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Designing Safe Healthcare Facilities—What are the data and where do we go from here?

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"Architecture is stifled with custom, it is the only profession in which progress is not considered necessary, laziness is enthroned and in which the reference is always to yesterday"

--- Le Corbusier, 1932

The paper begins with an extensive review of the patient safety movement to help set the stage for what we know and don't know about evidence based research on the impact of design on health care outcomes. We then present a summary of the knowledge in healthcare about these factors in impacting patient safety outcomes. We conclude with a review of the key areas where we should focus our research efforts in the next decade as we shape a roadmap to make health care design safer and more reliable.

I.A. Background

The evidence is overwhelming. The healthcare environment -- where care is actually provided and received -- has substantial effects on patient health and safety, care effectiveness, staff efficiency, and morale. The United States spends approximately 14 percent of its Gross National Product on healthcare, much of which is provided in hospitals. Yet, despite this enormous expenditure and the available technological resources, today's hospital care frequently runs afoul of the cardinal rule of medicine – "*above all else, do no harm*." The physical environment in which that complexity exists has a significant impact on health and safety; however, enhancing patient safety or improving quality have not been integrated aspects of the design of hospital buildings. Despite the recent discussions in architectural literature regarding design of "patient-centered" health care facilities, little assessment has been conducted of the impact of the built environment on patient outcomes. Studies have focused primarily on the effects of light, color, views, and noise, yet there are many more considerations in facility planning that can influence the safety and quality of care. These include: the path and frequency of patient movement, patient visibility to staff, patient room configuration, details of design, and standardization. High turnover of nurses and other staff has also been blamed on the hospital

work environments. Crowded, noisy, poorly thought out nursing stations add to stress and reduce efficiency and increase the risk of medical errors. Poor design of the hospital environment is a contributing factor to all these problems. For example: nosocomial infections are strongly related to air quality, ventilation, presence and arrangement of hand-washing stations, room occupancy, and finishes; poor lighting/day-lighting is linked to depression, medication errors, and order entry errors; and room arrangement, surface finishes, and lighting are linked to patient falls. In short, hospitals are not designed to foster creative and collaborative teamwork which are the foundations of providing safe and effective care.

The opportunity to build a new health care facility emerges infrequently; indeed, most are in a continuous cycle of remodeling and expanding existing facilities to meet to changing demands. Quite extraordinarily, we are in the midst of the largest hospital building booms in U.S. history, with over 500 facilities being planned, designed or constructed. This program will have a $200 billion impact. We have a unique opportunity to shape them by creating clear evidence-based, scientific guidelines, which will assure that they are built for safety and effectiveness of care. The challenge is to change the traditional hospital design process to incorporate safety-driven design principles and to create or enhance the culture of safety. In planning for the new facility, the hospital design process has been approached with a blank sheet of paper, an appreciation of the evidence that there is ample opportunity to improve hospital patient safety, and the belief that improving hospital facility design will not only increase patient safety directly but also indirectly promote a safety–oriented organizational culture. The new foundation for understanding the occurrence of human errors considers that healthcare providers make mistakes because the systems, tasks, and processes they work in are poorly designed. Organizational accidents have multiple causes involving many people operating at different

levels, which translate to failures at the point of service (e.g., a physician ordering a drug to which a patient is allergic; patient falls due to use of over smoothed surface materials). Based on this idea, exceptional design of healthcare institutions will provide an environment of patient safety as well as a safety-oriented organizational culture. It will require a constant focus on safety by hospital leadership, physicians, and staff and will only be accomplished through a continuous cycle of evaluation and improvement of the facility, equipment, technology, and processes.

B. Traditional Design Approach

The traditional hospital design process starts when architects are given functional program objectives which are then translated into specific space requirements. Those are followed by creation of departmental adjacency diagrams. After those steps, room-by-room adjacencies are developed and then a detailed design of each room is completed. The room-by-room design, together with other building requirements, are described in drawings and specifications that define how individuals, equipment, and technology will function together. Equipment and technology planning generally occurs in the later stages of the design process. Typically, the building standards drill is more routine and has little to do with addressing patient safety opportunities. (Dickerman, K, Barach P, 2005) Typically, no detailed discussion of patient safety takes place, creating the probability that latent conditions which exist in current settings and which contribute to active failures (adverse events, sentinel events and near misses) will be repeated. Human factors and ergonomics, and the interface and impact of equipment, technology and facilities are also not often explored in the design process. Global performance, in terms of outcome, risk management and safety, is influenced by local interactions and synchronization of system components (e.g., providers, patients, technologies, information and material resources,

physical and temporal constraints). As a result, adverse events and unintended consequences are impossible to understand in terms of simple rational rules. To date, reductionist approaches towards hospital design have failed to adequately control risk or reduce the number of adverse events. Conditions in which providers work such as fatigue from 24-hour duty rotations or double shifts, high workloads, confusing labels, look alike names, poor handwriting, and poorly designed equipment and health care buildings, can lead to errors. These are open or ill-posed problems that best are understood through controlled observations, cases study and modeling, with insights drawn from other complex adaptive systems such as emerging economies and dynamic social systems. Now, a brief overview of the patient safety advances in the last three decades.

