Chapter 3. Results

Evidence on the Effects of Working Conditions

A total of 115 studies were found to have evidence relevant for answering the key questions and were included in evidence tables. In some cases, additional studies were found to provide evidence that was indirectly related to key questions. These studies are referred to and cited in the text but not included in evidence tables. The volume of available evidence also varied considerably among the categories of working conditions, which reflects extensive variability in the amount of research conducted in these domains. Three studies that provided evidence on more than one category of working conditions were included in more than one evidence table.[42-44]

Over 1,000 papers were retrieved and read, and of these, 912 papers were excluded. Of the excluded papers, 730 were healthcare related and 182 focused on industries outside of health care. The bibliography includes the excluded studies.

Evidence about the effects of working conditions on patient safety was derived from research conducted in both healthcare and non-healthcare settings. Generally, evidence from non-healthcare sources was consistent with that from health care, and we found no examples of significantly divergent findings between the two sources. Trends found in other industries tended to be replicated when evaluated in healthcare settings. For example, studies of ambient noise conducted in factory settings had results very similar to subsequent studies of noise exposure conducted among dispensing pharmacists. Nevertheless, much of human factors research conducted outside of health care has not been replicated or successfully adapted to the healthcare environment. For example, although there is an extensive body of research on crew resource management for aviation, this approach has had only limited success when applied to medical settings.[45]

Evidence applicable to the key questions is summarized in the following sections. The sufficiency of evidence to answer the key questions was greatest for the categories of workforce staffing and workflow design and least for the personal/social category. For some sub-categories of workforce staffing and physical environment, evidence from non-healthcare settings contributed substantially to answering key questions. However, most of the evidence judged sufficient for answering key questions came from research in health care.

Workforce Staffing

The literature searches on workforce staffing yielded the largest number of citations of all the working condition categories (Appendix C). More than 80 percent of the identified citations and retrieved documents were obtained through searches of MEDLINE. Most studies in this domain have been observational, and few clinical trials were identified. However, because similar approaches have been used in multiple studies, it is possible to assess consistency of findings across multiple international sites.

Research on workforce staffing in health care has been conducted for more than 25 years, and the investigations have addressed questions about workload issues, scheduling and coverage, and professional qualifications. Nearly all of the research has focused on nursing and physician staff. Thus, few conclusions can be drawn about staffing and scheduling for other health

professionals. Likewise, there has been relatively little research on workforce staffing outside of health care.

Much of the research about workforce staffing has been based on data from administrative data sets. These data sets have been derived from single hospitals, groups of hospitals, statewide sources (particularly New York, Maryland, Pennsylvania, and California), or national samples. The majority of studies has examined inpatient clinical care and has used adverse events as the outcome measure. Most of the adverse outcomes examined in these studies have clinical risk factors that affect their incidence, and nearly all the studies providing useful evidence have included methods of casemix adjustment. However, the casemix measures have varied considerably. Some studies include patients having only a single principal diagnosis, without additional severity measures for that chosen disease. Another common approach has been to use ICD-9 codes from discharge summaries to calculate diagnosis-based casemix measures. A common feature of these approaches is that the data source is clinical information drawn from administrative sources.

The available evidence on workforce staffing falls into three major categories: workload, professional qualifications, and work schedules. The concept of workload refers to the amount of direct patient contact a healthcare worker experiences over a defined period of time. Studies of workload have been conducted examining both nursing staff and physicians. However, the reported relationship between workload level and patient safety has been based on different conceptualizations for these two professional groups. For both licensed and unlicensed nurses, workload has been defined as the number of patients for which an individual is responsible to provide care during a work shift. Higher workload (i.e., a lower nurse to patient ratio) has been hypothesized to be associated with poor quality of care, because of time pressures that affect the ability to follow ideal clinical practices. For physicians, workload has been defined as the number of cases of a technical procedure performed by the physician over a certain time period. Higher workload has been hypothesized to be associated with better quality of care, because it leads to greater experience (and increased skill) in performing complex technical procedures. This difference is not surprising, in that the unit of measurement differs between the two groups. Nursing workload is typically measured by the number of patients cared for during an 8-hour shift, while physician workload is typically measured by the number of technical procedures performed per year.

Nurse Staffing

The evidence on the relationship between nurse staffing levels and measures of patient safety is provided by 26 studies summarized in Evidence Table 1.[42, 43, 46-69] Twenty-two of these studies have been published since 1996, and 21 were cross-sectional studies examining the relationship between measures of nurse staffing levels and adverse occurrences. Most commonly, these studies have examined in-hospital deaths and non-fatal adverse outcomes in the hospitalized setting, including various types of nosocomial infections, decubitus ulcers, and falls. In some studies, process errors have been measured, including medication errors. One additional study[70] was included in this table because it was based on a similar hypothesis (that higher workload leads to a greater number of errors). This study examined physician workload in an experimental setting, and its outcome measure was charting errors.

An important methodologic issue in this set of studies is the unit of analysis. All of the studies examining nursing workload used nurse-to-patient ratio as the method to estimate

workload. None of the studies examined individual nurses, so they all estimated workload by compiling staffing and patient occupancy data. For some studies, this was compiled by individual nursing units, while others aggregated these data for entire hospitals. One study[63] aggregated these data across groups of hospitals. A particular problem of hospital-level aggregation is that divergent nursing units are combined, including pediatric units, adult units, and intensive care units. Furthermore, these studies often have estimated hospital staffing levels by using payroll data reported to governmental agencies. This source of staffing data has been found to be consistently inaccurate, although not systematically biased.[68, 71]

The studies that aggregated data at the unit level were judged to have better quality than studies that aggregated data at the hospital level, due to the elimination of data pooling across individual units. Studies comparing similar units (such as studies of only intensive care units) were also judged to have higher quality. In one study that aggregated data at the unit level,[49] intensive care units were found to have consistently higher rates of all adverse events, regardless of staffing levels.

The measures of outcome in studies of nurse staffing are recorded at the patient level, by recording incidence of such adverse events as decubitus ulcers. From the patient's perspective, nursing workload can be characterized as the amount of staff time devoted to that particular patient. With higher nursing workload, a lower amount of time is available for any single patient. Thus, nursing workload has typically been reported using such measures as nursing hours per patient per day. A lower value of this ratio denotes a higher level of nursing workload for an individual staff member. The term "staffing" also has been used to denote this ratio, and higher levels of staffing connote higher nurse-to-patient ratios.

Non-fatal adverse events such as decubitus ulcers and patient falls have a plausible direct relationship to the availability of nursing staff. A consistent finding across most of the studies summarized in Evidence Table 1 is that lower nurse-to-patient staffing ratios were associated with higher rates of non-fatal adverse events. This result was found in studies that aggregated data at both the nursing unit and hospital level. While most of these studies used data from acute care hospitals, three[48, 67, 68] used data from statewide or multi-state samples of nursing homes. The findings from the nursing home studies are similar to those for acute care hospitals, with higher staffing being associated with lower adverse event rates. All three studies of nursing homes examined staffing ratios for both licensed nurses (registered nurses, licensed practical nurses, and licensed vocational nurses) and unlicensed nurses (nursing aides). Lower staffing ratios for both categories of staff were associated with higher adverse event rates.

Patient mortality conceptually is an imperfect measure of problems attributable to nurse staffing. While some patients die as a result of injuries related to health care, others die as a result of overwhelming disease. All of the studies evaluated for this report that used patient mortality as an outcome measure lacked methods for attributing the cause of death to preventable or non-preventable causes. Thus, it is not surprising that there was not agreement among the studies on whether lower nurse-to-patient ratios are associated with higher patient mortality (measured as either in-hospital mortality or death within 30 days of admission). The strongest evidence supporting such a mortality relationship examined patients with AIDS.[42] This study was conducted in 20 hospitals, aggregated data at the nursing unit level, and had good casemix controls. However, there have not been studies demonstrating a relationship between nurse staffing levels and patient mortality for other diagnoses. Among studies that did not select patients by diagnosis, a study examining a single intensive care unit[55] and two nationwide studies that aggregated data at the hospital level[43, 66] also found that lower nurse-to-patient ratios were

associated with higher patient mortality. Other studies examining multiple intensive care units[46, 50] and hospital-level staffing ratios[52, 63] did not find such a relationship.

The most common approach to examining staffing levels has been to record licensed nurse staffing and unlicensed nurse staffing as separate variables. In an attempt to provide insight into how overall staffing affects patient safety, some studies using data from acute care hospitals have examined ratios of registered nurses (RNs) to non-licensed nursing personnel. The best evidence that this ratio is important comes from a study that aggregated data at the unit level and had good casemix controls. That study found that a higher ratio of RNs to unlicensed nurses was associated with lower rates of both medication errors and decubiti.[49] Another study that aggregated data at the hospital level found that higher ratios of RNs to unlicensed nurses were associated with lower mortality rates.[64] A study that did not include casemix adjustment found no association between RN to unlicensed nurse ratio and non-fatal complications.[61] Another study that found a higher RN to unlicensed nurse ratio to be associated with higher medication error rates probably reported a spurious finding, because it compared intensive care units (ICUs) to general nursing units.[56] Blegen[72] also conducted a study that did not focus on nurse staffing levels but examined whether nursing units having higher proportions of registered nurses with baccalaureate degrees experienced lower complication rates for inpatients, but that association was not found. That study did find that units having lower complication rates tended to be staffed by nurses with a greater number of years of nursing experience.

The cumulative evidence on nursing workload is sufficient to provide answers to three of the key questions, as follows:

1. *Does nursing workload affect patient outcomes that are related to patient safety?* There is sufficient evidence to conclude that higher nursing workload is associated with higher rates of non-fatal adverse outcomes in both inpatient and nursing home settings. Increased staffing levels of either licensed nurses or unlicensed nurses was associated with lower rates of non-fatal adverse outcomes. The evidence is not consistent in demonstrating that higher nursing workload is associated with higher rates of patient mortality.
2. *Does nursing workload affect the rate of medical errors?* There is sufficient evidence to conclude that higher nursing workload is associated with higher incidence of medication errors.
3. *Does nursing workload affect the rate of recognition of medical errors after they occur?* There is insufficient evidence to answer this key question.
4. *Does nursing workload affect the probability that adverse events will occur following detected or undetected medical errors?* There is insufficient evidence to answer this key question.
5. *Does the complexity of the plan of care affect whether nursing workload affects patient outcomes that are related to patient safety?* There is sufficient evidence to conclude that the magnitude of the effect of nursing workload on patient outcomes differs between ICU and non-ICU settings.
6. *Do nursing working conditions affect measures of service quality in industries other than health care?* No studies in other industries were identified that examined measures of workload comparable to nurse/patient ratios, so research in non-healthcare settings was not found to be relevant to this category.

