self-selected a target of approximately 25 minutes per module and completed 4-1/3 sections; each consideration was read aloud by the scribe with notes entered in the Excel file during the subsequent discussion.
Lessons Learned:	1. The group quickly learned how to navigate in the Excel file. 2. It was difficult to get the text large enough on the screen; the group felt they needed the consideration and notes on the screen together and hid the rationale column (which was adjacent to the consideration). *Post-Pilot – this was moved to allow the consideration and notes to be adjacent to one another.* 3. The group proceeded through the items sequentially without any orientation to specific topics within the section; they appreciated being able to see what was being typed in the notes (e.g., to catch "that's not what I meant"). 4. The Excel row numbers and item numbers were confusing, as they did not match and there needed to be clarification about the topic of discussion. *Post-Pilot – the Excel headings were hidden.* 5. The risk estimate was unclear and the group alternated between risk and priority – more often evaluating priority for the team. *Post-Pilot and post-seminar – priority and cost magnitude columns were added (high, medium, low).* 6. Rationale was rarely used, but when referenced (requiring the column to be unhidden), it did not clarify the question. 7. During design development, this became more of a checklist validating decisions, although there were still a number of interesting discussions retrospectively considering their choices. 8. The group discussed how the tool would have been an asset during master planning and could have been used during their lean process flow work with user groups. 9. It was difficult for the group to maintain focus at the same level for the entire session; a suggestion included doing one section at a time with the relevant expertise and two people (planning and architect) providing the continuity across sections and bringing any potential conflicts back to the group. 10. Several considerations were noted as duplicates; however, many times the group was not reading the detail in the question to clarify the difference between one statement and another. The duplications were not always considered sequentially in the order presented (sorted by underlying condition). *Post-Pilot/Post-Seminar – these were reorganized to be aligned with a general area of design (e.g., layout, HVAC) with similar considerations closer to one another. The most obvious duplicates (as determined during the seminar) were hidden.*

SRA Pilot Site Case Study #2 – UC (University of California) Health (June 2014)

Project/Site:	UC Irvine Medical Center (Orange, CA) Inpatient Unit Renovation – change from neuro-psych to oncology; structure and HVAC shafts to remain, all other interiors to be removed
Design Phase:	Master Planning (test fit only to date)
Participating Architect:	Taylor Architects
Participant Poles:	Architecture, Interior Design, Sociology, Capital Planning, Infection Control, Health & Safety, Pharmacy, Nursing (Unit Manager), Regulatory Compliance
Familiarity with Project:	One participant involved in content development (infection control)
Format and Timing:	SRA orientation conducted prior to onsite session; 4 hours onsite: User-led from Excel tool on screen, design drawings available on table: tool and project orientation

	(25 minutes); observation of use (170 minutes); survey and feedback session (45 minutes); a working lunch was planned
Modules Attempted:	1. Infection Control 2. Medication Safety
Time Use:	The group did not select a target time for completion of a module and the goal was to see how far they could get, given the early design phase. Additional time was needed during discussions to incorporate larger-scale design and strategic issues. Although the first module (infection control) had not been completed after 70 minutes, the group self-selected to move to a second module (medication safety) for the balance of the time – 100 minutes. The discussion for both topics was much more organic than merely following a list, and the group did not always use the tool sequentially.
Lessons Learned:	1. It was difficult to get the text large enough on the screen; the only two visible columns were the consideration and notes (i.e., no item number, rationale). This was still too small for some. 2. Even though re-ordered following the first pilot and seminar, the considerations were not reviewed sequentially due to the nature of an early design phase discussion with many larger-scale issues to consider. As a more organic design discussion, notes were often taken in any available cell, and time was needed to determine if there was a related consideration they should be taking into account. 3. Although priority and cost magnitude columns were added to facilitate the decision-making, these columns were not used; the risk estimate was not referenced. 4. The rationale was rarely used by the group, but when referenced (requiring the column to be unhidden), it did not clarify the question. (The scribe regularly checked the rationale.) 5. There were a number of important discussions pertaining to strategic decisions that arose from the SRA. These included the appropriateness of the unit type, the number and location of isolation rooms as balanced with workflow and policy issues, the desire for single or multiple medication rooms, and the visibility of medication preparation. 6. With a sociologist present, there were several discussions about the need to conduct workflow observations and work with front-line staff. There were numerous references to behavior-based considerations. 7. The group felt they could have spent more time in a single sitting without losing focus. They felt there was benefit to the diversity of the participants being present for the full session. 8. There was a perceived return on investment for the time committed (expense) to the process by nearly a dozen people. 9. The group agreed they would have been more effective had the session been facilitated to organize broad categories of consideration, perhaps with an introduction of the five top areas of concern. *Post-Pilot: Pilot site 3 should follow a facilitation model.* 10. The group wished they had been able to spend time with the tool before use, but even without prior review they felt it was a good way to establish a focus and ensure nothing was overlooked. It also served to confirm any assumptions that were being made but may not have been overtly stated.