C. Patient safety and National Health Policy Drivers of Healthcare

Reducing mishaps from medical management is central to efforts to improve quality and lower costs in health care. Nearly 100,000 patients are estimated to die preventable deaths annually in hospitals in the United States, with many more incurring injuries at an annual cost of $9 billion. (IOM, 1999) Underreporting of adverse events is estimated to range from 50%–96% annually. This annual toll exceeds the combined number of deaths and injuries from motor and air crashes, suicides, falls, poisonings, and drownings. Many stakeholders in health care have begun to work together to resolve the moral, scientific, legal, and practical dilemmas of medical mishaps. To achieve this goal, an environment fostering a rich reporting culture must be created to capture accurate and detailed data about nuances of care. Outcomes in complex work depend on the integration of individual, team, technical, and organizational factors. A continuum of cascade effects exists from apparently trivial incidents to near misses and full blown adverse events. Consequently, the same patterns of causes of failure and their relations precede both

adverse events and near misses. Only the presence or absence of recovery mechanisms determines the actual outcome.

D. Emergence of the patient-safety movement

The safety movement in health care, however, can be described as being dormant for many decades, with explosive interest and growth beginning in the mid-1990s. Although "first do no harm" has always been a primary guiding principle for physicians, there are many legal, cultural, logistic, and other barriers to obtaining an honest appraisal of the extent of preventable patient injuries and doing something about the understanding gained. A number of forces converged in the past 15 years to break down these barriers and question long-standing taboos. These forces include a relentless drive for cost containment by payors, changes in social mores that are moving decision-making authority to patients and groups of stakeholders (i.e., away from the traditional paternalistic, physician-driven model), easily available information to all on the Internet, and an emboldened media that has kept celebrated cases of gross mishaps on the front pages. In addition, several relatively recent large epidemiologic studies of harm due to medical management have been picked up by the popular press and replicated in other industrialized countries with similar findings. Despite imperfect methodologies, the studies portray an unacceptable picture of a huge cottage industry that is morally and fiscally irresponsible.

In health care, an analogy can be made to the creation and formalization of the field of injury control that has its roots in the lessons of wartime and transportation safety in the1960s. The likely end result of the safety movement over the next few decades will be the creation of a new science and field of practice in patient safety that will reflect, even more richly, similar developments in industries other than injury control. A range of thoughtful policies will be

needed to institutionalize new approaches to learning, an improved balance of incentives for continuous safety improvement, and a refreshed ethical foundation for improved health care economics.

E. Driving policy—the Epidemiologic Case

Preventable harm due to medical management has been a constant, if infrequent, topic in major medical journals throughout the twentieth century. Case reports and admonitions to improve quality and safety were the norm with exception, such as the Hyderabad report on the dangers of chloroform in the late nineteenth century, and scholarly analyses pointing to the problems to come. (Moser, RH 1956) A seminal article collecting continuous data on 500,000 operative cases for the purposes of studying mortality and morbidity marked the beginning of a new era emphasizing a scientific approach to improving the quality of care. Despite strong conflicting opinions about the methods and conclusions of this study, the impact was to raise the bar in conversations about studying the outcomes of medical management. (Beecher, H 1954; Abajian J, 1955)

A national report on the potential dangers of halothane, a potent halogenated anesthetic volatile agent, appeared in the late 1960s and had the effect of greatly limiting the use of the drug due to suspected liver toxicity leading to death in isolated cases. One of the important corollary findings of the study—significant, unexplained variation in outcomes in leading medical institutions unrelated to the primary objective of studying halothane toxicity—was overlooked in the ensuing policy discussions (Moses LE, 1968) however. Unexplained variation in the degree to which surgical procedures were recommended and performed across the country was elegantly

documented by Jack Wennberg, MD beginning in the 1970s. (Wennberg JE, 1984) "Geography was destiny" as opposed to an overarching evidence base for the best quality and safest practices.

Lucian Leape, MD, and a team of investigators performed a large epidemiologic retrospective 1984 chart-review study in the State of New York. (Leape, L, 1994) They were facilitated by the vision of the Commissioner for Health, David Axelrod, to begin to create a reliable database to understand the incidence and prevalence of injury, preventability, negligence, and malpractice. The Harvard Medical Practice Study validated the work of a physician attorney in the 1970s in California (Mills DH, 1978) but had larger impact because the more in-depth results were published in three consecutive articles in the *New England Journal of Medicine* in 1991. (Brennan TA, 1991) Adverse events occurred in 3.7% of all hospitalizations identified in a retrospective review of 30,121 charts from 51 hospitals, and 28% of these adverse events were judged by physician reviewers to be sufficiently below the standard of care to be labeled "negligent." Nearly 20% of all adverse events occurring in hospitals were due to problems with medications.

