ORIGINAL ARTICLE

Barriers to Implementation of Patient Safety Systems in Healthcare Institutions

Leadership and Policy Implications

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Abstract: The objective of this study was to identify barriers to implementation of patient safety systems in healthcare institutions to serve as baseline data for healthcare senior leadership and policy makers. The Delphi method for gaining consensus from a group of experts and forecasting significant issues in the field of the Delphi panel expertise was used. Data collection included a series of questionnaires. Twenty-three experts in healthcare quality and healthcare systems approach, representing 18 U.S. states, participated in the survey rounds. The first iteration of the survey returned a variety of barriers to implementing patient safety systems in healthcare institutions. All suggested barriers were grouped thematically, and 29 different barriers were formed. During the second and third survey rounds, the Delphi panelists were asked to rank the importance of each barrier on a 4-point Likert scale. Addressing the identified "top 7" barriers to implementation of patient safety systems carries great potential for enhancing the implementation of safety healthcare systems. Importantly, all "top 7" barriers are systemic in nature. Thus, the efforts of individual institutions, while very important, will be less successful than a broader systemic approach across the U.S. healthcare system. This study is significant because the results are expected to assist healthcare administrators and healthcare policy makers in eliminating barriers to healthcare quality and improving patient safety.

Key Words: barriers to patient safety, healthcare quality improvement, patient safety systems implementation, healthcare policy making

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The contemporary American healthcare model still carries the characteristics of the craftsmanship of the 18th century and, instead of evolving with technology and scientific advancements, the new healthcare complexity leads to fragmentation of the service model and increased rate of iatrogenic incidents.[1] The Institute of Medicine (IOM) report *Crossing the Quality Chasm: A New Health System for the 21st Century* suggested that there are still large gaps between the care patients should receive and the care they do receive, and recommended searching for a new system design to improve performance. This report also clearly articulated the gap between scientific knowledge, evidence-based science, and healthcare practice in the United States.[2] A study of the current research on patient safety in the United States[3] found that the lack of clear nomenclature for error reporting, the complexity of the healthcare system, the culture of blame, insufficient funding, legal constraints, and the lack of experts and qualified researchers in this newly emerging research field present significant barriers to patient safety research. Further hindrances to building patient safety systems include the need for different research methodologies to overcome the barriers to access information about errors in healthcare delivery, a lack of studies on adverse event reporting processes, no studies of actual prevalence of medical errors, a lack of basic understanding about the causes of errors and system failures, a lack of error reporting processes and methods, and a lack of studies of healthcare organizational culture.[3] Identification of the barriers that prevent the introduction, management, and improvement of patient safety systems in healthcare institutions will assist healthcare providers, administrators, and policy makers in decision-making and proactive measures for elimination of those barriers to patient safety improvement. Given these significant issues, the purpose of this study was to gain a national perspective of the barriers to implementing patient safety systems in healthcare institutions and thereby assist healthcare administrators and policy makers in eliminating these barriers to improve patient safety.

METHODS

The Delphi method for gaining consensus from a group of experts and forecasting significant issues in the field of the Delphi panel expertise was used. The Delphi technique supports informed decision-making, gives a way of structuring a large mass of information, evidence, and expertise to achieve informed judgment, decision-making, and forecasting, and can be used in discussing problems of both numerical and non-quantifiable nature. The technique, as a systematic way to draw on the informed judgment of a group of experts, has the capacity to deal with ambiguity and multi-dimensionality and has been widely used to support decision-making in the fields of sociology, medicine, and policy making.[4–9] Data collection included a series of 3 questionnaire rounds. Twenty-three experts

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in healthcare quality and healthcare systems improvement, representing 18 U.S. states, participated in the survey rounds.

To maintain the rigor of the Delphi technique, a response rate of 70% must be maintained between consecutive rounds.[10] All 23 experts that had made a commitment to serve on the Delphi panel participated in the first survey round; 20 of the experts continued their participation in the second survey round (response rate of 87%); and these 20 experts also continued in the third study round (response rate of 100%). All 23 experts received the results of the second and third survey round, and all 23 experts were contacted at the end of the study for obtaining permission to publish their names as Delphi panelists for the study.

The Delphi panel included medical doctors, doctors of philosophy, nurses, and administrators from healthcare institutions that have applied for or won national quality awards, or have won state quality awards. The expertise of the panel ensured representation throughout the continuum of patient care, from direct encounter with patients to senior healthcare executives. (For list of Delphi experts indicating their institutional affiliation and position, see Acknowledgments section.)