Pilot site #3 is scheduled for August 12, 2014 and will be conducted as a facilitated workshop. Preliminary details are included below.

SRA Pilot Site Case Study #3 – Memorial Sloan Kettering (August 2014)

Project/Site:	MSK Oncology Unit Renovation (New York, NY) Inpatient Unit Renovation – demographic includes neuro and ortho oncology patients; structure and HVAC shafts to remain

Design Phase:	Schematic Design
Participating Architect:	HOK Architects (New York office)
Participant Roles:	16 participants (1 partial) (Nurse Leader, Nursing, Architecture/Medical Planning, Interior Design, Capital Planning, Infection Control, Health & Safety, Pharmacy, Hospital Administrator, MD, Quality & Safety, Construction/Fire Safety, Dir. Design - MSK)
Familiarity with Project:	One participant involved in Year 2 testing at Garfield, but not modules selected for pilot site (medical planner)
Format and Timing:	SRA orientation conducted prior to onsite session to part of audience; 3.75 hours onsite including abbreviated SRA orientation and project orientation: Facilitated discussion from Excel tool on screen, design drawings available on table; tool and project orientation (30 minutes); facilitated use (150 minutes); survey and feedback session (45 minutes)
Modules Attempted:	1. Falls 2. Medication Safety 3. Infection Control
Time Use:	The session was held as a facilitated discussion. The group was informed that the session would cross modules while keeping large-scale issue in common, for example, unit layout or room design. It was explained that they might not complete everything in the modules. The goal was to evaluate the efficiency of a more directed conversation while still allowing an organic design discussion and determine whether a facilitated workshop is an acceptable format. There were significant limitations associated with the existing project infrastructure and budget.
Lessons Learned:	1. As with the previous team, the group wished they had been able to spend time with the tool prior to use, but even without prior review, they felt it was a good way to establish a systematic approach, ensure nothing was overlooked, and promote a method to leave personal agendas aside. 2. In order to get the text large enough on the screen, the only two visible columns were the consideration and notes (i.e., no item number, rationale). However, the facilitator could also explain rationale during discussion and move to other sections of the tool, due to familiarity with the content. 3. Participants felt crossing risk categories (falls, medication safety, etc.) in a hierarchy of decision-making (e.g., unit layout) was an effective way to keep everyone engaged and participating in the discussion. 4. Although priority and cost magnitude columns were added to facilitate the decision making, only the priority column was addressed. The patient population had been previously identified as high risk due to co-morbidities, and the cost magnitude seemed to create too many barriers to flow. 5. The priority became confusing, as participants were often basing the priority as “high” on what they could do (or what policies were already in place). This prompted a discussion on “jobbing” the tool and not harnessing the full value. 6. There were a number of topics that had not yet been addressed due to the level of detail. Many of these fell into categories of institutional standards (e.g., FFE), suggesting that organizations may want to pre-populate certain considerations or have a higher level discussion about whether any standards need to be updated in the context of safety.

13

7. Some in the group felt they could have spent more time in a single sitting without losing focus. However, based on observations of the room, the facilitator ended the discussion several minutes early due to multiple conversations, some participants needing to leave, and a general sense of mental fatigue.

