# Evidence Report

# Chapter 1. Introduction

## Patient Safety and Medical Errors

The healthcare delivery system includes a broad range of technical resources and personnel. Healthcare services expose patients to the risk of unintentional injuries that can range from trivial and nondisabling to severe permanent disability or death. Efforts to minimize these injuries have led to the patient safety movement, and the generally accepted definition of patient safety is the prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care.[1]

In order for health care to be safe, efficacious, and of high quality, it is essential that there be optimal coordination of the structural and cultural elements of the system.[2] Because this requirement is not always met, medical errors occur, and patient safety is threatened. The sources of error are diverse, including failure of process safeguards, faults in equipment, or lack of teamwork. Patient safety is thereby dependent on the optimal interactions of the components of the healthcare system, with errors being minimized. A medical error is defined as the failure of a planned action to be completed as intended ("error of execution") or the use of a wrong plan to achieve an aim ("error of planning").[1] Because of the complexity of the healthcare system, errors may occur in hospitals, outpatient clinics, nursing homes, pharmacies, urgent care centers, and patients' homes.

Distinguishing between active and latent error provides insight into the need to understand a work process and its weaknesses.[3] Active errors occur at the level of the frontline operator, and their effects are felt almost immediately. Latent errors are removed from the direct control of the operator and include poor system design and poorly structured organizations. Latent errors pose the greatest threat to safety, because they often are unrecognized and have the capacity to result in multiple types of active errors. A focus on active errors lets the latent failures remain in the system, making the system even more prone to future failure. The key to reducing errors is to focus on improving the systems of delivery of care as well as the performance of individual workers.

Clinicians and managers accept that efforts should be made to reduce errors, but the best strategies for error reduction have not always been well understood. In recent years, systematic efforts to improve quality have become widespread,[4] and there has been progress in understanding how the processes and outcomes of care are related.[5, 6] The progress in quality improvement in health care has led to an environment of proactive approaches to recording information about the processes of clinical care that makes investigations of medical errors more feasible.

Contemporary research on patient safety has its origin in the examination of adverse outcomes of care. Adverse outcomes are defined as injuries caused by health care rather than by underlying disease. While not all adverse events are preventable, some are due to preventable errors. Adverse outcomes were first systematically measured in a study conducted by the California Medical Association in the 1970s.[7] The study found that significant adverse events occurred in 4.65 percent of hospitalizations. Two subsequent large-scale studies reported adverse event rates of 3.7 percent[8] and 2.9 percent.[9] By pooling the data from multiple studies, it has been estimated that significant adverse events occur in 3 to 4 percent of hospitalizations.[10] Patients undergoing surgical procedures account for two-thirds of all adverse events.[11] There has

been less examination of the incidence of adverse events among outpatients. One study reported the rate to be less than one per 10,000 clinic visits, but this is undoubtedly an underestimate.[12]

While the earlier studies focused on negligence as a cause of adverse events, other research examined errors due to faulty implementation of systems of clinical care. Optimal clinical systems feature safeguards to compensate for simple mistakes made by individual clinicians. In one study, failures at the system level were responsible for 75 percent of adverse drug events.[13] System improvements have also been shown to reduce error rates and improve the quality of health care. The Agency for Healthcare Research and Quality (AHRQ) recently published an evidence report on patient safety practices, defined as processes or structures whose application reduces the probability of adverse events resulting from exposure to the health care system. When applying this definition, the report focused on a broad range of specific health care practices, most of which are applicable only to the inpatient setting.[14]

## Purpose and Scope of this Report

The purpose of the current report is to compile and summarize existing evidence on the aspects of the work environment that impact patient safety. While much of the relevant evidence comes from research conducted in healthcare settings, this report also has compiled evidence from the large body of human factors research conducted in the non-healthcare setting. This non-healthcare evidence provides insight into how work environment changes may improve patient safety.

Theoretical and empirical research from industries such as aviation and nuclear power provide a basis for a classification system of working conditions. This work allows us to organize the evidence derived from research conducted in healthcare and non-healthcare settings. The classification system used for this report is consistent with definitions used in the human factors research field.

We convened a panel of experts to define the working conditions addressed in this report. The panel identified five distinct categories of working conditions, as follows:

- Workforce staffing
- Workflow design
- Personal/social
- Physical environment
- Organizational factors

A common feature of these five categories is that the working conditions are potentially amenable to change. However, the resources needed to bring about change can vary greatly across the categories. For example, changing physical environment working conditions usually requires control over the mechanical and aesthetic aspects of healthcare facilities. Alternatively, changing staffing conditions requires access to financial resources and deployment of workers across organizational levels.

The audience for this report includes clinicians, health system managers, policy makers, and health services researchers. Individual clinicians can use the information in this report to improve their understanding about how features of their jobs affect their professional performance. This understanding can then be used to evaluate whether any changes in their own

job procedures are indicated. Health system managers can use the information to evaluate how changes in the organization of clinical delivery systems can achieve improvement in patient outcomes. Policy makers can use the information to guide decisions about resource commitments for system changes and research priorities. Health services researchers can use the information to identify gaps in knowledge that can guide new research initiatives.