During the first round, the experts were asked with an open-ended question to list the 5 most important barriers to introducing patient safety systems in healthcare institutions. This round returned a variety of barriers to implementing patient safety systems in healthcare institutions. The Delphi experts suggested a list containing more than 100 different barriers. The determination of the barrier themes used qualitative methodology and, more specifically, *naturalistic inquiry*, as developed and described by Lincoln and Guba.[11] Using a method of constant comparison between and among all barriers suggested by the study participants, themes were identified in the gathered data. Data having a similar theme (ie, describing one and the same problem that constitutes a barrier to the implementation of patient safety systems in healthcare institutions) were grouped and labeled as a barrier according to the prevailing original wording of the Delphi experts. Grouping, or *categorizing,* was accomplished in accordance with naturalistic inquiry methodology whereby data are unitized and categorized; patterns are filled in and member checks are used to provide validation.[11–13] Utilizing this methodology, 29 barriers were identified. There was no prioritization in the sequence of presentation of the 29 barriers to the Delphi panel during the subsequent survey iterations.

During the second and third survey rounds, the Delphi panelists were asked to rank the importance of each of the identified barriers on a 4-point Likert scale, where:

Rank of 4 represented a "very important" barrier, that is, patient safety systems cannot be implemented unless this barrier is eliminated or modified;

Rank of 3 represented an "important" barrier, that is, patient safety systems may begin but cannot be continued unless this barrier is eliminated or modified;

Rank of 2 represented a "not very important" barrier, that is, patient safety systems may begin and continue, but at limited effectiveness, unless this barrier is eliminated or modified;

Rank of 1 represented an "unimportant" barrier, that is, patient safety systems can be implemented in the presence of this barrier.

The results of experts' individual barrier ranks were compiled and analyzed by descriptive statistics and then returned to each participant to provide them with an opportunity to examine the results and compare their individual responses to the group results. The criteria for consideration of each barrier as "very important," "important," "not very important" or "unimportant" were based on the 4-point Likert scale, which represented a continuum of perspective. While individual responses could provide discrete values, in summing and deriving the mean, the data needed to be interpreted within the context of the continuum. The mean as a measure of central tendency represented the group opinion of the panel. For the purpose of the study, a rounding approach was selected to reflect a range for each of the 4 values on the Likert scale. The range was selected to provide consistent weighing for each group mean value:

values from 3.5 through 4.0 were viewed as "4" or "very important";

values from 2.5 through 3.4 were viewed as "3" or "important";

values from 1.5 through 2.4 were viewed as "2" or "not very important";

values from 1.0 through 1.4 were viewed as "1" or "unimportant."

Thus, barriers to patient safety with a consensus group mean equal to or higher than 3.5 were considered "very important," that is, patient safety systems cannot be implemented unless such barriers are eliminated or modified; barriers with a group mean between 3.4 and 2.5 were considered "important," that is, patient safety systems may begin but cannot be continued unless such barriers are eliminated or modified; a group mean between 2.4 and 1.5 described the barrier as "not very important," that is, patient safety systems may begin and continue, but at limited effectiveness, unless these barriers are eliminated or modified; and a barrier with a group mean equal to or lower than 1.4 was considered "unimportant," that is, patient safety systems can be implemented despite the presence of these barriers.

RESULTS

The group consensus results of expert opinions on how important is the elimination of each barrier for successful implementation of patient safety systems in healthcare institutions are presented in Table 1. Systemically addressing all barriers identified as "very important" or "important" is critical and provides significant opportunities, if not a mandate, for improving patient safety systems.

Only 1 barrier (Competing priorities for scarce resources in a system where patient safety is not considered a top priority, Mean = 3.6, SD = 0.502) was classified as "very important," that is, patient safety systems cannot be implemented unless this barrier is modified or eliminated. Twenty-four of the barriers were classified as "important," (Mean = 2.5–3.4), that is, in their presence patient safety systems may begin but could not be continued unless the barrier is

TABLE 1. Barriers to Implementation of Patient Safety Systems in Healthcare Institutions