A follow-up study by the Harvard team funded by the Agency for Healthcare Research and Quality (AHRQ; at that time, the Agency for Health Care Policy and Research) focused on establishing a better understanding of adverse events due to drugs. In-depth approaches to intensive daily chart reviews stimulated confidential reports by medical personnel, and biweekly confidential systems analyses of ongoing reports of incidents led to capture of rich data about the nature and incidence of these types of events. Publication of these results in the *Journal of the American Medical Association* occurred at roughly the same time as the celebrated death of Betsy Lehman, a reporter for the Boston Globe. (Bates DW, 1995; Leape L, 1995) Lehman suffered multiple preventable drug overdoses during a complex chemotherapy program at the

Dana Farber Cancer Institute and died as a result. Despite her repeated protestations to her care team that something was terribly wrong, they did not find the problem. It took 4 months for routine audit to discover a huge overdose of medication. Another article based on findings from the AHRQ-funded researchers on adverse drug events indicated that the great majority of events, including preventable ones, were not being reported to decision makers and managers who had the knowledge and power to make the needed systems changes to improve safety. (Cullen D, 1995)

The IOM report made a series of recommendations designed to:

- Establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety
- Identify and learn from errors through immediate and strong mandatory reporting efforts, as well as encouragement of voluntary efforts, with the aim of making sure the system continues to be made safer for patients
- Raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups
- Create safety systems inside health care organizations through the implementation of safe practices at the delivery level

The IOM report concluded that a reduction in medical errors of 50% over the next 5 years is achievable and should be a minimum target for national action. A hallmark of the report was its emphasis on subjects not normally considered under the quality umbrella, including human factors, interdisciplinary teamwork, cultures of safety, and complex issues associated with mandatory and voluntary reporting of events of patient harms and near misses. The report

quickly led to a presidential mandate to all federal agencies dealing with health care to prepare an action plan for improving patient safety. The emphasis in the Quality Interagency Coordination Task Force report on research and the development of program infrastructure rather than mandated program elements is an indirect acknowledgment of the relative immaturity of patient-safety science. It is worth noting, with respect to the mandatory incident-reporting system to be developed by the Health Care Financing Administration for hospitals, that the proposed pilot program will focus on a set of "egregious errors that are preventable and should never occur."

The National Quality Forum (NQF) represents another important development, although it is not confined to federal action. Originally conceived by the President's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry, the NQF was established as a public-private venture in 1999. The NQF mission is to support care that is effective, safer, more efficient, and of high-quality service. To accomplish these goals, the NQF has placed a high priority on developing standardized, readily available safety and quality performance and reporting measures. This action will create a level playing field of comparable information about safety and quality and drive appropriate purchasing decisions by payors and consumers. The high priority, strategic areas for NQF action include (1) making patient safety a leadership and management priority, (2) having organizations make an unequivocal commitment to patient safety, (3) creating a health care culture of safety, (4) initiating routine audits for patient-safety hazards, (5) implementing recognized safe practices, (6) increasing education about patient safety, (7) being accountable for patient safety, (8) recognizing and dealing with professional misconduct, (9) making patient-safety research a priority, and (10) supporting efforts to create a non-punitive environment for health care–error reporting. Finally, patient safety has become an

issue internationally. For example, the Australian (Runciman WB, 2000) and British (Department of Health, 2002) governments released their national patient-safety reports, calling for major changes in the way we "incentivize" safe care, train and credential health care professionals, and regulate health care. These reports have come to similar conclusions about the magnitude of the problems surrounding the delivery of safe and high-quality care and the need to redesign the system of health care.

F. Role of accreditation

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) has played a major recent policy role in attempting to improve patient safety. Beginning in 1996, JCAHO was stung by media reports of the ineffectiveness of triennial JCAHO surveys in assuring safe health services. Despite winning top JCAHO accreditation status, several hospitals were found by the media and state department of health investigators to have shortly thereafter experienced tragic sentinel events involving preventable death or injury to patients. Gaps in accountability were also found in terms of lack of compliance with state adverse-event reporting requirements.

JCAHO, therefore, instituted a "sentinel-event policy" that underwent significant revision over the next few years in response to intense feedback from health industry stakeholders. The relationship of JCAHO to the industry it regulates is complex and is discussed in a recent Office of the Inspector General report, which suggests a longer arm's length stance as more appropriate (Office of Inspector General, 1999). The complete sentinel policy is readily obtainable; in summary, a range of options is available to health care organizations to manage actual and potentially new legal liabilities that might be encountered during root-cause investigation of

serious adverse events and sharing of event data or investigation-process data with JCAHO for accreditation purposes. The core purpose of the policy is to ensure that health care organizations are knowledgeable and able to employ in-depth systems analyses tools to better understand why serious adverse events are occurring, how to prevent them, and how to demonstrate to JCAHO that they have a functional process for doing so. Despite the small fraction of events that are reported to JCAHO versus the number that are actually occurring, over a thousand such de-identified analyses have been compiled on a Web site for easy public access and use in safety improvement. In addition, JCAHO developed new patient-safety standards. An awareness of the importance of leadership to lead change that challenges old customs, marshals resources, and creates safety culture led to a large thrust of these new standards being directed specifically at the leadership function of hospitals and networks. One of the most controversial of this new group of standards concerns mandatory disclosure of adverse events to patients and their families.

