CRITICAL PROCESSES AND PERFORMANCE MEASURES

FOR PATIENT SAFETY SYSTEMS IN HEALTHCARE INSTITUTIONS:

A DELPHI STUDY

A Dissertation

by

RALITSA B. AKINS

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

DOCTOR OF PHILOSOPHY

August 2004

Major Subject: Educational Administration

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Approved as to style and content by:

Bryan R. Cole (Chair of Committee)	Elvin E. Smith (Member)
Yvonna S. Lincoln (Member)	Yvonna S. Lincoln (Head of Department)
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ABSTRACT

Critical Processes and Performance Measures for Patient Safety Systems

in Healthcare Institutions: A Delphi Study. (August 2004)

Ralitsa B. Akins, M.D., Varna Medical University

Chair of Advisory Committee: Dr. Bryan R. Cole

This dissertation study presents a conceptual framework for implementing and assessing patient safety systems in healthcare institutions. The conceptual framework consists of critical processes and performance measures identified in the context of the 2003 Malcolm Baldrige National Quality Award (MBNQA) Health Care Criteria for Performance Excellence.

Methodology: The Delphi technique 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 where the first round questionnaire was based on literature review and the MBNQA criteria for excellence in healthcare, and tested by an instrument review panel of experts. Twenty-three experts (MBNQA healthcare reviewers and senior healthcare administrators from quality award winning institutions) representing 18 states participated in the survey rounds. The study answered three research questions: (1) What are the critical processes that should be included in healthcare patient safety systems? (2) What are the performance measures that can serve as indicators of quality for the processes critical for ensuring patient safety? (3) What processes will be critical for patient safety in the future?

The identified patient safety framework was further transformed into a patient safety tool with three levels: basic, intermediate, and advanced. Additionally, the panel of experts identified the major barriers to the implementation of patient safety systems in healthcare institutions. The identified "top seven" barriers were directly related to critical processes and

performance measures identified as “important” or “very important” for patient safety systems in the present and in the future.

This dissertation study is significant because the results are expected to assist healthcare institutions seeking to develop high quality patient safety programs, processes and services. The identified critical processes and performance measures can serve as a means of evaluating existing patient safety initiatives and guiding the strategic planning of new safety processes. The framework for patient safety systems utilizes a systems approach and will support healthcare senior administrators in achieving and sustaining improvement results. The identified patient safety framework will also assist healthcare institutions in using the MBNQA Health Care Criteria for Performance Excellence for self-assessment and quality improvement.

DEDICATION

To my son Ivan

Hopefully, I have inspired you to strive to discover your highest potential.

Just remember: *Vita nostra brevis est.*

ACKNOWLEDGMENTS

Many faculty and friends deserve acknowledgment and recognition for their support during my work on this dissertation. I would hope that the following acknowledgment will help them understand how much I appreciate their support, although this acknowledgment in no way can fully express my gratitude to them.

First and foremost, I would like to recognize Dr. Bryan R. Cole, Chair of my dissertation committee, for guiding me through the process and wholeheartedly supporting my research. Moreover, he has supported me from the very beginning of my studies at Texas A&M University, both academically and personally. I am eternally grateful for that.

I must also recognize the support I received from my committee members: Dr. Yvonna S. Lincoln, Dr. Elvin E. Smith, and Dr. Eddie J. Davis. I am in debt to them for their unequivocal support and encouragement.

A special acknowledgment is due to Dr. Homer Tolson, for always being ready to help students and me in particular. Also, I must recognize Ms. Jane Poulter with the Malcolm Baldrige office for her invaluable help in the early stages of my research. I would like to recognize Dr. Josie R. Williams with the Rural and Community Health Institute at the A&M Health Science Center for her input to the pilot survey instrument.

Undoubtedly, I also must recognize the support I received from the members of the Delphi panel. A complete list of their names is included in Appendix 1 in this volume. They replied to a substantial document during three survey rounds and they shaped the final outcome of this research. I want to acknowledge them for their commitment, patience and support.

Finally, I wish to acknowledge my friends Carolyn, Ginny, Margo, Becky, Janine, Kathy and Josie, who gave me comfort and encouragement that sustained me during an incredibly difficult time of my life. I placed a heavy burden on them and they supported me through many difficult times. I am eternally grateful.

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CHAPTER I

INTRODUCTION

The 2002 Malcolm Baldrige National Quality Award (MBNQA) Healthcare Criteria for Performance Excellence placed the patient in the center of healthcare delivery and services. Patient-focused excellence started to be considered a strategic concept that demands "rapid and flexible response to emerging patient desires and healthcare market requirements" as well as "awareness of new technology and new modalities for delivery of health care services" (Baldrige National Quality Program, 2002, p. 1). A recent study of the current research on patient safety in the United States found that the lack of clear nomenclature for error reporting, the complexity of the healthcare system and the culture of blame, along with the insufficient funding and legal constraints are significant barriers to patient safety research (Cooper, 2001). The lack of experts and qualified researchers in this newly emerging research field was a major constraint cited in the document. Cooper (2001) used data from six government agencies and seven private organizations, utilizing a total of 90 active research projects. The author identified 23 gaps in the current research. Among the major gaps were: need for different research methodologies to overcome the barriers to access information about errors in healthcare delivery, lack of studies on adverse event reporting processes, no studies of actual prevalence of medical errors, lack of basic understanding about the causes of errors and system failures, lack of error reporting processes and methods, and lack of studies of healthcare organizational culture.

The Institute of Medicine's (IOM) Committee on Quality of Health Care in America report *To err is human: Building a safer health system* (2000) revealed that "at least 44,000 Americans die each year as a result of medical errors" and that this number "may be as high as 98,000. Even when using the lower estimate, deaths due to medical errors exceed the number

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The style and format of this dissertation will follow that of *The Journal of Educational Research.*

attributable to the 8th- leading cause of death. More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16, 516). […] Despite the cost pressures, liability constraints, resistance to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort" (Institute of Medicine Report, 2000, p.1). According to the report *To err is human*, a number of recommendations for safe medication practices have been suggested by organizations focusing their attention on medication safety in inpatient and outpatient environment. The report cited such organizations as the National Patient Safety Partnership, the Massachusetts Coalition for the Prevention of Medical Errors, the National Coordinating Council for Medication Error Reporting and Prevention, the Institute for Healthcare Improvement, and the American Society for Health-System Pharmacists. The IOM Committee on Quality of Health Care in America called with this report for wide implementation of the recommended medication safety practices, drawing attention to the fact that although most of the medication safety recommendations of the organizations focusing on medication safety were consistent with one another, none of the suggested medication safety practices had been universally adopted. Furthermore, the conclusion was that some of the recommendations were "not in place in even a majority of hospitals" (Institute of Medicine Report, 2000, pp. 183 & 192).

The 2001 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. Scientific evidence has indicated that performance measurement, audit and feedback about the performance utilizing interactive workgroups, aggressive education of patients utilizing case management, community involvement, and interactive practitioner education result in improved healthcare delivery and services (Thomson O'Brien, Oxman, Haynes, Freemantle, & Harvey, 2000; Thomson O'Brien, Freemantle, Oxman, Wolf, Davis, & Herrin, 2001; Currell et al., 2000).

Errors in medicine have a high cost. The 2000 MedMARx report estimated that additional direct costs of more than $ 420,000 would be incurred by the participating facilities in the MedMARx reporting system due to medication errors. In addition to the direct costs for extra laboratory tests, prolonged hospitalization and near-death events, other financial burdens such as malpractice costs might also be sustained (MedMARx, 2002).

An adequate understanding of the system medication error risks and processes and a good reporting system, coupled with a rapid cycle change methodology of implementing continuous quality improvement (CQI) approach have proven effective in other sectors of the economy (Berwick, 1989; Berwick, Godfrey, & Roessner, 1991; Staker, 2000). There is compelling evidence that a prospective evaluation of error risks via failure modes and effects analysis (FMEA), retrospective evaluation of error events via root cause analysis (RCA) and the introduction of an effective system for reporting adverse medication events can contribute to reduction of medication error rates (Marder & Sheff, 2002; Andersen & Fagerhaug, 2000).

Implementation of Quality Management tools has also been recognized as a very effective approach to culture change (Shortell, 2000). Such an approach emphasizes understanding and improving the system in which work takes place and the processes and protocols that guide the work. However, the introduction of such systems and their conscientious use are not without problems as evidenced by the experiences of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), The United States Pharmacopeia (USP) Convention and the National Aeronautics and Space Administration (NASA) (JCAHO, 2002; MedMARx, 2000; NASA, 2002; Stark, 2002). Medical systems changes have been more effective and lasting when this approach was accomplished by the workers at the "sharp end" (healthcare practitioners that come in contact with patients) and if the "sharp end" workers participate in designing and implementing of the new system (Woods & Cook, 2002).

As a part of its Accreditation Process Improvement Initiative aiming to make the healthcare institutions' accreditation process more focused on individual healthcare organization's needs, in 2002 JCAHO approved two critical initiatives for testing in year 2003: priority focus process and organizational self-assessment. These critical initiatives required establishing continuous improvement processes based on organizational self-assessment (BHC Accreditation News, 2002).

Statement of the Problem

In 2002, a report on physician clinical performance assessment concluded, "In quality improvement, measurement of physician performance may promote 'best practices' and improvement of care for patients through the redesign of patient care microsystems and processes of care" (Daley, Vogeli, Blumenthal, Kaushal, Landon, & Normand, 2002, p.65). Furthermore, recognizing that quality issues in healthcare delivery are related to process failure rather than to individual failure to meet professional standards of care, the report strongly recommended commitment to the principles of quality improvement and performance measurement.

The IOM 2001 report *Crossing the quality chasm* called all healthcare constituencies, from purchasers to professional providers to policymakers and regulators, to join efforts in redesigning the healthcare delivery processes and improving healthcare delivery, focusing on medical care processes and outcomes. The report stated, "The current health care delivery system is not robust enough to apply medical knowledge and technology consistently in ways that are safe, effective, patient-centered, timely, efficient and equitable. As we strive to close this gap, we must seek healthcare solutions that are patient-centered, that are humane and respectful of the needs and preferences of individuals" (Institute of Medicine Report, 2001, p. 35).

According to the IOM 2000 report *To err is human*, safety is an important aspect of healthcare quality. The report made two specific recommendations in regard to creating safety systems in healthcare organizations. The first recommendation stated, “Healthcare organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with a defined executive responsibility” (p.156). The second recommendation declared, “Health care organizations should implement proven medication safety practices” (p.157). Additionally, the report recognized that knowledge of the root causes of the errors and about quality improvement concepts is a requirement for designing safety systems in healthcare.

Assuring that patient safety is a newly identified trend in healthcare delivery, the lack of appropriate research approaches to patient safety has been identified as a major constraint for research in the area (Cooper, 2001). Creating a framework for patient safety systems in healthcare settings would assist healthcare institutions in designing quality patient safety systems and improving the quality of healthcare delivery.

Purpose of the Dissertation

The purpose of this dissertation study was to identify critical processes and performance measures of quality that could serve as a framework for healthcare institutions implementing continuous quality improvement programs and patient safety systems. This study identified critical processes and performance measures in the context of the Malcolm Baldrige Quality Award Healthcare Criteria for Performance Excellence (Baldrige National Quality Program, 2002; Baldrige National Quality Program, 2003). In addition, the study examined the future importance of the identified critical processes for patient safety systems in healthcare institutions and identified major barriers to introduction of patient safety systems in healthcare institutions.

Research Questions

The following research questions were posed for the study:

1. What are the critical processes that should be included in healthcare patient safety systems?
2. What are the performance measures that can serve as indicators of quality for the processes critical for ensuring patient safety?
3. What processes will be critical for patient safety in the future as forecasted by healthcare experts on the Delphi panel?

Operational Definitions

Consensus – Change in the ranking of a critical process or a performance measure between two consecutive survey rounds that is smaller than or equal to 0.6 or falls within one Standard Deviation for the respective item, whichever is less. All critical processes and performance measures, for which consensus has not been reached, are subject to re-evaluation by the experts in a successive survey round (Scheibe, Skutsch, & Schofer, 1975).

Continuous quality improvement programs – A plan or procedure designed to address in a systematic manner improvement and sustaining success in meeting and exceeding customer needs, utilizing quality improvement strategies and tools.

Critical processes – A method or strategy by which a healthcare institution or its departments address a specific function and has been found to produce results which are replicable over time.

Delphi study – A method used to investigate consensus amongst a panel of experts using repeated rounds of a questionnaire instrument. This method is used in many fields, including education and healthcare, when a consensus must be reached on problems under conditions of uncertainty, with insufficient data, or the studied phenomenon/a are incompletely defined (Linstone, & Turoff, 1975).

Healthcare institutions – Organizations delivering medical services to patients.

Healthcare quality improvement and patient safety experts – Examiners, senior examiners or judges for the Malcolm Baldrige National Quality Award in healthcare, leaders of organizations for healthcare quality and patient safety at a state or national level, or administrators in senior/leadership positions in healthcare institutions, who at the time of the study were either serving as examiners, senior examiners, or judges for the Malcolm Baldrige National Quality Award in Healthcare, or their institutions had applied for or won the Malcolm Baldrige Quality Award in Healthcare or won a State Quality Award.

Malcolm Baldrige Quality Award – An award given by the United States Department of Commerce under the authority of the U.S. Congress by Public Law 100-107. The Malcolm Baldrige Quality Award recognizes superior continuous improvement programs focused on achieving and sustaining quality improvement for the long term (Hart, & Bogan, 1992).

Malcolm Baldrige Quality Award Health Care Criteria for Performance Excellence – Performance Standards for measuring quality in organizational management and processes, grouped in seven categories: (1) leadership, (2) strategic planning, (3) focus on patients, other customers and markets, (4) information and analysis, (5) staff focus, (6) process management, and (7) organizational performance results (Baldrige National Quality Program, 2002).

Patient safety systems – Healthcare institution-wide or department-wide approach or strategy for delivering healthcare services with minimized rate of occurrence of sentinel events (Institute of Medicine Report, 2000).

Performance measures – Information on the results of patient safety related processes that rank the input, output and factors influencing those processes for the purpose of their quantitative quality rating.

Quality – A state of excellence as assessed by a known instrument for quality measurement or by an agreed-upon acceptable level of performance as assessed by health institution's stakeholders (Hertz, Reimann, & Bostwick, 1994).

Assumptions

1. The study methodology offered the most logical and appropriate design for this particular research project.
2. The Delphi experts understood the language of the instrument, were highly competent in the field of healthcare quality and patient safety, and responded objectively and honestly.
3. The interpretation of the collected data accurately reflected the intent of the Delphi experts.
4. The instrument used in this study provided valid data and accurately identified critical processes and performance measures of patient safety systems for healthcare institutions.

Limitations

1. This study is limited to information acquired from literature review and the perceptions and expertise of the Delphi panel.
2. The study is limited to the expertise provided by the Delphi panel, consisting of healthcare experts – examiners for the Malcolm Baldrige Quality Award in Healthcare or serving in healthcare institutions, which have won or applied for the Malcolm Baldrige Quality Award in Health Care or have won a State Quality Award.

Significance of the Dissertation

In July 2002, JCAHO approved six National Patient Safety Goals to be effective for one year, beginning January 1, 2003. The patient safety goals provided a clearly defined, practical and achievable approach to the most critical threats to patient safety in U.S. healthcare delivery systems. The patient safety goals aimed improvement in the following areas: patient identification, healthcare communications, administration of high-alert medications, wrong-site surgery, use of infusion pumps and effectiveness of clinical alarm systems (JCAHO approves National Patient Safety Goals, 2002). A seventh patient safety goal was added effective January 1, 2004 – reduction of the risk for hospital-acquired infections – and all JCAHO-accredited healthcare institutions are surveyed for all seven patient safety requirements (JCAHO, 2003). A special evidence report on patient safety practices provided a critical appraisal of the current evidence on the topic. The report identified and evaluated existing practices in healthcare and concluded that patient safety is particularly challenging since patient safety practices are multidimensional, difficult to assess and they engage different organizational levels (Making Healthcare Safer, 2001). Better healthcare systems must be developed to ensure that clinicians provide the care they intend to provide (Leape, Berwick, & Bates, 2002).

Identified performance measures and critical processes in the area of patient safety would be useful for healthcare institutions in designing and improving patient safety systems. The results of this study are intended to assist healthcare institutions seeking to develop high quality programs, processes, performance measures and services in regard to patient safety. The identification of critical processes in introducing patient safety programs along with a provision of performance measures will support healthcare senior administrators in understanding the role processes play in improving healthcare delivery and services as well as in achieving and sustaining improvement results. These measures will also serve as a means of evaluating existing patient safety initiatives or guiding the planning of new processes and improved healthcare delivery. The identified patient safety performance measures will assist healthcare institutions in using the MBNQA's Health Care Criteria for Performance Excellence for self-assessment and quality improvement.

Organization of the Dissertation

This study consists of five chapters. Chapter I is an introduction of the topic of Continuous Quality Improvement of Patient Safety Systems in Healthcare Institutions. Chapter II provides a review of the relevant literature on patient safety and continuous quality improvement in healthcare institutions as well as an overview of the Malcolm Baldrige National Quality Award criteria for performance excellence in healthcare. Chapter III describes the research methodology used in the study. Chapter IV explains and analyses the results of the study. A summary of findings, conclusions and recommendations for further research are presented in Chapter V.

CHAPTER II

LITERATURE REVIEW

Introduction

In March 1992, an 82-old patient died in Kennestone Hospital, Marietta, GA, due to administration of insulin instead of penicillin, and two months later, in May 1992, a 64-year old cancer patient at Crouse Irving Memorial Hospital in Syracuse, NY, died because of the administration of a wrong chemotherapy drug (Medication errors, 1992). In early 1995, Betsy Lehman, a health reporter for the *Boston Globe* died in the Dana Farber Cancer Center due to a massive overdose of chemotherapy (Leape, 1996). In December 1995, a seven-year-old boy from Florida received adrenalin instead of lidocaine during anesthesia for ear surgery and died; in 1997, a newborn in Houston, TX, received an injection of digoxin containing ten times the appropriate dose and died (Spath, 2000). In October 1996, a healthy 7-pound male newborn infant died at Centura St. Anthony Hospital in the outskirts of Denver, CO, due to the administration of a ten-fold overdose of intramuscular Penicillin intravenously (Smetzer, 1998). In February 2003, 17-year-old Jesica Santillan died after receiving a heart-lung transplant from a donor with the wrong blood type at Duke University Medical Center in North Carolina (House passes bill on medical mistakes, 2003). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reported that 75% of the sentinel events reported to the agency between January 1995 and June 2002 resulted in patient's death (Sentinel event statistics, 2002).

Leape (1996) asserted that the error rate in healthcare is substantially higher than the error rates tolerated in other industries, particularly hazardous ones such as aviation and nuclear power industry, and attributed the hesitancy of healthcare organizations to make serious efforts in reducing patient safety hazards to the fear of undermining the public confidence in healthcare, to the malpractice litigation which provided a strong incentive to silence, and to the culture of perceiving medical errors as personal failure of the medical professionals. Leape (1996) called the latter the "blame and train" approach that shutters mistake reporting and masks the real magnitude of the problem of medical errors. Furthermore, accidents are functions of the systems in which people work and more often than not they "wait to happen" in complex systems with a poor design (Leape, 1996).

The opinions of the medical professionals and the public on the quality of healthcare and the problem of medical errors differ widely (Robinson, Hohmann, Rifkin, Topp, Gilroy, Pickard, & Anderson, 2002). For example, a survey on the physician and public opinions on healthcare quality and medical errors with large samples of Colorado and national physicians and Colorado households revealed that compared to the public opinion, physicians were less likely to believe that the quality of healthcare is a problem and less likely to believe that a national agency is needed to address the problem of medical care. Additionally, the survey identified the fear of litigation as the major barrier to reporting of medical errors and emphasized the need for physician education on medical errors (Robinson, Hohmann, Rifkin, Topp, Gilroy, Pickard, & Anderson, 2002).