Barrier	Mean	SD
1. Competing priorities for scarce resources in a system where patient safety is not considered a top priority.	3.6	0.502
2. Lack of resources: inadequate staffing and work overloads.	3.4	0.502
3. Availability and cost of patient safety technology.	3.3	0.587
4. Resistance to change (the assumption that providers are already providing safe care).	3.2	0.444
5. Culture of blame (current healthcare culture is punitive in nature).	3.2	0.523
6. Lack of senior leadership understanding of and involvement with patient safety issues.	3.2	0.523
7. Culture of healthcare workforce perceptions, attitudes and behaviors of error "cover up."	3.0	0.510
8. Reliance on measurement systems that depend on voluntary reporting of errors.	2.9	0.825
9. Inadequate education of staff, professionals, management, and leadership in regard to patient safety.	2.9	0.394
10. Current legal system: fear of litigation.	2.9	0.510
11. Complexity of healthcare systems.	2.9	0.686
12. Insufficient data about institutional performance and benchmarking.	2.9	0.510
13. Communication: lack of transparency and openness in regard to patient safety issues.	2.9	0.686
14. Reliance on human capabilities for ensuring safety.	2.9	0.686
15. Lack of positive feedback: no change occurs after reporting.	2.9	0.640
16. Culture of physicians considered the ultimate authority.	2.8	0.745
17. Research-driven best healthcare practices are not adopted.	2.8	0.695
18. Lack of operational planning and deployment skills regarding implementation of patient safety systems.	2.8	0.695
19. Culture of quality "inspection" (regulatory oversight is sufficient, no further effort is needed).	2.8	0.695
20. Disbelief, denial, and lack of knowledge about the ubiquitous nature of errors.	2.7	0.638
21. Cumbersome, complicated, and time-consuming error reporting processes.	2.7	0.656
22. Cumbersome, complicated, and time-consuming healthcare safety processes.	2.6	0.598
23. Bureaucracy.	2.5	0.686
24. Culture of hesitancy of healthcare organizations to allow consumers to participate in decision-making.	2.5	0.686
25. Need of standardization of patient safety terminology, technology, and approaches.	2.5	0.827
26. It is difficult to find an approach that smoothly integrates into existing systems without creating added costs and complexity.	2.4	0.825
27. Overexpectations of potential and capability of technology to solve healthcare safety problems.	2.3	0.670
28. Difficulties in creating patient safety peer review for healthcare professionals.	2.2	0.786
29. Fear that a non-punitive system will miss an individual's pattern of errors.	2.0	0.561

eliminated or modified. Given the large number of barriers that were identified as important and the reality of the time and resources in attempting to improve all of those simultaneously, institutions in the healthcare system could begin by prioritizing the "top 7" barriers, the barriers that received the highest group rank means and thus are perceived to be most critical to achieving improved patient safety. However, healthcare institutions, given their particular context, can refer to Table 1 for the rankings of the additional barriers.

The "top 7" barriers and the issues related to them, as identified by the Delphi panel, were as follows (presented in descending order of the group consensus rank means):

1. **Competing priorities for scarce resources in a system where patient safety is not considered a top priority (Mean = 3.6, SD = 0.502).** This barrier included allocation of resources for personnel dedicated to designing, implementing, monitoring, and evaluating patient safety systems, redesigning of patient care safety processes so that error-free patient care requires minimum effort to deliver, and implementation of computerized medical records and other healthcare data entry systems. Healthcare leaders, including chief executive, financial and information technology leaders, and chief of staff, have to shift focus from day-to-day operations to building infrastructure to accommodate patient safety and provide resources for

allowing culture change. Leadership commitment to patient safety is critical.

2. **Lack of resources: inadequate staffing and work overloads (Mean = 3.4, SD = 0.502).** This barrier included the concerns that inadequate staffing and work overloads interfere with the ability to practice patient safety and are restrictive for error reporting, especially if additional paperwork is required to report. Under the pressure to perform under such circumstances, staff is reluctant to learn new methods, such as Root Cause Analysis (RCA) and Failure Modes and Effects Analysis (FMEA), which would require additional effort and time.

3. **Availability and cost of patient safety technology (Mean = 3.3, SD = 0.587).** This barrier discussed the issue that although sophisticated technology exists to support patient safety, the cost of implementation of such technology makes it unavailable to many financially restricted healthcare organizations, small and rural organizations in particular. Additional costs are related to training or re-training of staff to use the new technology and providing interfaces with existing institutional electronic systems, such as admissions, billing, and laboratory. Thus, the existing patient safety information technology support becomes virtually unavailable to many healthcare institutions.

4. **Resistance to change (Mean = 3.2, SD = 0.444).** Included within this barrier was the assumption that providers are already providing safe care and no changes or improvement efforts are needed. This assumption is permeating many healthcare institutions and is embraced by a majority of healthcare individual providers.