Physician Workload

Studies of physician workload have focused on a different hypothesis than that used in studies of nursing workload. The studies of physicians have mostly examined physicians who perform technical procedures, such as surgeons and cardiologists. The conceptual model of these studies is that repeated practice is necessary to maintain high-level technical skills. This leads to the hypothesis that physicians who perform fewer procedures over a defined time period will experience a higher rate of adverse events. In contrast to the research on nurses, the research on physician volume is not based on the premise that higher volume hinders availability to meet patient needs. Physicians have been classified as high volume on the basis of caring for as few as 3 patients per year with a particular diagnosis,[73] and physicians considered to be high volume operators often perform fewer than 100 procedures per year.

Many studies have used the hospital as the unit of aggregation and tested the hypothesis that hospitals with higher case volumes experienced lower complication rates. Such studies often have no data about individual physicians, so there are no data about working conditions as applied to individual physicians. Rather, they address the issue of whether certain procedures should be centralized in high-volume hospitals. A recent systematic review found substantial evidence that hospitals with higher case volumes experience lower complication rates.[28] That review also compiled evidence from studies that aggregated data on case volume to the level of the individual physician and concluded that physicians performing high rates of technical procedures experience lower rates of adverse outcomes. However, some studies that controlled for both institutional and physician volume failed to find that physician volume had a significant effect, suggesting that improved results may be due to institutional rather than physician-specific factors.[74,75] Additional evidence that institutional factors have a major effect on adverse event rates comes from a national prospective study of outcomes of surgical procedures conducted in Department of Veterans Affairs hospitals.[76] In that study, there was no relationship between volume of surgical cases and 30-day mortality rates. Institutional factors also may be responsible for the finding that case fatality rates decreased over time among cardiac surgery patients, independent of surgeon volume.[77]

Most studies of physician volume have selected cases based on the criterion that a particular procedure was performed. Relatively few studies have examined case volumes based on diagnoses rather than procedures. Studies based on cases defined by receiving a particular invasive technical procedure are inherently subject to the bias that the decision to perform a procedure is physician-dependent and may be influenced by past experience. Studies based on patients who have a particular condition (such as blunt trauma), rather than having received a particular procedure, permit examination of case volume independent of decisions about procedures. A recent systematic review[78] evaluated published studies examining the effects of institutional and physician volume on the outcomes of care for patients with cancer. That review found that there have been relatively few studies of patients with nonsurgical cancers and that the data from those studies are not sufficient to draw conclusions about individual physicians.

We found four studies that reported data about physician volume for patients identified by a particular diagnosis rather than performance of a procedure. These studies are summarized in Evidence Table 2.[44,73,79,80] We also included one additional study[81] that enrolled patients identified on the basis of having undergone coronary angioplasty. This study was included because it had complete data about all procedures performed at the five participating centers and included detailed and angiography data that permitted correcting for the severity of coronary

artery disease. Three of the five studies found that higher physician volume was associated with lower patient mortality rates, and these studies had higher methodologic ratings than the two studies with negative findings. One study[44] also examined the relationship between outcomes and physician case volume in relation to other characteristics of individual physicians. Older physicians experienced higher mortality rates, but other physician factors (faculty status and location of prior training) were not associated with mortality rates.

The cumulative evidence on physician workload is sufficient to provide answers to two of the key questions, as follows:

1. *Does physician workload affect patient outcomes that are related to patient safety?* There is sufficient evidence to conclude that higher physician workload is associated with lower in-hospital mortality rates. This finding has been observed both in studies of patients undergoing specific technical procedures and in studies of patients hospitalized for medical conditions that may or may not require performance of procedures.
2. *Does physician workload affect the rate of medical errors?* There is insufficient evidence to answer this key question.
3. *Does physician workload affect the rate of recognition of medical errors after they occur?* There is insufficient evidence to answer this key question.
4. *Does physician workload affect the probability that adverse events will occur following detected or undetected medical errors?* There is insufficient evidence to answer this key question.
5. *Does the complexity of the plan of care affect whether physician workload affects patient outcomes that are related to patient safety?* The identified studies have been limited to patients hospitalized with serious diseases, and there is little variation in complexity of care. There is insufficient evidence to conclude that complexity influences the rates of adverse events.
6. *Do physician working conditions affect measures of service quality in industries other than health care?* No studies in other industries were identified that examined measures of workload comparable to those used to evaluate physician performance, so research in non-healthcare settings was not found to be relevant to this category.

Professional Qualifications

Professional qualifications as a working condition affecting patient safety have been examined among both physicians and nurses. Many of the studies of physicians have compared fully trained physicians to trainees or less experienced trainees to more experienced trainees. We did not review these studies because it is widely accepted that medical school and residency training programs improve physician skills.

Studies conducted in pharmacies have found that pharmacists and pharmacy technicians have similar performance in the rates of medication errors. A single randomized trial compared pharmacists to pharmacy technicians as dispensers of prescriptions for ambulatory patients.[82] That study found that there was no significant difference in medication dispensing errors between the two worker groups. A non-experimental study comparing pharmacists to specially trained pharmacy technicians in the accuracy for identifying unit dose errors also found similar error rates between the two groups.[83]

For fully trained physicians, specialty certification has been examined in multiple studies. These studies have been based on the hypothesis that certain specialists provide better medical care than similarly trained physicians without specialty certification. The studies have measured both errors (such as inadequate tumor resection) and adverse events as outcomes. These studies are summarized in Evidence Table 3.[84-88] Four of the five studies examined surgical results and are consistent with the conclusion that physicians who have had more prior training on certain surgical procedures have better results when performing the procedure. The other study[88] found that patients with acute myocardial infarction had lower in-hospital mortality when cared for by a cardiologist.

The cumulative evidence on physician specialty is sufficient to provide answers to one of the key questions, as follows:

1. *Does physician specialty affect patient outcomes that are related to patient safety?* There is sufficient evidence to conclude that physicians with specialty training experience lower rates of fatal and non-fatal adverse outcomes for certain procedures and medical conditions.
2. *Does physician specialty affect the rate of medical errors?* There is insufficient evidence to answer this key question.
3. *Does physician specialty affect the rate of recognition of medical errors after they occur?* There is insufficient evidence to answer this key question.
4. *Does physician specialty affect the probability that adverse events will occur following detected or undetected medical errors?* There is insufficient evidence to answer this key question.
5. *Does the complexity of the plan of care affect whether physician specialty affects patient outcomes that are related to patient safety?* There is insufficient evidence to answer this key question.
6. *Does employee specialization affect measures of service quality in industries other than health care?* No studies were identified that examined professional qualifications similar to those for assessing physician performance, so research in non-healthcare settings was not found to be relevant to this category.

Experience and Educational Qualifications

The experience and educational qualifications of healthcare professionals has been examined in studies conducted in a variety of settings involving both physicians and nurses. The factors addressed in this category include the perceived quality of prior training, the duration of experience, and the efficacy of targeted training on the patient care skills of health professionals. There are 10 studies that provide evidence about the relationship of these factors to measures of patient safety (Evidence Table 4). Eight of the studies examined physician characteristics,[44, 89-95] one study examined nurses,[96] and one study examined physicians, nurses and other clinical staff.[97]

Of the three studies that examined physician experience,[44, 89, 93] none demonstrated that greater duration of physician experience with surgical procedures was associated with lower rates of post-operative complications. These studies also suggest that participation of trainee surgeons in surgical procedures that are supervised by senior surgeons is not associated with higher complication rates, but both studies examining this question studied only a small number of physicians. A study of physicians' ability to recognize physical findings associated with HIV

infection[94] found that general internists and family practitioners who had greater experience caring for HIV patients were better able to identify oral leukoplakia but did not differ from the comparison physicians in two other physical examination skills. The one study that examined the duration of practice of registered nurses[96] found a lower rate of medication errors on patient care units having more experienced nurses. That study also found that care by baccalaureate-prepared registered nurses was not associated with lower rates of medication errors or patient falls, when compared to associate degree registered nurses.

The available evidence does not permit concluding that the perceived quality of prior educational preparation of healthcare professionals affects any aspect of patient safety. For length of experience and targeted training, the following conclusions can be drawn:

1. *Does professional experience affect patient outcomes that are related to patient safety?* There is evidence from one study of registered nurses that longer duration of experience is associated with lower rates of patient falls. The evidence from this single study is not sufficient to conclude that professional experience affects rates of adverse outcomes.
2. *Does professional experience affect the rate of medical errors?* There is evidence from one study of registered nurses that longer clinical experience is associated with lower rates of medication errors. There is not sufficient evidence to conclude that professional experience affects rates of medical errors.
3. *Does professional experience affect the rate of recognition of medical errors after they occur?* There is no evidence on this question.
4. *Does professional experience affect the probability that adverse events will occur following detected or undetected medical errors?* There is no evidence on this question.
5. *Does the complexity of the plan of care influence whether professional experience affects patient outcomes that are related to patient safety?* Two studies of the performance of surgeons found that greater experience was associated with worse outcomes, which is the opposite to the findings of the one study of inpatient nurses. These three studies suggest that care complexity influences the effects of professional experience on patient safety, but the evidence is not sufficient to draw this conclusion.
6. *Does professional experience affect measures of service quality in industries other than health care?* No evidence was identified on this question.

Temporal Factors

Work schedules and lengths of workshifts have received considerable attention in health care, but much of the evidence on these factors comes from research conducted outside of health care. There has been a long interest in the effects of fatigue upon airplane pilots, and the federal government established mandatory restrictions on pilots' work schedules in 1964. More recently, it has been estimated that 58% of long-haul truck accidents are due to fatigue.[98] Work schedules, including assignments to evening, night, or rotating shifts, have been recognized as a potential contributor to fatigue-related accidents, and research in various industries has provided useful information.[99, 100]

A major focus of fatigue-related problems in health care has been the work schedules of trainee physicians.[98] A systematic review of the effects of fatigue among resident physicians found that there is limited evidence to conclude that fatigue causes higher rates of errors on repetitive tasks and tasks requiring prolonged vigilance.[101] This evidence has contributed to

regulatory efforts to limit work hours of trainee physicians. Although there have been case reports of adverse patient outcomes attributed to resident fatigue,[98] we found no controlled studies of the effect of physician work schedules on measures of patient safety.

Temporal factors related to workforce staffing have been examined in nine studies that provide evidence about aspects of patient safety (Evidence Table 5).[102-110] These studies have been conducted in both healthcare and non-healthcare settings and have examined a variety of questions including the effects of length of work shift, variation in outcomes during days of the week, comparison of day and night shifts, and effects of season of the year. The strongest evidence on the effects of shift length comes from a study conducted among workers in natural gas utility plants.[102] This was a prospective study that examined changes in experimental measures of cognitive function and motor skills before and after workers' changes in shift assignments. That study demonstrated that performance was poorer with 12-hour shifts than 8-hour shifts. A second study examining this question was conducted among German intensive care unit physicians.[104] That study found no difference in complication rates of patients after the physician coverage changed from two 12-hour shifts per day to three 8-hour shifts per day.