Wide variation in healthcare delivery in the United States has been documented (e.g., less than 55% of the adult patients receive the care recommended for their condition) and establishment of a national clinical performance base-line has been recommended in order to decrease the number of deaths that could have been prevented. For example, blood pressure control could prevent more than 68,000 deaths annually, vaccination could prevent more than 10,000 deaths annually, and colorectal cancer screening could prevent more than 9,600 deaths annually (McGlynn, Asch, Adams, Keesey, Hicks, DeCristofaro, & Kerr, 2003).

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 to take place. 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 in order to design effective safety systems. Marx (2001) 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 violate established procedures but by twist of fortune did not cause extreme damage, and those who are well-meaning but had a more severe outcome (Marx, 2001).

Reason (2002) argued that human error cannot be eliminated; rather, strategies can be employed to moderate the unwanted consequences of human fallibility. Error reduction (limiting error occurrence) and error containment (detection of errors and minimization of their unwanted consequences) are two distinct parts of error management. Thus, effective error management should involve all four stages of human action control, i.e. planning, intention storage, execution and monitoring of the human action. In medicine, certain properties of the healthcare tasks, such as great information loading in a particular task step, functionally isolated procedural steps, repeated procedural steps, unexpected task interruptions, tasks involving planned departures from traditional/procedural action consequences, etc., have been identified as increasing the probability of omission errors (Reason, 2002).

Reason (2002) identified five universal criteria for effective reminders, namely:

- *conspicuous*, i.e. attention catching,
- *contiguous*, i.e. appearing close to the action in location and space,
- *context-related*, i.e. specifying when and where the task should be performed,
- *content-related*, i.e. what should be done, and
- *count*, i.e. specifying the discrete actions comprising the task.

For the most common human error type, *errors of omission*, Reason suggested a three-stage omission management program including: (a) task analysis, (b) assessment of omissions likely to occur at each task step, and (c) choice and application of suitable reminders (Reason, 2002).

It has been argued that in the field of healthcare 99.9% of proficiency is far from satisfactory; W. E. Deming, as cited by Leape (1994), had 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” (Leape, 1994, p.1851). 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 (Leape, 1994). 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 (Meurier, Vincent, & Parmar, 1998). 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” (Leape, 1994, p.1852).

Malcolm Baldrige Award Criteria for Performance Excellence in Healthcare

The Malcolm Baldrige National Quality Award (MBNQA) was established in 1987 to address the importance of quality as the most significant factor for the trade balance of the

United States and is the most prestigious national quality award in the U.S. This award is given by the United States Department of Commerce under the authority of the Malcolm Baldrige National Quality Improvement Act of 1987. The Act was passed on January 6, 1987, signed by President Ronald Reagan on August 20, 1987, and became Public Law 100-107. The United States Government took the leadership in creating, validating, and improving the national quality award program and its processes (Reimann, 1989). The Malcolm Baldrige National Quality Improvement Act of 1987 established specific requirements for managing the award program; it defined the categories for award, and the criteria for award qualification. The award criteria required written application and rigorous peer evaluation including establishment of board of overseers, board of examiners, and site visits (Reimann, 1988; Reimann, 1989). Heavy performance orientation in the national quality award program and a clear focus on the importance of integration of quality in the institutional business planning, together with four program design elements (establishment of award criteria, scoring system, evaluation process, and quality award program organizational structure) ensure the integrity and continuity of the Malcolm Baldrige National Quality Award Program (Reimann, 1989). Judges and examiners for the National Quality Award are selected on the basis of their experience, quality expertise, and peer recognition, and special efforts are made to have broad representation of experts from various industries (DeCarl, & Sterett, 1990). Presidential involvement in the award process (the award is presented by the President of the United Stated or the Secretary of Commerce) ensured national impact, visibility and prestige for the award winners, wide peer recognition for winners' achievements as well as deployment of their results throughout industries in the nation (DeCarlo, & Sterett, 1990). The Baldrige Program is managed by the National Institute of Standards and Technology (NIST). The American Society for Quality (ASQ) contracts with NIST for administration of the program (NIST, 2004).

The Malcolm Baldrige National Quality Award Criteria were selected based on their importance and applicability to all businesses. Input was sought from quality leaders in various positions in manufacturing, service, and academia, quality consultants and retired experts. As a result, a list of characteristics that should be reflected in the award was developed to include:

- quality improvement,
- total quality management,
- senior level institutional leadership,
- statistical process control,
- human resource utilization,
- performance measurement,
- innovative approaches to quality improvement,
- quality measurement system,
- customer satisfaction,
- incorporation of quality as early as process design stages, and
- support for building institutional, local, and national quality infrastructure (Reimann, 1988).

The interviews with over 200 business professionals, conducted by Dr. Curt Reinmann, the first Director of the National Quality Award, resulted in the selection of criteria to be included in the Baldrige framework. The selected criteria served three purposes – they were a communication tool, a diagnostic tool, and a performance evaluation scoring system (Hart, & Bogan, 1992). In addition to serving as the basis for the national quality award, the Malcolm Baldrige National Quality Award criteria were also intended to be used as a self-assessment tool, training and educational tool, coordination and competition among companies or company sub-divisions, quality promotion and long term goal setting, as well as a basis for state and local quality awards (Reimann, 1989). These criteria were initially organized into seven examination categories; while the award program was expected to continuously evolve and improve following the feedback and recommendations of award examiners, these seven categories were intended to remain stable to ensure strong program foundation and a basis for continuity. The evolvement of the national quality award program annual improvement cycles included sharpened category boundaries, streamlined application process, reliable scoring and reporting system, and an elaborate site visit examination system (DeCarlo, & Sterett, 1990).

The MBNQA has five sector categories: Manufacturing, Service, Small Business, Education, and Healthcare. The category of healthcare was added in 1998. As Hertz, Reimann, and Bostwick (1994) noted, the large annual increases in health premiums (20% to 50%) and the large amount of national income (more than 30%) spent on healthcare led to the question whether the Malcolm Baldrige Quality award, or a similar one, could improve healthcare institutions' competitiveness and healthcare outcomes, facilitate quality measurement and management, and enhance deployment of successful quality improvement strategies. Extending the national quality award to healthcare would not only recognize successful institutions' accomplishments (such as delivering high quality healthcare services at minimum cost) but also build quality awareness and a path for quality information transfer among peer institutions. Setting of "stretch goals" and incorporating concepts specific to healthcare (such as patient satisfaction, comparative performance of healthcare plans, cost-effective treatment, healthcare effectiveness, and healthcare outcomes research) could serve for institution's performance improvement, productivity enhancement, meeting customer needs, and cost containment. Thus, establishing a Baldrige quality award category specific to healthcare became highly desirable for the healthcare community (Hertz, Reimann,& Bostwick, 1994). Eligible applicants in the category of healthcare include hospitals, health maintenance organizations, long-term healthcare facilities, healthcare practitioner offices, home health agencies, and dialysis and ambulatory surgery centers.

The healthcare criteria for performance excellence are built upon 11 core values and concepts:

- Visionary leadership (i.e. senior institutional leadership creates clear institutional values, high performance expectations and patient focus);

- Patient focused excellence (including patient education, ensuring patient safety, and setting high quality performance standards for achieving patient satisfaction both in the current and in the future);
- Organizational and personal learning (continuous improvement of institutional quality approaches, adaptation to change, and incorporating new improvement approaches; acquiring and sharing new knowledge on all levels – from individual, to team, to department, to institution);
- Valuing staff and partners (creating a work environment conducive to staff satisfaction, development, and well-being);
- Agility (i.e. capacity for rapid change and flexibility);
- Focus on the future (i.e. understanding all factors, both short-term and long-term, affecting healthcare institutions and markets; strategic planning for improvement of healthcare institutional performance and outcomes);
- Managing for innovation (introducing meaningful change to improve services and processes);
- Management by fact (collection and analysis of appropriate data to serve as a means for strategic planning, goal setting and improvement);
- Social responsibility and community health (healthcare institutions have the responsibility to abide by applicable federal, state and local regulations, to improve the health of their community and to exercise ethical behavior);
- Focus on results and creating value (measurement and analysis of key performance results to create value for customers and all stakeholders);
- Systems perspective (alignment and integration of institutional processes) (Baldrige National Quality Program, 2004).

The MBNQA recognizes superior continuous improvement programs focused on achieving and sustaining quality improvement for the long term. The MBNQA framework consists of core values and concepts, embodied in seven criteria categories: Leadership; Strategic planning; Focus on patients, Other customers and markets; Measurement, analysis and knowledge management; Staff focus, Process management, and Organizational performance results.

Applicants considered for the award receive over 1,000 hours of review of independent board of examiners. The framework for healthcare (Fig. 1) is adapted from the business quality framework.

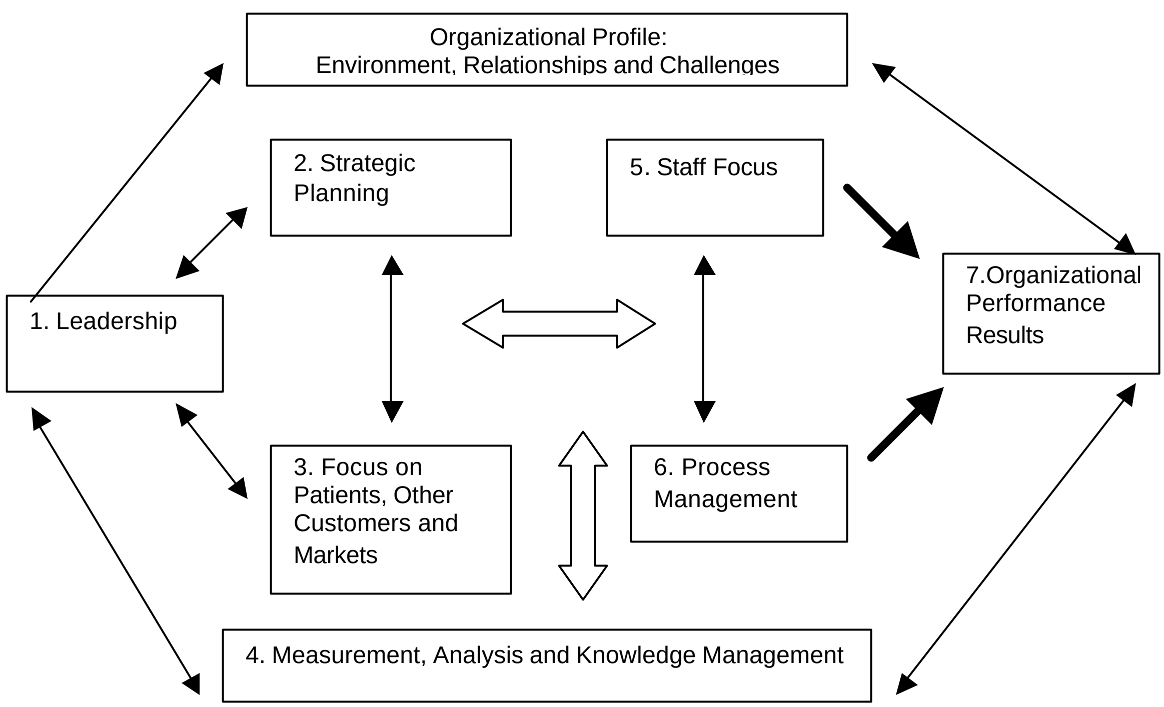

FIGURE 1. Baldrige Healthcare Criteria for Performance Excellence: Conceptual Framework (From: *Baldrige National Quality Program*, 2003, p. 5)

Using a common framework throughout different sectors of the economy enhances inter-sector cooperation and information sharing. The primary aim of the Baldrige Program is fostering economical growth and success along with improving marketability of U.S. businesses and organizations.

The Baldrige framework consists of 7 categories, 19 items, and each item consists of one or more Areas to address. The performance excellence criteria focus on organizational performance results, including healthcare results, patient and other customer-focused results, financial and market results, staff and work-systems results, governance and social responsibility results, and organizational effectiveness results. Although the criteria are results-oriented, they are non-prescriptive and adaptable. Thus, organizational structure and quality approaches may differ widely from one organization to another; healthcare organizations are expected to create innovative approaches for quality "breakthroughs," achievement of optimal results, and in support of their goal-oriented improvement plans (Baldrige National Quality Program, 2003).

Healthcare organizations vary widely in their mission and primary customers. Additionally, in healthcare the term "Senior Leadership" has been defined to include not only the organizational top management team, but also separate administrative, management and healthcare provider leadership, and the relationships between these two sets of leadership teams (Baldrige National Quality Program, 2003).

Although the primary focus in healthcare is the delivery of healthcare services, a variety of business processes, such as business technology acquisition, information and knowledge management, housekeeping, medical record management, mergers, finance, accounting, security, billing, etc., play a substantial role in the overall organizational results and marketability. Thus, healthcare organizations should address both stakeholder (patients, staff, payors and community) requirements and the need to efficiently use their resources. Since maintaining and improving health and quality of life is the ultimate goal of all healthcare organizations, sharing their results and best practices would positively impact the healthcare systems throughout the U.S.

The flexibility and adaptability of the Baldrige framework allows it to change and better assess organization's quest for quality. For example, compared to the 2002 criteria, the 2003 performance excellence criteria had an increased focus on organizational government and leadership's responsibility for organization's legal and ethical behavior, better reflected the growing importance of deployment of organizational knowledge, and through separate Governance and Social responsibility items strived to encourage ongoing monitoring and improvement of these areas (Baldrige National Quality Program, 2002; Baldrige National Quality Program, 2003). In an effort to stabilize the healthcare framework and allow healthcare organizations to continue their quest for excellence after the changes in the 2003 criteria, no substantial changes occurred in the 2004 healthcare criteria (Baldrige National Quality Program, 2004).

Based on individual healthcare institution's organizational profile, mission, goals and objectives, institution's performance is evaluated in seven distinct (and related) categories:

1. Category 1, Leadership, emphasizes the role of institution's senior leadership in achieving quality results, in responsive governance of the institution and in ensuring the institution's proper legal and ethical behavior.
2. Category 2, Strategic planning, focuses on how healthcare institutions are planning to achieve and sustain changes as targeted by the goals in the institution's action plans.
3. Category 3, Focus on patients, other customers and markets, assesses how the institution meets and exceeds customer expectations and relevant requirements.
4. Category 4, Measurement, analysis and knowledge management, addresses the continuously changing organizational needs for measurement and analysis,

as well as the challenges to reply to industry changes and implementation of innovations.

5. Category 5, Staff focus, focuses on work environment, staff measurement systems, career development, recruitment and staff motivation.
6. Category 6, Process management, emphasizes the integration of healthcare system design, healthcare delivery and support processes.
7. Category 7, Organizational performance results, is intimately related to categories one through six and primarily assesses the institution's healthcare delivery outcomes (Baldrige National Quality Program, 2002, 2003, & 2004).

The Baldrige National Quality Program encourages healthcare institutions to use the Baldrige framework to guide their self-assessment efforts starting at the very early stages of institution's journey to performance excellence. The *Ten Steps for Self-Assessment and Action* program helps organizations to discover the gaps in their performance and address those gaps through action planning and implementation. The ten-step program is an easy guide to ensuring that all appropriate areas within an institution are included in the assessment, that data and information are consistently collected, and that self-assessment and action champions are leading the assessment and improvement activities, and the ten-step program also offers an online-accessible self-assessment and action planning tool (Getting started, 2003).

The Baldrige National Quality Program has established a rigorous set of criteria for selection of a national board of experts capable of evaluating applicants for the award. In order to expand the national pool of trained knowledgeable examiners, a number of the examiner board members is replaced each year, and prospective board members, including those who have already served as examiners, have to re-apply each year. The applicants for the MBNQA board of examiners are expected to have in-depth knowledge and extensive experience relevant to the seven Baldrige categories in at least one, and preferably more than one industry or service sector. The examiners appointments on the MBNQA board is for one award year (approximately one calendar year) and requires a commitment of at least 40 hours per application during stage one, and up to 10 days of 12-18 hour work per day during the site review stage. Additionally, some of the examiners prepare scorebooks that serve as applicants' feedback reports. The expectations from, and the commitment of, board examiners are to strive to enhance and advance the MBNQA effort to stimulate improvement in the quality, productivity, and overall performance of U.S. companies (NIST, 2004).

First Winner of the MBNQA in the Healthcare Category

The first award in the healthcare category was given in 2002 to SSM Health Care, a non-profit healthcare system based in St. Louis, MO, which provides acute healthcare and nursing services in four states: Illinois, Missouri, Oklahoma, and Wisconsin. SSM Health Care started their quality journey in 1999 with 14 teams (clinical collaboratives including multidisciplinary representatives of healthcare professionals and administrators) and by 2002 the number of teams reached 85. The accomplishments of the teams is showcased annually and the results are deployed throughout the system consisting of more than 20 separate entities, one of the largest healthcare Catholic systems in the U.S. (White, & Savitsky, 2003). SSM Health Care uses Performance Measurement Process in assessing organizational performance and achievement of short- and long-term goals. The organization emphasizes performance measurement, improvement of clinical outcomes, information technology utilization and improvement of communication processes. Use of quality improvement methodologies has increased SSM Health Care market to 18% over only three years, while during the same period three of its five competitors lost their market shares.

2003 Winners in the Healthcare Category

There were two winners of the Malcolm Baldrige National Quality Award for Healthcare in 2003 – Baptist Hospital, Inc. and Saint Luke's Hospital of Kansas City – selected from a total of 19 healthcare applicants.

Baptist Hospital, Inc. is a subsidiary of Baptist health care and consists of a large 492-bed tertiary-care hospital in Pensacola, FL, a 60-bed medical and surgical hospital in Gulf Breeze, FL, and an ambulatory care complex in Pensacola, FL. The inpatient and outpatient overall satisfaction, the ambulatory surgery overall satisfaction and home health care services satisfaction has been around the 99th percentile over a five-year period. The institution's Clinical Accountability Report of Excellence (CARE) measures more than 50 departmental and institution wide indicators and the results of the medication adverse events indicator and the pressure ulcers indicator have been steadily outperforming the established benchmarks. The organization collects data that allows tracking of the overall performance of the institution and identifying of opportunities for improvement.

Saint Luke's Hospital is the largest hospital in Kansas City metropolitan area and provides 24-hour coverage in all healthcare disciplines. The hospital is highly ranked by consumer organizations and consumer surveys showed that the facility is ranked as number one in its respective market area. The institution tracks 58 performance indicators , and in the year 2002 over 95% of the indicators were within the control limits. Saint Luke's hospital has designed clinical pathways for high-volume and high-cost diagnoses and a team approach is utilized to assess clinical processes and introduce best clinical practices. Currently, the hospital applies 134 clinical pathways that capture 60% of the patients. Additionally, the institution has developed and deployed a set of 12 Customer Contact Requirements which are a part of a new patient-focused care delivery model. Importantly, the operations of the institution are aligned from top to bottom utilizing Strategic Planning Process, Balanced Scorecard, Process Scorecards, Performance Management Process and Performance Improvement Model approaches.

Continuous Quality Improvement in Healthcare and Patient Safety

In the mid-1990s, a series of tragic medical errors brought the issue of medical errors to the public attention and into the focus of medical professionals. Wrote Hatch (2001), "The major advances in medicine which have occurred in recent years have not only given doctors the power to confer great benefits on patients, but also the ability to cause great harm (Hatch, 2001, p.1339). The first Annenberg Conference on Examining Errors in Healthcare, held in October 1996, brought together people from multiple disciplines to discuss the issue of medical errors – an issue that had been a taboo until then (Spath, 2000). As argued by Shojania, Duncan, McDonald and Wachter (2002), the problem in healthcare is not the lack of tools to improve patient safety, rather the low priority traditionally assigned to this goal. Healthcare futurists have put the issues of patient safety and quality improvement, along with the issues of implementation of clinical information systems, e-health, and electronic medical records among the top trends in the U.S. healthcare nowadays (Weber, 2003).