5. **Culture of blame (current healthcare culture is punitive in nature) (Mean = 3.2, SD = 0.523).** This barrier included issues related to the current culture in medicine, such as professional autonomy, collegiality, and self-regulation. Errors are not viewed from a systems perspective; rather, a professional making an error is perceived as incompetent.

6. **Lack of senior leadership understanding of and involvement with patient safety issues (Mean = 3.2, SD = 0.523).** The relevant issue for this barrier was senior leadership involvement in defining institutional patient safety goals and strategic planning objectives. Unfortunately, visionary leadership is lacking in many healthcare organizations. To be able to support and understand the importance of patient safety strategic planning and improvement initiatives, and to empower managers and staff, healthcare leaders must be educated about patient safety and must understand its principles and importance. Leadership knowledge and prioritizing of patient safety drive budgetary decisions in support of achieving patient safety.

7. **Culture of healthcare workforce perceptions, attitudes, and behaviors of error "cover up" (Mean = 3.0, SD = 0.510).** This barrier discussed the process of professional education and training, and the work environment, where healthcare professionals learn the culture and behaviors of the workplace and traditions they are immersed into. A punitive approach to individuals making an error leads to the practice of "error cover up," thus preventing learning from the mistakes that occur. In particular, nurses have been notorious for punishing error ("eating their young") and for practices such as "3 strikes and you are out."

Barriers 1 through 3 reflect the strenuous resource availability that healthcare institutions are struggling with, as well as the importance of making patient safety a top institutional leadership priority. Additionally, the seventh barrier, the culture of "cover up," may be considered as a consequence from the traditional culture of blame in healthcare (barrier number 5) and a reflection of the prevailing traditional punitive patterns permeating physician and nurse education. However, the Delphi experts chose to preserve the identified barriers in consecutive study rounds, and these barriers were not combined.

The other 18 "important" barriers (Table 1, barriers number 8 through 25) offer additional significant opportunities for improving patient safety. Their relevance to the delivery of quality healthcare, along with addressing the "top 7" barriers, is validated not only by this study but also by the research outlined in the Discussion section. The "top 7" barriers carry a great potential for improvement of patient safety across the healthcare system. Because the patient safety outcomes are primarily a function of the design of the patient safety systems,[14] the approach to eliminating barriers to patient safety should use a systems approach.

DISCUSSION

While there has been no comprehensive study of barriers to patient safety systems, there have been a number of studies that validate the barriers identified in this study. Consequently, the results of this study, coupled with the results of the findings of the studies outlined below, provide an important source of baseline data for initiating systemic improvement in healthcare patient safety systems.

Healthcare institutions are organizations with high reliability on individual expertise and have a well-developed hybridization of hierarchy and specialization. Therefore, healthcare institutions exhibit the full range of characteristics common for high-reliability organizations, such as preoccupation with failure, reluctance to simplify operations, vigilance for potential unsafe events, commitment to resilience, and ignorance to information outside the realm of expectations.[15] Patient safety is primarily a result of the healthcare system design and not necessarily of individual system components; thus, finding systemic vulnerabilities has greater potential for improvement than searching for individual flaws. Healthcare professionals function under resource and performance pressures in an environment where interconnections and interdependencies between parts and activities are increased to achieve greater productivity and efficiency, and the increased interconnectivity (ie, coupling between system parts) increases both operational complexity and difficulty of the problems that arise.[14] Although by definition patient safety practices are processes or structures whose application reduces the probability of adverse events resulting from exposure to the healthcare system across a range of diseases or procedures, they, too, may prove to be unsupported by clinical evidence and even harmful,[16] if not considered within a systems context. The attributes of patient safety are considered to be subsets of healthcare quality, that is, delivery of quality healthcare guarantees patient safety, but quality measurements in healthcare may not reflect patient safety aspects that are more difficult to measure than waiting times or adherence to clinical practice guidelines.[3]

The report of the Agency for Healthcare Research and Quality *Making Health Care Safer* presented a number of methodological challenges in patient safety research, including difficulties in identifying "near misses," multidimensionality of effective practices, and the fact that many of the patient safety problems capturing the national attention are statistically rare (eg, wrong-site surgery).[17] The intent of the report was to inform healthcare providers and healthcare organizations on improvement practices and to inform research agencies on potential areas for successful research on patient safety. Besides the randomized trials, considered the standard in clinical medicine, other approaches, such as detailed case studies and industrial engineering research, are widely used in other high-risk industries. The report concluded that perfecting individual skills was not sufficient for preventing medical errors; rather, improving patient safety depended on the team effort of multiple healthcare players and adoption of successful strategies from other high-risk industries, such as aviation, aerospace, and nuclear engineering.[17] This is consistent with the findings of this study that most barriers to patient safety are systemic in nature.