There is limited evidence that work schedules requiring changing shifts affects error rates. A survey of registered nurses and licensed vocational nurses examined estimated rates of medication errors for nurses who worked fixed or rotating shifts.[106] Nurses who rotated among shifts reported the highest rate of medication errors. Night shift nurses reported more near miss medication errors than day-shift nurses but no more actual medication errors. A study conducted among factory workers found that rotating shift workers had higher rates of reported workplace injuries.[107] A study conducted in a nuclear power plant[108] found poorer measures of performance among the night-shift workers. However that study was flawed because of a small sample size and limited generalizibility to other settings.

Other studies have examined whether period of the week or year may affect measures of patient safety. A retrospective cohort study conducted in Canada compared patients admitted on weekend days to patients admitted during weekdays.[103] That study found that patients who were admitted on weekends for a variety of principal diagnoses experienced higher in-hospital mortality. However for many other diagnoses, the mortality rates were not different. This study has suggestive findings, but it is not adequate to draw conclusions about weekly variation because of a poorly developed conceptual model regarding the classification of diagnoses. It also is not possible to determine from this study what actual aspects of patient care may be responsible for the reported differences.

Booker and Roseman[105] examined seasonal variation in medication error rates in a 140-bed acute care hospital in Alaska, where the length of darkness ranges from 18.6 hours per day in December to 4.5 hours per day in June. These investigators used existing independently collected hospital data from 1985 through 1989 on medication errors and nine potentially confounding variables, including nursing job vacancies, new nursing hires, amount of overtime, number of temporary worker shifts, leave taken by nurses, number of admissions, number of discharges, total monthly inpatient days, and monthly patient deaths. The relationship between these variables and the monthly average time of darkness per day was examined using Poisson regression analysis. After controlling for measures of workload, seasonal variation in medication errors persisted. Over the 5 years of data they examined, medication error rates were greatest one to two months after the month of greatest darkness.

The following conclusions can be drawn regarding the influence of temporal factors:

1. *Do temporal factors affect patient outcomes that are related to patient safety?* There is evidence from one study that the shift length of physicians is not associated with differences in patient outcomes. The evidence from this one study is insufficient to answer this question.
2. *Do temporal factors affect the rate of medical errors?* There is evidence from one study of non-healthcare workers and a survey study of nurses that performance errors are higher among workers having rotating shift assignments. The studies of 8-hour vs. 12-hour shifts have had conflicting results, but studies conducted among resident physicians have found adverse effects of longer shifts on technical performance. A single Alaskan study found a higher rate of medication errors during the winter season. This evidence is suggestive that rotating shift assignments or longer work shifts are associated with higher rates of medical errors, but it is not sufficient to reach this conclusion.
3. *Do temporal factors affect the rate of recognition of medical errors after they occur?* There is evidence from one study that near-miss errors are more frequently recognized among night-shift nurses, but this evidence is insufficient to answer this question.
4. *Do temporal factors affect the probability that adverse events will occur following detected or undetected medical errors?* There is no evidence on this question.
5. *Does the complexity of the plan of care influence whether temporal factors affect patient outcomes that are related to patient safety?* There is no evidence on this question.
6. *Do temporal factors affect measures of service quality in industries other than health care?* Five of the studies that provided valid evidence on temporal factors were performed in non-healthcare settings.

Workflow Design

Workflow design includes healthcare tasks and workplace design issues relevant to accomplishing the tasks. The key words used in the literature search represent potential domains or conditions in task design (complexity, redundancy, distraction, hand-offs, monotony, and role definition) and in workplace design (shared work space, ergonomics, forced posture, technology, information technology, and equipment). We focused our review in areas of workflow design that had observational or experimental data and that were not already reviewed in the recently published evidence report, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*.[14] Several important areas of workflow design are "patient safety practices" and were comprehensively reviewed in that report. Aspects of workflow design reviewed in that evidence report and excluded from this review include information transfer, role definition of pharmacists and intensivists, medical devices, computerized physician order entry with clinical decision support, adverse drug events detection and alerts, unit-dose drug distribution systems, automated medication dispensing devices, bar coding, and clinical decision support systems. Because we did not identify data supporting an association between shared workspace or forced posture and medical errors or patient safety, those aspects of workflow design are not covered in the present report.

Task Complexity

Reducing task complexity has been identified as an important strategy to reduce medical errors.[4] However, we did not identify direct observational or experimental data in health care or

other industries supporting the association between task complexity and medical errors or patient safety. General information is available in the psychology and healthcare literatures to support a conceptual framework to explain why task complexity might increase medical errors. The framework is described in the "Transitions or Hand-offs During Care" section below.

Monotony and Redundancy

We did not identify observational or experimental data supporting a connection between monotony or redundancy and medical errors or patient safety. This working condition is discussed in the aviation and anesthesia literature, where tasks have been described as "hours of boredom interspersed by moments of terror."[111] Anesthesia tasks include high workload during times of induction and emergence from the anesthetic state. The maintenance period between these two tasks is a lower workload state requiring vigilance and monitoring skills. Practicing anesthesiologists describe adding other tasks during these periods to avoid boredom and lack of vigilance. [111] Other domains of health care that feature task monotony and redundancy include telemetry monitoring, dialysis, cytology, and transfusion medicine.

Interruptions and Distractions

The management of mental workload or "attentional dynamics" is an important cognitive factor that affects the performance of workers in complex settings. An interruption is generally defined as an external factor causing the cessation of productive activity, before a current task is complete. A distraction is defined as a stimulus from an external source that results in an observable response but not the cessation of activity.[112] A distraction is alternatively defined as preoccupation by one task to the exclusion of others.[113] Interruptions and distractions appear to affect "prospective memory," or the ability to remember to do something that must be deferred.[114] We depend upon prospective memory for tasks for which we do not receive a cue to remember. This type of memory is associated with the context in which it was formed, and changing the context, or in this case getting distracted, impedes recalling the memory. It may take 10-40 seconds to forget to do something upon distraction unless it is strongly connected to a cue.[113] Reason[3] described the phenomenon as belonging to a particular class of errors that he called "omissions following interruptions." Temporary losses of memory, such as when you enter a room and forget why you went there, are known as "activation errors" and are thought to be due frequently to interruptions.[115]

Cognitive research supports that a second task processed concurrently with another task can lead to "interference" or a bottleneck in human information processing.[116, 117] Interference occurs when the resources required of each task overlap. Most people can do two things at once successfully only in very specific task type combinations. Regularly practiced or "automatic" tasks can successfully be paired, such as taking a patient history and formulating a differential diagnosis. "Consciously processed" tasks require more deliberate and sequential thought. This type of information processing is used for more novel or difficult tasks, and these tasks usually cannot be paired without risking error.[114]

Research on interruptions and distractions has been conducted in non-healthcare settings. Lapses of attention have been found to contribute to many aviation accidents.[113] In an analysis of 37 major aviation accidents from 1978-1990, interruptions, distractions, or the preoccupation with one task to the exclusion of another have been determined to play a role in nearly one-half

of flight crew incidents.[114] Often in aviation, the crew becomes pre-occupied with one task to the exclusion of another important one. As an example, Dornheim[114] describes a 1972 crash of an Eastern Airlines L-1011 after the crew became preoccupied with a landing gear problem and failed to notice that the autopilot had become disconnected. In an analysis of 107 reports to NASA's Aviation Safety Reporting System involving competing tasks, radio communication among the crew was the largest cause of distraction (68 of 107 incidents). Most discussions were relevant to the flight but could have been deferred. The main task that was neglected was monitoring the status of the aircraft or the pilot's flying (69 percent of cases).[114]

A study in the nuclear power plant industry revealed that in more than 15 percent of plant shutdowns, operators had been distracted during execution of the current task.[118] In a study among commercial telecommunications workers, interruptions to customers' calls resulted in an increase in the processing time required for the current task, a significant effect of temporal strain on performance, and an increase in the error rate at the beginning of processing the second task.[119]

The commercial airline industry has developed a multi-faceted approach to deal with interruptions, distractions, or the preoccupation with one task to the exclusion of another. The industry has developed a concept known as the "sterile cockpit." Take-off and landing were determined to be critical safety sensitive times. Thus, an administrative procedure forbids the flight crew from talking about anything unrelated to flying when the plane is below 10,000 feet.[120] Surveillance for violations is possible because everything that is said in the cockpit is recorded. The most successful interventions also may not rely upon human memory or behavior. Many approaches to human error among aviation crews address cognitive frailty through improved design of the technology-human interface, also called human factors engineering. An example is the change in equipment that led to the development of a noticeable electronic indicator of the disconnection of the autopilot function.[114] These practices have been adopted by the aviation industry primarily because of their face validity. Although it is difficult to connect evidence to a single intervention, the airline industry has an impressive safety record, with only about 125 deaths/year from 20×10^7 passenger boardings.[121]

Multiple studies in a variety of settings have demonstrated that health professionals experience frequent interruptions and distractions in the course of patient care. Surveys of residents in pediatrics[122] and internal medicine[123-125] as well as time-motion observational studies of interns[124] have documented how frequently pagers interrupt physicians in training in the course of patient care. Studies of emergency physicians in multiple hospitals have demonstrated high rates of interruptions and competing attentional demands of simultaneous patient care.[126-128] Similarly findings of frequent interruptions and simultaneous demands competing for attention have been demonstrated for nurses in the United Kingdom.[129] Other studies suggest that the frequency of interruptions can be reduced.[130]

Few well-designed studies have analyzed the extent to which interruptions and distractions contribute to medical errors and adverse patient outcomes. We identified six observational studies, one with a concurrent control group and greatest design suitability (comparison of interrupted and uninterrupted prescription dispenses),[112] one with a concurrent control group and moderate design suitability,[134] and the other four without controls and of the least or moderate design suitability (Evidence Table 6).[121, 131-133] Peterson[131] conducted a cross-sectional survey of Tasmanian pharmacists addressing their perceived temporal trend in medication errors and the factors that contribute to or minimize the risk of medication dispensing errors. Flynn[112] examined medication dispensing using videotaped task analysis and a measure of distractibility,

the group embedded figures test (GEFT), to determine the effect of distractibility and interruptions and distractions on medication dispensing errors. Ely[133] performed a cross-sectional evaluation of a focus group and in-depth interviews with family physicians in Eastern Iowa to explore causes of their most memorable errors. Gladstone[132] carried out a retrospective analysis of drug error incident reports and interviews with nurses and managers. Cooper[121] performed a retrospective critical incident analysis of anesthesia errors and equipment failures using structured interviews and a voluntary reporting form. The study findings are outlined in Evidence Table 6.

A quasi-experimental study[134] conducted at a mid-sized acute care hospital in a city in Southeastern Texas measured the effect of two interventions to decrease nurses' distractions during medication administration. Twenty-four medication administration cycles were observed among LPNs and RNs. A control group used customary medication administration procedures. One intervention group used a protocol that specified no conversation during medication administration, teamwork, and a checklist. The second intervention group used the Medsafe intervention, which included the same procedures as the first intervention and added wearing a special vest to indicate to others that distractions were not acceptable during medication administration. The intervention groups had significantly reduced distractions as compared to the control group.