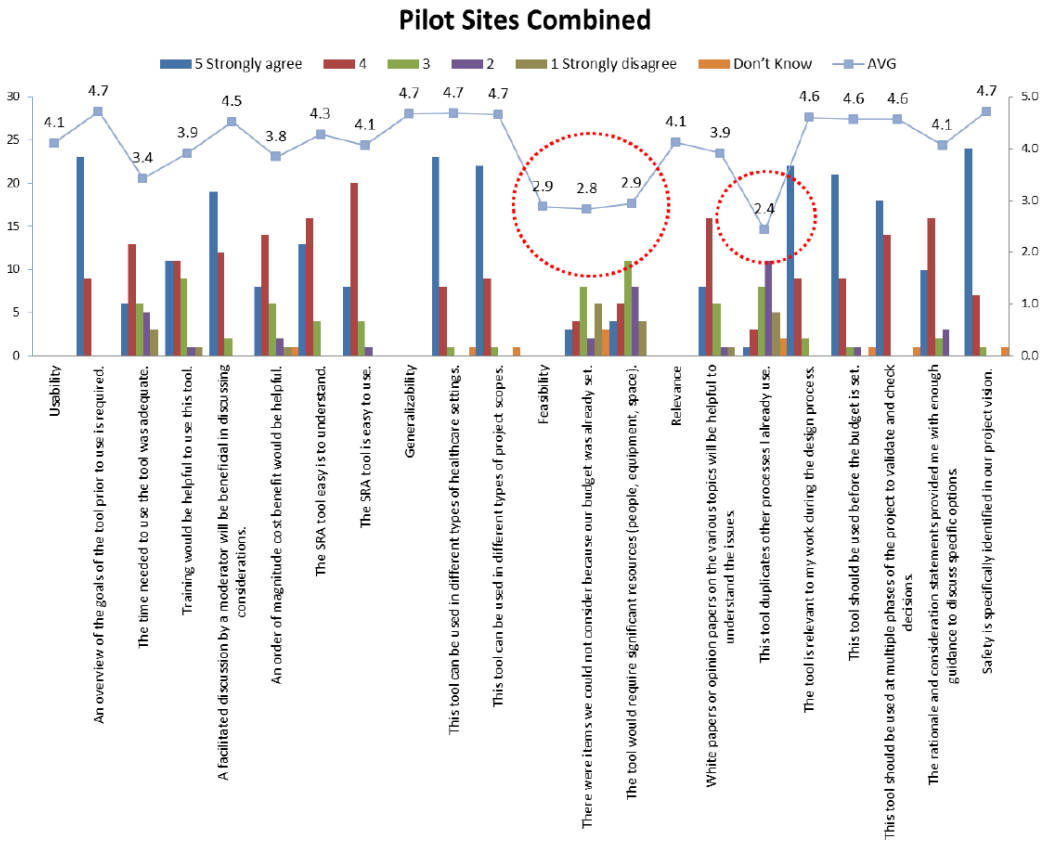
8. Participants felt a benefit to the diversity of views for the full session and remarked on the importance of having a dedicated time to focus on safety, rather than rolling the discussion into other design-related meetings. Planners in particular commented on the usefulness of hearing multiple points of view simultaneously and having a discussion around the issue, rather than meeting with individual groups and taking what was last said or trying to speculate on reasoning.

9. Nearly a dozen people expressed a perceived return on investment for the time committed (expense) to the process.

10. The group had positive feedback about a facilitated discussion and felt that someone from the organization should be trained in the use of the tool to be the "keeper" of the process for all projects going forward.

11. Even though some details had not yet been considered, the group felt the level of detail was beneficial and started to prompt discussions that often happen too late in the process. Some participants stated that the tool should be used during the development of the functional program to ensure the right considerations were brought forward into the project.

The combined survey results are shown below.



The SRA tool

The SRA tool contained the following major components (each of which includes one, two, or more tabs). The revisions made during this year were indicated with italic underlined text below.