David Marx, a human error management consultant to hospitals, air carriers, and regulators, who received the 2000 Whittle Award for Outstanding Contribution to Flight Safety from the International Federation of Airworthiness for his contribution to the development of the air carriers' safety system, noted that contemporary corporate systems prohibit recognition of human error through social condemnation and disciplinary actions, consequently not allowing learning from the mistakes that take place.[18] In his report *Patient Safety and the Just Culture,* Marx called for establishing a reasonable balance between the need for disciplinary actions in cases of intentional protocol or procedure violations and the need to learn from mistakes to design effective safety systems. Marx argued that hospitals are unaware of the real extent of occurring errors and injuries because health workers are afraid to report their errors in an extremely outcome-based disciplinary decision-making environment, which does not distinguish between healthcare professionals who intentionally and recklessly violated established procedures but by twist of fortune did not cause extreme damage, and those who are well-meaning but had a more severe adverse outcome.[18]

The lack of single typology of medical errors, coupled with the lack of standards and infrastructure for systematic data collection, have been identified as major constraints for patient safety improvement.[19] Furthermore, reporting of medical errors is hindered by the current culture in medicine fostering autonomy, collegiality, and self-regulation, fear that the trend toward utilization of clinical guidelines and "best practices" will increase litigation, and the general lack of uniform standards to support judgments about behavior of colleagues and error reporting.[20] Additional barriers to re-porting of medical errors include: the narrow definition of reportable events; the short length of personal contact, providing an incentive to keep silent; the documentation required in error reporting, which increases professionals' workload; the tendency to cover-up for an "otherwise good" nurse or doctor; the assumption that reporting does not bring about change; and the uncertainty of which is the right way to go. The discussion about what constitutes the best quality in healthcare presents an additional barrier to patient safety in an environment where local hospital cultures play an important role in an individual's decision whether to report or not.[21] A study with physicians and nurses in a large academic medical center specifically explored the barriers to reporting a medical error and added to the list of known barriers the uncertainty about the usefulness of the report, the perception that reporting was time-consuming and increased the workload, the lack of clarity as to what should be reported or how to report, the lack of anonymous reporting, the hesitancy to report an error that did not result in an adverse outcome, and the fear of litigation.[22] Lawton and Parker observed that healthcare professionals, particularly medical doctors, were more likely to report a medical mistake to a colleague than to a staff member and that violations of protocol events were more likely to be reported compared with other types of mistakes.[20] To the critical component of current medical culture, Leonard identified additional factors, such as communication factors, human factors (eg, multitasking, distraction and interruptions, fatigue, and stress), lack of senior leadership involvement with quality improvement, and resistance to culture change, that may act as barriers to optimal functioning of patient safety systems.[23] The proposed *Patient Safety and Quality Improvement Act of 2004,* recently discussed in Congress, is expected to markedly improve the environment for patient safety reporting.

It has been recognized that in the field of healthcare, 99.9% of proficiency is far from satisfactory. W. E. Deming, as cited by Leape, pointed out, "If we had to live with 99.9%, we would have: 2 unsafe plane landings per day at O'Hare, 16,000 pieces of lost mail every hour, 32,000 bank checks deducted from the wrong bank account every hour".[24] In medicine, where the primary focus is on professional perfection in diagnosis and treatment, physicians are expected to function without mistakes, the role models are authorities in their respective fields and reinforce the concept of infallibility, the message to all practitioners is that errors are clearly not acceptable, and individual physicians react to errors as to faults in character.[24] Healthcare professionals tend to perceive medical errors as internal, controllable, and unstable, and the more severe the outcome of the error, the more importance is attached to the error and the more likely are the professionals to accept responsibility, blame themselves for the failure, and overlook any other contributing system factors.[25] Wrote Leape, "If you are responsible for everything that happens to the patient, it follows that you are responsible for any errors that occur. While the logic may be sound, the conclusion is absurd, because physicians do not have the power to control all aspects of patient care … this need to be infallible creates a strong pressure to intellectual dishonesty, to cover up mistakes rather than to admit them".[24]