There is sufficient evidence that interruptions and distractions play a role in medication dispensing errors.[112] The evidence of effectiveness of interventions to reduce medication dispensing errors through the reduction of interruptions and distractions is insufficient.[134] The evidence of the association between interruptions and distractions and errors in other areas of medicine is insufficient. This is based upon the limited number of observational studies, three of which rely upon the distant memory of errors.[121, 132, 133]

Interventions to reduce interruptions could be quite simple and inexpensive to implement, as exemplified by those described by Pape.[134] Others have suggested the use of message boards or voice or electronic mail messages for non-urgent messaging, all of which are already commonly available in many healthcare environments.[122]

Transitions or "Hand-Offs" During Care

Individuals with chronic illness often require care from different practitioners in multiple settings. For example, in a given month, the same person with chronic illness may receive care from his or her primary care physician or a specialist in the ambulatory setting, a hospitalist physician and nursing team during an inpatient admission, a different physician and nursing team during a brief stay in a skilled nursing facility, and a visiting nurse in the home. Yet during these times when these patients are most vulnerable and their informal caregivers are often overwhelmed, systems of care may fail them by not ensuring that: (1) the critical elements of their care plan developed in one setting are transferred to the next; and (2) the essential steps that need to take place before and after transfer are executed. In particular, hospital discharge has been identified as a vulnerable time for medical errors and adverse events, and numerous programs have attempted to bridge the gap between the inpatient and outpatient setting.

Transitions between care settings are very common in older adults. In a 2-year study of patients aged 65 or older, 18 percent had at least one post-acute or long-term care transition.[135] Twelve percent of transitions had a followup emergency room visit, an "avoidable hospitalization," or both. A transition was defined as a change in location lasting a day or more

with the place of origin or destination a rehabilitation facility, a nursing home, formal home care, or other formal care setting. The unplanned readmission rate for elderly patients in the first month after discharge is approximately 6 percent, and hospital readmissions of Medicare recipients represent at least one quarter of all admissions.[136, 137] Readmission rates of elderly patients of 25-40 percent within 12 months have been observed.[138]

The risk of errors during transitions from the inpatient to outpatient setting may have increased as the average length of hospital stay for older adults has continued to decline. This trend began with the implementation of Medicare's Prospective Payment System in 1983, and the number of elders discharged with unresolved health problems has increased.[139, 140] If the workflow design does not adequately provide the tools for healthcare workers to exchange information and responsibility successfully, early discharge could be expected to result in higher rates of medical errors and/or adverse events.

Considering how common hospital discharge is we found relatively few studies addressing the rates of errors and adverse events at hospital discharge. More information was available on process gaps. In a secondary analysis of results from a hospital discharge program, barriers to care that had to be addressed during hospital discharge included multiple health providers, multiple settings, and multiple insurers.[141] In a survey of 70 randomly selected patients seen in the general medicine clinic within 2 months of discharge from the inpatient medicine service at the Mount Sinai Medical Center in New York,[142], 52 percent had at least one medication error, 13 percent had at least one test followup error, 7 percent had at least one error in "work-up" or diagnostic evaluation, and 59 percent had an error in one or more of the three categories. The average number of discharge medications among patients with medication errors was significantly higher than those without medication errors (7.2 vs. 5.1, p=0.001). In a similar study, Diem[143] found 10 percent medication and 2.8 percent test scheduling errors at a resident discharge clinic 10 days after hospital discharge.

Discontinuities and inconsistencies between inpatient and outpatient medications, errors in medication labeling, poor patient understanding, and lack of medication adherence after discharge are important sources of errors, especially in the elderly.[144-147] A summary of this area and a review of inpatient to outpatient pharmacy communication interventions can be found in *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*.[14] Murff[148] noted that in elderly patients, hospital providers changed 53 percent of the drugs prescribed in the outpatient setting, and 32 percent of medications prescribed at discharge were not being taken 2 days after discharge. In a Scottish study of elderly patients given a 5-day supply of medication at hospital discharge and visited 5 days after discharge, 27 percent had not received continuing prescriptions for their medications, and among new prescriptions issued, 19 percent were inaccurately labeled.[145]

Gaps in physician-patient communication at discharge appear to be common. In two studies from the US and Canada, 20 percent of patients discharged from the hospital reported that they were not told about important medication side effects nor when they could resume normal activities.[149, 150] Calkins et al.[151] surveyed 99 patients who had been recently discharged from an academic medical center in Boston and their attending physicians. Physicians reported that 89 percent of the patients understood the potential side effects of their medications, but only 59 percent of patients reported understanding (p<.001). Physicians reported that 95 percent of patients understood when to resume normal activities, but only 58 percent of patients reported that they understood (p<.001).

The gaps in processes surrounding hospital discharge may be important to patient outcomes. Brook et al.[152] evaluated through chart review and patient interview 403 consecutively discharged patients from the medical service of a Baltimore teaching hospital and found that 30 percent received follow-up care rated as inadequate. There was frequent lack of communication of hospital records (34 percent of 124 with private physicians), and 25 (6 percent) were not given follow-up care. In 39 patients (10 percent), a poorer outcome was judged to be due to inadequate care. Inadequate process was associated with poorer outcome ($p<0.01$).

Patients likely contribute substantially to errors during transition. As trends have moved toward shorter hospital stays, increasingly complex medication regimens, and community-based long-term care, the opportunity for important miscommunications and gaps in expected followup have increased. By default, facilitating successful care transitions becomes the responsibility of patients and their caregivers, who may not possess the necessary skills or confidence for this role. A qualitative study of the needs of the elderly in the first week after hospital discharge revealed needs in four major areas: continuing care needs, the need for an available and able caregiver, caregiver uncertainty, and the need for information.[153]

A number of other process gaps have been identified around discharge planning, exchange of information, and transfer of responsibility. These include patients being told at the last moment that they were being discharged, with subsequent insufficient information about the requirements for care; and inadequacy of the discharge plan, patient and caregiver understanding of the plan, and essential resources, e.g., money or transportation.[139, 154]

Many complex factors have been associated with gaps in planning the transition from the inpatient to the outpatient setting. Multiple factors were significantly associated with less adequate social worker ratings of discharge plans in 286 older patients with Medicare: financial impediments, patient confusion, lack of family availability, difficulties working with families, Medicare/ Medicaid guidelines, and team disagreement regarding the patient's psychosocial situation.[155] In a random sample of 133 elderly patients with unplanned readmission to a UK hospital, factors associated with readmission included relapse of the original condition, development of a new problem, caregiver problems, complications of the initial illness, need for terminal care, problems with medication, and problems with service.[136] In that study, service problems significantly associated with readmission included "too early" discharge, in the general practitioner's opinion; no advice given at discharge; and no discharge notice given to the general practitioner. Another study of factors associated with hospital readmission of elderly patients found unavoidable medical deterioration, inadequate medical management, patient non-compliance, social problems, and inadequate rehabilitation as significant.[156]

Is discharge planning effective in reducing errors? A recent Cochrane review (last updated in August, 2000) reviewed 8 controlled trials of discharge planning involving 4837 patients.[157] Four trials recruited patients with a particular medical condition and four recruited patients with a mix of medical and surgical conditions. There was a small reduction in hospital length of stay for elderly medical patients allocated to discharge planning (weighted mean difference -1.01, 95% CI -2.06 to 0.05), but overall the results of the trials were mixed.

We extended the findings of the Cochrane review by evaluating interventions that did not focus on a particular medical condition and had an outpatient component. We identified 10 randomized controlled trials and four observational studies of hospital discharge programs for the aged that met our criteria (i.e., were not single disease focused and had an outpatient component to the intervention). The trials are summarized in Evidence Table 7. All designs were rated to have the greatest suitability. The average patient age in all studies was $\geq$65 except

for Smith,[158] where the average age was 52. The studies were conducted at Veterans Affairs hospitals,[143, 159] a community hospital in the UK,[160, 161] US, [162] or Denmark,[163] and academic medical centers.[141, 158, 164, 165]

Lipton[162] utilized pharmacists to prevent medication errors. The other interventions were delivered by nurses,[141, 158, 164] a nurse practitioner and geriatrics team,[165] nurses and health care assistants,[161] a nurse and a primary care physician,[159, 163] medical residents,[143] or a care attendant,[160] and provided support for multiple aspects of care, including medication. The intervention intensity was variable as outlined in the table, with dedicated staff in six studies[141, 160-162, 164, 165] and staff given additional responsibilities in four studies.[143, 158, 159, 163] Length of outpatient intervention followup was variable, with 1 week,[158, 159] 10 days,[143] 2 weeks,[160, 163, 164] 4 weeks,[141] 6 weeks,[161] 3 months[162] or unclear length of followup.[165]

Most studies did not provide detailed information about the types of interventions provided by staff. Naylor[139] did describe six strategies that were utilized by the advanced practice nurses: comparing patient and caregiver data, anticipating outcomes, individualizing care, empowering patients and caregivers, crossing barriers, and creating solutions.[139] Two-thirds of the nurses' interventions were in the surveillance area, which included initial assessment and ongoing monitoring. Teaching, guiding, and counseling comprised 20 percent of the interventions, case management 14 percent, and treatments and procedures 1 percent. Clinical outcomes included mortality,[143, 160, 163, 165] non-elective hospital admission,[141, 143, 158-161, 163-165] time to first hospital readmission,[141, 164] length of hospital stay,[164] nursing home admission,[161, 163, 165] morale,[160] quality of life[159, 165] and physical independence.[160] Other outcomes included medication errors,[162] emergency room utilization,[143] and satisfaction.[159, 165]

All ten studies of hospital discharge programs for the aged are rated good for their quality of execution, but the evidence for their effectiveness is mixed. This may be in part due to the large variation in intervention design and intensity. Six studies utilized dedicated staff, [141, 160, 161, 162, 164, 165] and four studies utilized nondedicated staff.[143, 158, 159, 163] Of the trials with dedicated staff for the intervention five of six had a positive impact on readmission rates or a related outcome. Of the trials without dedicated staff (i.e., additional tasks for existing staff), one of the four had a positive impact and one of the four had an increase in readmissions in the intervention group.

We also found three observational studies evaluating transitional programs at hospital discharge in older adults. In a project that employed a liaison nurse before and after hospital discharge in the Dutch Zaandam region, a pre- and post-questionnaire to patients suggested that the quality of discharge planning was improved.[154] Significant results were achieved in the areas of need for aftercare discussed with patients, home health staff being informed, and patients taught about proper handling of surgical dressings. In a survey of registered nurses, the absence of medication discharge planning for elderly patients with congestive heart failure was significantly associated with hospital readmission ($p<0.05$).[166]

Patients discharged from a UK teaching hospital who received an informational booklet about their care at discharge were more likely to know the medications they were taking and the correct dose and frequency than patients who did not receive the booklet.[167] Sixty of 165 elderly patients consecutively discharged from the hospital that received pharmacist counseling made less than one-third of the medication errors made by the uncounseled group.[168]

This body of evidence is sufficient to conclude that hospital discharge programs employing a dedicated staff and having an outpatient component reduce readmission rates and hospital days. However, the evidence is not sufficient to conclude that these programs reduce medical errors and associated adverse events, because these studies did not report these outcomes. While it is

possible that higher readmission rates are associated with worse patient outcomes, the small amount of evidence on this point is insufficient to permit any conclusion. In the one study reporting an increase in readmissions[159], patients in the intervention group had higher satisfaction and no decrement in quality of life relative to controls. Conversely, an intervention that reduced readmission rates also had no effect on functional status.[141]

Weinberger[169] evaluated the cost-effectiveness of the Smith[158] intervention described above. High-risk patients in the intervention group had significantly higher outpatient costs ($131/month vs. $107/month; p=0.02) but lower inpatient costs ($535/month vs. $800/month; p=0.02) than the control group.

