

Research Methods

Studying Patient Safety in Health Care Organizations:

Accentuate the Qualitative

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The study of patient safety in complex, dynamic, and idiosyncratic health care environments is challenging. It requires a diverse array of theoretical and methodological approaches, some of which can take into account the social, subjective, and contextual underpinnings of adverse medical events. This article emphasizes the need for and benefits of taking a more diverse approach to studying safety in organizations. The learning objectives include: (a) highlighting the complexity of how patient safety and medical errors play out in the everyday clinical setting, (b) identifying methodological approaches that capture this complexity and allow for more people-focused, contextually based, and “real-time” study of patient safety and medical errors in the everyday clinical setting, (c) highlighting the need to complement the use of deductive, quantitative approaches to studying safety and error in health care organizations, and (d) identifying action steps for health care organizations interested in conducting qualitative studies of safety in their work settings.

Paying Attention to How Patient Safety Is Studied

The idea that every stakeholder involved in health care is concerned about quality care and the reduction of medical error is uncontested. The U.S. Agency for Healthcare Research and Quality spends the majority of its research funding on patient safety. Private sector alliances such as The Leapfrog Group push insurers and providers to improve the quality of their services. Think tanks such as the Institute of Medicine provide thoughtful, detailed opinions on the issues. The Joint Commission on Accreditation of Healthcare Organizations incorporates

Article-at-a-Glance

Background: The study of patient safety can benefit from greater methodological diversity to improve scientific knowledge and to increase the effectiveness and tailoring of strategies aimed at improving it.

Methodological Diversity to Better Capture Causal Mechanisms and Processes: Additional methods for studying patient safety and errors to reflect the complexity of what goes on within health care organizations should be made routine. Interviews, focus groups, and observation—the predominant methods used in qualitative research—are infrequently used in health services research, generally and specifically in the study of errors and patient safety. However, they offer several advantages over quantitative designs. They often are less expensive and quicker to implement; they may not need a lot of advance work; and they can be used to study retrospectively a particular failure event, outcome, or situation.

Action Steps: Organizations can use an action agenda to better implement and promote the use of qualitative methods. Implementing these action steps can help achieve the attributes—trust, honesty, communication, participation, and efficiency—necessary to facilitate the qualitative approach in health care work settings.

Summary and Conclusion: Qualitative approaches should be used in studying patient safety as a complement to (not a substitute for) quantitative approaches. They can be implemented more easily in organizations through structural and cultural adjustments that provide a more supportive foundation for this work.

Table 1. Approaching the Study of Patient Safety in Organizations: Rationale for Using Diverse Methods and Examples

- Health care organizations are complex, chaotic, and dynamic work environments. These realities shape safety related efforts, and therefore the study of patient safety issues must embrace this complexity, chaos, and dynamism instead of controlling for and ignoring it.

Example: Studying patient safety in an emergency room or trauma setting, where events unfold quickly, and there is little certainty related to work flow and types of services given, benefits from "real-time" data collection that can capture a reliable picture of events at the point in which they occur, in addition to researchers being able to see all relevant contextual factors in play.

- The study of patient safety in organizations can benefit from more people-oriented, "real-time" contextually focused research approaches that emphasize relatively inexpensive and incremental knowledge building about patient safety enhancement and error reduction, even if it is less generalizable.

Example: When an error or near miss occurs, individuals involved in the event can be asked right away what they thought of the event, why it happened, and what can be learned from it. These vignettes can be collected and integrated to determine larger patterns that then can be tested empirically.

- Each methodological approach to studying patient safety enables one to see some things clearly and miss other things completely. One must start with an understanding of what needs to be seen, then pick which methods to use. There is no "gold standard" for patient safety research.

Example: If the focus is near misses, as opposed to adverse events, different methods may be needed in the way of direct observation of clinical settings and discussions with physicians and nurses because near misses may never be documented or recorded anywhere.

- Qualitative methods such as observational and interview approaches work best in situations where important work processes are hidden from view, where key aspects of the work context change unpredictably and fast, and where less is known about what people think, how they act, and how they make sense of their behaviors within a culture.