G. Educational drivers

Medical education and training play key roles in ensuring that patients receive the best quality care. The content and methods of teaching and acquiring professional knowledge and skills continually advance in response to developments in science and society. The current major emphasis on improving patient safety and the overall quality of health services has significant implications for medical education. Strong federal policy recommendations have addressed improving provider education and training for information and systems management, teamwork, and building cultures of safety and excellence. Although other means of better managing risk and complexity must be implemented at the systems-design level, a number of these solutions (such as introducing new technologies or procedures) explicitly and implicitly depend on linked improvements in medical education, training, assessment, and feedback for their ultimate

effectiveness.

In consideration of these trends and current needs, the Accreditation Council for Graduate Medical Education Outcomes Project in conjunction with the American Board of Medical Specialties described six core competencies in 1999. These competencies represent goals and processes intended to provide a framework for governing the next generation of medical education from initialization of trainees to licensure, lifelong learning, and recertification. The six competencies that comprise this framework are patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice [37]. Residents must be able to demonstrate interpersonal and communication skills that result in effective information exchange and teaming with patients, their patients' families, and professional associates … demonstrate an investigational approach to clinical practice [and] effectively call on systems resources to provide care that is of optimal value. Investigators performing root-cause analyses of near-miss events in patient care discovered, however, that inadequate educational preparation and organizational causes together played into creating situations with potential for significant patient harm. (Battles J, 2001)

In addition, in September 2000, the Council on Graduate Medical Education and the National Advisory Council on Nurse Education and Practice convened a joint meeting under the aegis of the Health Resources and Services Administration to discuss Collaborative Education to Ensure Patient Safety. (COGME, 2001) Key recommendations included the need for systems reforms to address the dysfunctional historical divide between the medicine and nursing professions and need for improved interdisciplinary training and practice. The use of advanced reporting systems for learning, clinical computing, and practice-based research to

improve complex systems of care and suggestions on how to redesign the structure of clinical education were among the position papers offered. In risky industries such as aviation, nuclear energy, maritime, automotive, and space travel, simulation has become institutionalized for training, certification, and research purposes to insure safety. In the most advanced of these industries, there is an underlying recognition of the role that teamwork plays in error management and carrying out complex work efficiently. Medical simulation techniques have existed for millennia in simple forms and, in the modern age, a convergence of forces is maturing medical simulation as a field in its own right. These include rapidly advancing computer and robotics technologies, cognitive science, and social norms demanding improved quality and safety from complex, risky, and cost-limited health services.

Simulation with immediate video performance feedback has become a recognized method to train and assess for teamwork. Although the field of medical simulation has been rapidly growing in the past 10 to 15 years, there is a need to externally validate the relatively small number of studies and protocols for education and assessment in health care. The increasing formalization of use of Standardized Patients and Objective Structured Clinical Exams (OSCE) has occurred in this context over the past 30 years, resulting in Canadian adoption of OSCE licensing examinations and the United States National Board of Medical Examiners requiring simulations for licensure in 2004. The evolution of advanced technology simulation tools and approaches plays into these developments.

Ultimately, there is a fundamental ethical drive in health care to (1) allow medical trainees to learn without putting patients at risk; (2) introduce new procedures more safely whereby experienced providers are the learners; (3) adopt new methods to help shape and modify provider behaviors and attitudes; (4) systematically train and test to more relevant, inclusive core

competency standards including team skills, professionalism, and systems thinking across the continuum of a provider's career; (5) improve knowledge retention; and (6) continuously improve medical education and training.

H. Legal policy

In an ideal patient-safety environment, all incentives would be aligned with systems focused safety-oriented goals. Our current liability system, however, cuts in exactly the opposite direction, requiring that individual clinicians be blamed for adverse events that injure patients before patients can be compensated for their injuries. Moreover, our current system is enormously inefficient as it plays this "blame game," devoting upwards of 50% or more of all dollars spent on attorney and expert-witness fees. Recent liability statues have led to widespread paranoia and a growing reluctance of providers to share real data. (Barach P, 2005) Safety science tells us that we must move the focus from individual blame to systems improvement if we are to make real progress in reducing medical errors. Discussion of the myriad federal and state-proposed statutory and regulatory issues concerning patient safety is beyond the scope of this article. The central issue is the creation of mandatory event-reporting systems at the level of the states, which will eventually be standardized to facilitate public accountability at the level of the NQF and Centers for Medicare and Medicaid Services (previously known as the Health Care Financing Administration). States that are unwilling or unable to comply with mandatory reporting programs that capture the requisite "never events" and targeted accountability issues will likely be required to adopt a standardized federal system.