Naylor[164] found that 6 weeks after hospital discharge the mean charge for the intervention group was 63 percent less than the mean charge for the control group. In the 1999 Naylor study,[141] at 24 weeks after discharge, total Medicare reimbursements for health services were $1.2 million in the control group vs. $.6 million in the intervention group (p<.001).

Other transitions in care may contribute to medical errors and adverse events. We found one study of medication dispensing for a random sample of over 50,000 Medicare registrants in Quebec in 1990.[170] This study concluded that the greater the number of prescribing physicians, the greater the risk was that the patient received a potentially inappropriate drug combination.

Computer Interface Design

Clinical decision support systems have been shown to be effective in reducing nosocomial infections,[171-173] improving dosing of nephrotoxic medications,[171-173] and accelerating recognition of serious laboratory abnormalities.[171-173] Computerized physician order entry has been shown to reduce the incidence of adverse drug events.[13] Alerts, reminders, and other decision support features have been demonstrated to reduce errors in prescribing,[174, 175] improve preventive and chronic disease care, and improve physician and patient satisfaction in controlled settings or inpatient environments.[172, 174-178] A recent review concluded that vigorous application of alerts and reminders could substantially reduce mortality for multiple conditions.[175]

Caution is appropriate, however, before widespread deployment of information systems meant to improve the reporting and reduce the occurrence of medical errors.[14] Lessons from other domains, including aviation and military applications, suggest that information systems may sometimes worsen the situation. Problems include such phenomena as “automation surprise,” when computer systems designed for typical conditions behave unpredictably under conditions of stress or crisis; “automation complacency,” where situation awareness is reduced when pilots are removed from the information loop by automation; and “mode confusion,” where it is not clear to the human operators which mode of operation the automated system has assumed. Extensive research in the military, aviation, and nuclear power industries documents such dysfunctional interaction between information systems and the individuals they are meant to assist[179] and investigations of aviation accidents confirms the difficulty of designing software that helps rather than hinders expert decision makers in urgent, complex, uncertain conditions.[180]

Ongoing research in human performance with complex systems in high reliability domains emphasizes how information systems must function as team players that interact effectively with other members of a team to collaboratively manage complex situations.[181] This collaboration requires understanding not only the traditional one-to-one human-computer interaction of traditional human factors studies, but also the complex situation that arises when the technology is added to existing teams of humans.

Two studies have examined computer interface design in health care, and neither evaluated medical errors nor patient safety. One study compared nurses' response time, errors, and satisfaction comparing text-based computer interface to prototype graphical interface. The nurses had significantly faster response times, fewer user errors and were more satisfied with the graphical interface.[182] The second paper is a case study of the implementation of a "user-centered" computerized command-and-control system in an ambulance service that concluded that there was an improvement in time to ambulance-on-the scene and lower subjective anxiety and systolic blood pressure in the workers after system implementation.[183]

Summary of Key Questions for Workflow Design

1. *Do workflow design working conditions affect patient outcomes that are related to patient safety?* The evidence for the association between workflow design factors and patient safety has focused on the incidence of medical errors and such adverse events as re-hospitalization but not adverse patient outcomes. There is insufficient evidence to conclude that workflow design factors affect the incidence of adverse outcomes.
2. *Do workflow design working conditions affect the rate of medical errors?* There is sufficient evidence to conclude that interruptions and distractions increase the incidence of medication dispensing errors. The strength of the body of evidence for the association between hospital discharge factors and medical errors is also sufficient. The evidence that pharmacist discharge programs can reduce medication errors in the elderly is sufficient. The other areas reviewed had insufficient evidence.
3. *Do workflow design working conditions affect the rate of recognition of medical errors after they occur?* There is insufficient evidence to support this in all areas reviewed.
4. *Do workflow design working conditions affect the probability that adverse events will occur following detected or undetected medical errors?* There is insufficient evidence to support this in all areas reviewed.
5. *Does the complexity of the plan of care affect whether workflow design working conditions affect patient outcomes that are related to patient safety?* There is insufficient evidence to support this in all areas reviewed.
6. *Do workflow design working conditions affect measures of service quality in industries other than health care?* There is insufficient evidence to support this in all areas reviewed.

Personal/Social Working Conditions

This section of the report is concerned with the evidence for a relationship between the personal, professional, or social aspects of the healthcare work environment and the safety of patient care. The underlying assumption is that the ability of health professionals to provide safe patient care will be influenced by personal factors such as stress, burnout, and job dissatisfaction; social factors such as collectivism or discord within a work group; or professionalism in the form of the ethics and values that are cultivated within a professional discipline such as nursing, pharmacy, or medicine. Studies focusing on the effects of these conditions at the individual or work group level are included in this section, while studies focusing on the broader organization and its organizational structure or culture are included in the subsequent section on organizational factors.

This report is restricted to direct evidence regarding the impact of these working conditions on patient safety or medical error. It is beyond the scope of this report to review the vast literature that exists on the effects of these working conditions on other variables, including their physiologic, metabolic, and psychological effects in individual workers or their organizational effects such as absenteeism or job turnover. By way of background, several of the relevant constructs are briefly described below.

Stress is a construct that refers to one's response to an imbalance between the expectations or demands placed on individuals and the resources or capacities available to meet them. Stress has been defined in the research literature as a stimulus variable, an intervening variable, and a response variable.[184] In an extensive review of stress and its physiologic, metabolic, and psychologic sequelae, Levine[185] notes that a) stress-related decrements in performance have been replicated across a wide range of stressors and populations in laboratory tasks; b) interventions that increase control and predictability are effective in reducing these effects; c) evidence for these performance effects is largely based on laboratory studies, and evidence in naturalistic settings is limited; and d) a pervasive finding in the literature is the curvilinear ("inverted U") relationship, whereby arousal is associated with improvements in performance, while stress is associated with performance decrements. Jones, however, emphasizes the multidimensional nature of the stress-performance relationship, concluding that stress effects are situation-specific, individual-specific, and task-specific.[186]

Burnout has been described as a state characterized by emotional exhaustion, depersonalization, and reduced personal accomplishment, especially prevalent in human-service related occupations, with consequences on job satisfaction and performance that have been evaluated in a wide range of occupations and professions.[187] Burnout may be distinguished from stress in that burnout refers to a longer lasting, more stable condition while stress is generally, though not always, more transitory. Burnout is distinguished from depression in that burnout involves a person's relationship to their work, while depression has pervasive effects on multiple aspects of an individual's life.

The potential relationship between job satisfaction and job performance has been a subject of intense investigation by industrial psychologists for many decades, but the research remains inconclusive. In a critical review of this literature, Judge et al. examine seven potential models of this relationship and found the literature to be inconsistent, in part due to the piecemeal nature of the research, with many models being proposed but no systematic and coherent approach to thoroughly testing them.[188] Based on a meta-analysis of 312 studies, these authors conclude that a relationship does exist and propose a multidimensional model as a basis for future research.

Social dimensions of the work environment include collectivism, the belief of a group member that one's individual welfare is closely tied to that of the group.[189] According to this construct, individual behavior and overall group performance are potentially affected by the degree of collectivism in a work group. A related concept, work group cohesion, has been identified as an important determinant of job satisfaction.[190] Social support has been identified as one of the factors that can mitigate stress-related effects on performance.[185]

Professionalism may also impact the ability to provide safe patient care. Health professionals include themselves among the learned professions, espousing values such as excellence, altruism, and personal accountability.[191] Teaching these values is incorporated into their training and symbolized by recitations of the discipline's oath at graduation or other ceremonies. Maintaining these values is an ongoing activity within the profession, as evidenced by

publications that respond to perceived threats to these values by redefining professionalism and/or calling for its renewal.[192, 193]

To impact patient safety, working conditions must affect health professionals, this effect on health professionals must interfere with or alter their clinical work practices, and the altered work practices must result in harm to patients. As an example, working conditions might produce stress or burnout among clinicians such as physicians, nurses, or pharmacists. Clinicians with stress or burnout may thereby be more likely to make medication errors. Medication errors, in turn, may result in harm to patients. Steps in this theoretical chain of causation are independent, and every step in the chain must be present for an impact on patient safety to occur. This allows for the possibility that a working condition can affect health professionals without affecting clinical practices, or that clinical practices may be affected without necessarily resulting in harm to patients.

Eleven studies provide evidence pertinent to the effects of personal/social working conditions and are summarized in Evidence Tables 8 and 9. Five studies reported on the impact of stress on patient safety[194, 195] (one single publication[195] reported results of four distinct, original studies). Four studies were concerned with the impact of dissatisfaction and burnout.[196-199] Two reported on the effects of social aspects of the work environment.[189, 200] These studies are grouped together by topic and discussed individually.

Stress in the Hospital Work Environment

Two publications reported five studies related to stress in the hospital work environment.[194, 195] Three of these were cross-sectional studies examining the association of stress levels with rates of malpractice claims (Evidence Table 8, top frame). The last two evaluated stress reduction interventions (Evidence Table 8, lower frame).

Dugan et al.[194] examined the relationship between stress among hospital nurses, burnout indicators, nursing injuries, and patient incidents in a moderate sized hospital in the Midwest United States. Stress was measured using reported stress symptoms and a single item measure of perceived stress, but response rates to the mailed survey were low. Prospectively collected hospital department data were used for burnout indicators (unit-level sick leave, other absences, and turnover), nursing injuries (nursing needle-stick and back injuries), and patient incidents (medication errors, IV errors, and patient falls). Data were aggregated for comparison at the level of hospital units, which included a broad spectrum of hospital nursing care. Correlation between the two stress measures was only 0.59, indicating that convergent validity was less than expected. Medication errors and patient falls were found to be significantly associated with perceived stress but not with reported stress symptoms. Intravenous administration errors were not correlated with either measure of stress, nor were nursing injuries or burnout indicators. This study provides only weak evidence of a relationship between perceived stress and medication errors or patient falls.