Franke (2000) wrote, "Physicians may be the star quarterbacks of their practices, but they still need someone to block, run, and catch the ball. They cannot ensure their patients' health and satisfaction on their own. They must defend themselves against system errors through teamwork" (p. 35). The multifaceted effort to improve the outcomes of healthcare includes defining the clinical issue, determining evidence-based clinical performance measures, collecting and analyzing data, identifying process barriers, development and implementation of system interventions to improve existing processes, and educating both healthcare providers and patients about appropriate care. The main three sources for data about healthcare are: (a) abstraction from medical records or existing databases, (b) administrative claims, and (c) surveys. (Bing, Abel, Pendergrass, Sabharwal, & McCauley, 2000).

Spath (2000) observed, "So, there is activity, and there is progress, but it is frustratingly slow. Healthcare is undergoing a profound culture change in which all workers, from the CEO to the newest orderly, learn to feel personal responsibility for patient safety, and where discovering and reporting errors is rewarded, not punished. It is counterintuitive and flies in the face of much that we teach and have been taught. But systems theory is solidly based in science. Even more important, it works, and therefore it will prevail. It's just not easy" (p. xxii). While quality experts agree that the cause for the majority of performance problems is the healthcare delivery system itself, and accident investigators agree that most disasters in complex organizations have long incubation periods and manifest with multiple discrete "small" events over a long period of time, the study of human error in medicine is a relatively new field that tries to establish its boundaries, terminology, and taxonomy, and currently the focus of attention is still predominantly on individual performance and responsibility (Spath, 2000).

Systems Model of Human Error in Healthcare

Reason (1990) developed a model for organizational accident in complex industrial systems that considered not only the actions of the individuals involved, but also the conditions in which the tasks were performed and the organizational context in which the incident occurred. He distinguished between *active* failures as unsafe acts of omission or commission and *latent* failures stemming from managerial decisions, process organization and system design. Thus, latent failures provide the work conditions for occurring of unsafe acts; such conditions include inadequate knowledge, training or expertise, heavy workloads, inadequate supervision, inadequate systems of communication, inadequate maintenance of plant and equipment, and stressful environment (Reason, 1990). The accident opportunity has to penetrate through several layers of defense systems on managerial, psychological, environmental and local levels (an error opportunity window sometimes called "the Swiss cheese model") before an opportunity window allows the error to reach a patient (Reason, 1990; Hatch, 2001). Thus, discipline should not be the first but rather the last action taken against staff members in result of reported errors (Joiner, 1994). Focusing on systems analysis, education, development and dissemination of clinical practice guidelines, using automated “fail-safe” systems, and computer reminders have been identified as contributing factors for adverse events in healthcare, and studying these factors as well as their interrelations has been recommended for prevention of medical errors (Leape, Brennan, Laird, Lawthers, Localio, Barnes, Hebert, Newhouse, Weiler, & Hiatt, 1991).

In 1998, Vincent, Taylor-Adams, and Stanhope presented a framework for analysis of risk and safety in clinical medicine encompassing a variety of system factors that influence clinical medicine such as nature of performed tasks, healthcare teams, work environment, and organizational factors organized in seven influential groups:

- Institutional context, including the economic and regulatory environment;
- Organizational and management factors, including policy standards, organizational goals, financial resources and constraints, and safety culture and priorities;
- Work environment, including staffing levels, workload and shift patterns, design, availability and maintenance of equipment, and available administrative and managerial support;
- Team factors, including verbal and written communication, supervision and team structure;
- Staff factors, including knowledge, skills and motivation of healthcare professionals;
- Task factors, such as task design, clarity of structure, availability and utilization of protocols, and accuracy of test results; and
- Patient characteristics, including personal and social factors, such as complexity and seriousness of illness and communication/language capabilities.

Therefore, safety in healthcare organizations needs to be assessed based on system design, and the presence of adverse events in healthcare calls for investigation of a broad variety of system, process and individual factors in order to understand the complexity of the chain of events leading to unwanted outcome (Vincent, Taylor-Adams, & Stanhope, 1998).

Woods and Cook (2002) asserted that patient safety is a property of the healthcare systems and not of their components; thus, safety is created and broken in systems, not individuals, and finding systematic vulnerabilities is much more efficient than searching for individual flaws. Healthcare professionals function under resource and performance pressures. Thus, interconnections between parts and activities are increased in order to achieve greater productivity and efficiency and the increased interconnectivity (i.e. coupling between system parts) increases both operational complexity and difficulty of the problems that arise (Woods & Cook, 2002). The limited resource pool calls for prioritization of tasks and activities and need to capture change patterns and sequences through a comprehensive feedback. Woods and Cook (2002) suggested an action framework to move forward from human error in complex systems, such as healthcare systems. The nine-step action framework starts with uncovering the true causes for failures and transition from reactive to proactive response to failures, proceeds with a thorough understanding of the clinical work as experienced by the practitioners at the "sharp end" of the system (i.e. at the points with immediate contact with patients) and exploration of the system points of vulnerability, goes on to study what strategies are utilized by clinical practitioners to guard against known patient safety hazards and the underlying patterns of systemic factors, examines the impact of economic, organizational and technological changes on patient safety and searches for newly produced vulnerabilities and "paths to failure" as a result of these changes, and finally, since people and technology are neither separate nor independent, suggests use of technology to support and enhance human expertise and creation of a system of integrated feedback to capture patterns of relationships in the complex system.

Quality Improvement Approaches in Healthcare

Joiner (1994) considered quality improvement methodologies based on meaningful data collected from interdependent system processes the most beneficial for improvement of patient safety and medication safety in particular. To improve the quality and value of healthcare in the twenty-first century, the healthcare system should have the capability to produce changes in the design and delivery of services. Moreover, the re-design efforts must lead to better outcomes, measured in biological, functional, and satisfaction parameters (Batalden, & Splaine, 2002). Furthermore, cost and quality cannot be separated in the assessment of the healthcare interventions; thus, the twenty-first century healthcare leaders are expected to be able to recognize, manage and bring about change in daily healthcare practice. Batalden and Splaine (2002) described three clusters of processes of leading: (1) building knowledge of moral and ethical imperatives, (2) taking actions towards accountability, and (3) reviewing the processes and outcomes to assess the fit between change efforts and patient needs. According to Batalden and Splaine (2002), eight domains outlined the needed knowledge and skills for continuous improvement in healthcare:

- Knowledge about healthcare as process or system to meet the healthcare needs of individuals and communities;
- Understanding the role of variation and measurement in improving healthcare design;
- Knowledge of customer needs and preferences;
- Skills to lead the change in healthcare, including change in complex organizations, strategic management of people and processes, and development of supportive organizational climate for work, learning and care;
- Interpersonal and teamwork skills to foster effective collaboration in groups;
- Understanding of the social context, related expectations and financial impact of healthcare;
- Skills to develop new knowledge through empiric testing;
- Discipline-specific knowledge and ability to apply core professional competencies as specified by professional boards, accreditation and certifying bodies.

Successful healthcare leaders for the twenty-first century are expected to build the capacity of the healthcare system for improvement. Chief executive officers in healthcare organizations should be able to recognize the importance of aligning all organizational strategies for improvement (operations, professional development, and financing) and systematically approach organizational and personal improvement through performing patient assessment, process assessment, data gathering, and critical assessment of the current literature. Batalden and Splaine (2002) suggested that the best approach for cultivating the twenty-first century healthcare leaders is to offer them a model for application of the quality improvement approaches starting during the education of the future medical doctors.

Healthcare senior leadership's involvement is critical for implementation of successful quality improvement programs in healthcare institutions. Senior leadership support in goal setting, interdisciplinary collaborations, and management of patient safety risk may serve as a catalyst of quality improvement and culture change in healthcare institutions. Management's personal involvement in quality and patient safety initiatives, establishment of caring relationship with clinical staff, promotion of organizational culture change in support of the quality improvement efforts, building patient safety infrastructure, and allocating institutional resources towards quality improvement are important managerial strategies (Bradley, Holmboe, Mattera, Roumanis, Radford, & Krumholz, 2003).

Patient Safety Status of U.S. Healthcare

In December 2003, the Agency for Healthcare Research and Quality (AHRQ) issued the first comprehensive report on the healthcare quality in U.S. (U.S. Department of Health and Human Services, & Agency for Healthcare Research and Quality, 2003). The report on healthcare quality assessed the effectiveness of selected quality measures for cancer care, diabetes, end stage renal disease, heart disease, HIV and AIDS, maternal and child health, mental health, respiratory diseases, and nursing home and home healthcare. The report data showed that in healthcare areas where clinical care measures have been trended over time, improvements were observed; e.g. in 20 of the trended 57 clinical measures in diabetes care, cancer care, heart disease care and asthma care, improvement has been reached. Emphasizing the fact that 95% of the $1.4 trillion spent on healthcare in the U.S. have been spent towards direct healthcare services and only 5% towards disease prevention, the report concluded that major opportunities to stop diseases from occurring or deteriorating have been missed (U.S. Department of Health and Human Services, & Agency for Healthcare Research and Quality, 2003).

The 2003 AHRQ report was intended as a tool for Federal and State policy-makers for improving the U.S. healthcare system. The report defined four components of healthcare quality – effectiveness, patient safety, timeliness, and patient centeredness of the healthcare services – and documented gaps in some of the patient safety areas (such as increased number of accidental lacerations during a procedure and increased number of pressure ulcers) while achieving improvement in other areas (e.g. the intensive care unit, ICU, infection rate decreased during the period 1995-2002 and the anesthesia complication rates were as low as 0.72 per 1,000 surgical discharges during the same period). The report suggested that there were enormous opportunities for improvement. For example, the data showed that less than 21% of the patients with diabetes have received the five basic tests (annual retinal eye exam, annual influenza vaccinations, annual HbA1c checks, annual foot exams, and biennial lipid profiles) during the last two years (U.S. Department of Health and Human Services, & Agency for Healthcare Research and Quality, 2003).

Targeting to find which clinical interventions could reduce medical errors, Shojania, Duncan, McDonald and Wachter (2002) identified 83 distinct clinical safety practices supported by 70 systematic reviews and 293 additional primary investigations. However, some of the discussed practices, such as decreasing the number of verbal orders, decreasing the number of work hours and removing potassium chloride from ward stocks, lacked supporting clinical evidence.

Leape, Berwick and Bates (2002) called for establishing clear criteria for determining "best practices" and noted, "Anesthesia is the only system in health care that begins to approach the vaunted 'six sigma' level of perfection that other industries strive for. Mortality from elective anesthesia has declined 10-fold in the past several decades as the result of a concerted effort to improve safety. This outstanding achievement is attributable not to any single practice or development of new anesthetic agents or even any type of improvement (such as technological advances) but to application of a broad array of changes in process, equipment, organization, supervision, training and teamwork" (pp.505-6). Leape, Berwick and Bates (2002) asserted that the positive changes in anesthesia were based on the understanding of human factor principles, such as standardization, simplification, and use of protocols and checklists, and promoted the idea that patient safety could be achieved by making many little changes that could bring about a huge aggregated difference. Furthermore, healthcare executives and policy makers were urged to give a serious consideration to evidence-based practices and make reasonable judgments based on the best available evidence combined with successful experiences in healthcare for achieving improvement in patient safety (Leape, Berwick, & Bates, 2002).

Barriers to Patient Safety

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 (Shojania, Duncan, McDonald, & Wachter, 2002). Patient safety and healthcare quality are two terms that have not been fully differentiated between. Although many of the attributes of patient safety are considered to be subsets of healthcare quality, i.e. delivery of quality healthcare guarantees patient safety, 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 (Cooper, 2001).

The lack of single typology of medical errors coupled with the lack of standards and infrastructure for systematic data collection has been identified as major constraints for patient safety improvement (U.S. Department of Health and Human Services, & Agency for Healthcare Research and Quality, 2003). 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 (Lawton, & Parker, 2002). To the critical component of current medical culture, Leonard (2003) identified additional factors, such as communication factors, human factors (e.g., multitasking, distraction and interruptions, fatigue, and stress), senior leadership involvement with quality improvement and culture change that may act as barriers to optimal functioning of patient safety systems. Williams (2000) noted, "The future in the debate over quality of care depends on the will of physicians to carefully evaluate the performance evaluation skills and tools that are being imported from other disciplines, such as business, economics, social sciences, statistics, and marketing, in addition to time-honored scientific principles" (p.10).

Adoption of electronic medical record (EMR) systems has been viewed as a major tool in increasing patient safety, decreasing medical errors, facilitating of 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 (Medical Records Institute, 2003).

A two-phase survey administered in the fall of 2001 on 200 physicians and 100 nurses from geographically dispersed hospitals of 200 beds or more, revealed that quality of care was considered the most important contemporary issue in healthcare, more important than efficiency or cost of healthcare. The survey results suggested that large-scale physician adoption of modern information technology could support improvement of quality in healthcare through reducing variability of healthcare delivery, improving medication safety, eliminating unnecessary process steps and enhancing healthcare team communications (The adoption of clinical information technology, 2002).

A 2000 national needs assessment study, conducted by the National Patient Safety Foundation (NPSF), identified current culture of denial and complacency in respect to medical errors, the persistent authority gradient, the reactive punitive approach to medical errors, and the limited patient safety educational opportunities as some of the major barriers to introducing patient safety systems in healthcare institutions. The study recommended that educational topics for patient safety in healthcare institutions should include such topics as: defining patient safety and medical error, human factors, system error analysis, healthcare team communication, financial and legal consequences of errors in medicine, utilization of technology, need for systems thinking and culture change, patient education, and how to learn from mistakes (VanGeest, & Cummins, 2003).

Stallion and Duvall developed a Patient Safety Staff Survey and administered it to over 6,000 staff members of the Cox Health Systems (S. Duvall, personal communication, 10/18/2002). The survey identified the following causes for medical errors (in order of priority): distractions, excessive workload, communication, inattention, carelessness, inadequate training, complex processes, and insufficient policies. Seventy-nine percent of the 1,810 respondents were more likely to report a medical error if confident that something would change. The major cited reasons for not reporting a medical error were: lack of time, too complicated error report forms, and incident was considered too minor to report. Lawton and Parker (2002) reported 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 to other types of mistakes.

The 2001 AHRQ report *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 (e.g. wrong-site surgery). The intent of the report was to inform healthcare providers and healthcare organizations on improvement practices and to inform research agencies, such as the sponsoring agency, AHRQ, 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 utilized 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 (Making health care safer, 2001).

Evidence-based Patient Safety Practices

The practice-based improvement in healthcare is based on knowledge, understanding and skills in four major areas: population-based measurement, process-based evaluation, evidence-based therapeutics, and outcomes-based monitoring. Practice-based learning and improvement provide the basis for improvement in clinical healthcare practice; PDSA-cycles and rapid cycle-testing allow physicians to test evidence-based therepeutics models and plan improvement interventions (Staker, 2000).

The 2001 AHRQ report on patient safety *Making healthcare safer* presented information about the prevalence and severity of the targeted healthcare quality and patient safety problems, the current utilization and evidence of efficiency of clinical practices, data on utilization costs, and potential harm from implementation of these practices. For each of the suggested 79 healthcare safety practices, data were gathered on potential impact, strength of supporting evidence, and implementation details (e.g. costs, barriers, and policy issues). A team of four experts compared and discussed the ratings of each suggested safety practice in a number of pre-established categories to assess the "strength of the evidence" supporting each practice. The expert team recognized the relative paucity of the supporting evidence and recommended 11 practices with strongest supporting evidence for clinical implementation:

- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk;
- Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality;
- Use of maximum sterile barriers while placing central intravenous catheters to prevent infections;
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent perioperative infections;
- Asking that patients recall and restate what they have been told during the informed consent process;
- Continuous aspiration of subglotic secretions (CASS) to prevent ventilator-associated pneumonia;
- Use of pressure relieving bedding materials to prevent pressure ulcers;
- Use of real-time ultrasound guidance during central line incertion to prevent complications;
- Patient self-management for warfarin (Coumadin) to achieve appropriate outpatient anticoagulation and prevent complications;
- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients;
- Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections (Making health care safer, 2001).

Additionally, a patient safety research agenda was suggested consisting of 12 promising safety practices including:

- Improved perioperative glucose control to decrease perioperative infections;
- Localizing specific surgeries and procedures to high volume centers;
- Use of supplemental perioperative oxygen to decrease perioperative infections;
- Changes in nursing staffing to decrease overall hospital morbidity and mortality;
- Use of silver alloy-coated urinary catheters to prevent urinary tract infections;
- Computerized physician order entry with computerized decision support system to decrease medication errors and adverse events primarily due to the drug ordering process;
- Limitations placed on antibiotic use to prevent hospital-acquired infections due to antibiotic-resistant organisms;
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent perioperative infections;
- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk;
- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and post-surgical patients;
- Use of analgesics in the patient with acutely painful abdomen without compromising diagnostic accuracy;
- Improved hand-washing compliance utilizing a variety of educational and technology approaches (Making health care safer, 2001).

Importantly, the expert team recognized that recent patient safety research supported by Federal, foundation and industry funding, has been primarily focused on predominantly clinical areas and less attention has been paid to system approaches (Cooper, 2001; Making health care safer, 2001).

The 2002 consensus report of the National Quality Forum, *Serious Reportable Events in Healthcare*, identified 27 preventable adverse events in six areas that constituted major patient safety lapses and compromised the quality of healthcare. The identified reportable events were as follows:

- Surgical events, including wrong site, wrong patient or wrong surgical procedure, retention of a foreign object after surgery, or patient's post-operative death;
- Device events, including patient's death or disability related to use of a medical device;
- Patient protection events, including patient suicide, patient elopement, or discharge of an infant to the wrong adult;
- Care management events, such as patient's death or disability due to medication errors, hemolytic reaction, labor or delivery, neonate hyperbilirubinemia, spinal manipulations, or development of pressure ulcers after admission;
- Environmental events, including patient's death or disability related to electric shock, use of wrong gas or contaminated substances, burns or restraints while being cared for in a healthcare institution;
- Criminal events, such as abduction, sexual or physical assault (The National Quality Forum, 2002).

Healthcare Microsystems

The small aggregations in healthcare consisting of practitioners, clinical, information technology and administrative support staff, and defined patient subpopulations, form healthcare microsystems, where the healthcare delivery occurs. Such microsystems are formed in various settings: outpatient, inpatient, home care, primary and specialty care (Batalden & Splaine, 2002). Since healthcare is sought, created and delivered at a microsystems level, the healthcare microsystems hold an enormous potential for defining the quality and safety of healthcare delivery. Mohr and Batalden (2002) suggested that understanding the patient safety role of the microsystems in healthcare changes the focus of healthcare executives to seeking a tight alignment of the microsystem's vision, mission and goals with the vision, mission and goals of the overarching healthcare institution, while allowing flexibility via locally appropriate strategies in achieving safe care. Since healthcare microsystems are theoretically designed to achieve the outcomes they currently produce, healthcare Microsystems improvement must be led and carefully managed (Staker, 2000).

Medication Safety

The increase of the number of critically ill patients, complex drug therapy, introduction of multiple new drugs, and use of more potent drugs have changed the use of drugs within healthcare systems, have increased the potential of medication errors, and called the pharmacists, as the experts in medication therapy, to assume new leadership role in identifying potential problems within the medication process, serving as a multidisciplinary information source, and providing multidisciplinary patient education (Proulx, Wilfinger, & Cohen, 1997). Since medication errors occur due to system failures in the medication process, communication and collaboration between and among physicians, pharmacists, nurses, hospital executives, risk managers, and other hospital staff are essential for medication error prevention.

Successful strategies for medication error prevention include implementation of a formal review for interdisciplinary medication error analysis, and understanding of the factors that lead to medication errors (Proulx, Wilfinger, & Cohen, 1997). Healthcare managers and risk management practitioners have been encouraged to focus on the underlying reasons for medical errors rather than concentrating on individuals who have committed an error (Medication errors, 1992).