Research suggests that professional discipline and liability tend to produce very limited improvement in patient safety.[26] The patient safety movement is analogous to the legal doctrine of "last clear chance," where an accident is the product of a chain of events and prevention might have occurred at each of the steps prior to the accident. The patient safety view of adverse events is that a variety of system and process flaws have manifested in order for an accident to occur. Importantly, legal sanctions are retrospective, while patient safety activities are focused on prevention of future adverse events in the system and are continuous, rather than one-time events.[26]

Adoption of electronic medical record (EMR) systems has been viewed as a major tool in increasing patient safety, decreasing medical errors, facilitating work flow improvement, and meeting legal, regulatory, and accreditation requirements. However, a recent survey conducted by the Medical Records Institute found that the majority of healthcare institutions are slow to adopt EMRs due to financial barriers or lack of support by the medical staff.[27]

It has been widely argued that introducing Computerized Physician Order Entry (CPOE), bedside technology, and smart infusion pumps is required for patient safety improvement. However, the high cost, in both dollars and other resources, of healthcare information technology projects is a serious hindrance of its quick and wide adoption across the country. For example, the experience of Vanderbilt showed that it took $6 million and 6 years to implement a CPOE

system across one hospital. Although it might be easy to require physicians to use the CPOE in some healthcare systems, in other facilities it might be the case that physicians strongly resist the change because it interferes with the established workflow and the learning curve requires a significant amount of time. Additionally, introducing a healthcare information technology system (eg, CPOE) still mandates interfacing with other existing or later added IT systems, adding to the cost and frustration. Relying solely on the technology to solve the faults of processes and systems is unrealistic.[28] Cost, uncertain return on investment, potential negative impact on physician workflow and physician resistance, lack of information technology infrastructure, and the lack of public support and incentives for improvement of healthcare quality have been identified as major barriers to introducing CPOE in healthcare institutions.[29,30]

A national educational needs assessment survey, conducted under the auspices of the National Patient Safety Foundation, placed the existing culture of medicine as the leading barrier to patient safety systems and clearly indicated that this is a systems issue. Other impeding factors to patient safety identified by the survey included: the growing complexity of healthcare, the rapid advancement of medical technology, the culture of tolerance to errors in the healthcare industry (manifested as denial, complacency, or professional authority gradient), limited patient safety education opportunities, the perception that reporting an error does not change anything in the existing system, and the punitive reaction to errors, accompanied by fear of punishment and humiliation.[31,32] The National Quality Forum consensus also pointed out that the widespread misunderstanding of the nature and causes of medical errors, the prevailing "name and blame" culture in medicine, the lack of user-friendly reporting mechanisms, and the fear of punishment hinder progress toward achieving patient safety.[33]

The culture of blaming individuals, underreporting of errors, and negligence in analyzing and improving systems have been found to be barriers to enhancing medication safety in a variety of healthcare settings. The complexity of information and healthcare information systems, use of high-risk medications, prevalence of verbal medication orders, and the safety of infusion pumps have been recognized as contributing factors to the need of introducing safer healthcare systems.[34]

Without organization-wide systems for communication and coordination, the growing complexity of healthcare will bring about more opportunities for errors. When tasks and information cross inter-departmental lines, the potential for mistakes rapidly increases, and highly specialized but segregated knowledge decreases the ability to detect errors. Clinical guidelines and protocols will not be able to absorb and cover all possible clinical situations, thus leaving space for doubt and errors. Additionally, hierarchical limitations in healthcare institutions present a paramount barrier to patient safety systems.[35] Whereas a systems approach to patient safety is the better venue to improvement, the ultimate patient safety booster seems to be market pressure, a factor not yet truly recognized as a leading cause in healthcare improvement.[26] Research is needed to provide the scientific evidence for the business case of patient safety and to support the reliability and validity of practices considered quality practices. Currently, the lack of patient safety measures at the system level or measuring the outcomes in a specialty field (eg, pediatrics) is impeding the progress of patient safety initiatives.[30]

The similarities in the barriers to patient safety as identified in this study utilizing a systemic institution-level approach and as outlined in the research cited above with a department-based or service-line focus validate the identified 29 barriers resulting from this study as consistently existing at both departmental and institutional levels across the healthcare system in the U.S. The identified 29 barriers establish a baseline for elimination of patient safety barriers at the institutional level and provide valid information to support leadership decisions in policy making at the institutional, regional, state, and national levels.