Jones et al.[195] in a single publication reported the results of four studies examining the relationship of job stress and patient safety. Study 1 examined the relationship between the malpractice risk of 91 departments of five hospitals and stress in those departments. Stress was measured with the Human Factors Inventory, which included subscales for job stress, organizational stress, job satisfaction, and personal stress. High malpractice risk departments were defined as those having one or more malpractice claims attributed to human error in the preceding year or were identified as having unacceptable clinical practices in interviews with at

least two hospital personnel. The 13 high malpractice risk departments had significantly higher scores than the 78 low malpractice risk departments for job stress, job dissatisfaction, and organizational stress, but not for personal stress. In a repeat analysis comparing the 13 high-risk departments with 13 low risk departments matched for the acuity of patient care provided in those departments, the finding persisted, suggesting that the findings are independent of the type of department or the acuity of care provided therein. These data suggest an association between job stress, organizational stress, and job dissatisfaction in a hospital department and the malpractice risk experienced by that department, although the direction of causation is uncertain.

The second study in the report by Jones et al.[195] examined the relationship between the malpractice experience of hospitals and the average level of stress measured among the hospital's employees. Aggregate hospital scores for job stress, organizational stress, and job dissatisfaction were highly correlated with one another and with a hospital's malpractice claims experience, while personal stress was not. After controlling for number of hospital beds, job stress and organizational stress remained significantly correlated with malpractice claims experience, while personal stress and job dissatisfaction were not. These data suggest an association between employee stress and the malpractice claims brought against those hospitals. High stress could be the cause of clinical practices associated with higher malpractice risk, but malpractice claims also could be the cause of higher employee stress.

Two studies of a stress management intervention were also reported by Jones. Based on analysis of stress data obtained using the Human Factors Inventory, a five part program was implemented, including 1) high level management information and feedback about hospital employee stress scores; 2) departmental modifications in communication, organization, and personnel policies implemented by managers of high stress departments working with consultants; 3) feedback sessions with employees about stress levels and stress management; 4) viewing of stress management training videocassettes by hospital employees; and 5) a program for employee counseling and assistance. A pilot pre-/post-intervention study (Study 3) demonstrated that the frequency of medication errors dropped by half after implementation of the program at a single hospital, but did not attempt to document that the intervention reduced employee stress levels. The fourth study, a nonrandomized, controlled trial, reported by Jones et al.[195] then assessed the impact of this same stress management program on hospitals' malpractice claims rates. Hospitals agreeing to participate in the trial (n=22) were compared to control hospitals (n=22) matched for size, prior frequency of malpractice claims (the dependent variable in the study), location, and the types of patient care services offered. Following implementation of the stress management programs rates of malpractice claims fell in the intervention hospitals and rose in the control hospitals. The studies found a consistent relationship between employee stress and various measures related to patient safety and provide a strong argument for recommending further research about stress among health professionals and particularly the effects of stress reduction programs conducted in hospitals. The limitations of this trial are (1) the main outcome measure, malpractice claims, is a poor surrogate for patient safety; and (2) because it was not a randomized trial, it is likely that hospitals that adopted the intervention differed from those in the control group.

The limited available evidence on the effects of stress among health professionals does not lead to judgments about sufficient evidence to answer any of the key questions, but the available evidence does suggest that further research is indicated.

1. *Does stress affect patient outcomes that are related to patient safety?* Organizational stress and job stress were associated with higher malpractice risk[195] and patient falls.[194] Malpractice risk was lower in a controlled trial of a stress management program.[195] Malpractice events are a poor measure of patient safety, so there is insufficient evidence to conclude that stress causes increased adverse patient outcomes.
2. *Does stress affect the rate of medical errors?* Separate studies having relatively weak designs found that medication errors were higher on hospital nursing units with high stress[194] and that medication errors fell following implementation of a stress management program.[195] However, there is insufficient evidence to conclude that stress leads directly to medical errors.
3. *Does stress affect the rate of recognition of medical errors after they occur?* No studies addressed this question.
4. *Does stress affect the probability that adverse events will occur following detected or undetected medical errors?* No studies addressed this question.
5. *Does the complexity of the plan of care affect whether stress affects patient outcomes that are related to patient safety?* No studies addressed this question.
6. *Does stress affect measures of service quality in industries other than health care?* No studies addressed this question.

Dissatisfaction and Burnout

Bond and Raehl[196] conducted a survey study to examine the relationships between pharmacists' estimates of the risk of medication dispensing errors and pharmacist worksite, workload, workflow, and job satisfaction. A lower estimated risk of dispensing errors was correlated with pharmacists' satisfaction, including satisfaction with career, working conditions, work hours, time for clinical activities, level of staffing, level of technician support, and level of technician training. Pharmacists estimated a higher risk of dispensing errors under conditions of greater workload (prescriptions per hour) and in certain work sites. A lower estimated risk of dispensing errors was associated with 1) greater clinical time (consulting with physicians, counseling patients, etc.); 2) management time (practice management, committee work, etc.); 3) professional society membership and professional development activities; and 4) longer experience. No consistent pattern was evident between type of worksite and the other variables that were associated with a higher estimated risk of dispensing errors. The strongest predictor of low risk of dispensing errors was the time available for dispensing each prescription.

DeVoe et al.[197] used a survey to examine whether career dissatisfaction was associated with a perceived inability to provide high quality care among family physicians. Nearly 18 percent of the respondents reported dissatisfaction with their career, and dissatisfaction was more frequent among physicians reporting inadequate time spent with patients, inadequate freedom to make decisions that meet patient needs, and overall inability to provide high quality care to patients. Firth-Cozens and Greenhalgh[198] investigated the relationship between self-reported stress and inadequate patient care among physicians practicing in the United Kingdom. These authors collected narrative accounts of circumstances "where stress related symptoms have affected your patient care" and coded the narratives according to a previously developed schema for causes of stress and consequences of stress. Causes of stress in the schema included tiredness, overwork pressure, anxiety/depression, alcohol, and boredom. Consequences of stress in the schema included irritability and anger, a lowered standard of care, serious nonfatal mistakes, and patient

deaths. Physicians in the sample were members of a cohort being followed since medical school in 1984. Of 302 surveys, 255 were returned, 76 of which contained answers to an open-ended question about the impact of stress on care, including 82 narratives. Results of coding these narratives indicated that tiredness (57.4 percent) and pressure from overwork (27.7 percent) were most often cited as causes of inadequate patient care, while depression or anxiety (8.5 percent), the effects of alcohol (5.4 percent) and boredom (1.0 percent) were less frequently indicated. The effects of stress on patient care were mainly a lowered standard of care (50 percent) and irritability and anger (40.2 percent), while serious mistakes (7.4 percent) and patient deaths (2.4 percent) were less frequently reported. Two patient deaths were reported and were attributed to tiredness and pressure from overwork. Six incidents of serious mistakes were reported, four of these were attributed to tiredness and two were attributed to tiredness and overwork. The authors caution that their data are self-report by informants and may be biased by informant perceptions and beliefs, but suggest that their data support a model in which tiredness and overwork interact with stress, self-criticism and lowered standards of care in a self-reinforcing cycle.

Shanafelt et al.[199] examined the relationships among working conditions, resident burnout, and patient care practices. An anonymous survey was mailed to 151 resident physicians in a multi-hospital university training program in the Northwest United States. Three quarters of the respondents met the criteria for burnout. Residents with burnout more frequently reported suboptimal patient care practices (defined as errors in medication or treatment, discharge of patients to reduce team workload, paying inadequate attention to the social or personal impact of illness on a patient, and not fully discussing treatment options or answering a patient's questions). Depersonalization, a subscale of the burnout inventory, exhibited a 'dose-response' relationship with self-reported suboptimal care, while the emotional exhaustion and personal accomplishment subscales were not significantly associated with suboptimal patient care practices. Among residents with burnout, positive depression screen results were more common (44/87 vs. 8/28) as was self reported depression (27/87 vs. 3/28) and career dissatisfaction (36/87 vs. 3/28). Stressors contributing to burnout that were identified most often by residents were inadequate sleep (41 percent), frequent shifts over 24 hours in length (42 percent), and insufficient leisure time (42 percent). Personal coping strategies identified as most helpful in dealing with stress were talking with family (72 percent) or talking with other residents (75 percent). Residency program features identified as most helpful for managing stress were having at least four days off per month (97 percent), the availability of ancillary help for patient care (95 percent), and the presence of night float call system (64 percent).

Leppa[200] examined the relationships among disruption of the nursing unit work group, nurses' job satisfaction, and their perceived quality and safety of patient care. Nurses were surveyed to assess job satisfaction and perceived quality and safety of patient care. Nursing unit work group disruption was assessed by measures of absenteeism, turnover, and degree of agency nurse use. The authors reported a) that nursing unit work group cohesion was most strongly correlated with job satisfaction; b) that nursing unit work group cohesion was inversely related to short-term disruption, indicated by the use of agency nurses, but not to long-term disruption, indicated by new hires, terminations, and transfers; and finally that c) the degree of agency nurse use was inversely related to perceived quality of patient care.

Carey[189] has characterized job satisfaction using a multi-component model that includes error orientation, perceived workload, job control, monotony, collectivism and autonomy. Self-report survey instruments were returned by 209 of 710 nurses from a broad spectrum of nursing work

sites and job types in the United States. The survey combined items from extant validated instruments and scales for the work variables listed. A panel of eight subject matter experts was used to assess nursing work types according to the criticality and pace of care, the expertise required, the expected frequency of errors and crises, the amount of stress, and the degree of autonomy associated with each nursing work type. Error orientation, a recent construct in industrial and organizational psychology, is composed of eight subscales: Error Competence (ability to handle errors); Learning from Errors (learning something that can be applied long term); Error Risk Taking (flexibility and openness to errors; Error Strain (stress experienced when errors are made); Error Anticipation (a pessimistic attitude toward errors; Covering Up Errors (seeing errors as a threat within the organization); Error Communication (telling others and asking for help in correcting errors); and Thinking About Errors (analysis of errors).

Error Orientation was found to be correlated with Job Control and Collectivism, but not with Workload or Monotony, although overall the amount of variance explained in a regression analysis was small. Examining subscales of Error Orientation, Job Control was associated with Error Competency (the ability to handle errors when they occur), Learning from Error (learning something that can be applied in the long term), and Error Risk Taking (flexibility and openness to errors). Collectivism was correlated with Error Communication (telling others and asking for help), Thinking About Errors, and Collectivism was inversely correlated with Error Anticipation (pessimism about errors). Increased Workload was correlated with Covering Up Errors, while Autonomy was associated with Error Risk Taking (flexibility and openness to errors). All data in the study were based on self report, and no external or objective measure of either working conditions or error behavior was included in this study.

Overall, there is weak and inconclusive evidence that health professional burnout and dissatisfaction have a significant impact on patient safety.