Example: The communication between physicians and patients that occurs in exam rooms is often hidden from view. Observation of such interactions, as well as interviews and focus groups, with each of these two parties soon after an exam room interaction occurs can help develop a descriptive picture of the various types of interactions possible and determine whether or not the interactions enhance or undermine patient safety in any way.

it meaningfully into its standards. Advocacy groups, managers, health care providers, and patients each emphasize from their own perspectives that attention to patient safety and error reduction are meaningful issues about which not enough is being done.

Although consensus on the importance of the topic is laudable, consensus that restricts the range and variety of methods used to study patient safety is not. The complexity and dynamism of patient safety phenomena require that individuals and organizations interested in studying it adopt a diverse set of approaches and focus on learning: (a) how different methods work, that is, their strengths and weaknesses, costs and benefits, what is seen and missed, and (b) the extent to which different methods incorporate rather than control for the inherent complexity, chaos, and dynamism that typifies health care work settings.

The basic argument is that context matters, as well as time, and that research must incorporate considerations of both context and time to matter (Table 1, above).

Organizations must pay greater attention to conducting timely studies of error and safety that occur in proximity to events as they occur in their natural environments. When untoward events occur, it is not always clear whether we are dealing with "errors" or with the unintended consequences of attempted solutions enacted in ambiguous, ill-structured environments.¹ In addition, it is important to understand the multileveled nature of work systems. Individuals are embedded in groups and units, which are embedded in organizations, which in turn are embedded within larger environments that involve government oversight, competition, and advocacy groups.² Thus, safety is shaped both by bottom-up and top-down elements, which means

that managers and researchers must understand that there are various levels of change to be targeted within organizations for patient safety improvement. These different change levels may require different methodological approaches.

For example, qualitative methods are suited particularly for studying intraorganizational processes around error and safety.^{3,4} They are also advantageous because they can be implemented quickly; can be performed soon after error events occur; reflect workplace variety; develop a rich description about how things work “in the trenches” of patient care; achieve intensive examinations of single error incidents and cases; emphasize the discovery of hidden cultural realities that define people’s attitudes and behaviors around safety; and focus on developing, testing, evaluating, and then modifying incremental interventions in real time.^{4,5} Some of these methods are already being used in health care. For example, root cause analysis (RCA) uses qualitative techniques such as interviewing, personal testimony, and chart review to develop contextually-based pictures of a given work environment at the time of a specific error or adverse event.

Overemphasizing any single methodological approach (for example, large-sample quantitative designs) to studying patient safety to the exclusion of others at this early point is bound to constrain the advancement of scientific knowledge as well as the types of changes that are envisioned and implemented. It may even result in effects contrary to what is intended—reducing errors and creating safer environments.⁶ The rush for quick solutions may encourage researchers to overlook or ignore other viable research methods that may better accommodate the contextual realities of today’s health care organizations, focus on what the people directly involved in the work of health care think about safety and errors, how they act and interact around these issues, and how the myriad of contextual factors in their everyday workplace shape these attitudes and behaviors.⁷

Studying patient safety through the use of highly quantitative, “neat and clean” empirical studies (for example, case-control designs) may produce patient safety “improvements” that seem generally sensible but work nowhere in particular. Such studies tend to oversimplify the organizational environment to the point of

fantasy.⁸ Qualitative research compliments quantitative approaches because it enables individuals and organizations to gain a deeper understanding of a process or phenomenon as it exists within its own unique environment.⁹ It does not control for the environment but instead acknowledges it as a key actor that shapes how the process or phenomenon looks and plays out on an everyday basis.⁷ For example, a computerized prescription order entry (CPOE) system—an intervention assumed to be universally favorable in reducing prescription errors—may enhance patient safety in one clinical setting but may increase error risks in other settings.¹⁰ A qualitative approach focusing on comparing and contrasting the two settings may yield important insights into the nature of why this difference exists. By using interviews and observation to delve into dynamics such as how the CPOE is being implemented on an everyday basis, the ease or difficulties associated with using the local system, how key medical personnel feel about using it, and the orientation of personnel to solve or work around problems, researchers can gain a more nuanced insight about the contextual variables surrounding the CPOE technology itself and how these variables influence the relationship between CPOE and a reduction in prescribing errors.