Tort reform is unlikely to provide relief in the near future, given the stimulus of a widely appreciated epidemic of preventable patient harms in an industry that has been perceived to be slow to adopt evidence-based practices. (Liang B, 2000) Indeed, the third major malpractice

crisis of the past 30 years is well underway, with insurers leaving the market due to fierce competition in the 1990s and artificially low premium rates, historically low reinvestment rates due to limited inflation, and increasing numbers of very high jury awards that leave reinsurers unable to accurately predict future losses. It is hoped that in this environment, insurers will be more likely to incentivize the adoption of and experimentation with safety practices through a trial of premium discounts.

II. What we know and don't know in patient safety research (Appendix 1)

A. NOISE

The research literature on noise in healthcare environments is large, running to at least 140 studies. We know the following:

- Hospitals are much too noisy, with dB levels far exceeding WHO guideline values. Hospitals are excessively noisy because noise sources are unnecessarily numerous and loud, and many environmental surface are hard and sound-reflecting, causing noise to echo and propagate over large areas.
- The key to achieving a quiet healthcare building is found mainly in appropriate design of the physical environment, not in modifying organizational culture or staff behavior. There are highly effective design strategies available for quieting healthcare buildings, including: providing single-bed rooms, installing high performance sound-absorbing ceiling tiles that reduce reverberation and diminish propagation, and eliminating noise sources (for example, replacing overhead paging with a noiseless system). These measures, despite their proven effectiveness, are inadequately implemented in new healthcare buildings.

Safety-relevant gaps in noise research

- Several laboratory studies involving non-healthcare participants have shown that cognitive tasks or activities involving high load in working memory, such as sustained attention to multiple cues or complex analysis, are directly sensitive to noise and performance suffers. Performance on *short* duration tasks is not consistently impaired by noise when there is incentive or pressure to maintain accuracy. Maintaining accuracy, however, comes at the cost of increased effort as evidenced by heightened physiological mobilization (cardiovascular activity, for example) and fatigue.

- These findings have implications for healthcare settings, where busy and preoccupied staff must maintain exacting performance and accuracy over long periods despite often high levels of uncontrollable noise. There is little rigorous research on the relationship between noise in healthcare settings and staff fatigue. Further, there is a conspicuous lack of research concerning the possible detrimental effects of noise on performance and errors by physicians and clinical staff engaged in tasks involving high load in working memory.
- There is also considerable evidence from laboratory research and studies in non-health contexts (schools, for example) that poor acoustic conditions characterized by background noise and especially by longer in contrast to shorter reverberation times, reduce speech intelligibility and sharply heighten comprehension errors. A longer reverberation time indicates that the decay of a sound is comparatively slow (more echo), causing blending and overlapping of sounds that erode speech intelligibility and recognition accuracy.
- Long reverberation times (e.g., 0.8-1.0 second for sound to decay 60 dB) are commonly measured in healthcare spaces with hard sound-reflecting surfaces. There is a clear and pressing need for research to ascertain whether poor acoustic conditions are linked to increased speech recognition mistakes among clinical teams, and may thereby worsen patient safety in treatment settings such as emergency departments.

B. DESIGN TO REDUCE MEDICATION AND DATA ENTRY ERRORS

Medications are pervasive in hospitals and error rates related to systems for prescribing, dispensing and administering medications are known to be high. A small number of rigorous studies have identified latent conditions tied to the physical environment that can influence medication error rates. This limited amount of research indicates the following:

- Studies strongly suggest that medication dispensing errors decline steeply when distractions or interruptions are reduced or eliminated, such as telephone calls or when other staff make remarks. Other human factors and human performance research in non-health settings indicates that data entry errors likewise decline when distractions or interruptions are eliminated.
- Studies of pharmacists have found that dispensing errors also can be lowered by providing appropriate -- usually brighter -- work surface lighting levels (1500 lux).

Design research needs for reducing errors

- The finding that bright lighting reduces medication errors raises the possibility that the low illumination levels (200-500 lux) often found in healthcare spaces, due to greater use of computer terminals and pressure to reduce electricity costs, may be too low to support high accuracy in medication dispensing or paper-based reading and data entry tasks. In this regard much research has shown that persons past the age of 40 usually require higher on-task illumination for accurate work.
- The aging of the U.S. nursing work force (average age: 47.5 years) implies that work surface illumination levels of 1500-2000 lux might be needed to help lessen errors in dispensing medications and performing paper-based reading and writing tasks.
- Studies in this area together suggest that a worst-case environment from the standpoint of latent conditions that foster errors is one that may actually exist on many patient floors. This would be a dispensing or other work space with low illumination adjacent to a busy or noisy central nurse station or hallway that generates distractions and interruptions.
- Conversely, errors might be lessened by providing a dispensing space that is separated from work areas where staff cluster, minimizes distraction and interruptions, and has adjustable

task lighting to enable bright illumination as needed. Research is necessary to evaluate this and other hypotheses for designing medication dispensing and work spaces that improve safety by eliminating latent conditions that foster errors.