- Cover page and home page providing an introduction of the background and purpose of the tool and direct links to other parts of the tool
- Safe design roadmap, including an instruction page and a checklist of 39 key safe design strategies used by healthcare administrators in four major phases of construction projects. (i.e., strategic planning, facility master planning, process and operational planning; programming and design; construction and commissioning; and sustainment / occupancy). A 3-point scale was used: 1 - not developed, 2 - in process, and 3 - fully developed/work well.
- Project data page for documenting project information and the SRA components to be completed based on project needs
- A page providing links to all risk components, including links to risk data, design consideration, and external resource pages for each risk component
- Risk data and SRA checklist for the six individual topic areas. At the beginning of each topic area section, users were instructed to evaluate the risks and potential harms by using tables and a "heat map." This was followed by a checklist including all the design considerations as well as rationale developed in Year 1. Users were asked to record their evaluation about each design consideration (i.e., estimated risk, priority, and cost magnitude) and optional notes related to the evaluation.
    - 100: infection control
    - 200: medication safety

- 300: falls
- 400: patient handling
- 500: behavioral health/psychiatric injury
- 600: security

A series of tags was used to provide information related to each design consideration that might be helpful in decision-making (i.e., risk estimate, relevance to FGI guidelines [required, suggested, not included], location, source [research, consensus, or opinions]). Sorting function was embedded in the tool so that users can sort the design considerations by the tags (e.g., sorting by building category, risk level, or inclusion in FGI guidelines). This would allow users to focus on design considerations that were most relevant for a particular construction project (e.g., unit layout considerations could be omitted for a plumbing renovation project). For the area of HAI, an existing tool for infection control during construction phase (called Infection Control Risk Assessment [ICRA]) was also incorporated for user's convenience.

- A glossary providing definitions of terms used in the tool
- A list of research references in supporting design considerations

The user guide

The PPT user guide described background information (e.g., the significance of including SRA requirement in the FGI guidelines, the process of developing the SRA tool, the major components of SRA tool) as well as recommended steps for using the tool:

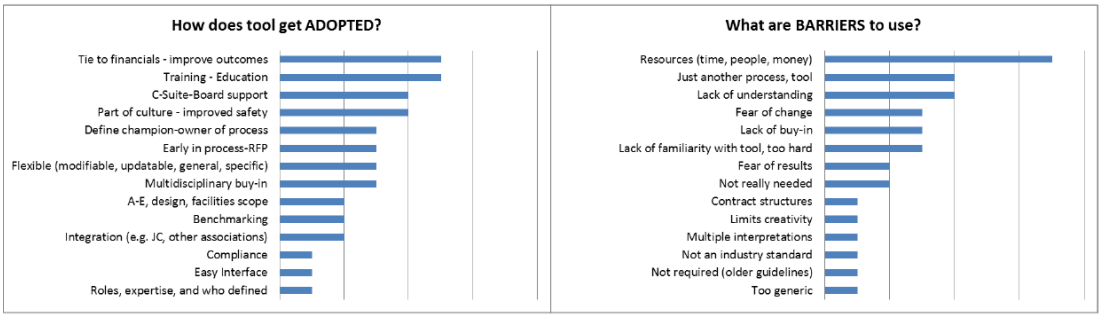
- Preparation and planning
- Identification of key safety goals
- Team composition and participants
- Resources
- Use under various design conditions
- The Excel-based SRA tool (including a detailed description of the tool with annotated screen shots)
- Actions after completing the SRA (e.g., building design improvement, reporting, post-occupancy evaluation)

The user guide also included a list of potential future work to update, expand, and implement the tool, an acknowledgment of contributors, and a request for comments and suggestions to further improve the tool.

Seminar results

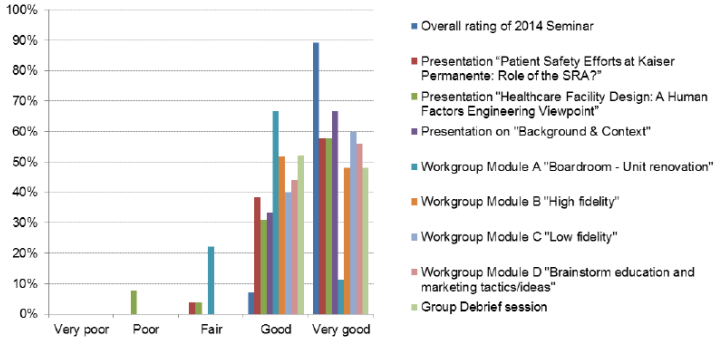
Participant feedback about the seminar (post-seminar surveys)

In the Year 1 (2013) seminar survey, most of the 29 respondents reported that the seminar was well organized and effective in reaching the goal of building consensus around key SRA items. All survey respondents expressed willingness to devote time and energy for further development of the SRA tool in the second and third years of the project.