Although considered a basic skill, medication administration is a complex process in which the delivery of a single dose of a medication involves between 10 and 15 distinct steps, and each and every step is an opportunity for error (Joiner, 1994; Leape, 1996). As a part of expert testimony for a court trial, the Institute for Safe Medication Practices (ISMP) conducted an in-depth system analysis of the medication error that had led to the death of an infant and found over 50 separate system failures, such as language barrier for effective communication, inconsistency of procedures, poor documentation, staff inexperience, non-standardized methods for drug orders, insufficient drug information, unclear definitions of prescriptive authorities, etc., that allowed this failure to occur (Smetzer, 1998).

Although medication error rates seemed to be an attractive measure for comparison between healthcare institutions, Leeuwen (1994) argued that there were big discrepancies among hospitals in the definition of errors and the methodology for reporting errors, so that comparisons between hospitals were not only unreliable, but could also be misleading. A healthcare institution with a standardized error reporting system may have a high error report rate, while a hospital's low error reporting rate may be signaling either a successful error-prevention program, or, on the contrary, may be a sign for increasing neglect (Leeuwen, 1994). Errors of omission and administering of the wrong drug dose are the ones most commonly reported (Joiner, 1994). A historically accepted threshold for medication errors is 1% to 3% in acute care setting and 5% in long-term care facilities, but different facilities use different numbers for the numerator (e.g., number of medication error reports, number of medications involved in incidents, or number of doses involved in the reports) and for the denominator (e.g., total number of reports or total number of dispensed doses) for calculation of the error rate, which make comparisons between and among healthcare institutions very difficult (Joiner, 1994).

Medication error prevention has been considered to be a function of the medication system and guideline sets for preventing medication errors in hospitals have been presented to address the needs for medication safety on organizational, departmental, and individual level. It has been estimated that routine medication delivery was associated with an error (such as late delivery, loss of copy of order, loss of patient profile by the pharmacy, or inadequate 24-hour medication supply) in 79% of the time (Hackel, Butt, & Banister, 1996). However, self-reporting of medication errors has proved ineffective in determining the real scope of the problem (Barker, & McConnell, 1962). In its medication safety guidelines, the American Society for Hospital Pharmacists (ASHP) recommended that policies and procedures should be established to prevent errors and that there should be a systematic, ongoing safety program, multidisciplinary team approach and wide implementation of computerized systems to enable easy error discovery and prevention (ASHP, 1993).

Spath (2000) argued that serious medication errors occur in 5 to 10 percent of admitted inpatients with errors without adverse events occurring ten times as often, with an average of 78% of patient incidents that did not result in pain or harm to the patient, thus less likely to be reported. Shipon and Nash (2000) observed that due to variation in clinical practices, improper medication treatment of acute myocardial infarction (e.g., thrombolytics, beta blockers, aspirin, and/or angiotensin-converting enzyme, ACE, inhibitors have not been applied) leads to over 18,000 preventable deaths per year.

Proulx, Wilfinger, and Cohen (1997) in discussion of the data from the Institute for Safe Medication Practices (ISMP) on voluntary medication errors reporting systems and related publications, found that deaths linked to medication errors predominantly occurred in association with several drugs, namely: insulin, lidocaine, magnesium sulfate, neuromuscular blockers, potassium chloride injection concentrate, vasoactive substances, and parenteral narcotics. Furthermore, one-third of all serious medication errors were associated with only five drugs (heparin, insulin, opiates, potassium concentrates, and allergy medications) and one type of medical device (PCA infusion pumps for patient controlled analgesia). Additionally, negative contributing factors were identified to include stressful work environment, frequent task interruptions, poor packaging and labeling of drugs, and lack of unit-dose medication packaging. Proulx, Wilfinger and Cohen (1997) suggested a systems approach to medication error reduction consisting of activities in six general areas:

- Establishing a trustworthy system for communication of drug orders;
- Introducing systems that support effective patient information transfer to physicians, nurses, and pharmacists;
- Development of a sound system for patient education about their drug therapy;
- Introducing unit-dose packaging, clear drug labeling, and a system to deal with look-alike and sound-alike drug names;
- Building multiple checks into the medication system from ordering to administration;
- Ensuring free information exchange about patient safety as the best safeguard against errors (Proulx, Wilfinger, & Cohen, 1997).

Observation of medication administration in 36 hospitals and nursing facilities in Georgia and Colorado (Barker, Flynn, Pepper, Bates, & Mikeal, 2002) revealed that 19% of the doses were in error, with most frequent errors of wrong time (43% of the errors), omission (30%), wrong dose (17%), and unauthorized drug administration (4%). Seven percent, or approximately 40 errors per day per a 300-patient facility were potentially harmful. Moreover, the study showed that accreditation by JCAHO was not a differentiating factor in the percentage of occurrences of medication error rates, averaging 1 error in 5 doses (Barker, Flynn, Pepper, Bates, & Mikeal, 2002).

A six-month observation study conducted in two tertiary-care hospitals revealed 334 medication errors (including all stages of the medication administration process) that caused 264 preventable adverse drug events. Most of the errors occurred in the stages of physician ordering and nurse administration, followed by transcription and pharmacy dispensing. The identified proximal causes for the observed adverse drug events included lack of standardization, inadequate knowledge, lack of information on the patient, faulty drug identity checking, errors in dose checking, inadequate monitoring, and others. In result, 16 system failures, such as lack of standardization of procedures, devices, doses and drug distributing, poor conflict resolution, inadequate staffing and work assignments, lack of feedback, poor knowledge and patient information dissemination, etc., were identified. The study concluded that possible remedies for the system deficiencies were top-level management commitment to institution-wide changes, simplifying complex processes and systems, utilization of computerized physician order entry systems and inclusion of pharmacists in the physicians' rounds (Leape, Bates, Cullen, Cooper, Demonaco, Gallivan, Hallisey, Ives, Laird, Laffel, Nemeskal, Petersen, Porter, Servi, Shea, Small, Sweitzer, Thompson, & Vliet, 1995). Another medication errors study (Wolf, McGoldrick, Flynn, & Warwick, 1996) revealed that over 60% of the observed errors were of commission, mainly during drug administration (over 75% of the total number of errors) and most frequently involved administering of the wrong dose or the wrong drug, misread drug order, medication not ordered, incorrect dose calculation, unclear orders, extra dose or wrong time of administration.

To prevent the errors occurring in medication administration and minimize their potential consequences, Cohen, Senders, and Davis (1994) suggested a 12-step program acting as "error-trap." Their 12-step program included:

- Building in redundancies in the system (i.e. multiple check points);
- Adding a fail-safe system (e.g., premixed I.V. drug containers that do not require any additional manipulation to obtain the dose, or I.V. pumps that use automatic clamping mechanism);

- Eliminating dangerous items and procedures (e.g., removing items that are not part of the routine patient care from unit stock, and standardizing concentrations for critical care drug solutions);
- Limited use or access to concentrated injections such as potassium chloride concentrate injection, or limited number of doses a patient can receive over a period of time through automatic pharmacy checks;
- Avoiding confirmation bias through marking similarly looking drugs in different colors;
- Adopting “lock-and-key” design to prevent I.V. administration of oral medications;
- Use of tactile cues and special packaging (e.g. different package shape or material);
- Placing of hazard warnings in visible areas;
- Use of technology (e.g., infusion pumps alarm systems, computer generated medication administration records, bar coding, bedside terminals, etc.);
- Following established protocols and procedures;
- Recognizing the value of documentation as a valid check point for patient care;
- Providing education to both staff and patients (Cohen, Senders, & Davis, 1994).

Extra Costs Related to Medication Errors

In determining the excess length of hospital stay, the extra costs, and mortality attributable to adverse drug events on a total of 91,574 patients in a tertiary healthcare institution over a four-year period, Classen, Pestotnik, Evans, Lloyd, and Burke (1997) found that adverse drug events occurred in 2.43% of admissions and the patients that suffered an adverse drug event had over three times higher mortality rate, almost two times longer hospital stay and approximately two times higher cost of hospitalization (each adverse drug event added a mean of $2,262 to hospitalization cost). A conservative estimate of the annual costs attributable to adverse drug events in a 700-bed hospital (excluding cost for injuries to patients and malpractice costs) were estimated to be $5.6 million, and half of these costs ($2.8 million) were associated with preventable events (Bates, Spell, Cullen, Burdick, Laird, Petersen, Small, Sweitzer, & Leape, 1997). The IOM report *To err is human* (2000) estimated that national costs, such as lost income, lost household production, disability and healthcare costs, due to preventable medical errors were between $17 and $29 billion.

Safe Medication Practices

Patient education and computerization of drug prescription have been recommended as strategies to minimize medication errors and adverse drug events (Brodell, Helms, KrishnaRao, & Bredle, 1997). Additionally, as the number of adverse drug events is reportedly a function of the number of administered medications, reducing the number of drugs used in intensive care units (ICUs) has been identified as an effective approach in reducing preventable medication errors (Cullen, Sweitzer, Bates, Burdick, Edmondson, & Leape, 1997).

Davis (1997) considered the lack or failure of safety systems a major cause for medication errors and suggested implementation of safety systems including safety checks, quality checks, computer reminders, barcode verifications, forcing mechanisms (such as specially designed syringe fits and automatically closing infusion pumps that do not allow free drug flow), making potentially dangerous items unavailable on the patient floor, and assessment of tasks for potential error-prone steps.

Despite numerous local medication practices innovations have proven successful, the majority of the promising improvements have remained isolated, fragmented and not deployed. To respond to the need of supporting the deployment of safe medication practices, in April 2000 the Institute for Healthcare Improvement (IHI) and Premier, Inc. started the Idealized Design of Medication Systems project (Idealized design, 2003). The project started with novel expert ideas based on room service operations and proceeded with identifying important lessons for improving the safety and efficiency of medication systems, such as application of “just-in-time delivery,” minimizing “hands offs,” and placing a single person in charge of an order, and leveling the load away from peak delivery times to even out the medication system flow (Idealized design, 2003).

In December 2000, the Washington State Department of Health issued its *Medication errors report and recommendations* on methods for reducing medication errors which adopted systems approach to safety strategies and recommended the following action steps:

- Increasing prescription legibility through eliminating hand-written orders by 2005 and encouraging the use of computerized physician order entry (CPOE) electronic devices;
- Minimizing confusion in prescription drug labeling and packaging through notations on the prescription label of purpose and when the patient is a child;
- Developing medication error reporting plans and requiring that healthcare sites with established quality improvement programs have a mandatory evaluations and plans for reduction of medication errors;
- Encouraging healthcare organizations to implement proven medication safety practices, including utilization of automated drug-ordering systems;
- Reducing confusion created by similar-sounding drug names including elimination of abbreviations use on all prescriptions;
- Increasing patient education about their medications through allocating funds for patient education and focusing on patient education about interactions between prescribed and over-the-counter medications.

Beginning in May 2000, the Institute for Safe Medication Practices (ISMP) and the American Hospital Association (AHA) distributed the ISMP Medication Safety Self-Assessment survey to 6,180 hospitals throughout the U.S. By October 2000, 1,435 hospitals (23%) had replied to the 194 self-assessment survey items organized in 20 core characteristics and 10 large domains (Smetzer, Vaida, Cohen, Tranum, Pittman, & Armstrong, 2003). While the majority of the responding hospitals scored high in domains such as medication storage, distribution, labeling and packaging, environmental factors, and infusion pumps, the hospitals scored generally low on domains related to accessible patient information, communication of medication orders, patient education and organization culture, where an enormous opportunity for improvement exists. Hospitals demonstrated better scores in areas that did not involve automated processes, e.g. 96% of the hospitals reported that pharmacists and physicians monitored and adjusted medication doses for patients with renal or liver diseases. However, only 10% of the respondents had in place a CPOE system, and the CPOE system was fully implemented in only 1% of the hospitals. Additionally, only 11% of the surveyed hospitals had a policy prohibiting the use of verbal orders in situations other than emergency. The survey also revealed that both physicians and nurses (64% and 67% respectively) did not consistently educate patients about prescribed drug therapy. Furthermore, in only 46% of the hospitals there were implemented error-reduction strategies targeting the system and not the individual and even fewer (37%) had the board's commitment to patient safety (Smetzer, Vaida, Cohen, Tranum, Pittman, & Armstrong, 2003).

Patient Safety Research and Root Causes for Medical Errors

Eric Knox, M.D., former director of patient safety at Children's Hospitals and Clinics, Minneapolis, Minnesota, in his key-note address to the American Society for Healthcare Risk Management (ASHRM) 2002 Annual Conference noted that there are three major root causes for errors in medicine: inhibitions from hierarchy (a.k.a. "hierarchy gradient" inhibiting the teamwork of nurses and physicians), production pressures (when healthcare professionals are trying to accomplish more work with less resources without understanding of the tolerable levels of risk), and the "hazard of deafness" (if the leadership of a healthcare facility fails to take responsibility for patient safety) (ASHRM keynote speaker examines root causes of medical errors, 2002).

In exploration of the medical errors in primary care family practices, Dovey, Meyers, Phillips, Green, Fryer, Galliher, Kappus and Grob (2002) studied 344 physician reports from family practitioners evenly distributed throughout the U.S. and found that 83% of the errors were due to healthcare system dysfunctions and 13% were due to inadequate knowledge or skills, where ten errors resulted in patients being admitted for hospital treatment and one patient died. The medical errors that occurred were classified in the following major categories:

- Process errors:
    - office administration (filing, patient charts, appointments, message handling, patient flow);
    - investigations (errors in ordering, implementation and reporting laboratory and/or diagnostic imaging tests);
    - treatment (errors in ordering, implementation and administration of medication orders);
    - communication (with patients, physicians and other staff)
- Knowledge and skills errors:
    - execution of a clinical task;
    - wrong diagnosis;
    - wrong treatment decision.

While only 11% of the errors were recognized at the time of, or immediately after the event, another 50% were recognized in retrospection within two weeks after the event (Dovey, Meyers, Phillips, Green, Fryer, Galliher, Kappus and Grob, 2002).

Between April 30 and November 5, 2001, the Princeton Survey Research Associates conducted a survey on patient safety sponsored by The Commonwealth Fund (Davis, Schoenbaum, Collins, Tenney, Hughes, & Audet, 2002). The national survey included a random sample of 6,722 adults, had a response rate of 53%, was conducted in six languages (English, Spanish, Mandarin, Cantonese, Vietnamese, and Korean), and the weighted survey results, corrected for age, sex, race/ethnicity, education, marital status, household size and geographic region, were representative of the 193 million adults (18 years of age or older) living in continental U.S. The survey results estimated that one of five Americans (22% of the respondents, which translated to 22.8 million people) had experienced a medical error, and one in five errors turned to be a serious one, which translated to approximately 8.1 million households reporting a family member experienced a serious mistake. According to the report, 20% of the females over 18 did not receive a Pap test for cancer screening in a three-year interval, 20% of the women over 50 years of age did not have a mammogram for breast cancer screening within two years, 41% of the total population over 50 years of age did not have colon cancer screening, and 45% of the diabetics did not receive any of the three basic screening tests (eye exam, foot exam and blood pressure test). Furthermore, the report revealed big gaps in the doctor-patient communication with one-fifth of adults (including high school and college graduates) reporting difficulties in communicating with their physicians, 33% of the participants were not able to understand materials from the doctor's office and approximately two-thirds did not have a long-term relationship with their physician. The report recommended that fail-safe systems should be introduced in care delivery systems to ensure reliable, consistent, evidence-based and patient-centered healthcare (Davis, Schoenbaum, Collins, Tenney, Hughes, & Audet, 2002).

Dunn (2000) reviewed and compared patient safety research between American inpatient hospital data and corresponding Texas patient safety data. Data from the Texas Medical Foundation (TMF), the Medicare peer review organization for Texas, presented 317,333 chart reviews from over 400 hospitals for the period 1998-1992 and revealed adverse event rate of 0.8% (i.e. adverse events related to medical errors were found in 2,582 charts), while data from Harvard studies of 30,000 charts from 51 hospitals in New York for the year of 1984 and 15,000 charts in 28 hospitals in Utah and Colorado in 1992 revealed an approximately six times higher adverse event rate of 4.6%. Dunn (2000) suggested that patient safety programs could build on reported successes in developing pharmacy fail-safe programs, development of healthcare guidelines and disease management programs, and patient care performance improvement strategies.

Spath (2000) emphasized that reacting to previous mistakes cannot lead to a better system reliability; that only proactive patient safety initiatives can bring about improved patient safety; that the system redesign must make the healthcare processes less prone to mistakes and more resistant to error occurrences. Quality management strategies including interdisciplinary task forces, ad hoc quality improvement committees, cross-functional teams, and “zero errors” are efficient in promoting systems approach to patient safety (Joiner, 1994).

The American Nurses Association (ANA), representing the nation’s over 2.2 million Registered Nurses, launched in March 1994 its multi-phase initiative to investigate healthcare restructuring on quality of healthcare and patient safety. The Nursing’s Safety and Quality Initiative targeted nurse education about quality measurement principles, informing the public about the quality of healthcare and providing data for empirical evaluation of healthcare quality and patient safety. Furthermore, in 1998 ANA started a national database (housed in the Midwest Research Institute, MRI, in Kansas City, MO and managed jointly by MRI and the University of Kansas School of Nursing) to collect and analyze data on ten nursing-sensitive quality indicators, including nursing staffing mix and levels, nursing care hours per patient per day, pressure ulcers, patient falls, patient satisfaction with pain management, patient satisfaction with educational information, patient satisfaction with overall care, patient satisfaction with nursing care, nosocomial (i.e. intra-hospital) infection rate, and nurse staff satisfaction. The results from the ANA’s Nursing’s Safety and Quality Initiative suggested that registered nurses are in a position to ensure critical, cost-effective difference in providing quality healthcare (Nursing’s Safety and Quality Initiative, 1999).

Identifying the causes for errors in healthcare as the first step in error analysis has been considered paramount to the evaluation of errors. In the process of analysis of errors, it is imperative to focus on the underlying system failures and not on blaming individuals (Horns, & Loper, 2002).

Shipon and Nash (2000), following suit with the Institute of Medicine definition, defined the quality of care as ability to achieve desired healthcare outcomes that are consistent with contemporary professional medical knowledge. They suggested a six-step strategy for quality improvement in healthcare including increased accountability at all industry levels, standardization of healthcare through utilization of clinical care guidelines, patient empowerment for more active participation in their healthcare, improved access to healthcare information through a centralized database, and implementing incentives for both patients and medical professionals. Furthermore, Shipon and Nash (2000) recommended that education of healthcare professionals should include knowledge of scientific quality improvement methodologies in order to boost quality improvement in healthcare.

Process and Outcome Performance Measures

Holcomb (2000) argued that the disagreement between physicians and their professional organizations upon the definition of quality of healthcare leads the purchasers of healthcare to make purchasing decisions based solely on cost of service. In healthcare, two types of performance measures have been used: (a) process measures, providing information whether the healthcare professionals are following the accepted processes, i.e. whether they are doing the "right thing," and (b) outcome measures, providing information on the outcome of the healthcare process, i.e. whether the healthcare professionals perform well. *Process* performance measures could be used to evaluate compliance with safety regulations, adequacy of equipment maintenance, staff competency, certification, training and continuing education, staff scheduling, workplace ergonomics, and information systems maintenance and performance. *Outcome* measures reflect the cumulative outcome of the healthcare delivery and occurrences (counts) of unwanted or unintended events (such as patient's death, prolonged hospital stay, patient impairment, need for surgical intervention, etc) are used as outcome measures. Since healthcare organizations usually create department or service-specific measures and reports, data are collected and reported separately, and no particular individual or department has comprehensive information on the whole organizational picture (Spath, 2000). While process measures have the advantage of being gathered more readily using administrative data and more easily interpreted with clear indications for improvement actions, outcome measures are more meaningful to clinicians, patients and payors because they focus on the changes of the patient health status, diagnosis and treatment; however, it is somewhat difficult to attribute a healthcare outcome to a specific single process or behavior (Daley, Vogeli, Blumenthal, Kaushal, Landon, and Normand, 2002).