1. *Do burnout and dissatisfaction affect patient outcomes that are related to patient safety?* Anecdotal data from qualitative studies suggest that physicians attribute some patient deaths to 'overwork pressure' and tiredness,[198] but the evidence is insufficient to answer this question.
2. *Do burnout and dissatisfaction affect the rate of medical errors?* Surveys suggest that pharmacists' dissatisfaction is associated with higher rates of dispensing errors,[196] that burnout among physicians in training is associated with suboptimal patient care practices,[199] and that among family physicians the inability to provide high quality care is associated with career dissatisfaction. Anecdotal data from qualitative studies suggest that physicians attribute some instances of 'serious mistakes' and lowered standards of care to 'overwork pressure' and tiredness.[198] These results are suggestive that higher levels of burnout and dissatisfaction cause higher rates of medical errors, but the evidence is not sufficient to reach this conclusion.
3. *Do burnout and dissatisfaction affect the rate of recognition of medical errors after they occur?* No studies addressed this question.
4. *Do burnout and dissatisfaction affect the probability that adverse events will occur following detected or undetected medical errors?* No studies addressed this question.
5. *Does the complexity of the plan of care affect whether burnout and dissatisfaction affect patient outcomes that are related to patient safety?* No studies addressed this question.
6. *Does stress affect measures of service quality in industries other than health care?* No studies addressed this question.

Physical Environment

Healthcare professionals spend their workdays in a person-made environment that has many physical characteristics, including color, visual and auditory stimuli, thermal quality, and aesthetics. Research on environmental working conditions has been conducted in a variety of industrial settings, and many reports have provided recommendations on workplace design in both healthcare and office settings.[201-211] These recommendations include a variety of lighting and color techniques to improve workers' efficiency and moods. Other environmental factors advocated for the comfort of workers and patients include the provision of indoor plants, fresh air, controlled temperatures, and the presence of windows. Windows perform several functions including admitting light, ventilation, allowance for vision in and out, and providing aesthetic benefits.

Lighting in the workplace has been conceptualized as visual stimuli. Lighting is central to the human visual system and is measured by luminous flux, luminous intensity, illuminance, and luminance.[212] These characteristics directly affect performance of the human visual system, as well as affecting circadian rhythm and metabolic functions. Aesthetically, it has been proposed that lighting also has an impact on human mood and behavior. However, the exact mechanisms by which light characteristics cause psychological and physiological problems are not fully understood.

The science of color consists of the technique of measurement of color, known as colorimetry, the production of color stimuli, and the visual perception of color. Color consists of many dimensions including saturation, value (lightness/darkness), and hues (warm/cool). Color is measured in wavelengths, with longer wavelength colors (reds, yellows, and oranges) being labeled as "warm colors." Shorter wavelength colors (blues, greens and purples) are labeled "cool colors." Most research on the effects of color on humans has explored the impact of warm and cool colors on human feelings, or affect. Longer wavelength colors are labeled as more exciting, while shorter wavelength colors have a calming or quieting effect. However, there has been limited research on the effects of environmental colors on gross and fine psychomotor activities, physical coordination, and human behaviors.

Auditory stimuli include both noise and sound. Noise has been defined as a change in auditory stimuli that has no relationship to the task that is being performed. On the other hand, sound has been defined as auditory stimuli that provide direction to the task at hand. Both noise and sound are complex variables that consist of continuous and intermittent auditory stimuli and loudness, as measured by decibel levels (dBA). In addition, the control one has over the auditory stimuli and the predictability of auditory stimuli can have an influence on how they are perceived.[213]

Thermal stress includes both hot and cold conditions. Measures of thermal stress include air temperature, wind speeds, and the submersion of one's body, or body parts, into cold or hot conditions.

For more than 100 years there has been interest in the impact of the physical environment on patients' ability to heal.[214] A recent systematic review addressed the impact of the physical environment on patients' health outcomes.[215] Eighty-four studies met inclusion criteria for this review. Eleven of the 84 studies examined the impact of auditory stimuli, or noise, on patient outcomes. The patient outcomes included subjective and objective measures of sleep, anxiety, coping, heart rate and respiratory rhythms. Thirteen of the 84 studies examined the impact of light on patient outcomes. Of these 13 studies, the population studied in eleven was neonates.

Outcomes were presence/absence of conjunctivitis, activity levels, heart rate, respiratory rate, bilirubin, sleep/wake cycles, presence of retinopathy, cortisol levels, and weight gain. The two remaining studies evaluated elderly and psychiatric patients. The first study examined the impact of light on serum vitamin D levels. The second study examined the impact of light on length of hospital stay for psychiatric patients. One study explored the impact of windows, a visual stimulus, on the patient outcome of delirium and depression in an ICU. Thermal stress was the focus of 5 of the 84 studies. The population in all of the thermal stress studies was neonates. The outcomes of interest included water and heat loss, mortality, body temperature, vomiting, edema, weight gain, oxygen consumption, jaundice, and cerebral irritation. None of the studies evaluated the relationship of physical environment factors to healthcare working conditions.

Thirteen studies were found to have evidence relevant for assessing the effects of physical environment characteristics on patient safety (Evidence Table 10).[213, 216-227] Three of these studies were conducted in healthcare settings, and the rest were conducted in a variety of simulated or actual workplaces. One study[216] examined an intervention to reduce both ambient light and noise levels in a neonatal intensive care unit, while the others examined single environmental characteristics. Of the studies examining single factors, two examined effects of noise, one examined the effect of cold temperature, and nine examined the effects of light intensity, environmental colors, or presence of windows.

The three studies conducted in healthcare settings all examined medication errors as a measure of patient safety, although one of the studies[216] also measured adverse outcomes (intravenous infiltration, accidental intubation, nosocomial infections, and mortality). The Walsh-Sukys study evaluated medication errors by nurses, while the two other studies[213, 223] evaluated dispensing errors by pharmacists working in hospital-based pharmacies.

Lighting and Color

Laboratory work conducted prior to the 1960s forms the basis of most current recommendations on workplace lighting. This work included studies to determine illumination levels that are appropriate for various tasks, quality of illumination such as brightness and glare, uniformity of illumination, and quantity of illumination. A review of this older literature by Megaw[212] found that there is a relationship between lighting and human performance, but it is confounded by individual characteristics, such as age, hormonal influences, eye functioning, and by task dimensions.

The intensity of workplace lighting has been found to affect the incidence of dispensing errors by pharmacists. Buchanan, et al.[223] found that a markedly increased level of workplace lighting was associated with a 30 percent reduction in the rate of medication dispensing errors. Although only five pharmacists were studied, the benefit of the high lighting level was observed for all five of the study subjects. This study also found no difference in error rates between two lower levels of workplace lighting. Another recent study[216] examined whether reducing levels of lighting in a neonatal intensive care unit affected the incidence of medication errors by nurses. No significant difference in errors was found between the unit with conventional lighting and the unit with lower lighting. These studies suggest that changing lighting levels within the usual range has little effect on medication errors but that substantially increased lighting may reduce error rates.

Five studies in non-healthcare settings examined the effect of the color of the workplace on human performance.[217, 219-221, 226] All five studies were conducted in simulated office environments, and the subjects were college students who were paid or given course credit for their participation. Four of the studies manipulated the color of walls, and the fifth[217] altered the color of the workplace lighting. Two of the studies found significant relationships between color and work performance, but the direction of the effect was opposite in these two. While it is possible that environmental colors impact healthcare workers differently than office workers, these studies suggest that the effects are minor.

Other visual stimuli that have been proposed to have an impact on human performance are plants and windows. No empirical evidence exists to support the popular notion that plants in the work place have a positive effect on human performance. Three studies examined the impact of windows on human performance.[218, 222, 224] Two of the studies were simulated environments, on college campuses. Both studies failed to find significant effects of windows on performance. One study examined the effect of window shape on human performance.[224] This study reported a significant difference between square and round window shapes, with a square window resulting in less error on an observational task. This well-designed study has limited applicability to healthcare settings but may provide insight into such specific tasks as patient monitoring. The methodological and theoretical approaches of this study could be adapted to future studies in the healthcare setting.

The cumulative evidence on the effects of workplace lighting is not sufficient to provide answers to any of the key questions. The strongest evidence is provided by Buchanan's study[223] that found a positive effect of increased workplace lighting on pharmacists' dispensing errors, but this single study does not provide enough evidence to make a recommendation. However, limited further research should clarify whether this finding can be replicated.

Sound and Noise

Smith[228] reviewed the literature between the years 1950-1990 on the impact of noise on human performance and accidents and concluded that noise could be one of many contributing factors to workplace accidents, but the mechanisms are still not clear. We identified one study conducted in a healthcare setting that evaluated the impact of auditory factors on errors (Evidence Table 10).[213] This observational study was designed to determine the impact of sound and noise on pharmacist error. The pharmacists who participated in the study were aware that they were being studied. The study found that some types of auditory stimuli appeared to decrease error, while other types had no impact. None of the measures of sound or noise were found to be increased in the cases having dispensing errors. Another study examined whether reducing both light levels and noise reduced medication errors and adverse outcomes in a neonatal intensive care unit.[216] It found no significant changes in any of the measures of patient safety. One additional study examined the impact of noise on human performance that used methods comparable to those of studies of working conditions in health care.[225] This study used a cross-sectional design to examine relationships between accident rates and workplace noise levels among male textile workers. No significant differences were found in the incidence, frequency, or severity of accidents between low-noise and high-noise work sites.

The studies on workplace noise provide sufficient evidence to answer one key question:

1. *Do noise levels affect patient outcomes that are related to patient safety?* There is evidence from one study that noise levels do not affect safety-related outcomes, but this is not sufficient to provide a definitive answer to this question.
2. *Do noise levels affect the rate of medical errors?* There is sufficient evidence from studies conducted in both healthcare and non-healthcare settings to conclude that ambient noise levels do not affect the incidence of medication errors.
3. *Do noise levels affect the rate of recognition of medical errors after they occur?* There is insufficient evidence to answer this key question.
4. *Do noise levels affect the probability that adverse events will occur following detected or undetected medical errors?* There is insufficient evidence to answer this key question.
5. *Does the complexity of the plan of care affect whether noise levels affect patient outcomes that are related to patient safety?* There is insufficient evidence to answer this key question.

Environmental Temperature

The impact of thermal stress on human performance has been of central interest to professions that are exposed to extreme conditions, such as those that exist at the South Pole, Antarctica, factories, or work conducted in underwater cold conditions. Previous literature reviews[229-231] have concluded that heat affects performance, but this effect was also influenced by the difficulty and complexity of the task being conducted and by individual characteristics, such as age, sex, fitness levels, skill levels, experience, and training. Enander[232] and Enander and Hygge[233] reviewed the effects of cold on human performance and found that, while there is evidence of adverse effects of cold temperature, further methodological and theoretical work is necessary in this area.

We identified no studies examining high levels of heat on human performance relevant to health care, but we identified one study that examined the impact of moderate cold on performance.[227] This study found that cold temperatures impair manual dexterity, which could be relevant to performance of medical procedures in external environments (such as some aspects of the work of emergency medical technicians).

The cumulative evidence on the effects of environmental temperature is not sufficient to provide answers to any of the key questions. The strongest evidence is provided by one study that found manual dexterity to be reduced in a cold environment. This study was conducted using non-healthcare tasks in a simulated environment and does not provide strong enough evidence to make a recommendation.