Embracing the Complexity of Health Care Settings

There is a tendency to oversimplify what goes on within organizations, and health care organizations are no exception. This oversimplification is both a cause and consequence of the methods used most often by researchers, clinicians, and managers. Sources of complexity in health care settings result from the inevitable blend of art and hard science that pervades many approaches to diagnosis and treatment,¹¹ the fragmented nature of the delivery system,^{1,12} fast-moving technological, clinical, and financial changes,¹³ the different economic and social structures of health care markets,¹⁴ a continued lack of control by organizations over physicians,¹⁵ the hidden nature of much medical work,¹⁶ and strongly entrenched professional, scientific, technical, and managerial cultures that bring into the medical workplace their own beliefs about how to do things “right.”¹⁷

It is in embracing the “why” and the “hows” of this complex reality, rather than ignoring it away and focusing only on the “what” of medical errors, that we open ourselves up to using a variety of diverse methodological approaches. Moreover, to truly advance scientific knowledge in the patient safety domain, rather than simply to “solve problems,” diverse methods are a necessity.⁴

The scientific theory-building process is built through a cycle of observation, induction, and deduction. Because observation is such a large part of our daily lives, it is often the starting point:

Scientific thought takes its ultimate point of departure from problems suggested by observing things and events encountered in common experience; it aims to understand these observable things by discovering some systematic order in them; and its final test for the laws that serve as instruments of explanation and prediction is their concordance with such observations.^{18(p. 326)}

Studies of patient safety must use methods that capture people’s insights and understandings about what causes events and how things work at the point of production in health care (whether rational or irrational, good or bad). Without these understandings, theories of how to control events may be incorrect. For example, a common theory borrowed from aviation is that error-reporting systems will improve safety. But the applicability of this theory to the issue of medical error may need to be revisited, as some current studies suggest—not because it is incorrect but because of the differences between the aviation and health care work settings.

Examples

Two examples, which come from recent fieldwork study using extended observation and interviews, illustrate the complexities of health care settings.

Example 1. On the basis of the findings, at least within the single academic medical center studied, one might be hard pressed to establish a reliable error reporting system, quantify the full range of errors and near misses occurring on a daily basis, implement safety-oriented continuing medical education programs, or ask the physicians to take a more “learning oriented” approach to errors—all widely accepted safety interventions—without first attending to the potential realities of disengaged and/or frightened physicians,

cultures of competitiveness among health care personnel, and fatigue-producing work contexts, as represented in the following excerpts:

I don’t like particularly to bring up or talk about errors any more. Even with residents. A lot of it is because I feel burned. I made a mistake once...and I talked with another surgeon about it. Just on the side. Informally. Wouldn’t you know it, a year later I’m getting sued for the thing by the patient and the lawyer is deposing my colleague, asking him about what I said and when I said it. That convinced me that these things can’t often be shared. With anyone. Regardless of the reason. That one incident affects my whole outlook on the issue of errors.
— *Attending surgeon on the hospital trauma team*

I saw the senior resident struggling to put the trach tube in. It drove me nuts to watch this. She is struggling, the attending is getting mad...not really confronting her directly but rather talking around her, and the resident is yawning under her mask, opening her eyes dramatically like she is having trouble focusing. She looked dead on her feet. So did he. Who wouldn’t be after a morning and afternoon of nonstop procedures? I was exhausted and all I did was watch. So, finally, after watching the resident struggle without offering any feedback, the attending just grabs the tube and puts it in himself. No “what’s wrong?” Nothing said that makes any constructive sense. He’s just mumbling the whole time to no one in particular. The resident doesn’t say a word. I never hear anything about it after the procedure, and I hung around for a couple of hours with the team. Who picks up on this stuff? How many of these near misses, and even mistakes, fall into the abyss and never get examined? Why is this happening?

— *Observation by a research team member of a tracheotomy procedure in the operating room*

These observations might lend credibility to a conclusion that error-reporting systems grossly underestimate errors. Yet these insights are not generalizable in the statistical sense. But they are meaningful and important, especially if they are present on a wider scale within an organization.