- There is an urgent need for research to investigate the possible effects on error rates for entering data and performing other tasks at bedside (or in patient rooms) versus decentralized and centralized nursing/charting stations. On the basis of human factors considerations, it might be contended that bedside data entry could worsen errors when there are distractions and questions from patients and family.
- Are errors reduced when nursing units are designed with hallway charting stations where clinicians enter data or perform tasks without distraction? Is information acquired by clinicians at bedside retained fully in working memory when they leave the room and walk to a nearby charting station? The absence of sound research on these and other questions is worrisome given that large investments in electronic technology and nursing unit architecture often are tailored to support either bedside (in room) or charting station data entry.

C. DESIGN MEASURES TO REDUCE HEALTHCARE ASSOCIATED INFECTION (HCAI)

A large body of scientific evidence (more than 145 studies) shows that the built environment influences HCAI rates, especially for airborne and contract-spread infections. We know the following:

- Airborne infections are linked to bacteria, fungi and other pathogens that are small enough to become suspended in the air. Much research has shown that hospital air quality and ventilation (air changes per hour, type of filter, direction of airflow and air pressure)

decisively affect concentration levels of airborne pathogens and thereby strongly influence infection rates.

- The literature suggests a clear pattern for infection rates to be lower when there is very good air quality. For example, bone marrow transplant recipients, burn patients, and other high-acuity or immuno-compromised patient groups have lower incidence of infection and often reduced mortality when housed in single-bed rooms with HEPA-filtered air or laminar airflow.
- Single-bed patient rooms, compared to multi-bed rooms, are far superior with respect to reducing airborne transmission through air quality measures such as filtration, negative room pressure to prevent a patient with an aerial-spread infection from infecting others, or creating positive pressure to protect an immuno-compromised individual from airborne pathogens in nearby spaces.
- More than a score of studies have identified hospital construction and renovation activities as sources of airborne infection outbreaks due to dust or particulate generation. Effective prevention or control measures during construction include portable HEPA filters, installing barriers between patient care and construction areas, sealing patient windows, and creating negative air pressure in construction areas relative to patient care spaces.
- Although airborne infections are a serious safety issue, most infections are now spread via contact transmission. Many environmental surfaces and features become contaminated in rooms with infected patients (e.g., computer keyboards, bed privacy curtains, overbed tables). These and other contaminated features act as reservoirs for pathogens that increase cross-infection risk. There is considerable evidence implicating unwashed staff hands as a key source of contact transmission.

- A great deal of research has shown that staff handwashing rates usually are low, and this represents a major patient safety problem. Handwashing compliance rates in the range of 15% to 30% are typical; rates above 40% to 50% are the exception.
- Research suggests that single-bed rooms, compared to multi-bed rooms, help to lessen risk of infections acquired by contact. Multi-bed rooms, compared to singles, are more difficult to decontaminate thoroughly after a patient leaves the unit, and therefore worsen the problem of multiple environmental surfaces acting as pathogen reservoirs that can potentially spread infection.
- Patients in single-bed rooms, unlike multi-bed rooms, are protected from contact with roommates who are admitted with undiagnosed infection that flourishes in the hospital setting. Proactive assignment to single rooms is needed, for example, to separate newly admitted patients for the two-three days required to obtain diagnostic test results for dormant infections such as MRSA.

Design research needs for HCAI

- Air quality standards for operating theaters (air changes, filtration, etc.) appear questionable or possibly obsolete, to the extent they are based on a limited number of studies that in some instances were carried out several decades ago.
- Given the tremendous morbidity, mortality and cost associated with high rates of HCAI, research is urgently needed to identify more effective ways for producing substantial and sustained increases in handwashing.
- Costly and intensive programs to increase handwashing through education have produced disappointing or, at best, mixed results. Some education programs have succeeded in raising

handwashing compliance but the increases usually are transient, lasting only two to three weeks.

- Findings from a few studies are encouraging in the sense they raise the possibility that certain design measures, including providing numerous conveniently located alcohol gel hand rub dispensers and sinks, may produce sustained increases in handwashing. There is a clear need for studies that include controlled prospective experiments that systematically vary the number and locations of hand-cleaning dispensers or stations. Research also is plainly needed to define *accessible* and appropriate locations for gel dispensers and sinks in an evidence-based manner--that is, on the basis of empirical analysis of staff visual fields, movement paths, and work processes.
- The neglect of human factors knowledge and research methods is a glaring and unfortunate weakness of handwashing research and, more generally, of the infection control literature. We recommend that research to address to gap should be carried out by teams that include a human factors specialist and often an environmental psychologist. This research direction warrants very high priority.