CONCLUSIONS

Wide variation in healthcare delivery and patient safety in the United States has been well documented.[36–38] Theoretically, patient safety is viewed as a leadership and management issue. Although patient safety is primarily dependent on systemic factors, it is local in occurrence; that is, the patient safety outcome is finalized at the point of interaction between medical professionals and patients. Therefore, physician involvement is crucial for the success of patient safety initiatives, and taking a systems approach is a must in redesigning the healthcare system for safer care delivery.[39] The causes for medical errors are rooted in the organizational and policy levels of healthcare. A narrow focus on one isolated process without taking into consideration the systemic nature of medical errors leaves healthcare institutions vulnerable to mistakes in patient safety. Human errors (eg, fatigue, inadequate training, logic errors, communication problems, etc.), organizational-level barriers (such as workplace design, strategic planning, policies and procedures, leadership and management, etc.), and technical impediments (inadequate automation, malfunctioning equipment, information overload, lack of checklist, etc.) must be addressed simultaneously to evoke a boost in the patient safety outcomes.[40]

Although studies of patient safety barriers are gaining momentum, the majority of them exhibit a limited department-based or service-line focus. Thus, the institution-wide perspective and patient safety systems characteristics have remained insufficiently addressed. The approach for this study was systems oriented and institution-level based; thus, it presents a broader perspective on the variety of impediments to patient safety at a systems level. The consensus results from the third, final round of this study indicated that there are at least 29 barriers to implementation of patient safety systems in healthcare institutions. The experts in this study ranked 7 of the barriers as "very important" or "important" with a consensus group rank mean of 3.0 or higher, and these "top 7" barriers were considered to have systemic origins. Improving the identified "top 7" barriers to implementation of patient safety systems as an initial step carries great potential for enhancing the implementation of safety healthcare systems. Importantly, all "top 7" barriers are systemic in nature and address many of the issues cited in supporting literature. Thus,

the efforts of individuals and individual institutions, while very important, will be less successful than a broader systemic approach to improvement across the U.S. healthcare system.

REFERENCES

1. Merry MD. Healthcare's need for revolutionary change. *Qual Prog.* September, 2003;36:31–35.
2. Institute of Medicine, Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, DC: National Academy Press; 2001.
3. Cooper JB. *Current Research on Patient Safety in the United States.* Chicago, IL: National Patient Safety Foundation; 2001.
4. Adler M, Ziglio E. *Gazing Into the Oracle: The Delphi Method and Its Application to Social Policy and Public Health.* Bristol, Pa: Jessica Kingsley Publishers, Ltd.; 1996.
5. Calzone KA, Jenkins J, Masny A. Core competencies in cancer genetics for advanced practice oncology nurses. *Oncol Nurs Forum.* 2002;29: 1327–1333.
6. Wang CC, Wang Y, Zhang K, et al. Reproductive health indicators for China rural areas. *Soc Sci Med.* 2003;57:217–225.
7. Catlin AJ, Carter BS. Creation of a neonatal end-of-life palliative care protocol. *J Neonatal Nurs.* 2002;21:37–49.
8. Sharp D, Liebenau A, Stocks N, et al. Locally developed guidelines for the aftercare of deliberate self-harm patients in general practice. *Prim Healthc Res Dev.* 2003;4:21–28.
9. McBride AJ, Pates R, Ramadan R, et al. Delphi survey of experts' opinions on strategies used by community pharmacists to reduce over the counter drugs misuse. *Addiction.* 2003;98:487–497.
10. Hasson F, Keeny S, McKenna H. Research guidelines for the Delphi survey technique. *J Adv Nurs.* 2000;32:1008–1015.
11. Lincoln YS, Guba EG. *Naturalistic Inquiry.* Newbury Park: Sage; 1985.
12. Glaser BG, Strauss AL. *The Discovery of Grounded Theory.* Chicago: Aldine; 1967.
13. Erlandson DA, Harris EL, Skipper BL, et al. *Doing Naturalistic Inquiry—A Guide to Methods.* Newbury Park: Sage Publications; 1993.
14. Woods DD, Cook RI. Nine steps to move forward from error. *Cogn Technol Work.* 2002;4:137–144.
15. Perry SJ. Profiles in patient safety: organizational barriers to patient safety. *Acad Emerg Med.* 2002;9:848–850.
16. Shojania KG, Duncan BW, McDonald KM, et al. Safe but sound: patient safety meets evidence-based medicine. *JAMA.* 2002;288:508–513.
17. Agency for Healthcare Research and Quality. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices.* AHRQ; July 2001. Evidence report/technology assessment 43. Available at: http://www.ahcpr.gov/clinic/ptsafety. Accessed August 3, 2004.
18. Marx D. *Patient Safety and the "Just Culture": A Primer for Health Care Executives.* A report prepared under grant #R01-HL53772, Harold S. Kaplan, M.D., Principal Investigator, funded from the National Heart, Lung, and Blood Institute, National Institutes of Health. New York, NY: Columbia University; April 17, 2001.
19. US Department of Health and Human Services, Agency for Healthcare Research and Quality. *National Healthcare Quality Report.* Rockville, MD: AHRQ, December 2003. AHRQ Pub. No. 04-RG003.
20. Lawton R, Parker D. Barriers to incident reporting in healthcare systems. *Qual Saf Health Care.* 2002;11:15–18.
21. Firth-Cozens J, Redfern N, Moss F. *Confronting Errors in Patient Care: Report on Focus Groups.* Birmingham, UK: University of Birmingham; 2001.
22. Uribe CL, Schweikhart SB, Patnak DS, et al. Perceived barriers to medical error reporting: An exploratory investigation. *J Healthc Manag.* 2002;47: 263–280.