## Definitions of Working Conditions

Because the definitions of working conditions formed the basis for literature search strategies used in this project, a systematic process was used to solidify the definitions at the beginning of the project. A panel of experts on working conditions was identified and convened for a one-day meeting in November 2001 in Portland, Oregon. The members of the panel, listed in Appendix A, included healthcare researchers and human factors researchers in other fields such as aviation. The charge to the expert panel was to gain consensus on a classification system for working conditions that was broad enough to include all-important research relevant to patient safety. The panel was also asked to help with the conceptualization of the problem and definition of key questions to be addressed in the report. The panel was provided with background information on patient safety and a framework for understanding how patient safety is related to healthcare delivery.

The expert panel provided guidance on the categorization of working conditions that would permit sufficient coverage of all pertinent existing literature. Working definitions of the five categories then needed to be finalized before initiating the literature searches. These definitions were further refined during the search process and following review of all search results. Because the relevant literature needed to be assigned to single categories for reporting the evidence, the definitions were constrained so as to avoid overlap across categories. Specific factors (such as seasonal effects) that could reasonably be assigned to multiple categories were assigned to the category that was the closest fit. The final definitions of each category are summarized in the following sections.

### Workforce Staffing

Workforce staffing refers to the job assignments of healthcare workers. It includes four principal aspects of job duties:

1. The volume of work assigned to individuals. This has been defined in different ways depending on the nature of the job assignment. For pharmacists it has been defined as the number of prescription orders filled per day. For nursing staff, it has been defined as the number of patients cared for during a work shift. For physicians, it has been defined as the number of a certain procedure (such as coronary arteriography or resection of a gastric carcinoma) performed per year. The most common hypothesis is that higher workload is associated with a larger rate of errors and/or adverse outcomes. However, most research on physician performance has been based on the hypothesis that higher workload is associated with a lower error rate, due to differences in the unit of measurement and nature of clinical tasks.

2. The professional skills required for particular job assignments. This has usually been defined as attainment of advanced academic degrees or specialty certifications. However, some research has examined the effects of focused training programs for existing staff members. The usual hypothesis has been that higher levels of prior training are associated with lower error

rates. Current concerns over the demographic trends toward a shrinking workforce for some professional areas (particularly nursing) has also led to research on the effects of shifting some job duties to less highly trained personnel (such as using unlicensed personnel for performance of nursing tasks and using pharmacy technicians to provide pharmacy services as allowed by state/federal law).

3. The duration of experience in a particular job category. Duration is usually measured as the number of years an individual has worked in a particular job category. Some studies of physicians in academic settings have used faculty rank as a measure of experience. The most common hypothesis is that longer experience is associated with lower error rates.

4. Effects of work schedules, including length of shift, days of the week worked, and temporal cycle effects (such as influence of time of week or season of year). A common hypothesis is that longer work shifts are associated with a greater incidence of errors.

## Workflow Design

Workflow design focuses on the process of delivering health care. Healthcare facilities are complex collections of simpler units organized to support the workflow to deliver patient care.[15] Workflow design encompasses the interactions among workers and also between workers and the workplace. It also includes the nature and scope of the work as tasks are completed. In health care, as in other industries, hazards to workers and patients can be evaluated by examining specific work processes.[15] This allows for the analysis of risks in the system and the impact of those risks on the worker and patient. A useful framework for analyzing workflow design integrates approaches from several disciplines, including organizational psychology, industrial engineering, biomechanics and ergonomics.[16] For evaluating patient safety, workflow design includes task design and workplace design relevant to accomplishing the tasks. Task design includes such job characteristics as redundancy, complexity, distractions, and transfer of information and responsibility to others ("hand-offs"). Workplace design considers worker ergonomics for technology and equipment.

## Personal/Social

This category of working conditions is concerned with the personal, professional, and social aspects of the healthcare work environment. The personal factors include stress, burnout, dissatisfaction, motivation, and control over work. Social factors include interrelationships among workers, such as collectivism, role ambiguity, discord, and support. Professionalism includes the values that are cultivated within professional disciplines such as nursing or clinical pharmacy.

## Physical Environment

Physical environment working conditions include direct physical characteristics such as light, aesthetics, noise, air quality, toxic exposures, temperature, and humidity. This category also includes basic workplace design features, such as obstacles, physical layout, and distance from nursing stations.

### Organizational Factors

Organizational factors are structural and process aspects of the organization as a whole. For example, work structures such as the use of teams and the division of labor are organizational factors with potential influences on patient safety. Other organization-level factors include size, funding mechanisms (e.g., profit, not-for-profit), hospital type (e.g., teaching, private), and culture. Some aspects of the organization, such as size and funding base, are difficult to change. Other aspects, such as the use of team structures and culture, are more amenable to change. Organizational culture is what employees throughout an organization perceive and how this perception creates a pattern of beliefs, values, and expectations. Specific characteristics of organizational culture include managerial style, evaluation and reward systems, economic effects, hierarchy, accountability, decision latitude, and employee feedback.