D. DESIGN MEASURES TO REDUCE FALLS

Scores of studies have addressed the causes and risk factors related to patient falls in hospitals and other types healthcare buildings. It is disappointing there is not yet convincing evidence tying any single or specific environmental intervention (e.g., improved lighting, secure carpeting) with reliable reductions in falls. Other findings pertaining to falls have emerged, however, as outlined below:

- Several studies have found that most fall occur in the patient bedroom, followed by the bathroom. It appears that many if not most falls occur when patients get out of bed unassisted, for example, when walking to the toilet.
- Many bedroom falls occur at the edge of patient beds, or en route to or from the toilet through space lacking a handrail. There is considerable evidence that bedrails are ineffective for reducing falls and may actually increase the severity of fall injuries from beds.
- Design faults identified as contributing to falls in bedrooms and bathroom include slippery floors, inappropriate door openings (often too narrow), poor placement of rails and accessories, and incorrect toilet and furniture heights.
- Although there is no persuasive evidence that any single environmental measure reliably reduces falls, a few studies have found that multi-faceted fall-prevention programs can lessen patient falls (identifying high-risk patients in combination with multiple environmental interventions and care process adjustments).
- Carrying out research to identify effective ways to reduce falls is of great importance because patients who fall incur physical injuries, psychological duress, and have longer hospital stays. It is estimated that the total cost of fall injuries annually in U.S. healthcare buildings runs to billions of dollars.

Research needs for falls

- A promising strategy for sharply reducing falls is based on the premise that many falls occur when patients attempt to get out of bed unassisted or unobserved. To increase observation and improve assistance for patients and thereby reduce falls, Methodist Hospital in Indianapolis changed its coronary critical care floor from a unit with centralized nurse stations and two-bed rooms to one with localized nurse stations designed for high visual

access to patients, and large single-bed rooms furnished to support ongoing family presence. Comparison of data from two years prior and three years after the new unit opened showed that falls declined by two-thirds. Additional studies are needed to confirm and understand the effectiveness of this quite promising approach.

- Innovatively designed patient rooms are beginning to appear that place the door to the toilet on the same wall as the bed headwall, thereby shortening the distance substantially that a patient must cover when moving from the bed to the toilet. Importantly, headwall placement of the toilet entrance makes it possible to provide continuous wall-mounted handrail support from the bed to the toilet. It is possible that such room designs may reduce falls, and rigorous research is needed to test this hypothesis.
- Technology and devices are available for detecting patient motion or movements, including when they attempt to get out of bed. Some of this technology is intended for incorporation into the architecture of patient rooms. As an example, St. Joseph's Hospital in West Bend, Wisconsin was built with infrared motion detectors in the walls of patient rooms. If a patient attempts to get up at night, the detectors gradually turn on lighting in the room and toilet and notify nurses to assist or observe the individual. Studies are needed to evaluate the effectiveness of such systems and alarms in preventing falls.

E. REDUCING PATIENT TRANSFERS

There is increasing evidence that intra-hospital transfers worsen patient safety and markedly increase costs. Transfers (hand-offs) increase medical errors, including medication errors, heighten risk for cross-infection, cause manual lifting injuries to staff, and can trigger serious clinical complications including, for example, arrhythmia, hemorrhage (dislodgement of arterial catheter), and cardiac arrest.

Apart from patient transport, other reasons why transfers increase errors and erode safety include changes in staff caring for a patient, communication discontinuities, loss of information, changes in systems and computers, and delays or interruptions in patients receiving medications and care. If transfers generate errors and other threats to safety, it follows that safety should be enhanced if care processes and physical environments are reorganized and redesigned to eliminate many transfers and temper the negative effects of those that remain.

Research needs concerning transfers

- More studies are needed to achieve a better understanding of safety threats and costs associated with transports of specific categories of patients between different types of units and treatment areas. This knowledge could inform a rethinking of architectural adjacencies based on safety considerations. The knowledge would also be extremely important for estimating safety gains and costs savings that could be realized by reorganizing care processes and redesigning physical environments in ways that reduce transfers.
- A most promising approach for reducing transports involves an acuity-adaptable care process/staff model in combination with single-bed rooms having gas outlets and other equipment that permit the room to flex up or down in acuity according to the condition of the patients. Research by Hendrich and her colleagues found that such a unit for coronary patients reduced transfers by 90% and medication errors were correspondingly lowered by 70%. It is important that the acuity-adaptable care model be extended to other categories of patients and evaluated by rigorous research.

III. What are the Key Challenges to Make Health Care Safer?

The health care system has only recently begun to approach patient safety in a more systematic way. The traditional approach within medicine was to stress the responsibility of the

individual and to encourage the belief that the way to eliminate adverse events is to get individual clinicians to perfect their practices. This simplistic approach not only fails to address the important and complex systems factors that contribute to the occurrence of adverse events but also perpetuates a myth of infallibility that is a disservice to clinicians and their patients.