Healthcare *benchmarking* is the continuous and collaborative effort to measure and compare the results and best practices for key healthcare processes (a) internally, within the organization, or (b) with external competitors. Thus, performance data should be shared not only within an organization but, more importantly, between and among organizations, in order to identify and deploy best healthcare practices (Spath, 2000).

Electronic health information exchange for improving safety, quality and efficiency of healthcare has become a growing trend among practitioners, hospitals and payors from coast to coast (personal communication, Healthcare IT Weekly, Vol. 2, No. 53, December 22, 2003). However, the clinical evidence about the effectiveness of computer-aided drug utilization review has been controversial, mainly because of lack of clearly established consensus about which and how many drug criteria and characteristics should be included in a computer drug review software systems. Despite the theoretical benefits of computer-aided drug review programs, the conflicting views regarding their effectiveness call for comprehensive studies of variations among different existing systems in the national patient safety research agenda (Chrischilles, Fulda, Byrns, Winckler, Rupp, & Chui, 2002).

A review of the results of 2.5 million procedures performed in 14 types of cardiovascular and cancer conditions between 1994 and 1999 suggested that patients undergoing cardiovascular or cancer procedures have reduced operative death risk if the procedures are performed in high-volume hospitals (Birkmeyer, Siewers, Finlayson, Stukel, Lucas, Batista, Welch, & Wennberg, 2002).

Leape (1994) suggested a series of system approaches for reducing medical errors, including reducing reliance on memory, improving access to information, designing error-proof processes, standardization of common medical practices, medication doses, and location of equipment in patient units, training medical professionals in error reduction techniques, and building system buffers for "absorbing" human errors (e.g. multiple check points). It is widely agreed that systems lie at the base of the majority of medical errors and that improvement can be achieved through system re-design including patient and staff education, teamwork training information management and institutional self-assessment (Sentinel events, 1998). Proactive efforts have proven to be most successful in reducing preventable errors in healthcare settings. Data gathered in a learning process can enhance process and system redesign; however, error reduction calls for designing and implementing a system for error reduction throughout the healthcare organization. The responsibility of creating and endorsing such an institution-wide improvement system ultimately resides within the healthcare executive leadership. A system for patient safety improvement should be based on the principles of simplification, standardization, stratification, improved communication, designing easy "default" procedures, reasonable automation, process mapping, recognition of the limitations of human vigilance, and encouragement of error reporting. Overall, four major system patient safety strategies have proved efficient in healthcare settings:

- Utilizing automation and building in redundancy "buffer" systems;
- Standardization of procedures;
- Development of processes for training, examination and certification;
- Institutionalization of safety, i.e. direct reporting of medical errors to a centralized agency and data repository (Sentinel events, 1998).

Medical errors should be addressed through systems approach, non-punitive reporting systems, and reporting of “near misses” (a.k.a. “good catches”) – approaches considered to be essential for patient safety systems. Since healthcare delivery is the largest, most complex, and most expensive industrial system in the U.S., with multiple decentralized elements (such as hospitals, ambulance services, medical instruments, clinical laboratories, homecare agencies, physician’s offices, etc., each carrying a distinct culture, system change is slow decomposition of the bigger system to small manageable levels is required (Sentinel events, 1998). A successful systems oriented approach to patient safety and improvement changes in healthcare should address multiple hierarchical layers, including physical environment, human behavior, team structure, organizational management, and legal and societal pressures, where at each stage decisions should be revisited and processes redesigned. The basic assumption is that patient safety process design guards from human error through corrective points built into the process (e.g. redundancy buffers, process standardization, process simplification, and process redesign). Important patient safety lessons can be learned from anesthesiology, the medical specialty that became the pioneer of complete environment simulations, identification of error modes in clinical practice, monitoring clinical performance, and utilization of technology for error reduction (Sentinel events, 1998).

Clinical Performance Measures

Daley, Vogeli, Blumenthal, Kaushal, Landon, and Normand (2002) argued that establishing a framework for evaluating physician clinical performance and developing a set of physician clinical performance assessment measures can support healthcare quality improvement, maintenance of certification of physicians, patient and family choice of physicians, and rewarding physicians for excellent quality of care. Although there are certain scientific and methodological challenges in creating a valid, reliable and practical physician clinical performance assessment, in quality improvement, an appropriate use of physician clinical performance measures would demonstrate the variability in practice and promote improvement of care for patients as well as improvements in the healthcare micro-system. With evolving national consensus about standardized measures of physician performance, the adoption of physician performance measures would allow individual clinicians to receive an estimate of their individual performance and of their contributions to the process of healthcare (Daley, Vogeli, Blumenthal, Kaushal, Landon, & Normand, 2002).

The medical profession has declared its commitment to engage physicians in clinical performance measurement and quality improvement (Kmetik, Williams, Hammons, & Rosof, 2000). The American Medical Association (AMA) has encouraged physicians to standardize the level and measurement of their performance and has developed core Physician Performance Measurement sets for clinical care for adult diabetes, prenatal testing, and chronic stable coronary artery disease. Systematic work to improve patient outcomes has been reported to be successful in improving care for medical and surgical treatments, conditions, and populations, including asthma care, antibiotic use, cardiac surgery, and hypertension. Since most physicians care for only a comparatively small number of patients with a particular disease, it is important that precautions are taken for risk adjustment (i.e. considering the severity of the illness) and respective reliability measures when comparing individual physician performances (Kmetik, Williams, Hammons, & Rosof, 2000).

In March 2003, the Agency for Healthcare Research and Quality (AHRQ) published a list of Patient Safety Indicators as measures for adverse events that patients experience as a result of exposure to the healthcare system. As patient safety has been declared an issue of major national interest with the publication of the IOM reports, policy makers, healthcare professionals and consumers focused on the need to assess, monitor and improve the safety of healthcare delivery. AHRQ’s Patient Safety Indicators are based on data readily available from hospital administrative discharge reports and are considered to provide a “state-of-the-art” perspective on patient safety outcomes. To develop the patient safety indicators, the AHRQ study team utilized literature review, clinician panels, expert coders and empirical analyses.

The face validity of the indicators was established through consensus of a panel of experts (selected on the basis of their personal knowledge and recent work in the field of patient safety), and the construct validity was evaluated using the available literature. AHRQ defined two levels of patient safety indicators: hospital and area indicators. The hospital-level indicators measure the occurrences of potentially preventable adverse events (i.e. medical errors) and search for secondary diagnoses that flag treatment complications. The 20 hospital-level patient safety indicators include:

- Accidental puncture or laceration;
- Complications of anesthesia;
- Death in low-mortality diagnosis-related groups;
- Decubitus (pressure) ulcer;
- Failure to rescue;
- Foreign body left during procedure;
- Iatrogenic pneumothorax;
- Postoperative hemorrhage or hematoma;
- Postoperative hip fracture;
- Postoperative physiologic and metabolic derangement;
- Postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT);
- Postoperative respiratory failure;
- Postoperative sepsis;
- Postoperative wound dehiscence;
- Selected infections due to medical care;
- Transfusion reaction;
- Birth trauma – injury to neonate;
- Obstetric trauma – Cesarean delivery;
- Obstetric trauma – vaginal delivery with instrument;

- Obstetric trauma – vaginal delivery without instrument.

Six of the patient safety hospital indicators were selected for area-level indicators to assess the incidence of adverse events within a given geographic area. The area-level indicators include the following:

- Accidental puncture or laceration;
- Foreign body left during procedure;
- Iatrogenic pneumothorax;
- Selected infections due to medical care;
- Postoperative wound dehiscence;
- Transfusion reaction.

Because data on these indicators are reported as a part of the hospital administrative patient discharge data set, they provide a tool that can be used with any administrative inpatient data and are useful with the majority of hospital data systems throughout the U.S. Thus, regional and national benchmarking data can be provided through the available state hospital administrative data repositories (AHRQ quality indicators, 2003).

Clinical performance measurement serves the multiple purposes of providing quantitative basis for performance improvement, providing basis for quality oversight of accrediting agencies, assisting both consumers and payors in healthcare provider selection, and ensuring responsible management of healthcare resources. The American Medical Association (AMA) developed sets of performance measures for quantitative assessment of health care processes and outcomes to enhance accountability of individual healthcare practitioners, healthcare organizations, and healthcare systems and to serve as a basis for quality improvement (Taking the lead together, 2002). These performance measures were selected based on the importance of the topic area addressed by the measure, the usefulness of the measure in addressing improvement of patient outcomes, and for which the measure design assured documented reliability, validity and defined specifications. AMA's Physician

Consortium for Performance Improvement consists of clinical experts from over 50 national medical specialty societies, AHRQ and the Centers for Medicare and Medicaid Services (CMS). The Physician Consortium for Performance Improvement strives to be the leader for providing evidence-based clinical performance measurement tools for physicians and to provide an equitable participation of all medical professions in the leadership of quality improvement and safety of patient care. Cross-specialty work groups have developed clinical performance measurement sets for adult diabetes, chronic stable coronary artery disease, prenatal testing, asthma, and preventive care and screening. The implementation of the performance measurement sets in clinical practice is voluntary and represents a physician-driven effort to improve patient care and safety through standardized, evidence-based clinical outcome measures (Taking the lead together, 2002).

AHRQ sponsored the establishment of the National Quality Measures Clearinghouse interactive Internet site launched in February 2003. The clearinghouse serves as the primary source for the most up-to-date, clinically proven, healthcare quality measures submitted by the National Committee for Quality Assurance, JCAHO, AHRQ, RAND, the Institute for Clinical Systems Improvement, the Renal Physicians Association, the Veteran’s Health Administration (VA), the CMS, the Foundation for Accountability and other organizations. The available measures present information on access to care, outcome of healthcare services, patient experience and healthcare process adherence to clinical practice recommendations based on clinical evidence or expert consensus. The online detailed search of clinical measures allows searching for healthcare measures by keyword, disease, treatment, patient age or gender, special populations (children, disabled, elderly, homeless, illiterate, etc.), healthcare setting (ambulatory care, emergency health services, ancillary services, etc.), type of healthcare professional (advanced practice nurses, allied health personnel, clinical laboratory personnel, physicians, etc.), level of healthcare (national, state, regional, county, city, etc.), expected use of the measure (accreditation, organizational quality improvement, decision-making, etc.), domain for use of the measure (effectiveness, patient centeredness, safety, or timeliness), and year. For example, the rate of influenza immunizations appears as a measure for "patient safety" with specified sort order for "relevance" (NQMC, 2003).

A 2003 report on healthcare quality (U.S. Department of Health and Human Services, & Agency for Healthcare Research and Quality, 2003) used three sets of patient safety indicators to assess the current quality of healthcare in the U.S.:

1. AHRQ's 20 patient safety indicators (see above);
2. CDC's National Nosocomial Infections Surveillance (NNIS) data on respiratory tract, urinary tract, and bloodstream infections in ICUs and in low-birth-weight infants collected from over 300 hospitals;
3. Medical Expenditure Panel Survey (MEPS) data on medication safety use of 33 medications.

Compared with the six national targets for healthcare improvement as declared in *Healthy People 2010,* and comparing data for the period 1994-2000, the 2003 report on healthcare quality in the U.S. found an increase in the hospital acquired infections, increase in some injuries related to medical care (e.g. accidental lacerations and pressure ulcers), and substantial rate of complications of care (such as hemorrhage, pulmonary embolism, metabolic derangements, and respiratory failure). Data on medication safety and birth-related trauma for the same period were consistent with previous findings and a concern was raised about high mortality rates in Diagnostic Related Groups (DRGs) with low mortality (U.S. Department of Health and Human Services, & Agency for Healthcare Research and Quality, 2003).

Hanold, Koss and Loeb (2000) discussed the role of physicians as the natural leaders in effecting change in healthcare based on their direct influence on patient care and the respect they have in the healthcare environment. In reply to the calls for accountability and improvement in healthcare, JCAHO's ORYX initiative focused on measurement of disease-specific care outcomes. The core performance measures included measurement sets for acute myocardial infarction, heart failure, community acquired pneumonia, and pregnancy and related conditions. For example, the measurement set for acute myocardial infarction included nine measures, such as prescription of aspirin at arrival and discharge, prescription of ACE inhibitor at discharge, adult smoking cessation counseling, prescribed beta blocker at arrival and discharge, time from arrival to initiation of thrombolysis and primary PTCA (percutaneous transluminal coronary angioplasty), and inpatient mortality rate. Through establishment of a national comparative database JCAHO strived to stimulate and support improvement in healthcare organizations, as well as to increase the relevance and value of accreditation. The initial core measurement set focused on outcomes in acute myocardial infarction, heart failure, pneumonia, surgical procedures and their complications, and pregnancy and related conditions (Hanold, Koss, & Loeb, 2000).

The set of physician clinical performance measures is intended to measure individual physician's clinical practice behavior and adherence to evidence-based, objective clinical practice criteria. Thus, such an assessment would be based upon the availability of clinical evidence that certain processes and behaviors can be linked to patient outcomes. Such evidence is limited for the majority of clinical specialties. Thus, it is very difficult to formulate a robust measurement set which would encompass a substantial portion of clinical healthcare and great variation will continue to exist from specialty to specialty. Although at least 16 healthcare professional specialty societies have developed clinical performance assessment programs or guidelines for their respective specialty, there are many professional societies that have not initiated the process yet (e.g. American College of Radiation Oncology, American Academy of Dermatology, American Society of Nephrology) and many of the professional societies that have initiated performance assessment programs or have developed clinical practice guidelines, have not developed physician performance set of measures, e.g. American Society of Clinical Oncology, American Urological Association, American Association of Clinical Endocrinologists, American College of Gastroenterology, American Gastroenterological Association, American Society of Internal Medicine, Infectious Diseases Society of America (Daley, Vogeli, Blumenthal, Kaushal, Landon, & Normand, 2002).

The Agency for Healthcare Research and Quality (AHRQ) maintains The National Guideline Clearinghouse, which provides a central repository for hundreds of clinical guidelines. The proliferation of practice guidelines, coupled with the proliferation of "best practices" add confusion and further devoid the clinical performance measures of uniform national specifications (Daley, Vogeli, Blumenthal, Kaushal, Landon, and Normand, 2002). Identifying and studying random process variation (which is due to random events, thus is not amenable to systematic improvement) and systemic causes of variation (which are the causes of variation that can be improved) are the cornerstones of improving healthcare processes and enhancing the likelihood of positive patient outcomes. Feedback to physicians about how their performance compares with peers, such as the Healthcare Employer Data and Information System (HEDIS) which assesses how appropriately physicians are delivering preventive services, increases physicians compliance with the preventive care services requirements that are measured (Daley, Vogeli, Blumenthal, Kaushal, Landon, and Normand, 2002). Clinical decision support in regard to drug dose, patient allergies, drug interactions, clinical performance guidelines, substitute drugs, treatment, referrals, and test recommendations utilizing information technology systems such as computerized physician order entry (CPOE) have been found to reduce medication errors, and had been recommended for adoption in hospitals (Doolan & Bates, 2002).

Accreditation Standards

Accreditation is defined as the process of an impartial review of institution's operations for ensuring that the institution is conducting its business in a manner consistent with national industry standards. The Utilization Review Accreditation Commission (URAC, a.k.a. DBA or American Accreditation Healthcare Commission) conducts an accreditation process that consists of review of policies and procedures (the so called 'desktop review') followed by on-site visits. URAC accredits hospitals, preferred provider organizations (PPOs), health plans, healthcare managed organizations (HMOs), healthcare networks and provider groups. The URAC Online Resource Center provides access to over 7,300 medical management laws and regulations. URAC accreditation standards were developed by expert committees formed of providers, healthcare organizations, insurer organizations, and public representatives. The accreditation standards are updated every three years. URAC is one of the national leaders in the accreditation of health and managed care organization and offers more than 16 accreditation programs in all 50 states and Canada, serving more than 120 million people. URAC's accreditation programs include case management, claims processing, core accreditation, credentials verification, disease management, health acre center accreditation, health network accreditation, health plan, health provider credentialing, health utilization management, HIPAA privacy and security, independent review organization accreditation, vendor certification, worker's compensation utilization management, etc. Specific attention has been paid to utilization management in evaluating the appropriateness of medical interventions to define patterns, recommend intensity of care and identify potentially preventable medical errors (URAC, 2003).

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has studied the relationship between the accreditation criteria and the Baldrige National Quality Award framework to ensure compatibility with the principles of quality management (Hertz, Reimann, & Bostwick, 1994). JCAHO's accreditation process *Shared Visions – New Pathways,* effective January 2004, is focused on processes critical to safety and quality of care. The *Tracer Methodology,* part of the *Shared Visions – New Pathways* accreditation process was designed to "trace" the care experienced by individual patients while in a hospital (Joint Commission on Accreditation of Healthcare Organizations, 2004).

Healthcare organizations, accredited by JCAHO are expected to evaluate regularly a number of activities, such as operative and other procedures that place patients at risk, use of blood and blood components, medication use, patient restraint and seclusion, care provided to high-risk populations, management of the environment of care, and needs, expectations, and satisfaction of patients. A common method to assess these activities is to identify a group of patients that received a certain type of care during a certain period of time and to determine how many of these patients received good or acceptable care by counting the patients who received "good" care in the numerator, and using the total number of patients for the identified time period as the denominator (Spath, 2000). The JCAHO accreditation process is also a highly effective assessment strategy, where the performance measures are integrated into the accreditation process through the ORYX initiative (Sentinel events, 1998). Accredited hospitals are required to implement performance measurement sets in three of four areas: acute myocardial infarction, heart failure, community-acquired pneumonia, and pregnancy and related conditions (Joint Commission on Accreditation of Healthcare Organizations, 2004).

Beginning January 1, 2004, JCAHO surveys accredited organizations for the seven patient safety goals, including improved accuracy of patient identification, improved effectiveness of communication in healthcare, improved safety of high-alert medications, elimination of wrong-site, wrong patient and wrong procedure surgery, improved safety of infusion pumps, improved effectiveness of clinical alarm systems, and reduction of hospital-acquired infections. Importantly, JCAHO reviews not only the documentation, but the actual institutional performance on the goals and sets standards for compliance with the patient safety requirements (Joint Commission Resources, 2003).

Beginning July 1, 2004, compliance with JCAHO's Universal Protocol for preventing wrong site, wrong procedure and wrong person surgery is required from accredited organizations that provide surgical services. The Universal Protocol includes a preoperative verification process, proper marking of the operative site, final verification ("time out") immediately before starting the procedure, and use of applicable requirements adapted from "non-operating room" settings (JCAHO News release, 2003).

Executives of healthcare organizations, seeking to be accredited by JCAHO, are required to ensure that in their institutions programs are in place to reduce medical errors and proactive programs are introduced for identifying patient safety risks (DeRosier, Stalhandske, Bacian, & Nudell, 2002). Furthermore, organizations accredited by JCAHO are required to provide relevant patient education, exercise safe medication preparation and administration, and utilize clinical guidelines for improving clinical processes (Joint Commission on Accreditation of Healthcare Organizations, 2004). JCAHO accreditation standards specific for improving organizational performance and patient safety ("PI" standards) include:

- Standard PI.1.10: The hospital collects data to monitor its performance;
- Standard PI.2.10: Data are systematically aggregated and analyzed;
- Standard PI.2.20: Undesirable patterns or trends in performance are analyzed;
- Standard PI.2.30: Processes for identifying and managing sentinel events are defined and implemented;
- Standard PI.3.10: Information from data analysis is used to make changes that improve performance and patient safety and reduce the risk of sentinel events;
- Standard PI.3.20: An ongoing, proactive program for identifying and reducing unanticipated adverse events and safety risks to patients is defined and implemented.

Additionally, JCAHO leadership standard LD.4.40 requires that hospital leaders ensure that an integrated patient safety program is implemented throughout the hospital. Furthermore, standard LD.4.60 is related to whether the leadership allocates adequate resources for measuring, assessing and improving both, hospital overall performance and patient safety (Joint Commission on Accreditation of Healthcare Organizations, 2004).