## Analytic Framework

Our goals in constructing an analytic framework were to elucidate the major concepts pertinent to the work environment and the theoretical linkages between concepts. Our analytic framework is based on a model that characterizes working conditions as factors that can either improve work quality (referred to as resources) or impede work quality (referred to as demands).[17-19] The quality of work in turn affects patient safety and patient outcomes.

Antecedent variables can also affect human performance. Antecedent factors can potentially moderate the effect of working conditions on patient safety, which in turn influences patient outcomes. These variables include personal characteristics of workers and structural characteristics of the system that cannot be changed. They include worker age, gender, personal health, job commitment, geographic location, and regulations and legislation that affect the healthcare system (Figure 1). Some research has been conducted on the influence of these factors upon the job performance of health professionals. For example, professional impairment due to chemical dependency, psychiatric impairments, or other medical conditions upon job performance has been an important area of inquiry.[20-23] Since these antecedent variables were not classified as working conditions, research in these domains was not reviewed for this report.

In order to synthesize data reported in studies, it also is necessary to have a model of patient safety. We have extended a model originally developed by the federal Quality Interagency Coordination Task Force.[24] Our model (Figure 2) uses Haddon's system of analyzing injuries, with pre-injury, injury, and post-injury phases.[25] It also incorporates Reason's model of accidents based on system processes and human errors.[3] Because it includes elements of both processes and outcomes, this model provides a framework for classifying and tabulating the types of data reported in studies of working conditions in health care.

This report does not consider evidence about other effects of working conditions on health professionals, such as injuries, turnover, or absenteeism (though these are obviously important in their own right), except where they are included with more direct measures of patient safety or harm. Similarly, this report does not consider evidence about other effects of working conditions on clinical practices, such as measures of the relative desirability or quality of care, except where the focus is on errors or patient safety. Finally, the relationship between clinical practices and patient outcomes is often neither direct nor certain. Even when clinical practices are ideal, patients may or may not improve, and may even deteriorate (Figure 2). Likewise, when errors do occur, patient outcomes may or may not reflect this (a "close call" is an error that

does not lead directly to an adverse event). Further complicating this picture is the substantial disagreement that exists in expert judgments about whether errors have occurred and whether, when they have occurred, adverse outcomes have been the result.[26, 27]

## Key Questions

Our set of key questions was derived directly from the analytic framework. The core group of key questions applies to all five categories of working conditions. The key questions permitted the research team to classify the entire body of evidence for each category and to derive a judgment about the strength of evidence regarding the contribution of the working condition categories to overall patient safety. The six key questions are:

1. *Do working conditions affect patient outcomes that are related to patient safety?*
2. *Do working conditions affect the rate of medical errors?*
3. *Do working conditions affect the rate of recognition of medical errors after they occur?*
4. *Do working conditions affect the probability that adverse events will occur following detected or undetected medical errors?*
5. *Does the complexity of the plan of care influence whether working conditions affect patient outcomes that are related to patient safety?*
6. *Do working conditions affect measures of service quality in industries other than health care?*

## The Evidence-based Approach

An evidence report focuses attention on the strength and limits of evidence from published studies about the delivery of health care. The development of an evidence report begins with a careful formulation of the problem. In this phase, a preliminary review of the literature and input from experts, stakeholders, and patients may be used to identify the patient populations, interventions, health outcomes, and harms. An evidence report also emphasizes the quality of the evidence, giving more weight to studies that meet high methodological standards that reduce the likelihood of biased results. An evidence report pays particular attention to the generalizability of studies performed in controlled or academic settings. Studies that reflect actual clinical effectiveness in unselected patients and community practice settings are highlighted.

In the context of developing clinical guidelines, evidence reports are useful because they define the limits of the evidence, clarifying when the assertions about the value of the intervention are based on strong evidence from clinical studies. The quality of the evidence on effectiveness is a key component, but not the only component, in making decisions about clinical policies. Additional criteria include acceptability to physicians or patients, the potential for unrecognized harms, and cost-effectiveness.

## Previous Systematic Reviews

In conducting the literature reviews that formed the basis of this report, previously performed systematic reviews were identified and are summarized where pertinent in the following

chapters. When possible, we avoided duplicating work reviewed in other good-quality evidence reports and systematic reviews. Of particular note is AHRQ Evidence Report/Technology Assessment Number 43 (*Making Health Care Safer: A Critical Analysis of Patient Safety Practices*), published in 2001.[14] That report summarizes evidence on a variety of patient safety practices and includes information on several types of workflow design working conditions and also on some other categories of working conditions. Another notable systematic review examined the relation of hospital volume to quality.[28]