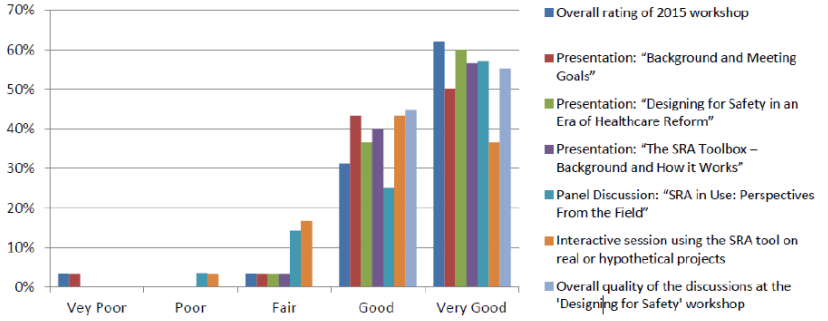


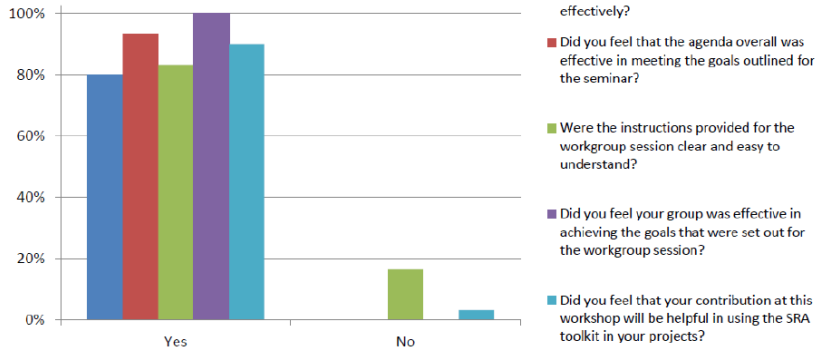
A total of 29 individuals responded to the survey after the Year 2 (2014) seminar. The majority of respondents rated the seminar high overall as well as the individual presentations and workgroup sessions (see figure below).

Most expressed willingness to contribute to the further development of the SRA tool including attending the Year 3 (2015) seminar to be held in conjunction with PDC Summit. Excel spreadsheet was the preferred format for the SRA tool (chosen by 65% of respondents) over a PDF format.



A total of 30 participants (attendees and faculty members) completed the survey after the Year 3 (2015) seminar. The majority of respondents rated the overall seminar as well as the individual presentations and workgroup sessions with high marks - 93% rated the seminar as “very good” or “good”. Feedback from attendees indicated that there is a learning curve that is required for using the tool. For example, some felt that more time was needed for reading the hypothetical scenario and discussing the SRA consideration items. (Unlike Year 2, this had been provided in advance.)





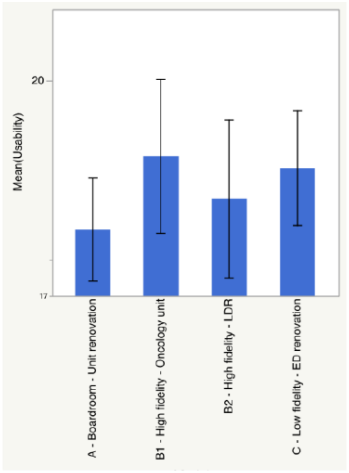
<u>Lessons learned on tool format & content (from the 2014 Seminar)</u>

17

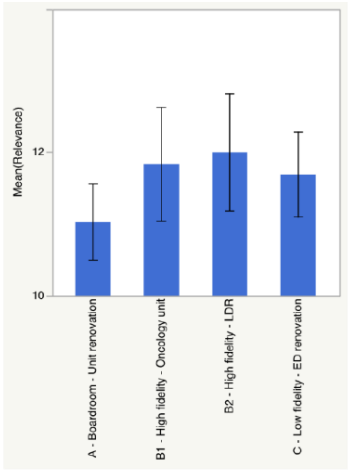
Workgroup members provided specific feedback regarding individual design consideration statements as well as the overall tool format. The notes recorded from the workgroup sessions were aggregated into an Excel spreadsheet and synthesized to inform further adjustments to the tool. Below is a list of suggestions/comments applicable to multiple considerations, multiple components, or the tool as a whole.