Example 2. A researcher was recently involved in a project in which several hospitals implemented clinical guidelines specifying the appropriate prophylactic approaches to prevent hospital-acquired deep vein

thrombosis (DVT) in patients; the absence of such prophylaxis for indicated patients is viewed as a medical error. On the basis of a literature review and opinions of clinical experts, and because it made sense from a medical standpoint, clinicians concluded that it was logical to implement this AHRQ-lauded best practice.¹⁹

However, after the guideline was launched, few physicians in the hospitals appeared to be using it in the intended manner, and rates of appropriate DVT prophylaxis did not increase as hoped. What happened? Perhaps the initiative was implemented in too strict a way, rankling physicians, who then resisted. Yet in any case the research team could not answer because the research emphasis was placed exclusively on performing a pre-post (guideline implementation) statistical analysis of outcome changes related to the number and type of DVT cases seen in the hospitals. When the desired and anticipated decrease in the incidence of DVTs did not materialize, it soon became apparent that the research design was inadequate to capturing data around the implementation of the guideline itself. In addition, given that physicians' use of the guideline had been assumed from the start, no data collection methods were prospectively employed to determine whether the guidelines were being used at all or in the intended manner and whether any specific barriers undermined guideline use.

As shown by these examples, research methods that can ferret out highly specific and essentially unique items of contextual information (which then can be synthesized into more general propositions which summarize observed uniformities of relationships between variables) are important sources of insight for clinicians, managers, and researchers, particularly at early stages in theory development. When research methods of this kind are used simultaneously with the design, implementation, and evaluation of safety-focused interventions, better understanding is gained of the processes leading to success or failure of the intervention.⁴

Methodological Diversity to Better Capture Causal Mechanisms and Processes

Additional methods for studying patient safety and errors should be made routine within organizations. Table 2 (pages 10–11) compares quantitative and qualitative

approaches. Interviews, focus groups, and observation, the predominant methods used in qualitative research,⁹ are infrequently used in health services research, generally²⁰ and specifically in the study of errors and patient safety. However, they offer several advantages over quantitative designs. First, they often are less expensive and quicker to implement.⁹ For example, an observational study requires only an observer and the time for that person to observe. Basic analytic skills can also be obtained in a timely manner. Unlike survey and case-control designs, qualitative designs may not need a lot of advance work. This makes them ideal for studying safety or error situations as the situations unfold in real time. Qualitative methods can also be used quickly to study retrospectively a particular failure event, outcome, or situation, such as in the conduct of RCAs or in support of prospective risk assessment (for example, Failure Mode and Effects Analysis) of a particular health care process or system. These advantages may be important for an organization lacking the resources for patient safety research, when there is a high degree of uncertainty about which types of safety or error issues will emerge, and when time is of the essence in understanding how to solve a particular patient safety or errors problem.

Research involving observation, interviews, and focus groups may also be used in tandem with case-control studies, surveys, and research rooted in chart review.²¹ Because they enable organizations to see things that quantitative methodologies cannot, they offer additional predictive or explanatory firepower in patient safety research. Qualitative research explores the particular ways that the relationships among and between the variables are manifested.²¹ It ferrets out key information to help understand implementation dilemmas within organizations. It also enriches the causal story by going beyond the identification of causal relationships to explain the mechanisms connecting two (or more) causally related variables.

Taking one of the previously described examples, consider how a research team's study of processes as well as outcomes would have increased its understanding of a medical error, such as not administering DVT prophylaxis in indicated patient cases. These processes would include how physicians thought about a DVT prophylaxis guideline, how they viewed the specific guideline, the "fit" of the guideline within the larger context of

Table 2. Advantages and Disadvantages of Different Methodological Approaches to Studying Patient Safety*