Organizational Factors

Organizational factors are structural and process aspects of the organization as a whole. For example, work structures such as division of labor or use of teams are organizational factors with potential influences on patient safety. Other organization-level factors include facility size, funding mechanisms (e.g., profit, not-for-profit), hospital type (e.g., teaching, private), and culture. Some organizational factors, such as size and funding base, are difficult to change, while others, such as organizational culture, can be changed through systematic initiatives.

In non-healthcare industries such as aviation and nuclear power, organizational factors have been identified as important for safety improvement.[234-236] Health care has also moved to a

perspective that involves analysis of the organizational system within which errors occur and development of system-level responses.[237-239] A systems perspective requires a focus upon the conditions and processes involved in the delivery of care and examination of how each step in the process contributes to both desired and adverse outcomes. This approach employs failure analysis strategies such as root cause analysis[240, 241] and information management technologies in the analysis and solution of error.[13, 242] In addition to the view that error results from the processes and procedures is the view that considers larger system culture, structure, and the context of practice. In this approach organizational culture and professional perceptions are emphasized.[243]

As health care has focused safety efforts toward the system within which care is delivered and away from the individual provider of care, a terminology of organizational factors has emerged, as evidenced by such phrases as culture of blame, [244, 245] culture of silence, [246, 247] and culture of safety.[248-250] These phrases indicate a clear belief that something about the work environment and in the context of the work itself influences positively and/or negatively the occurrence of errors and adverse events. The non-routine and sophisticated technologies, professional staffs, and dynamic environments found in health care necessitate culture management. [251] Despite culture's importance in high reliability systems,[252, 253] research into the relationship between organizational culture and patient safety remains sparse.

Early studies of the influence of organizational working conditions on patient safety examined magnet hospitals. Spurred by the nursing shortage of the mid 1980s, a number of studies of nursing indicated a need for greater involvement by nurses in hospital governance and working conditions.[254] Concurrently, the American Academy of Nursing examined characteristics of 41 hospitals that, despite the national scarcity of professional nurses, were successful in recruiting and retaining nurses. These hospitals were termed "magnet hospitals" for their ability to attract sufficient nursing staff to maintain high staffing levels.[255] Studies of these hospitals[256, 257] found that several organizational level elements were critical: autonomy, participative management, and support of professional development, relatively high organizational status of nursing, and collaboration.

Much of the difficulty in examining the role of cultural factors in patient safety results from definitional ambiguity. Culture and climate are often used interchangeably and may represent different approaches to measurement of the same phenomenon.[258] Organizational culture definitions are multiple and varied but generally characterize culture as the shared values, norms, and tacit assumptions of members within an organization, while others include more tangible characteristics such as social practices and capacities in the definition.[259]

Current studies define climate specifically, such as safety climate or lateness climate.[260] Further definitional ambiguity is added by use of other terms such as work environment, practice environment, work context, and job context.[261] To add another layer of complexity to the understanding of culture and patient safety is the need to consider national, professional, and organizational cultures[262] in addition to the subcultures within organizations. As workplaces become more diverse, these differing (and perhaps conflicting) types of culture become more salient. For the purposes of this evidence review, culture is defined broadly. Organizational working conditions refer to culture and climate as well as larger organizational influences such as structure.

The International Nuclear Safety Advisory Group (INSAG) coined the term safety culture in response to the Chernobyl incident and defines it broadly as organizational attitudes and structures that place overriding priority on safe plant operations.[263] The Veterans Health

Administration has operationalized a culture of safety that reflects the INSAG definition through 1) public commitments to improving patient safety, 2) resources for special centers, 3) employee education, and 4) incentives to promote safety.[249] Pizzi[264] has identified four factors from the literature that characterize a safety culture: 1) recognition of the risk of error in the organization's activities, 2) blame free environment for reporting, 3) collaboration across the organization, and 4) organizational resources for safety.

Our literature search yielded 19 studies of organizational factors that influence patient safety, and these studies are pertinent to four of the five key questions. Thirteen of the 19 studies provide evidence on the influence of organizational culture on patient safety (Evidence Table 11).[42, 260, 262, 265-274] The other six studies provide evidence about various other organizational factors, such as hospital ownership, team structure, and division of labor(Evidence Table 11).[43, 275-279]

Multiple studies have found that measures of organizational culture are related to the incidence of adverse patient outcomes. Shortell and colleagues[265] examined several organizational variables and organizational culture (using a culture instrument) in relation to various patient outcomes, including quality of care and risk-adjusted mortality. The study used selected items from a standard culture instrument, the Organizational Culture Inventory (OCI), and found significant differences across the hospitals sampled in the patient endpoints. However, little of the variation was associated with the culture measure. A second study[266] compared 39 magnet hospitals with 195 matched controls and observed 4.6 percent lower mortality (adjusted for patient composition) for Medicare patients in magnet hospitals as compared to nonmagnet hospitals. This supports a conclusion that organizational factors such as hospital-level differences in the organization of nursing care have a significant impact on patient outcomes. In a study of AIDS inpatient units, Aiken and her colleagues described favorable patient outcomes associated with a nursing practice environment characteristic of those found in magnet hospitals, including greater responsibility for decision-making and more egalitarian interprofessional relationships.[42] Jones and Redmond used the OCI in a prospective study of organizational redesign in three hospitals.[272] In this study the hospital most successful with redesign efforts and with higher nurse and patient satisfaction scores had a balanced culture, that is, a culture that exhibits characteristics of control and flexibility as well as internal and external focus. The other two hospitals had increases in Hierarchical (rule and procedure driven with control orientation and internal focus) and Market (outcome and market share driven with control orientation and external focus) orientations and concomitant decreases in satisfaction scores. However, this study had inadequate measures of patient outcomes.

A qualitative study[268] of accidents and near misses in an emergency department revealed that two organizational factors (division of labor and power differentials) contributed to the adverse events through poor communication. While these factors or latent conditions existed throughout the organization, the authors attributed the adverse effects on patient safety as especially problematic in an emergency department. This study is suggestive of the negative impact of structural-cultural factors upon patient safety. However it did not examine cases without adverse events in relation to the identified organizational factors and cannot be considered adequate evidence of the negative impact of these factors.

Two cross-sectional studies[43, 279] examined the relationship between organizational factors (hospital ownership and whether or not the hospital was a teaching facility) and mortality rates. Bond and his colleagues[43] found that private ownership (either non-profit or for-profit) was associated with lower overall mortality rates. Teaching status per se was not associated with

mortality rates, but size of the medical residency program was inversely related to overall mortality rates. Schultz and her colleagues[279] also did not find a significant relationship between teaching status and mortality rates among patients with acute myocardial infarction. Significant differences were found for the financial status of the hospitals, with nonprofit hospitals having a lower mortality rate. Both of these studies are limited by having inadequate measures of patient casemix, which limits their value as evidence regarding the effect of these organizational factors on patient safety.

A study that measured organizational culture using standard instruments examined the relationship of culture to what may be considered intervening variables in a model of patient safety. The study[274] used the OCI to gather culture data but did not directly measure the relationship between culture and outcomes. Culture type was associated with quality improvement (QI) implementation, and QI implementation was associated with better patient outcomes (scale included errors and inappropriate treatment). Because this study did not measure direct relationships, it provides only limited evidence on the effect of organizational culture on patient safety measures.

Three studies have examined the recognition and reporting of medication errors in relation to organizational culture. A recent survey study[271] examined culture in relation to medication error reporting. Using a standard measure of culture, the Culture Inventory, there were significant differences in cultures among hospitals, with the larger hospitals tending toward more hierarchical cultures, which are formalized and highly structured, focusing on rules and procedures. Correlations between culture and medication error reporting were non-significant, although in the expected direction, with hierarchical cultures negatively associated and group cultures (those more people-focused) positively associated with reporting. An earlier study[269] used qualitative methods (interview and observation) to assess several aspects of social or unit climate and reporting of errors. A unit ranking on "openness" made by the researcher blind to the quantitative results was matched with detected unit error rates. In general, lower detected error rates occurred on the units with the less open climates. The third study,[273] a phenomenological exploration of registered nurses' reporting of wrongdoing, identified several themes linked with either professional or organizational culture. Nurses' reporting was associated with hospital policies, consequences, professional ideals, and workplace dynamics. While these three studies provide insight into the use of measurement tools for organizational culture, they do not provide sufficient evidence to conclude that organizational culture affects reporting of errors.

Organizational factors have been extensively studied in industries other than health care. One of the largest studies on the influence of national, organizational, and professional cultures upon safety in the aviation industry is that of Helmreich and Merritt.[262] Using a modification of a well-accepted tool for assessing national culture, and expanding existing human factors questionnaires to measure organizational culture and attitudes, the researchers found that specific aspects of culture had significant impact upon error management. There were extensive data on airline crews, especially airline cockpit crews and lesser data on operating rooms. A study of utility company work crews showed a negative correlation between both the cooperation and quality climate subscales and accidents.[260] While using empowerment rather than culture as a variable, a study of chemical company work teams found significant correlation between empowerment and both safe behaviors and accidents; as empowerment increased, safe behaviors increased and accidents decreased.[270] In a study of inattention as a cause of railway accidents in Australia, Edkins & Pollack[276] found that a poor work environment of low morale and other organizational factors contributed to railway accidents. They recommended actions towards

improving the safety culture to decrease inattention errors. A meta-analysis of employee satisfaction and engagement[277] demonstrated a correlation between engagement and safety outcomes across 739 business units in 36 companies. However, an Australian study of values and safety behavior in hairdressers found no support for an effect of manager and employee prevention values on safety behavior.[267]

Two studies in non-healthcare industries showed a positive effect of the use of teams. The first,[275] showed that teamwork and goal setting (compared to goal setting alone) had a significant positive effect on the quality of ore excavated from a silver mine. The second,[278] showed a significant inverse relationship between the use of teams and injury rates in small manufacturing firms.

The multiple studies of organizational factors have used diverse methodologies and have examined a great variety of workplace settings. While they do not provide sufficient evidence to answer any of the key questions, they provide direction to further research in this area.

1. *Do organizational working conditions affect patient outcomes that are related to patient safety?* The studies examining the relationship between organizational culture and the incidence of adverse patient outcomes had inconsistent results, and there are too few studies of other organizational factors to provide sufficient evidence to conclude that any organizational factor has a significant effect on adverse outcomes. Nevertheless, the findings of the studies described above provide a useful framework for further studies to answer this question.
2. *Do organizational working conditions affect the rate of medical errors?* There is insufficient evidence to answer this question.
3. *Do organizational working conditions affect the rate of recognition and reporting of medical errors after they occur?* Three studies provided evidence suggesting that elements of organizational culture affect error-reporting rates, but the cumulative evidence is not sufficient to answer this question.
4. *Do organizational working conditions affect the probability that adverse events will occur after detected or undetected medical errors?* No studies were identified that contributed evidence for this question.
6. *Do organizational working conditions affect service quality in industries other than health care?* A variety of organizational factors have been studied in multiple industries, and these results are highly suggestive that organizational factors affect service quality. However, because of the variety of measurement techniques for both organizational factors and outcomes, there is not sufficient evidence to identify individual factors that could be applied to health care.