- The tool by itself was content driven. In addition to environmental design, other factors such as cultural issues and operational processes often impact safety. It might be helpful to provide a guide around the process, including:
  - The composition of SRA team (e.g., subject-matter experts) and individuals' responsibilities
  - The engagement of external facilitation services
  - Connection to cultural and operational issues, especially other existing safety processes
  - The required information to serve as input to the SRA (risk evaluation?)
  - How to address potential conflicts/trade-offs between components, etc.
- The decision on adopting a design consideration would depend on an accurate evaluation of its value vs. cost as well as its relative priority among all the considerations. Without clear budget constraints, there was a tendency to incorporate all or most of the items. Participants found more data (e.g., cost, patient demographics) were needed to evaluate risks and priorities.
- Design considerations addressing similar or closely relevant issues (e.g., design disciplines such as mechanical design) should be grouped together to make the tool easier to use.
- For a specific project (e.g., scenarios covering specific patient types), some design considerations might be irrelevant (i.e., NA-not applicable). It would be ideal to be able to filter out those irrelevant considerations to avoid fatigue in using a long tool with many NA's.
- The results of the SRA might be the relative priority levels (e.g., high, medium, low) of design considerations instead of simple yes-no-maybe answers. Some suggested that the column should be placed to the left of the "Notes" column.
- Because the mock-ups were only for patient rooms, the workgroup members used unit/building floor plans to address many design considerations that were relevant or connected to other spaces (e.g., storage space for patient handling devices).
- Rationales were useful but need revisions to further strengthen and clarify (e.g., references).
- Simulated environments (i.e., mock-ups) helped to visualize spaces and facilitate communication.
- Definitions were needed for some terms, especially for those not familiar with the subject. Some terminology might be outdated. This brought up the need to update terms.
- The tool would be helpful as a check-in across design phases.

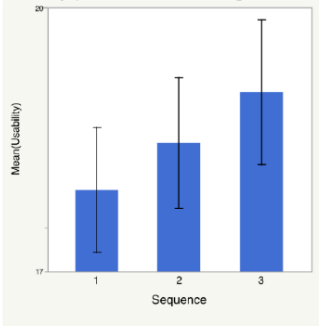
Feedback around the usability and relevance of the SRA tool was generally positive. Using the tool in mock-ups where design considerations could be more easily visualized was considered more effective than using it in a meeting room setting. The low-fidelity mock-ups were perceived favorably by some participants because the room layout could be adjusted by moving the furniture, fixtures, and equipment. An interesting finding was that ratings became more favorable when participants became more familiar with the tool. Some participants also reported that the tool became easier to use the second or third time than the first time. This indicated a possible learning curve in using the tool, such that appropriate training might be suggested.

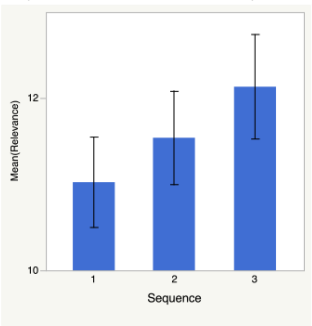


Usability (summation of 5 rating items on 5-point scale)



Relevance (summation of 3 rating items on 5-point scale)





Change of ratings over sessions 1-3

Ideas for tool dissemination

Several ways of informing end users about the existence and proper use of the SRA tool included:

- Disseminate messages about the tool and its value broadly across all relevant conferences, professional networks, and social media to all potential stakeholders such as general public, patient advocacy, regulator, and accreditors.
- Incentivize use of the tool by demonstrating its cost-effectiveness (e.g., ROI, story-telling).
- Provide assistance and training (e.g., recorded video instructions) on use of the tool including the time and cost.

Almost all stakeholders of healthcare (e.g., providers, professional organizations, healthcare administrators, patients, universities, etc.) should be targeted for dissemination. Methods of reaching out to the groups included tailored communication, engagement with professional organizations, and connection to existing safety processes.