There is a long tradition in medicine of examining past practice to understand how things might have been done differently; however, morbidity and mortality conferences, grand rounds, and peer reviews all currently share the same shortcomings: a lack of human factors and systems thinking, a narrow focus on individual performance to the exclusion of contributory team and larger social issues, hindsight bias, a tendency to search for errors as opposed to the myriad causes of error-induction, and a lack of multidisciplinary integration into an organization-wide safety culture instead of perpetuating a code of silence about potentially embarrassing or litigious events. The focus on the actions of individuals as the sole cause of adverse events inevitably results in continued systems failures and the resultant injuries and deaths of patients.

Unfortunately, shocking as they are, the IOM numbers probably underestimate the extent of preventable medical injury for two important reasons. First, they are based on data extracted from medical records. Many injuries and most errors are not recorded in the medical record, either by intent, by inattention or, more likely, because they are not recognized. The second reason is that the IOM-report estimates of the total burden of medical injury do not include injuries that occur in ambulatory care. Ambulatory care has expanded several-fold since 1984, with the majority of surgical procedures now occurring in ambulatory settings. None of the complications associated with outpatient care were included in any of the studies unless they resulted in hospitalization. In 1997, 31 million procedures nationally were performed outside of hospitals. We know very little about the extent of adverse events in ambulatory care, but a recent

study revealed a 10% error in office prescriptions.

We must now honestly address the increased public anxiety caused by the IOM report and the danger that our patients' visceral fear of a system now publicly branded “unsafe” could lead to exacerbated blame and litigation. The public discussion of the IOM report has the potential to transform the health care system. For this to happen, however, all stakeholders must thoughtfully and carefully move forward, motivated by a common goal, instead of instituting quick fixes that encourage divisiveness, gaming, and noncompliance. Attributing errors to system failures does not absolve physicians and nurses of their responsibility to be careful. In fact, it adds to that duty the responsibility to admit mishaps and errors, investigate them, and participate in redesign of a system for safety—a challenge much more difficult than punishing wrongdoers.

Virtually all of the progress in safety thus far has been derived from using multiple converging techniques to discover underlying vulnerabilities and potential paths to failure and innovating ways to cope with the potential form of failure in the context of the changing pressures and demands that is health care. The study of “errorology,” the search for the number of errors, is misguided and leads to an unproductive and ultimately divisive debate about an inexact, socially charged, and poorly defined quantity. The unwitting use of different referents for the label “error” confuses the discussion and limits progress.

IV. Summary

Policy initiatives on many fronts have converged to improve patient safety. However, five years after the IOM ground breaking report, we are far from where we hoped we might be. Wachter, recently gave the US efforts a grade C+ in reviewing what is the impact of the last 5 years of policy and implementation work. (Wachter, R, 2005) A major tension that characterizes

this process is the attempt to achieve a balance between learning and control in complex systems with technical, social, and organizational components. Efforts to improve learning are marked by better information flow, discovery, flexibility in thinking, embracing of failures as learning opportunities, and core incentives to promote voluntary participation of all stakeholders in the process. Efforts to improve accountability are traditionally marked by public disclosure, meeting of certain widely disseminated standards, availability of performance measures, exposure to legal liability, and compliance with mandated directives (statutes, regulations, accreditation requirements). In some sense, these directions are mutually exclusive. Although a more collaborative regulatory-improvement model would be helpful in creating an industry-wide safety culture, it is likely that learning and accountability functions will follow separate tracks. An exception would be policy that stimulates organizations to comply with regulation by showing how well and by what methods they are learning and how others can profit from these experiences. The health care system needs to transform the existing culture of blame and punishment that suppresses information about errors and adverse events into a culture of safety that focuses on openness and information sharing to improve health care and prevent adverse outcomes.

V. References

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APPENDIX

Physical environmental conditions critical for consideration in the environment:

- Infection Control
    - Selection of surface materials
    - Handwashing station provision
    - Space for maintenance of sterile technique
    - Ventilation design – filtration, air flow, temperature, humidity
- Patient Identification
    - Lighting intensity and quality
    - Sound/noise – design for aural quality
- Human Factors
    - Vibration
    - Noise and acoustic quality
    - Layout of room for:
        - Placement and movement of surgical systems, robots, imaging, etc.
        - Staff workflow
        - Access to supplies and emergency services
    - Room environment control design
- Staff Accommodation
    - Minimize stress
- Transfer
    - Physical – provision for patient transfer system
    - Information – environment for accurate, undistracted communication

- Utility Systems
    - Design for ease of maintenance and indication of failure
    - Clarity of controls, displays and indicators
    - Standardization of systems (important in other areas as well)

- Systems coordination
    - Design of systems to eliminate confusing alarms and indicators
    - Testing of systems in simulated surgeries to discover shortcomings