Another accrediting organization is the National Committee for Quality Assurance (NCQA). NCQA is a private, not-for-profit organization, one of the national leaders in measuring the quality of healthcare and healthcare plan performance. NCQA has credentialing (CR) and quality improvement (QI) standards for managed behavioral healthcare organizations (MBHOs), for PPOs and managed care organizations (MCOs). In 2003, NCQA suggested several changes in its 2004 accreditation standards, relevant to patient safety, as follows:

- Standard CR 10: Adding "quality issues" to the requirement of monitoring of sanctions and complaints; for a score of 100% the healthcare organization is expected to collect and review information from four quality factors and consider the findings in its evaluation of practitioners. Examples of quality issues include adverse events, quality activities data and performance on quality indicators. Additionally, the organization is expected to implement appropriate interventions when instances of poor quality that could affect patient health and safety are identified, and to take appropriate actions.
- Standard RR 8: Requiring organizations to address the readability of consumer information and assess the need of such information in languages other than English (i.e. languages spoken by 10% or more of the local population), ensuring that the information offered to providers and members is comprehensive and well designed.
- Standard QI 8: Adopting and disseminating of non-preventive evidence-based clinical practice guidelines for the provision of acute, chronic and behavioral health services, where two of the four required non-preventive clinical practice guidelines are related to behavi oral health. Information for this requirement is expected to be gathered from written policies, procedures, process flow and other documents describing the actual care processes within the organization. Utilization of non-preventive guidelines, such as the American Diabetes Association (ADA) guidelines or guidelines for screening for depression in patients with chronic conditions, targets improvement of healthcare processes and reduction of the unnecessary variation in healthcare and healthcare organizations are encouraged to collaborate between and among themselves in the development and adoption of clinical practice guidelines. At least two of the adopted guidelines have to correspond to the institution's disease management programs and offer written or online materials to both clinicians and patients in a timely manner. Additionally, the healthcare institution has to review and update its evidence-based clinical practice guidelines at least once every two years and to specify the process

used in the review. Institutional performance should be measured annually against institution's adopted guidelines.

- Standard QI 12: Requirement for at least two meaningful improvements in the quality of care and services (e. g. breast cancer screening rates, or rates of patient complaints per month) ensuring that the institution initiates and evaluates activities to continuously improve the quality of delivered services. Healthcare institutions were expected to review and analyze available data on performance indicators against organizational goals and activities. Organizations should undertake actions (such as increasing staff in customer service, increasing recruitment efforts for physicians, correcting inefficiencies in claims payment, etc.) to attain improvement goals and include at least one service area in their improvement activities. Healthcare effective quality improvement programs provide relevant activities with valid study design, quantitative and qualitative analysis of the results, analysis of barriers for improvement implementation and identification of timely interventions.

The suggested changes for the 2004 accreditation process did not require evidence of meaningful improvement in patient safety but only a meaningful improvement in clinical care. The 2004 NCQA accreditation standards were released on October 8, 2003 (NCQA, 2003).

Conclusion

Traditionally, more often than not, efforts for improvement in medicine have focused on individuals and have been centered in training, rules and sanctions, rather than on systems and system failures (Cobb, 1986; Ernst, Buchanan, & Cox, 1991; Lilley, & Guanci, 1995; Leape, Bates, Cullen, Cooper, Demonaco, Gallivan, Hallisey, Ives, Laird, Laffel, Nemeskal, Petersen, Porter, Servi, Shea, Small, Sweitzer, Thompson, & Vliet, 1995; Liang, 2002). However, medical errors occur as the end result of a chain of errors within a faulty system that is not designed to detect errors and intercept them. Thus, while maintaining individual's responsibility for deviating from policies and procedures remains important, errors could be eliminated only through focusing beyond the individual – through focusing on systems design changes supported by top-level management (Barker, & McConnell, 1962; Leape, Bates, Cullen, Cooper, Demonaco, Gallivan, Hallisey, Ives, Laird, Laffel, Nemeskal, Petersen, Porter, Servi, Shea, Small, Sweitzer, Thompson, & Vliet, 1995; Smetzer, 1998; Edmondson, Roberto, & Tucker, 2003). Napper, Battles, and Fargason (2003) commented on the importance of focusing on the systems in which healthcare professionals operate, i.e., putting forethought in the "blunt end" of the healthcare delivery system and shifting the "focus from the sharp end of the problem, where the actual interaction between a medical professional and a patient occurs, to issues such as organizational culture, management decisions, information technology deployment, and training that can precede these interactions by years" (Napper, Battles, & Fargason, 2003, p.359). For example, the results of a continuous quality improvement study conducted by the College of American Pathologists found a significant decrease in the number of wristband errors (from more than 8% in the first study quarter to less than 3% at the end of the study) in 217 healthcare institutions participating in a 2-year study of errors connected to patient wristbands (Howanitz, Renner, & Walsh, 2002).

In 2000, the National Patient Safety Foundation outlined the major characteristics of patient safety, where patient safety research should be focused:

- Patient safety, as a defining part of healthcare quality, should become an integrative part of the continuous quality improvement activities in healthcare institutions;
- Since patient safety does not reside in any single institution, department, or individual, patient safety efforts should focus on improving processes in the system components as well as improving the interactions between and among the system components;
- Patient safety improvement should address system issues throughout the continuum of healthcare delivery (National Patient Safety Foundation, 2000).

A national report on healthcare quality in the U.S. (U.S. Department of Health and Human Services, & Agency for Healthcare Research and Quality, 2003) concluded, "The quality of healthcare can be measured, monitored and improved over time" (p. 10) and recommended the following safety approaches:

- decreasing of variations in timeliness of care through use of information technology,
- practicing of patient-centered clinical medicine focused on increased participation of the patient in the decision making about patient's medical care for improved patient compliance and satisfaction, and
- standardization of patient safety definitions, terminology, and databases.

Furthermore, patient safety and quality definitions continue to be in the focus of expert debates. Within the last several years AHRQ has sponsored patient safety research to identify patient safety risks, design patient safety practices, educate healthcare professionals and monitor patient safety trends, and has started initiatives to identify best clinical practices and train patient safety researchers. Other agencies, such as CDC, FDA and VA have supported patient safety research and patient safety activities. Recent legislative efforts targeted creating of voluntary medical errors reporting systems. Despite all these efforts, patient safety improvements would not be achieved without standardizing definitions, terminology, measurement and databases in patient safety (U.S. Department of Health and Human Services, & Agency for Healthcare Research and Quality, 2003).

Recognizing the system roots of medical errors together with designing fail-safe systems and training medical professionals in error reduction techniques have been proven successful in healthcare settings. In addition, team-training approaches, such as the Crew Resource Management exercise utilized in aviation, improve communication among healthcare team members and support an active exploratory approach to patient safety. Traditionally, physicians have been trained to take personal responsibility and less to act as team members. For successful implementation of patient safety programs, healthcare institutions should recognize the great importance of teams in interdisciplinary tasks in the complex healthcare environment. Such healthcare teams may become the leaders in patient safety improvement through identifying performance measurement opportunities, design and recommendation of action plans for improvement, and achieving positive impact on organizational level. Research showed that there are three major training domains in achieving patient safety: (a) training for safety, (b) training for teamwork, and (c) training for dealing with errors. Furthermore, for successful patient safety programs, team training must be supported by risk management education and improved information management (Sentinel events, 1998).

Failure Mode and Effects Analysis (FMEA) have been used in other industries, such as airline, space and auto industries, for designing error prevention strategies. FMEA strategy has proven equally effective for error prevention in medicine (Proulx, Wilfinger, & Cohen, 1997; Marder, & Sheff, 2002). In 2001, the VA National Center for Patient safety (NCPS) introduced the Healthcare FMEA (HFMEA), a prospective hazards analysis model that combines FMEA, root cause analysis (RCA), and Hazard Analysis and Critical Control Point (HACCP) approaches. The HFMEA's five steps (defining the healthcare problem, assembling a multidisciplinary team, flowcharting the process, conducting a hazards analysis and development of outcome measures and action plans) allow a proactive evaluation and assessment of potential process vulnerabilities. Additionally, HFMEA requires sharing the results with other teams within the organization to deploy the findings on different processes, tasks and care points that have been assessed as hazardous to patient safety. The HFMEA has been used in the VA system since 2001 (DeRosier, Stalhandske, Bacian, & Nudell, 2002).

Leape (1994) wrote, "Systems that rely on error-free performance are doomed to fail" (Leape, 1994, p. 1852). Addressing the latent errors embedded in the design of healthcare systems has been recognized as a strong approach for ensuring patient safety (Cullen, Sweitzer, Bates, Burdick, Edmondson, & Leape, 1997). Systems approach to medical errors has the potential to improve quality of care, provide education regarding the root causes of error, and enhance the provider/patient relationship and communication through mutual respect, patient integration in the healthcare delivery process, and providing an appropriate, system-centered approach for quality and patient safety improvements (Liang, 2002).

A variety of continuous quality improvement methodology tools, such as run charts, control charts, and Pareto charts, have been successfully used in healthcare environment to reduce medication errors, including identifying opportunities to improvement, development of implementation strategies and measuring the intervention effectiveness (Carey & Teeters, 1995; Howanitz, P. J., Renner, S. W., & Walsh, M. K., 2002). Liang (2002) suggested that successful quality improvement programs start with setting institution-wide policies and procedures for recognizing, analyzing, and dealing with the systems nature of medical errors.

Healthcare processes are interdepartmental in nature and should be designed and assessed by cross-functional teams including clinical, administrative and other staff members; thus, linking patient information systems to administrative and financial information systems appears critical for measuring healthcare outcomes (Hertz, Reimann, & Bostwick, 1994). Daley, Vogeli, Blumenthal, Kaushal, Landon, and Normand (2002) asserted that healthcare delivery quality issues are due to faulty processes rather than individuals and the way to quality improvement is through development and deployment of systems for clinical performance assessment.

Healthcare organizations utilizing quality improvement tools for self assessment are in the position to identify areas of exemplary performance and learn how those processes became successful, and use weak areas for learning and establishment of improvement priorities. The role of leadership in using process data for improvement rather than for disciplinary actions is extremely important in the patient safety improvement effort. Importantly, performance data collection should be based on accepted performance guidelines sets, such as accreditation standards or the Baldrige Healthcare Criteria for Performance Excellence (Sentinel events, 1998).

CHAPTER III

RESEARCH METHODOLOGY

Introduction

Cooper (2001), in a study on current research on patient safety, identified the need for different research methodologies and consumer-oriented research, and emphasized the need for rigorous qualitative research as an existing methodological gap as well as a strategy to attract more social scientists to research in the field of patient safety. Furthermore, the study suggested that consensus building methods that use *experts* as a source of knowledge and information, such as the Delphi method, coupled with a comprehensive literature review, are reliable approaches in patient safety research (Cooper, 2001). In this dissertation, the Delphi method was used to create a framework of critical processes and related performance measures for patient safety systems in healthcare institutions, to identify barriers for their implementation and to forecast the significance of the suggested critical processes in the future. This chapter outlines the Delphi technique used to gain consensus from the study experts on the critical processes, performance measures and barriers for building, implementing and sustaining patient safety systems in healthcare institutions, and defines the methods utilized for selection of study participants, determination of when consensus was reached, selection of an importance ranking scale and the means of data analysis.

The Delphi Method

Linstone and Turoff (1975) defined the Delphi method as a “method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem” (p. 3). The method improves the generation of critical ideas, the structured collection of information and the processing of the collective input from a panel of geographically dispersed experts (Ziglio, 1996). The methodology originated in the early 1950's, when an Air Force-sponsored RAND project, titled "Project Delphi," sought to reach consensus, through series of questionnaires and controlled feedback, among military experts on possible U.S. industrial targets for attacks from Russia (Linstone & Turoff, 1975).

The Delphi methodology has applications in many fields, including healthcare, policy and forecasting (Linstone & Turoff, 1975; Thompson, 1973). The advantages of the method include:

- ability to conduct a study in geographically dispersed locations without physically bringing the respondents together;
- time and cost-effectiveness;
- discussion of broad and complex problems;
- ability for a group of experts with no prior history of communication with one another to effectively discuss a problem as a group;
- allows participants time to synthesize their ideas;
- allows participants to respond at their convenience;
- provides a record of the group activity that can be further reviewed;
- the anonymity of participants provides them with the opportunity to express opinions and positions freely;
- the process has proven to be effective in a variety of fields, problems, and situations (Rotondi & Gustafson, 1996).

Researchers use the Delphi method to translate scientific knowledge and professional experience into informed judgment (Linstone & Turoff, 1975). Additionally, the participating panel members need not commit themselves to an idea that may turn out to be unsuitable. Thus, the method allows consideration of ideas and concepts without any bias for the further discussion of an idea related to the person that suggested it (Turoff & Hiltz, 1996). The Delphi technique supports informed decision-making and its first applications were in the area of technological forecasting aiming at assessment of new technological inventions and the economic impact of the change in technology. The Delphi method gives a way of structuring a large mass of information, evidence and expertise in order to achieve informed judgment, decision-making and forecasting (Ziglio, 1996). The Delphi technique can be used in discussing problems of both numerical and non-quantifiable nature. The technique has the capacity to deal with ambiguity and multi-dimensionality (Thompson, 1973). Ziglio (1996) considered the Delphi method particularly important when the heterogeneity and/or anonymity of the expert group should be preserved in order to avoid domination in the communication process by a particular person or a professional group due to vested interest, reputation or personality characteristics. Furthermore, the Delphi method gives the panel members the avenue for asynchronous interaction, where they choose to participate in the group communication process at their convenience and to contribute most to those questions about which they feel most qualified. Adler and Ziglio (1996) viewed the Delphi method as a "Collaborative Expert System" where the experts are provided with a Delphi design and they dynamically and actively contribute their knowledge to the system.

The purpose of a Delphi study is to:

(a) ensure that all major considerations are gathered and assessed,

(b) estimate the impact and consequences of all presented options, and/or

(c) access the acceptability of the considered options.

Thus, the Delphi method is an important tool for decision-making when dealing with uncertainty because researchers can explore the nature of the problem, assess its magnitude and evaluate suggested ways to address it. The Delphi technique is considered to be a systematic way to draw on the informed judgment of a group of experts in support of decision-making and forecasting; this method permits individuals to generate new ideas and explore future scenarios, and is considered to be a highly motivating task for respondent experts (Ziglio, 1996). Rotondi and Gustafson (1996) discussed the need for in-depth conversation in the Delphi process among participants who are in a unique position to support change of the *status* *quo*, and noted, “One of a group’s strengths is its ability to combine the efforts of individuals with diverse experiences, expertise and wisdom, and to direct these efforts toward the achievement of a common goal” (p.35).

In the field of health services, the Delphi method has been used in planning for the future and formulating policies and programs in biomedical research, behavioral research, mental health, reproductive health, pharmacology, services for the elderly, family planning services, accidents and injuries, development of core competencies for advanced nursing practitioners and development of clinical care protocols (Adler & Ziglio, 1996; Calzone, Jenkins, & Masny, 2002; Wang, Wang, Zhang, Fang, Liu, Luo, Tang, Wang, & Li, 2003; Catlin & Carter, 2002; Sharp, Liebenau, Stocks, Bennewith, Evans, Jones, Peters, Goldberg, & Gunnell, 2003; Escobar, Quintana, Arostegui, Azkarate, Guenaga, Arenaza, & Garai, 2003; McBride, Pates, Ramadan, & McGowan, 2003). Jones and Hunter (1995) reported that the Delphi method, as a useful way of identifying and measuring uncertainty, has been widely utilized in medical and health services research to define professional roles and clarify issues in health services organizations, to aid design of educational programs, to make long-term projections of need for care for particular population groups, to develop criteria for appropriateness of interventions, and to define adverse effects of reducing medical staffing levels. Elnicki, Lescisin and Case (2002) used the Delphi methodology to modify the National Board of Medical Examiners (NBME) Medicine Subject Exam (Shelf) in order to align the national exams with the internal medicine clerkship curriculum developed by the Society of General Internal Medicine (SGIM) and the Clerkship Directors in Internal Medicine (CDIM). Hasson, Keeney and McKenna (2000) argued that consensus building through Delphi survey technique can contribute significantly to broadening knowledge and effective decision making in health and social care.

Nauman and Palvia (1982) used the Delphi methodology in selecting systems development tools. Nauman and Pavlia’s selection model for system development tools begins with defining the set of functions expected from the systems development tools, proceeds with weighing the acceptable valuations using the Delphi method, and concludes with computing benefits-cost data for the highest ranking alternatives (Nauman & Palvia, 1982).

Conventional Delphi Technique

The *conventional Delphi* study has four distinct phases (Linstone, & Turoff, 1975):

(1) Exploring the issue under discussion, where each Delphi expert contributes additional information pertinent to the subject;

(2) Reaching understanding of how the group views the issue;

(3) Exploring disagreements; and

(4) Final evaluation.

The *conventional Delphi* involves a questionnaire designed by a small team and a larger respondent group. The respondent group re-evaluates its initial answers at least once, based on a feedback about the group response. Thus, the smaller team carries the communication effort (Linstone & Turoff, 1975). In this dissertation study, the researcher was solely responsible for monitoring the communication of the participants in the study and analyzing the results.

Usually three survey rounds are sufficient to attain response stability with response distribution fitting a statistically normal curve. In Delphi studies, little change in responses has been observed after a third round. Moreover, after the third round, a decrease in the response rates has been observed. Thus, excessive repetition of Delphi questionnaires has been proven to be unacceptable to participants and to have no further value to study results (Linstone & Turoff, 1975). The focus in a Delphi study is on the stability of the group opinion rather than on individuals' opinions, thus measuring the group result is superior to measuring the change of each individual's rankings between rounds (Scheibe, Skutsch, & Schofer, 1975).

The first round responses are used to make questionnaire modifications before returning it to the group of experts. The modifications include all related suggestions made by the respondents during the first round. Jones (1975) argued that groups of experts, participating in Delphi studies, were able to make valuable contributions while rising above the desire to protect personal interests. As discussed by Ziglio (1996), experiments carried out in the 1960s and 1970s demonstrated that for subject matters where the best available information is the judgment of knowledgeable individuals, the Delphi method had demonstrated decision-making advantages over the traditional conferences, group discussions, brainstorming, or other interactive group activities.

The Delphi approach can be used as a senior management education tool, environmental planning tool, and for comparison with similar institutions. Putting together the structure of a model, developmental planning and exploration of policy options are among the explicit application areas identified since the early 1970's (Linstone & Turoff, 1975). The Delphi method has been used to delineate the barriers to performance in health services. Three types of barriers to optimal healthcare performance have been identified: solution development barriers, problem selection barriers, and evaluation barriers (Linstone & Turoff, 1975). It has been argued that the forecasting accuracy of Delphi studies is strongly reliable; for example, a Delphi study with medical doctors evaluating the forecasting application of the method, revealed that in 75% of the cases the estimated values proved to be less than 10% different from the observed (Linstone & Turoff, 1975, p.79).

Use of Electronic Means of Communication in Delphi Studies

The use of electronic means of communication has been recommended in cases when the individuals contributing knowledge, experience and expertise to a complex problem have no history of previous communication, when time is scarce and geographic distances are large, and when the problem is so broad, that more individuals would be involved in its resolution than could be afforded in a face-to-face meeting (Linstone & Turoff, 1975). In this dissertation study, electronic means of communication (e-mail) was used for keeping in contact with all study participants and for distribution (and receipt) of surveys to 22 of the 23 study experts.

Selection of Delphi Experts

The questions arising around the formation of a Delphi panel are typical for selection and formation of any group – committee, task force, panel, study group, etc. (Linstone & Turoff, 1975). Thus, while panel member selection is a problem that should be addressed, it is by no means unique to Delphi studies. Linstone and Turoff (1975) argued that the amount of bias expressed by study participants is offset by the fact that in answering the questions each participant exhibits a standard deviation which is comparable to, or greater than, participant's individual mean (i.e., an optimistic panelist is pessimistic in some of his/her responses, and vice versa).