Criterion	Observational studies [†]	Interview/focus groups	Case-control/quasi-experimental/pre-post statistical comparisons	Cross sectional survey (e.g., providers, patients)	Chart review
Data	<p>Qualitative</p> <ul style="list-style-type: none"> • Errors and near misses that go undetected • Safety issues, errors, and near misses that participants do not recognize as such • Underlying work culture in relation to safety and errors • Dynamic interaction of multiple variables around safety and error 	<p>Qualitative</p> <ul style="list-style-type: none"> • Mindsets, beliefs, values, and experiences that may illuminate motivations for individual attitudes and behaviors in relation to safety and errors • What different stakeholders at the point of production think about in relation to specific safety and error issues • Underlying work culture in relation to safety and errors 	<p>Qualitative</p> <ul style="list-style-type: none"> • How a specific error or safety variable/outcome looks before and after implementation of some specific intervention 	<p>Quantitative</p> <ul style="list-style-type: none"> • Mindsets, beliefs, values, and experiences that may illuminate motivations for individual attitudes and behaviors in relation to safety and errors • Point-in-time statistical relationships between multiple variables around safety and error 	<p>Qualitative/Quantitative</p> <ul style="list-style-type: none"> • The dynamic flow of the clinical decision making process around specific safety/error situations • Actual clinical behavior and decisions around specific safety/error issues • Overall clinical context within which specific patient care decisions are made
What you miss	<ul style="list-style-type: none"> • The ability to assert a widespread relationship between any workplace dynamics/interventions and enhanced safety/reduced errors • The ability to isolate single dynamics or interventions and study their unique effect on specific safety/error outcomes 	<ul style="list-style-type: none"> • Dynamic interaction of multiple variables around safety and error • How a specific error or safety variable/outcome looks before and after implementation of some specific intervention 	<ul style="list-style-type: none"> • Dynamic interaction of multiple variables around safety and error • The ability to record systematically how a single intervention to enhance safety/decrease errors interacts with other contextual variables over time • Errors and near misses that go undetected • Underlying work culture in relation to safety and errors 	<ul style="list-style-type: none"> • Dynamic interaction of multiple variables around safety and error • Actual instances of errors or safety issues occurring in real time • Actual instances of errors or safety issues occurring in real time • Event processes that do not end up described in charts 	<ul style="list-style-type: none"> • Errors and safety issues that do not end up written in a chart • Safety issues, errors, and near misses that participants do not recognize as such • Actual instances of errors or safety issues occurring in real time • Event processes that do not end up described in charts
Core Requirements	<ul style="list-style-type: none"> • Individuals with time to observe who can be viewed favorably by targets of observation 	<ul style="list-style-type: none"> • Individuals willing to spend time to provide data and open up honestly in relation to their thinking around safety/error issues 	<ul style="list-style-type: none"> • Pre-/postintervention data on outcome/variable of interest • A clear intervention to implement • Comparable groups/settings/situations 	<ul style="list-style-type: none"> • A well-designed survey with valid and reliable items/questions; easy way for subjects to complete • Individuals willing to spend time to provide data and open up honestly in relation to their thinking around safety/error issues 	<ul style="list-style-type: none"> • Detailed, well documented medical records; trained personnel to review
Drawbacks to conducting	<ul style="list-style-type: none"> • Can be intrusive on settings and observational targets • Can be time intensive 	<ul style="list-style-type: none"> • Can get nonresponsive/honest participants • Can be time intensive 	<ul style="list-style-type: none"> • Need full participation of individuals responsible for using intervention • Can be a numbers problem in terms of having enough outcomes to measure change • Randomizing controls or placebos may be problematic because of nature of issue (safety) 	<ul style="list-style-type: none"> • Need adequate participation of respondents to ensure adequate sample sizes • Can be expensive 	<ul style="list-style-type: none"> • Reviews only as good as documentation in charts • Can be time intensive and expensive

Table 2. Advantages and Disadvantages of Different Methodological Approaches to Studying Patient Safety* (continued)

Criterion	Observational studies [†]	Interview/focus groups	Case-control/quasi-experimental/pre-post statistical comparisons	Cross sectional survey (e.g., providers, patients)	Chart review
Primary units of analysis	<ul style="list-style-type: none"> The people, their interrelationships, their culture, and the surrounding work context Specific, emerging error and safety situations 	<ul style="list-style-type: none"> The people, their interrelationships, their culture, and the surrounding work context Specific error and safety situations 	<ul style="list-style-type: none"> The intervention or “treatment” implemented Pre-post changes in specific error or safety outcomes 	<ul style="list-style-type: none"> The people, their culture, and the surrounding work context 	<ul style="list-style-type: none"> Actual clinical decisions made Aspects of clinical decision making
Specific patient safety issues which can be studied (sample studies)	<ul style="list-style-type: none"> Improving the safety of heparin administration through changes in the medical work process (Harder et al., 2005) How work culture shapes error response/reporting (Hoff, Pohl, and Bartfield 2005) 	<ul style="list-style-type: none"> Identification of barriers to improving work processes that produce errors (Bayley et al. 2005) Improving decision support alerts for outpatient prescribing (Feldstein et al. 2005) 	<ul style="list-style-type: none"> Impact of physician use of a piece of technology on medication safety (Galt et al. 2005) Impact of a provider education program on physician adherence to a beta blocker clinical guideline (Quinn et al. 2005) 	<ul style="list-style-type: none"> Identification and assessment of relative importance of barriers to error reporting among health professionals (Harper and Helmreich 2005) Relationship between employee feelings/attitudes and rate at which medical errors are reported (Wakefield et al. 2001) 	<ul style="list-style-type: none"> Medical errors that do not lead to adverse events (Resar, Rozich, and Classen 2003). Examining physician compliance with a surgical antimicrobial prophylaxis regimen (Savino et al. 2005)