The marketing materials should include the following content: purpose and benefits of using the tool, rationale/research evidence, and instructions on how to use the tool (e.g., team composition, time, cost, process), and case studies (success stories) of using the tool. Multiple formats could be used for the marketing materials including face-to-face and virtual communication: web pages with links housed at industry websites, social media, video, YouTube, conferences, webinars, workshops; articles in popular trade magazines, white papers, hands-on practice, and so on.

Some potential barriers to SRA tool dissemination were identified: vague wording (e.g., “optimize,” “maximize”), lack of easy-to-understand output of using the SRA tool (e.g., a pass/fail score), unclear benefits, inertia to adopt

new tools, possible perception that this may be complicated process costing time and money and duplicating other existing processes, and lack of clear guidance for using the tool. (This was prior to the development of the user manual.)

Seminar format as an education module

The seminar format that was used for the PDC pre-conference workshop featured a combination of lectures and hands-on discussion/practices for realistic hypothetical building projects, as well as the involvement of experts and other professionals who participated in the development and testing of the SRA tool. This format was found to be effective in educating healthcare design and construction stakeholders on SRA and disseminating the SRA tool. This method can serve as an educational and training format for further integrating the SRA process in building design and construction.

7. PUBLICATIONS & PRODUCTS

Publications

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- Joseph, A., & Taylor, E. (2014, February). Safety First: Designing Healthcare Spaces To Avoid Adverse Events. Healthcare Design Magazine.

Planned publication:

- Joseph, A., Taylor, E., & Quan, X. (in progress). Creating safer healthcare environments using an evidence-based design process. In V. K. Singh (Ed.). Innovative, Lean & Evidence Based Healthcare Facilities Planning and Design.
- Taylor, E., Quan, X., & Joseph, A. (2015a). Testing a tool to support safety in healthcare facility design. Procedia Manufacturing, in press.

Joseph, A., Taylor, E., & Quan, X. (in progress). First, do no harm: Developing a safety risk assessment tool for healthcare building design. Innovation Learning Network online magazine.

Presentations

- Taylor, E., Quan, X., & Joseph, A. (2015b, July). Testing a tool to support safety in healthcare facility design. Research presented at the 6th International Conference on Applied Human Factors and Ergonomics, Las Vegas.
- Taylor, E., & Quan, X. (2015, June). You don't know what you don't know! Deliberately designing for safety. Webinar presented for The Innovation Learning Network "Virtual Thursday" Webinar Series.
- Taylor, E., & Quan, X. (2015, March). Tools You Can Use: Tracking Safety and Mitigating Risk in Healthcare through Facility Design. Webinar presented for The Center for Health Design ICONS and Innovators Webinar Series.
- Joseph, A., Taylor, E., & Quan, X. (2015, March). Using a Safety Risk Assessment in the Health Care Facility Design Process. Education Session presented at the 2015 PDC Summit, St. Antonio, TX.
- Joseph, A., & Taylor, E. (2014, November). Safety by Design: How Teams Can Proactively Use Facility Design to Reduce Adverse Events. Education Session presented at the Healthcare Design Conference 2014, San Diego.
- Taylor, E. (2014, September). Designing for Safety: Assessing Risks in the Healthcare-Built Environment. Learning Lab presented at the Exchange 2014, Tampa, FL.
- Joseph, A., Malone, E., & Taylor, E. (2014, March). Designing for Safety: Assessing Risks in the Health Care Built Environment. Education Session presented at the 2014 PDC Summit, Orlando, FL.
- Taylor, E., & Joseph, A. (2013, November). Developing a Framework for Conducting Safety Risk Assessment During the Healthcare Design Process. Roundtable presented at the Healthcare Design Conference 2014, Orlando, FL.

- Taylor, E. (2013, July). Patient Safety: Considering Risk in the Built Environment. Webinar presented for The Center for Health Design ICONS and Innovators Webinar Series.

Products

- Final SRA tool (in Excel and PDF formats)
- Final user guide
- Seminar pre-meeting materials
    - Agenda
    - Advisory committee
    - Speakers/faculty
    - Attendee lists
- Design for Safety Seminar results
    - Survey results
- Case study documentation

12.14 Appendix References

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