Ziglio (1996) argued that although experiments carried out in the 1950s and 1960s suggested that group error is reduced with increased group size, the sample size for constructing a Delphi panel was not a statistically-bound decision and that good results could be obtained by a small group (10 to 15) of homogenous experts. The selection of criteria that would qualify an individual to participate on the Delphi panel depends on the aims and context of the particular study. Some of the general criteria include:

- knowledge and practical engagement with the issue under investigation;
- capacity and willingness to contribute to the exploration of a particular problem;
- assurance that sufficient time will be dedicated to the Delphi exercise;
- good written communication skills;
- experts' skills and knowledge need not necessarily be accompanied by standard academic qualifications or degrees (Ziglio, 1996).

For example, the experts for a national two-round Delphi study on the effectiveness and risks of coronary angiography (Bernstein, Laouri, Hilborne, Leape, Kahan, Park, Kamberg, & Brook, 1992) were chosen on the basis of their clinical expertise, community influence, and diversity of geographic location.

Delphi participants are not selected randomly; rather, they are purposefully selected to apply their knowledge and experience to a certain issue based on criteria which are developed from the nature of the problem under investigation. Since the Delphi method relies on repeated questionnaires to the same initially selected sample of participants, the method requires a continued commitment from the panelists and is heavily dependant on the time and continued involvement on part of the study participants. Thus, it is extremely important that potential participants approached for recruitment be exactly informed what they will be asked to do, how much time they will be expected to devote to the study, and how the obtained information will be used. Providing adequate information is important in building research relationships and for attrition of participants. Although reminder letters and phone calls have been found to be helpful in conducting Delphi studies, still the response rate lies entirely within the discretion of the respondents. With the widespread employment of electronic communications, it is important to consider the computer literacy and skills of the target sample before utilizing electronic means of communication in Delphi studies (Hasson, Keeney, & McKenna, 2000).

Importance Rating Scale

Linstone and Turoff (1975) described a 4-point Likert scale to assess importance (priority, or relevance) of items in a Delphi questionnaire. An item rated as “Very Important” is a most relevant point, has a first-order priority, has a direct impact on the major issue and must be resolved or appropriately dealt with. An item rated as “Important” is relevant to the issue at hand, but has a second-order priority, and its impact would be recognized as significant only after other issues are addressed, thus such an item may not be fully resolved. A “Slightly

Important" item has little importance and is of a third-order priority and is not a determining factor to the major issue. Finally, an "Unimportant" item has no priority, is not relevant to the discussed issue, and since it has no measurable effect on the issue at hand, should be dropped from consideration.

This study utilized a four-rank scale for assessing the current importance of suggested critical processes and performance measures for patient safety systems in healthcare institutions and for predicting the future importance of the selected critical processes. The ranking scale was modeled according to the original Turoff's importance-ranking scale (Turoff, 1975). The participants in the study were asked to rank the importance of each critical process and performance measure from 1 to 4, where "4" represented *very important* to patient safety systems in healthcare institutions, and "1" represented *unimportant* (irrelevant). Additionally, in the second and third rounds, a similar 4-rank scale was applied towards assessing the importance of the barriers to implementation of patient safety systems identified by the experts during the first survey round.

Description of Study Questionnaires

The *first study questionnaire* was organized based on the MBNQA categories for performance excellence in healthcare (Appendix 2). The *Information sheet* to each Delphi expert provided detailed description of the time and effort commitment needed for successful conduct of the study and outlined a time-frame for the study. The *Information sheet* was placed to appear first in the mailed survey and to appear as page one of the e-mailed survey. Tables 1 to 6 of the questionnaire presented suggested items, areas to address, critical processes and performance measures for patient safety systems in healthcare institutions as identified in current literature on patient safety in healthcare and by national patient safety organizations and healthcare accreditation bodies. Each table provided space for ranking of the importance of the relevant critical processes and performance measures for patient safety systems in healthcare institutions. The importance of critical processes was ranked twice: once in terms of its current importance and a second time in terms of its future importance. Performance measures were ranked only once in terms of their current importance. Table 7 did not ask for the assessment of critical processes. It identified performance measures relevant to assessing healthcare institution's patient safety results and their current and future importance to patient safety systems in healthcare. For tables 1 to 7, the experts were asked to place a rank in each respective "Rank" column for each Critical Process and Performance Measure and to rank each item from 1 to 4, in the context of its importance to patient safety systems in healthcare institutions, where:

- "4" represented a "very important" item to patient safety systems in healthcare institutions;
- "3" represented an "important" item to patient safety systems in healthcare institutions;
- "2" represented a "not very important" item to patient safety systems in healthcare institutions;
- "1" represented an "unimportant" item to patient safety systems in healthcare institutions.

Each critical item, critical process and performance measure were numbered, where a one-digit designation referred to the seven MBNQA categories (e.g. 1.), a two-digit identification referred to a category item (e.g. 1.1.), a three-digit identification (e.g. 1.1.1.) referred to a critical process, and a four-digit identification (e.g. 1.1.1.1.) referred to a performance measure. In the space provided after each item, the experts were asked to add any new critical process that they believed should be included for that particular item in the space identified as "Critical process not included" and/or any new performance measure that they believed should be included for that particular critical process in the space identified as "Performance measure not included" and score the ones that they have added using the same ranking scale. Additionally, the study respondents were asked if they added a new critical process, to also suggest a performance measure for its assessment. If the experts wanted to add a new performance measure only, they were asked to refer to the critical process (e.g. 1.1.1.) it addressed. The Delphi experts were encouraged to re-word any critical process and/or performance measure in the space provided for comments at the end section for each table; additional space for comments was also provided at the end of the questionnaire. At the end of the first questionnaire, the experts were asked to discuss briefly what barriers they would consider the top five barriers to implementation of patient safety systems in healthcare institutions. The respondents were expected to return their filled-in questionnaires within two weeks of receipt.

The *second questionnaire* followed the organization of the first questionnaire (Appendix 3). For each critical process and performance measure, the Second Round tables provided the mean score for the group, individual panelist's score and space for change of rank, if deemed appropriate. The Delphi experts were asked, after considering the group mean and their previous rank, to provide new rank, when deemed appropriate, for each critical process and performance measure. If no change of rank was deemed appropriate, the study participants were instructed to leave the space for "New rank" blank. Critical processes and performance measures that had been re-worded by the Delphi panel during the first survey round were marked in bold with "Corrected!" Where more than one panelist suggested similar re-wording of a critical process and/or a performance measure, the new critical process or performance measure was included to accommodate all suggestions with the minimum possible modification to the original wording provided by the panelists. In light of the suggested modifications, the panelists were asked to give a careful review to their original ranking for each corrected critical process/performance measure and the need for a new rank, and provide new rank, when deemed appropriate, in the column labeled "New rank." New critical processes and performance measures suggested by the Delphi panelists were marked in bold with "New!" Where more than one panelist suggested similar new critical processes and/or performance measures, the new critical process or performance measure was included to accommodate all suggestions with the minimum possible modification to the original wording provided by the panelists. The Delphi experts were asked to rank all new critical processes and performance measures in the column labeled “New rank.”

Since the First Round questionnaire returned a variety of barriers to implementing patient safety systems in healthcare institutions, all suggested barriers were grouped and 29 groups were formed. There was no prioritization in the sequence of presentation of the barrier groups. The Delphi experts ranked the importance of each barrier group from 1 to 4, where:

- “4” represented a “very important” barrier: patient safety systems could not be implemented unless this barrier is eliminated/modified;
- “3” represented an “important” barrier: patient safety systems might begin but could not be continued unless this barrier is eliminated/modified;
- “2” represented a “not very important” barrier: patient safety systems might begin and continue, but at limited effectiveness unless this barrier is eliminated/modified;
- “1” represented an “unimportant” barrier: patient safety systems can be implemented in the presence of this barrier.

Based on expert’s perception whether a given barrier is related to the individual healthcare institution context (local issue) or is common to the national healthcare system (system issue), the Delphi panelists were asked to insert “local” or “system” in the column labeled “Local/System.”

The *third questionnaire* followed the organization of the previous two and included only those critical processes and performance measures for which consensus was not reached during the second round (Appendix 4). The third questionnaire also continued the exploration of the barriers for implementation of patient safety systems in healthcare institution and solicited experts’ opinions on a patient safety related issue, raised by several of the participants during the second survey round.

Modifications of the Questionnaire between Rounds

One of the advantages of the Delphi technique is that sequential questionnaire rounds allow modification of the survey instrument between rounds. Such modifications become necessary to sharpen/elaborate the format of existing items, or to include additional, subsidiary or related items that have been suggested by the respondents on the first round (Thompson, 1973).

After the first questionnaire round, several wording changes were made to the suggested critical processes and performance measures and new processes and related measures were added as suggested by study experts. After the second round no further re-wording changes were necessary, nor any new patient safety critical processes or performance measures were added.

Consensus in Delphi Studies

The question regarding which criteria should be used to judge whether consensus has been reached is central to conventional Delphi studies. Scheibe, Skutsch, & Schofer (1975) concluded that a change of 15% or less in response levels from round to round represents a state of equilibrium in the group opinion and recommended that every change over 15% should be tested in a successive study round. In this research, the Likert scale range was four; thus, a difference of 0.6 represented a 15% change level (15% of 4 equals 0.6). Therefore, a difference of 0.6 or less between the group means of item ranks in two consecutive rounds indicated that consensus was reached. As defined in the "Operational Definitions" section, consensus was considered to be reached if there was 0.6 or less change in item ranks between rounds, or less than one standard deviation for the respective item, whichever was less. For example, if the group mean for a critical process or performance measure was 3.1 in round one and 3.4 in round two, the difference between the two ranks was less than 0.6, and consensus was considered to be reached. The group mean at the round in which consensus was reached was referred to as "consensus mean." The "consensus mean" indicated that the group opinion was in equilibrium and the respective process or measure was not tested further in consecutive study rounds. All critical processes and performance measures, for which consensus was not reached, were re-evaluated by the experts in a successive survey round.

In 1992, Bernstein, Laouri, Hilborne, Leape, Kahan, Park, Kamberg, and Brook developed a methodology for determining consensus among Delphi study participants on the basis of a nine-member Delphi panel. Consensus was considered to be reached if, for a nine-member panel, no more than two individuals ranked a particular item outside a three-point region of the ranking scale. Hasson, Keeney and McKenna (2000) discussed different approaches to deciding when a consensus has been reached among study participants, ranging from 51% to 80% agreement among study participants, and suggested that stability of the responses through the series of rounds was a more reliable indicator than percentage measures. For the three Delphi rounds in this research project, all aforementioned definitions of consensus were satisfied.

Greatorex and Dexter (2000) argued that responses to Likert scales, which are usually used in Delphi studies, could be considered to be on an interval scale. Thus, the mean will represent the central tendency of the group opinion, while the standard deviation, as a measure of opinion spread, will represent the level of agreement among participants. If the mean is consistent across survey iterations, the panel opinion is considered to be stable across rounds; and if the standard deviation is consistent across survey iterations, the amount of agreement among the panelists is also considered to be stable across rounds (Greatorex & Dexter, 2000). Greatorex and Dexter (2000) used graphic representations of the means and standard deviations of items across survey rounds to show the overall extent of agreement and opinion changes with iterations of the surveys; the graphics showed an increase in agreement in consecutive rounds with lower standard deviations and means closer to the integer value of the respective Likert level.

Study Population

It was projected that the Delphi panel would include a national sample of 12 to 15 (and not fewer than eight in any round) healthcare experts, identified by an extensive set of criteria as knowledgeable about the theory and implementation of Continuous Quality Improvement/Total Quality Management and patient safety in the healthcare setting. The following criteria qualified healthcare quality and patient safety experts for inclusion in the study Delphi panel:

(a) Judges, senior examiners or examiners for the Malcolm Baldrige National Quality Award in healthcare;

(b) Senior administrators/leaders in healthcare institutions that have won or have applied for the Malcolm Baldrige National Quality Award in healthcare;

(c) Senior administrators/leaders in healthcare institutions that have won a state quality award within the last five calendar years;

(d) Leaders in state or national organizations or programs that emphasize continuous quality improvement and/or patient safety;

(e) Experts qualifying under more than one of the aforementioned categories.

Seventeen healthcare institutions applied in 2002 for the Malcolm Baldrige Quality Award (MBNQA) in the category of Healthcare. At the time of the beginning of this study in the spring of 2003, a total of 42 healthcare institutions had applied for the award (the author did not have information whether some healthcare institutions had applied more than once). The first winner in the MBNQA healthcare category was contacted and experts' names were solicited. Also, further referrals for senior administrators interested in participating were obtained.

Forty-five U.S. states have established State Quality Awards, based on the Malcolm Baldrige National Quality Award Criteria for Performance Excellence. All 45 state quality award program offices were approached in an attempt to identify healthcare institutions recipients of quality awards for the period since the initiation of the MBNQA for healthcare in 1998. Only several of the state awards have been granted to healthcare institutions within the last five years. All healthcare institutions winners of state quality awards were approached and senior administrator names were solicited. Additionally, several national healthcare quality/patient safety organizations were contacted and experts' names were solicited.

Since MBNQA applicants' names are kept confidential, obtaining information regarding application status of a healthcare institution is a subject of individual contact and institution's willingness to share such information. MBNQA reviewers for the category of healthcare (on the MBNQA *List of examiners*) were reached via phone and asked if they would consider sharing information on the MBNQA applicant status of their institution. Information was also solicited whether MBNQA examiners' organizations had won state quality awards within the last five years, and whether the examiners were senior administrators in their respective institutions. If the MBNQA examiners and senior healthcare administrators qualified as experts in healthcare quality improvement and patient safety, according to the criteria described above, they were invited to participate in the study.

Generally, the study participants were recruited via telephone and/or letter contact and were selected from (1) the list of MBNQA examiners, (2) senior administrators from healthcare institutions that had won national or state quality awards, and (3) referrals from (1) and (2). Twenty-three experts from 18 U.S. states participated in the first survey round. The details on the expert participation in the consecutive survey rounds are described in section "Response Rate" below. The characteristics of the Delphi panel are detailed in Chapter IV, Data Analysis, section "Delphi Panel Description."

The pilot instrument was evaluated by a panel of three experts in the area of quality improvement and patient safety. The instrument review panel included one representative from the MBNQA office, one MBNQA reviewer, and one patient safety and healthcare quality expert, serving on the Board of the National Patient Safety Foundation. The instrument reviewers made valuable suggestions and comments regarding needed wording changes in the formulated critical processes and performance measures, inclusion of additional patient safety critical processes and performance measures, and the relevance of the identified performance measures to the respective critical processes. After all revisions suggested by the instrument reviewers were made, the first survey instrument was sent out to the study participants.

Study Instrumentation

The Delphi technique 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 three questionnaires, where the first round questionnaire was based on a literature review and the Malcolm Baldrige Quality Award criteria for excellence in healthcare, and was evaluated by an instrument review panel of experts. Prior to the creation of the first instrument, the author reviewed the 2003 Malcolm Baldrige National Quality Award's Health Care Criteria for Performance Excellence. The language of the criteria was carefully examined and revised to reflect the terminology emerging and gaining popularity in regard to patient safety in healthcare institutions. The questionnaire evaluation by the pilot instrument review panel and the Delphi experts' rankings of the variables during the survey rounds established the content validity of the survey instrument.

Procedures

Three individuals, qualifying for the pilot instrument review panel were contacted via telephone, email or in person. After they agreed to revi ew the initial questionnaire, the draft survey instrument (developed after an extensive literature review), and a copy of the 2003 MBNQA Health Care Criteria for Performance Excellence were mailed (or e-mailed) to the three members of the instrument review panel. After the instrument review panel assessed the first questionnaire, changes were made as recommended by the instrument reviewers, and the survey, accompanied by the 2003 MBNQA healthcare criteria, was sent out to the 23 identified healthcare experts (Delphi panel), who had confirmed their commitment to participate in the study. The Delphi experts were given an option to choose if they wanted to work with a hard copy of the instrument (mailed), or preferred an electronic copy sent via email, or wanted to use a password-protected instrument posted on a web site (owned by the author). One study participant selected the mail option. One of the study participants selected use of the web site option or the e-mail option as his preferred choices. The majority of the Delphi panel experts preferred the e-mail option.

The names of the respondents were known to the researcher but not to other panelists. Hasson, Keeney and McKenna (2000) used the term “quasi-anonymity” to indicate that Delphi panelists are known to the researcher, and may be even known to each other, but their individual responses remain strictly confidential. At the end of the study, permission was sought from each Delphi expert to publish his/her name in the dissertation as well as in future publications related to the results from this Delphi study. Twenty-one experts agreed to have their names published and two experts requested their names to be kept confidential (Appendix 1).

It was estimated that Delphi panelists would need approximately 45 minutes to fill in each of the three questionnaires for this research. The time between survey rounds depended on the option chosen for survey completion (mail or e-mail), on the agreed deadlines for response, as well as on the time needed for data analysis for each round. Initially, it was anticipated that three to five questionnaires-survey rounds would be made, each lasting approximately six weeks. The first study round took the longest time due to the researcher’s efforts to obtain the highest possible response rate. Reminder e-mails were sent and telephone calls were made to individual participants that had not responded within the initially agreed response timeframe. The vacation summer time may have also contributed to the delays in participants’ responses. Of the 22 Delphi experts that chose the e-mail option, three participants asked to fax their responses and another three mailed their questionnaires back for the first survey round, four participants chose to fax their questionnaires and three experts mailed back their responses for the second survey round, and four experts mailed back their third questionnaires. The Delphi expert panel reached consensus within three survey rounds. The first survey round concluded in approximately 13 weeks, and the second and third rounds concluded in approximately 7 weeks each (a total of 6 months and 2 weeks for conclusion of the survey series).

Data Analysis

Spreadsheets were used to enter the responses for each critical process, performance measure, prediction of the future, and barrier to implementation of patient safety systems in healthcare institutions. The results of each round 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 responses. In consecutive rounds, survey instruments were prepared individually to include the group mean for each variable and the rank assigned to each variable by the respective Delphi expert. Once the survey round comparisons were made, the Delphi experts were asked to decide whether they would like to keep or change their rank for each critical process and performance measure. Additionally, the study participants were encouraged to add, delete or edit as they deemed appropriate the identified critical processes and performance measures for patient safety.

The qualitative data from participants' responses to the question of identifying barriers to implementation of patient safety systems in healthcare institutions were analyzed by grouping similar items together and providing one universal description for the newly formed group of items while preserving the original wording of the panelists to the maximum extent possible. Next, the Delphi experts were asked to rank the importance of each barrier on a 4-point Likert scale, similar to the scale used for ranking the importance for the critical processes and performance measures.

As described by Hasson, Keeney and McKenna (2000), when using a classic Delphi method, the study participants are the judges of the survey items in terms of importance and quality; thus, no items were added by the researcher during analysis, and the wording for new items, as suggested by the participants, with minor editing, was used in consecutive rounds.

Response Rate

The question regarding which criteria should be used in judging what constitutes a satisfactory response rate is important to Delphi studies. Furthermore, it is critical to consider what is the response rate usually obtained in surveys in a particular industry or study area. For example, a survey on the quality of healthcare and the problem of medical errors administered to a large random sample of Colorado physicians, national physicians and Colorado households, revealed response rates of 66% for the Colorado physician sample, 36% for the national physician sample, and 82% for the Colorado household sample (Robinson, Hohmann, Rifkin, Topp, Gilroy, Pickard, & Anderson, 2002). A patient safety staff survey, administered in September 2002 to over 6,000 staff members of the Cox Health Systems, MO, resulted in a response rate of 31% (S. Duvall, personal communication, 10/18/2002). Sexton, Helmreih, Rowan, Vella, Boyden, Neilands, Roberts, and Thomas (2003) in the psychometric validation process for their Safety Attitude Questionnaire in 160 healthcare sites in the U.S., England and New Zealand, obtained a response rate of 67%. Bertin (1996), in studying the use of Delphi technique for planning of social services obtained an 83% response rate from a group of 60 family doctors and a 100% response rate from a small group of hospital-based clinicians with a mean interval for reply of approximately 37 days. A pilot application of the Delphi technique to the drug field revealed a response rate of 83% (Thompson, 1973). Sumsion (1998), as discussed by Hasson, Keeney and McKenna (2000), argued that in order to maintain the rigor of the Delphi technique, a response rate of 70% must be maintained; thus, the researcher must pursue non-respondents in attempt to achieve a response rate of 70%.