* These approaches are not mutually exclusive. Often, they overlap within the same research study.

† Observational studies in this case refer only to studies in which there are one or more individuals who act as participant or non-participant observers, recording their observations of social behavior and interaction for later systematic analysis using accepted qualitative analytic techniques.

‡ References are as follows:

Bayley K.B., et al.: Barriers associated with medication information handoffs. In Henriksen K., et al. (eds.): *Advances in Patient Safety: From Research to Implementation*, vol. 3, Implementation Issues. Rockville, MD: Agency for Healthcare Research and Quality, 2005.

Feldstein, et al.: Decision support system design and implementation for outpatient prescribing: the safety in prescribing study. In Henriksen K., et al. (eds).

Galt K.A., et al.: The impact of personal digital assistant devices on medication safety in primary care. In Henriksen K., et al.: (eds).

Harder K.A., et al.: Improving the safety of Heparin administration by implementing a human factors process analysis. In Henriksen K. et al.: (eds).

Harper M.L., Helmreich R.L.: Identifying barriers to the success of a reporting system. In Henriksen K. et al.: (eds).

Hoff T.J., Pohl H., Bartfield J.: Implementing safety cultures in medicine: What we learn by watching physicians. In Henriksen K. et al.: (eds).

Quinn, et al.: Can an academic health care system overcome barriers to clinical guideline implementation? In Henriksen K. et al.: (eds).

Resar R.K., Rozich J.D., Classen, D.: Methodology and rationale for measurement of harm with trigger tools. *Qual Saf Health Care*, 12 (suppl 2), ii39-ii45, Dec. 2003.

Savino J.A., et al.: Implementation of an evidence-based protocol for surgical infection prophylaxis. In Henriksen K. et al.: (eds).

Wakefield B.J., et al.: Organizational culture, continuous quality improvement, and medication administration error reporting. *Am J Med Qual* 16, 128-134, Jul.-Aug. 2001.

everyday clinical care for DVT at-risk patients in each of the hospitals, the presence of competing demands with respect to preventing DVT incidence versus other quality-of-care issues, and the role of other interventions (for example, use of other health care personnel) in the DVT error-prevention process—all of which would be addressed by observational studies and interview/focus groups (Table 2).

Action Steps for Implementing Qualitative Methodologies in Patient Safety Research

Table 3 (page 12) provides general action steps and corresponding examples for organizations interested in implementing qualitative methodologies to address patient safety issues. Implementing these steps can help achieve the attributes—trust, honesty, communication, participation, and efficiency—necessary to facilitate the qualitative approach in health care work settings:

■ **Trust** is desirable because qualitative methods can be intrusive and require input from individuals across a range of professional attitudes and work situations that remain taken for granted and hidden from everyday view.

■ **Honesty** can help organizations acknowledge the true goals of their research efforts (for example, do we wish to know the “why?” “how?” or “what?”). This enables more individuals in the organization to buy into the research and participate in

Table 3. Implications for Safety Research in Organizations: An Action Agenda

- Think carefully about the goal of the research. Qualitative approaches are particularly appropriate for answering questions of "how" and "why" and are also important if one is interested in implementation and policy development issues.

Example: A hospital with an error-reporting system that appears to be underreporting adverse events decides it wants to examine why some errors and near misses get reported and not others, so it decides to speak in-depth with those closest to the point of production, i.e., physicians and nurses.

- Implement qualitative methods on a pilot basis in the organization, perhaps choosing relatively self-contained, short-term projects focused on patient safety processes or outcomes that have become "taken for granted" within the organization.