23. Leonard M. Lessons from the sharp end: Critical components of successful patient safety work. *Focus on Patient Safety: A Newsletter from the National Patient Safety Foundation*. 2003;6:1–2. (This newsletter is also available on line at: http://www.npsf.org/download/Focus 2003Vol6No2.pdf. This document was accessed online on December 4, 2004.)

24. Leape LL. Errors in medicine. *JAMA*. 1994;272:1851–1857.

25. Meurier CE, Vincent CA, Parmar DG. Nurses' responses to severity dependent errors: a study of the causal attributions made by nurses following an error. *J Adv Nurs*. 1998;27:349–354.

26. Bovbjerg RR, Miller RH, Shapiro D. Paths to reducing medical injury: professional liability and discipline vs. patient safety. *J Law Med Ethics*. 2001;29:369–380.

27. Medical Records Institute. *MRI Fifth Annual Survey of EHR Trends and Usage*. 2003. Available at: http://www.medrecinst.com/resources/survey/results03/part1.shtml. Accessed August 3, 2004.

28. CPOE, bedside technology, and patient safety: a roundtable discussion. *Am J Health Syst Pharm*. 2003;60:1219–1228.

29. Poon EG, Blumenthal D, Jaggi T, et al. Overcoming the Barriers to Implementing Computerized Physician Order Entry Systems in US Hospitals: Perspectives From Senior Management. *AMIA 2003 Symposium Proceedings, 2003*:975.

30. Dougherty D, Simpson LA. Measuring the quality of children's health care: a prerequisite to action. *Pediatrics*. 2004;113:185–198.

31. VanGeest JB, Cummins DS. *An Educational Needs Assessment for Improving Patient Safety: Results of a National Study of Physicians and Nurses*. Chicago, IL: National Patient Safety Foundation; March 20, 2003.

White Paper Report No. 3. Available at: http://www.npsf.org/download/EdNeedsAssess.pdf. Accessed August 3, 2004.

32. Sokol P, Cummins DS. A needs assessment for patient safety education: focusing on the nursing perspective. *Nurs Econ*. 2002;20:245–248.

33. Kizer KW. Patient safety: a call to action: a consensus statement from the National Quality Forum. *MedGenMed* [serial online]. March 21, 2001; *3*(2):10. Available at: http://www.medscape.com/viewarticle/408114. Accessed August 3, 2004.

34. Wilder GL. Medication safety in home infusion care. *J Infus Nurs*. 2003; 26:311–318.

35. West E. Organizational sources of safety and danger: Sociological contributions to the study of adverse events. *Qual Health Care*. 2000;9: 120–126.

36. McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. *N Engl J Med*. 2003;348:2635–2645.

37. Wennberg JE. Unwarranted variations in healthcare delivery: implications for academic medical centers. *BMJ*. 2002;325:961–965.

38. Fisher ES, Wennberg DE, Stukel TA, et al. The implications of regional variations in Medicare spending. Part 1: The content, quality, and accessibility of care. *Ann Intern Med*. 2003;138:273–288.

39. Moving beyond a punitive mind-set: A conversation with Lucian Leape, M.D. *Manag Care* [serial online]. July 2001. Available at: http://managedcaremag.com/archives/0107/0107.qna_leape.html. Accessed August 3, 2004.

40. McNutt RA, Abrams R, Aron DC. Patient safety efforts should focus on medical errors. *JAMA*. 2002;287:1997–2001.