Example: A hospital that has received numerous quality awards and has demonstrated low rates of adverse events associated with errors decides to create quick case studies of various clinical departments to update and describe work processes thought to be key in producing enhanced quality and safety.

- Have a few individuals in the organization learn qualitative methods, serve as champions, and put into action the principle that while systematic in their own right, these methods are accessible to use by the lay person, quicker to use, and often less expensive than quantitative approaches.

Example: A hospital trains and gives authority to "research leaders" across different clinical departments,

who become responsible for creating small, independent work teams that conduct pilot studies of safety for use by their department.

- Focus on building up trust among health care personnel working within the organization, emphasizing wherever possible the learning vs. punitive orientation of safety/errors research.

Example: A physician practice creates formal rewards/incentives for employees who identify work processes they feel are not working properly or have the potential to heighten the chance for errors to occur.

- Devote the critical resource of time for organizational personnel to be involved in qualitative studies.

Example: A physician practice formally allocates 5% of everyone's time in the practice to data collection and analysis related to ongoing quality-related research being done within the organization.

- Develop partnerships with academic departments within universities that provide a ready pool of trained qualitative researchers. Work with universities to develop new models of academic performance that value collaborations with industry.

Example: A hospital association representing hospitals within a geographic area provides assistantship support to the local university Ph.D. program, and funds doctoral internships that are used to bring researchers in quickly to study safety-related research questions arising in a given hospital setting.

observation, interviews, and focus groups. Honesty also makes employees aware of the key realities presently existing with respect to safety-related outcomes or processes within the organization, for example, what types of errors tend to go unnoticed or ignored in a given clinical setting. Pursuing trust and honesty help provide the social and psychological foundations for using qualitative methods effectively within organizational settings.

■ *Efficiency* relates to the manner in which qualitative methods should be used within the organization. Initially, short-term projects aimed at understanding "taken for granted" processes and outcomes around patient safety allow for qualitative methods to reveal the underlying complexity of issues that have become

oversimplified or misspecified through time. In addition, brief, self-contained investigations allow the organization to become adept at using these methods without significantly disrupting existing work or requiring too great an investment of resources.

■ *Communication* facilitates the use of qualitative methodologies to gather data around different types of safety or error events and at different levels of the organization. Organizations need to ensure that all employees have an opportunity to contribute, provide feedback, and perform as research subjects. This will maximize the quality (for example, validity, reliability) of any collected data. Communication also enables more reliable transmission of research data across sets of persons in the organization; it is important to

validate interpretations and findings among a diverse set of persons studied.

■ *Participation* is an essential requirement for qualitative methods, in that more “real time” workplace-focused examinations can be performed when all employees are included in the data collection and analytic phases. Participation also refers to the methodological “champions” and teams that should be established to promote and conduct certain types of examinations. This enhances buy-in and enables greater acceptance of both the goals and methods of patient safety studies among employees.

A recent qualitative study conducted by one of the authors [T.J.H.] and his colleagues illustrates implementation of these action steps. The study addressed how medical residents in a single academic medical center were being socialized and trained to deal with error in their everyday training and work. Three work environments were examined—trauma surgery, emergency medicine, and the medical intensive care unit (ICU). A qualitative approach was selected for several reasons. First, the research team deemed it important to capture residents’ immediate reactions to mistakes and the immediate interactions that occurred between them and their attending supervisors. The research literature supported the idea that errors were more likely to be glossed over or submerged within the residency culture with increasing distance from the incident. Second, we wanted to get underneath the superficial, sometimes overly scripted responses that might occur, given the sensitive nature of the topic and the hierarchical dynamics inherent in most residency programs, when a mistake or patient safety issue arises.

Several action steps of the types listed in Table 3 were undertaken to promote trust, honesty, communication, participation, and efficiency.

■ Before starting the study, at a meeting with all attending and resident physicians, we invited them to voice their concerns about the study’s goals or methods. As a result of this feedback, we changed several components of the study. For example, we decided to do interviews only after our observations were complete. We also met with nurses and other support personnel at each work setting because these groups were important in allowing

us access to as many medical care work situations in the settings as possible.

■ We included all attending and resident physicians in the study team at each medical work setting studied to increase the participants’ comfort level, that is, to show that no one was being singled out for special observation or for any reason that might be construed as ineffective performance.

■ We exposed several physician members at each of the three settings to the particular methods used in the research (for example, observation, analysis of qualitative data) to facilitate trust in the study.

■ We initially studied trauma surgery to determine what could be learned and applied to the remaining two work settings.

■ Attending and resident physicians were asked in “real time” (that is, immediately after a mistake had been observed) for their thoughts, reactions, and opinions about the safety event. Somewhat paradoxically, this seemed to make them feel more comfortable with researchers who were observing at the time.

■ Observational periods in each resident work setting were compacted so that researchers were in each setting for two to three weeks at most, with a maximization of the time of observation within each of those time periods. Research participants appreciated knowing upfront precisely how long we would be observing (and thus, precisely when we were leaving). We believe that it motivated some of them to answer our additional questions stemming from the observations. This compacted data-gathering approach also contributed to efficient movement of the study to the data analysis and interpretation phases.

■ Researchers made sure to exit each work setting at the specified end time, heightening trust within each of the three studied settings. In addition, within the observational periods, researchers made clear to one or more research participants in a given setting when they would be there the next day to observe, and when they would likely leave that same day. This did not, in our opinions, bias any observations. To the contrary, it seemed to relax research participants (particularly residents), who appreciated our overt consideration of the work and our structuring the data gathering accordingly. In our opinion, relaxed residents made for better observational subjects.

■ A research team that included physicians, nurses, and pharmacists in the hospital was brought together several times during the study to review preliminary analyses, which were made available to them in a standard format. At each meeting, persons who worked in the setting but who were not formally part of the data gathering or analysis teams were invited to offer their opinions about the accuracy of the interpretations.

Summary and Conclusion

More diverse methods, particularly qualitative methods, should be used in studying patient safety as a complement to (not a substitute for) quantitative approaches. Qualitative approaches can be implemented more easily in organizations through structural and cultural adjustments that provide a more supportive foundation for this work.

Conducting good qualitative research involves some level of guided instruction, followed by “on-the-job” immersion, which all health care organizations should promote through an ongoing commitment to study as many patient safety issues as possible using one or more qualitative methods. Recommended books on qualitative methods are listed in Sidebar 1, right. **J**

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Sidebar 1. Recommended Books on Qualitative Methods

1. Denzin N.K., Lincoln Y.S.: *Strategies of Qualitative Inquiry*, 2nd ed. Thousand Oaks, CA: Sage Publications, 2003.
2. Kvale S.: *Interviews: An Introduction to Qualitative Research Interviewing*. Thousand Oaks, CA: Sage Publications, 1996.
3. Krueger R., Casey M.A.: *Focus Groups: A Practical Guide for Applied Research*, 3rd ed. Thousand Oaks, CA: Sage Publications, 2000.
4. McCracken G.: *The Long Interview*. Newbury Park, CA: Sage Publications, 1988.
5. Miles M.B., Huberman A.M.: *Qualitative Data Analysis: An Expanded Sourcebook*, 2nd ed. Thousand Oaks, CA: Sage Publications, 1994.
6. Morgan D.L. (ed.): *Successful Focus Groups: Advancing the State of the Art*. Newbury Park, CA: Sage Publications, 1993.
7. Patton M.: *Qualitative Research and Evaluation Methods*, 3rd ed. Thousand Oaks, CA: Sage Publications, 2002.
8. Pope C., Mays N., eds.: *Qualitative Research in Health Care*. London: BMJ Books, 2000.
9. Strauss A., Corbin J.: *Basics of Qualitative Research*, 2nd ed. Thousand Oaks, CA: Sage Publications, 1998.
10. Whyte W.F. (ed.): *Participatory Action Research*. Newbury Park, CA: Sage Publications, 1991.
11. Yin R.K.: *Case Study Research: Design and Methods*, 3rd ed. Thousand Oaks, CA: Sage Publications, 2003.
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13. Scott W.R.: *Organizations: Rational, Natural, and Open Systems*. New Jersey: Prentice Hall, 1992.
14. Burns L.R., Wholey D.R.: Responding to a consolidating healthcare system: Options for physician organizations. In Blair J., et al.: (eds.): *Advances in Health Care Management*, vol 1. New York: JAI Press, 2000, pp. 273–335..
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