Based on the healthcare study response rates as found in the literature, it was concluded that for this study a response rate of 67% to 70% should be expected. Thus, to obtain at least 15 responses, the study should begin with 22-23 Delphi panelists. All twenty-three experts that had made a commitment to serve on the Delphi panel participated in the first survey round. Twenty of the experts continued their participation in the second and third study rounds. Thus, the dissertation study response rate was 100% for the first study round, 87% for the second round, and 100% for the third study round.

Reasons for Dropout of Study Participants

Greatorex and Dexter (2000) discussed the following reasons for expert dropout from a Delphi study:

- minority opinions are not explored;
- low motivation;
- disagreement with study design or content;
- lack of faith in the study results;
- innocuous reasons, such as illness.

After the first survey round, three of the experts had to withdraw from further participation in the study due to increased professional duties, change of occupation and extenuating personal circumstances respectively.

Dealing with Outliers

The contribution of the literature regarding the effects and treatment of outliers in Delphi studies is sparse. An extensive search of on-line major databases (including Academic Search Premier, Applied Science and Technology Abstracts, Business Source Premier, Clinical

Pharmacology, ERIC, Health Source Nursing/Academic Edition, MEDLINE, Military and Government Collection, Psychology and Behavioral Science Collection, Sociological Collection and other databases) about treatment of outliers in Delphi studies retrieved only three articles. In the first article, it was concluded that the definition of consensus, and the decision how to treat outliers, strongly affect the output of consensus building methods intended to develop clinical practice guidelines and to assist clinical decision-making (Black, Murphy, Lamping, McKee, Sanderson, Askham, & Marteau, 1999). In the second article, which was exploring the consensus of an expert panel regarding the clinical criteria for the diagnosis of carpal tunnel syndrome, Graham, Regehr, and Wright (2003) concluded that the Delphi panelists who were outliers on the first round demonstrated a much higher correlation with the group after the second round. In the third article, which examined the agreement among vascular surgeons regarding the treatment of severe limb ischaemia, the authors reported that they excluded the outliers, i.e. they removed the top 10% and the bottom 10% of the responses (Bradbury, Bell, Lee, Prescott, Gillespie, Stansby, & Fowkes, 2002).

Outliers, as described by Chambers (1986), are of two basic types:

- *Representative* outliers, with values that are correctly recorded and it could be expected that other similar outliers exist in the population;
- *Non-representative*, or unique outliers, with specific characteristics such that no more similar outliers could be expected in the target population.

Dealing with non-representative outlier results remains within the scope of survey editing (Chambers, 1986). According to Semon (1997), there is no good practical solution to the outlier problem. Outliers in surveys often indicate a minority opinion and usually subjective principles have been adopted for identifying, accommodation, and rejection of outlier data (Barnett, 1994). Dealing with survey outliers includes winsorization or reduction of the weight of survey outliers (Gwet, & Rivest, 1992; Espositol, & Fox, 1994), elimination of the outliers (Argys, Peters, & Waldman, 2001; Subar, Midthune, Kulldorff, Brown, Thompson, Kipnis, & Schatzkin, 2000; Kost 1991), and outlier accommodation or analysis as a separate group (Leite de Vasconcellos, & Portela, 2001; Storzbach, Rohlman, Anger, Binder, & Campbell, 2001). In healthcare studies, outliers have been used to assess the quality of healthcare services at the two opposite ends of the spectrum – from very high quality to raising concerns about the quality of care delivered (Pelonelo, Elliott, Barber, & Best, 1996; Daley, Forbes, Young, Charms, Gibbs, Hur, Henderson, & Khuri, 1997; Korda, 1994). Thus, careful consideration should be given to the decision whether to incorporate, accommodate or reject survey studies outliers.

In this research both types of outliers (representative and non-representative) were observed. The representative outlier ranks were incorporated in the study results without weight transformation. Because the uniqueness of the non-representative outlier was recognized in communication with the Delphi expert very late in the study, i.e. the outlier expert's ranks were included in calculating the group means and standard deviations fed back to the participants in consecutive study rounds, the non-representative outlier results are also incorporated in the study and the possible effects of these non-representative outlier results as an influencing factor in the overall study outcomes are discussed in Chapter IV, section "Non-representative outlier effects on the study results."

Statistical Analysis

In inferential statistics, researchers use samples to reach conclusions about a larger population. With repeated samples, sample statistics will vary across samples (Spatz, 2001). The raw scores from participants' questionnaires for each round were entered into spreadsheets. SPSS 12.0 software was used to obtain frequencies, measures of central tendency, and standard deviation for the raw data set for each round. The "consensus means" for each critical process and performance measure, as a reflection of the stable consensus of the group, were used in further analyses and discussion.

The Delphi experts were assessing a total of 132 variables in the first round, and 162 variables in the second. Only variables about which consensus was not reached were included in the third study round. In each questionnaire, there were three subsets of variables, relating to: (1) current and (2) future importance of suggested critical processes for establishing patient safety, and (3) current importance of related performance measures. Implementing such a large set of variables for assessment of patient safety systems may be difficult in healthcare institutions that are "beginners" in implementation of patient safety improvement. Obviously, some data reduction technique was needed to lessen the number of suggested critical processes and performance measures in designing the framework for patient safety.

The approach for data reduction in this project was to create a "beginners" patient safety framework, including only those critical processes and performance measures that were evaluated by the study participants as having the highest scores for each of the seven areas in the MBNQA Healthcare Criteria for Performance Excellence: (1) Leadership, (2) Strategic Planning, (3) Focus on Patients, Other Customers and Markets, (4) Measurement, Analysis and Knowledge Management, (5) Staff Focus, (6) Process Management, and (7) Institutional Performance.

Human Subjects in Research

The Institutional Review Board - Human Subjects in Research, Texas A&M University, reviewed and approved this research (protocol #2003-0071). The following conditions were pertinent to the study:

- There was no relationship of the investigator with any or all of the research participants, other than the investigator role;
- The study did not use deception or coercion;
- There was no compensation for the study participants;
- There were no specific risks or benefits for the participants;
- There were no exclusions from participation due to gender or racial/ethnic group.

An Information Sheet, specifying the details regarding participation commitment, was given to each survey participant prior to the start of the research. For participants who had chosen to work with questionnaires on a hard (paper) copy, the Information Sheet was placed in the envelope in a way to appear first. For participants that chose to work with electronic copies (sent via e-mail), the Information Sheet appeared as page 1 in the attachment containing the questionnaire.

Primary research data were gathered through surveys (paper and e-mail) with healthcare experts in patient safety. These surveys did not involve sensitive subjects but focused on questions about the critical processes and performance measures that should form a framework for patient safety systems in healthcare institutions and assessed the importance, both current and future, of these critical processes and the current importance of the related performance measures. Additionally, the study explored the barriers to implementation of patient safety systems in healthcare institutions and their importance as perceived by the Delphi panel.

Human Subjects Protection

Confidentiality of subject responses was ensured. For representation in consecutive surveys, data from the previous round was stripped from personal identifiers and aggregated for the panel of experts as a group. No individual was quoted, and there were no links between an individual and his/her responses. The methodology provided functional anonymity to individual respondents – i.e. none of the respondents knew the name or affiliated institution of the other panelists. External observers would not be able to link an outlier response to an individual. All information and data utilized for the needs of this project were confidential, i.e. all personal identifiers were removed and all events were discussed only after data congregation.

Inclusion of Women and Minorities

The inclusion of women and minorities was determined by their representation on the Delphi panel and by their representation as examiners for quality awards in healthcare or as senior healthcare administrators in healthcare institutions applying quality improvement approaches. There was no provision for gathering race/ethnicity data in the survey instrument, nor was this an objective of the study. The project was designed to work with examiners for national and state quality awards, and with senior administrators from healthcare institutions that apply quality improvement methodology, based on their expertise and experience, and regardless of their gender or ethnicity.

Innovation

This dissertation establishes a framework of critical processes and performance measures for patient safety, based on the Malcolm Baldrige Quality Award Criteria for Performance Excellence in Health Care. Furthermore, the results of the dissertation bridge the Criteria for Performance Excellence in Health Care with the experience, views and perceptions of senior healthcare administrators that are primarily responsible for identifying, funding and implementation of patient safety initiatives in their respective institutions.

Although targeted by some requirements of accrediting organizations, the issue regarding which is the best patient safety approach remains controversial. Additionally, current regulations have been implemented mainly in response to the number of observed patient safety issues reported in professional publications. If a problem has not been recorded or reported (which is often the case with patient safety-related issues), it is most likely not reflected by patient safety requirements. No system-wide approach or model has been agreed upon thus far. This study presents a patient safety framework for a system-wide approach and application, consisting of patient safety critical processes and performance measures for healthcare institutions. The study strives to expand in theoretically meaningful and practically applicable ways the existing knowledge in the area of patient safety.

CHAPTER IV

ANALYSIS OF DATA

Introduction

Three issues guide the process of data analysis in Delphi studies: (1) discovery of expert opinions, (2) determining importance of issues, and (3) managing experts' opinions (Hasson, Keeney, & McKenna, 2000). The discovery of experts' opinions was done through the repetitive use of a questionnaire based on the Malcolm Baldrige National Quality Award Criteria for Performance Excellence in Healthcare and an extensive literature review. The importance of patient safety critical processes and performance measures was determined by calculating the mean for the Delphi panelists as a group. Based on a 4-point Likert-type scale, the ranks were from 1 to 4, where "1" presented "unimportant," "2" presented "not very important," "3" presented "important," and "4" presented a "very important" issue for patient safety systems in healthcare institutions. Thus, the closer the group ranks mean to "4," the more important the identified critical process and/or related patient safety performance measure.

The Delphi experts were given the opportunity to edit the suggested critical processes and performance measures in the first survey, as well as to add new critical processes and performance measures as deemed appropriate. The Delphi experts were encouraged to nominate as many new critical processes and performance measures as possible in order to maximize the coverage of all potential patient safety issues in implementing and maintaining patient safety systems in healthcare institutions. The second iteration of the questionnaire contained all corrections and new items as suggested by the panelists during the first study round. On some of the survey variables consensus was reached during the second round. All processes and measures that elicited diverse opinions from the panelists during the second round were included in the third study round.

Across the survey rounds, there were no suggestions for removal of any of the suggested variables from the survey instrument. One hundred percent of the critical processes and performance measures variables in the surveys were rated as “very important” or “important.” Furthermore, 95.6% of the variables in the first round, 97.6% of the variables in the second round, and 90% of the variables in the third round had mean ranks of 3 or above. None of the critical processes and performance measures was ranked “not very important” or “unimportant.”

The first questionnaire (Appendix 2) also included an open question exploring the perceptions of the experts regarding which are the top five barriers to implementing patient safety systems in healthcare institutions. This open question brought back over 100 suggested barriers, which were grouped in 29 groups and returned to the panelists in consecutive rounds for further discussion. In the second and third survey iteration, the experts were asked to rank the importance of these barriers as well as to discuss whether a particular barrier presented a local or a healthcare system issue.

This chapter presents analysis of the study data based on the differences between the initial expert group rank means and standard deviations from the beginning to the end of study. While the group means assigned to a critical process or performance measure from the Delphi panelists identified the most important patient safety issues, the changes in the group standard deviation additionally highlighted the consensus of the group. The lower the standard deviation in ranking a particular critical process or performance measure was, the less dispersed the opinions of the individual panelists regarding that particular item were.

As discussed by Hasson, Keeney and McKenna (2000), the utilization of a panel of experts who have knowledge and interest in the topic increases content validity of the Delphi survey and the consecutive rounds of the survey increase the concurrent validity. Hasson, Keeney and McKenna (2000) emphasized the importance of knowing when to stop survey rounds: stopping too soon may not provide meaningful results and/or consensus, and going on with too many rounds may lead to sample fatigue and decreased response rate. This Delphi study concluded in three iterations.

Dealing with Missing Data

The first questionnaire explored the importance of 132 variables and had 0.8% of missing data (26 data points missing out of a total of 3,036 data points). The second questionnaire assessed 162 variables and had 1.8% of missing data (60 missing points out of 3,240 total data points). In the third questionnaire, there were 4 missing data points, presenting a missing data rate of 0.1%. There was no particular pattern of the missing data points in all three rounds, i.e. the missing data were random. Four of the participants that had chosen to work with electronic copies of the questionnaire had problems with displaying some portions of the second survey. These participants were additionally approached, a second copy of the problematic pages was sent to them as a separate file via e-mail, mail or fax (as preferred by the individual panelists) and their responses were added to the second round rankings. It was estimated that the problem with the e-mail transfer occurred due to incompatibility of the computer software versions of the program used by the researcher to create the survey and by the Delphi experts to open the survey files.

Data imputation (i.e. systematic replacement of missing data with plausible values generated by computer simulation) utilizing program NORM was discussed. However, data imputation proved inappropriate due to (1) the small percentage of missing data, and (2) the large number of variables assessed by a limited number of experts.

Delphi Panel Description

The Delphi panel for the first iteration included 23 experts from 18 states (Figure 2), identified by an extensive set of criteria as knowledgeable about patient safety as well as the theory and implementation of Continuous Quality Improvement/Total Quality Management in the healthcare setting. Twenty of the experts from 17 states continued their participation in both, the second and third study rounds.

FIGURE 2. Visual Presentation of the 18 Participant States (marked in red)

Several of the study participants represented hospital systems operating in more than one state. With the assumption that study participants working in the corporate headquarters of a hospital system have the potential to influence the operations in individual system components, the conclusion was that a total of 28 states throughout the nation had directly or indirectly influenced the study outcomes (Figure 3).

FIGURE 3. Extended Study Participation with States Participating Indirectly Marked in Lighter Red Line

Table 1 presents the characteristics of the expert sample. A complete list of qualification criteria for inclusion of Delphi experts for this study is presented in Chapter III, Methodology, section "Study Population."

The senior hospital administrators were employed in positions such as, but not restricted to "Vice President for Healthcare Improvement," "Director for Quality Management," "Vice President of Clinical Effectiveness," "Corporate Risk Manager." At the end of the study, permission was sought from individual experts for honoring their names as major contributors to this study. A list of the Delphi experts, their affiliated institutions and administrative positions is presented in Appendix 1.

TABLE 1 Characteristics of the Delphi Experts (total number of participants = 23)

Participant Characteristics	Number of Participants
Examiners for the Malcolm Baldrige Quality Award (including ranks of “Examiner,” “Senior,” and “Judge”)	14
Holding a professional M.D. degree” and/or a Ph.D. degree	6
Registered nurse or nurse practitioner	7
Representing an institution that has applied for or won the Malcolm Baldrige National Quality Award in the Health Care Category	6
Representing a healthcare institution that has won a state quality award	6
Senior hospital administrators	20
Leader in a national organization for healthcare quality and patient safety	1
Leader in a state organization for healthcare quality and patient safety	1
Female	17
Male	6

General Overview of Individual Survey Responses

Figures 4 through 9 present the distribution of individual panelist ranks for all items in categories 1 to 6, including both critical processes and performance measures for the third survey round. Data points represent in many cases multiple panelists’ responses. The four missing data points (out of a total of 3,240 data points) were replaced with the group means for the respective variables.

For the critical processes and performance measures in Category 1, Leadership, the majority of individual ranks were clustered at rank 3, Important, and rank 4, Very important. Only three individuals assigned lower ranks. For Category 2, Strategic planning, four panelists ranked some of the critical processes or performance measures lower than “3,” with prevailing majority of assigned individual ranks being “important” and “very important.” Category 3, Focus on patients, other customers and markets, presented broader differences in individual experts’ perceptions about the importance of the critical processes and performance measures included in this category. The majority of individual ranks for Category 3 was clustered between rank 2, Not very important, and rank 4, Very important, with one panelist assigning a rank of 1, Unimportant, to six of the items in the category. In Category 4, Measurement, analysis and knowledge management, six participants ranked 11 questionnaire items below 3, and one of them gave a rank of 1, unimportant to two of the items. Seven participants assigned ranks lower than 3 to some of the variables in Category 5, Staff focus, and one of them assigned three ranks of 1, unimportant. Only four participants assigned ranks lower than 3 to variables in Category 6, Process management, with one of them assigning three ranks of 1, and the majority of ranks clustered between rank 3, Important, and rank 4, Very important.

Non-representative Outlier

One of the study participants had consistently assigned ranks of 1 to items in all categories, assigning 30 of the 33 ranks of “1” present at the time the panel reached consensus on the importance of study variables. Thus, this expert was presenting an outlier ranking behavior and was approached for further discussion. Further communication with that participant revealed that in most instances, the expert had assigned a rank of “1” not based on the perceived importance of the item, but rather on the feasibility applying the item in question in the current healthcare environment (i.e. without implementing substantial changes). Although such a ranking approach diverted from the specified ranking system for the study, the participant did not change the already assigned ranks. The already assigned ranks had been included in the calculations for group means and group standard deviations fed back to the panel in the second and third study round. The explanation of the outlier participant about the assigned “unimportant” ranks provided a valuable explanation regarding evaluation of the group results. The influence of this non-representative outlier is further discussed in section “Non-representative outlier effects on the study results.”

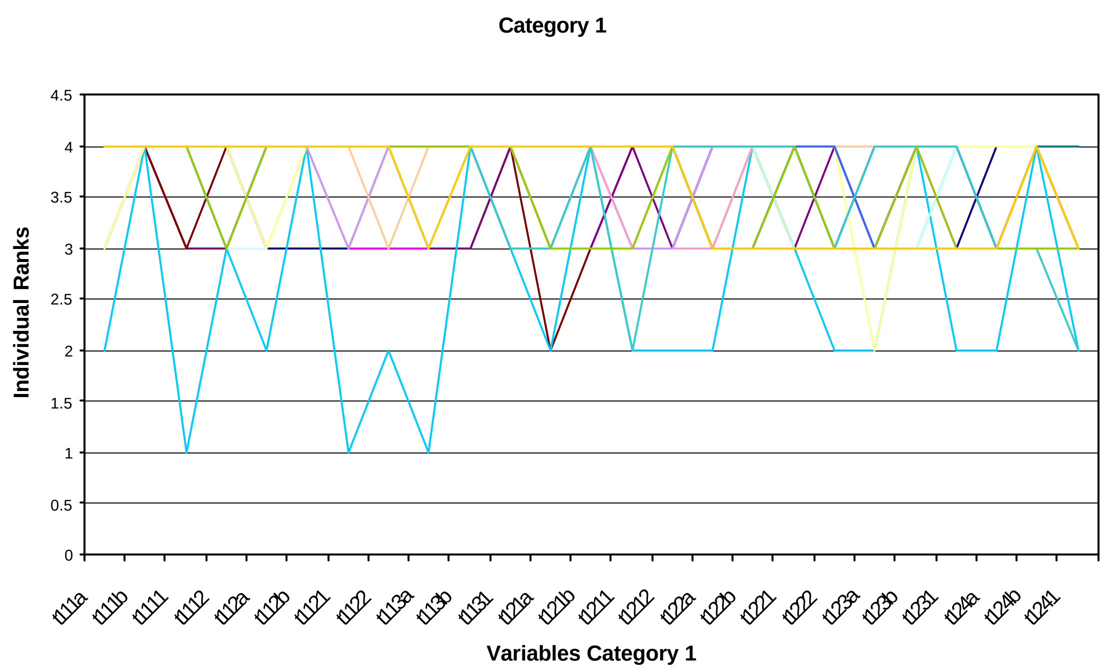

FIGURE 4. Distribution of Individual Participant Ratings for Variables in Category 1

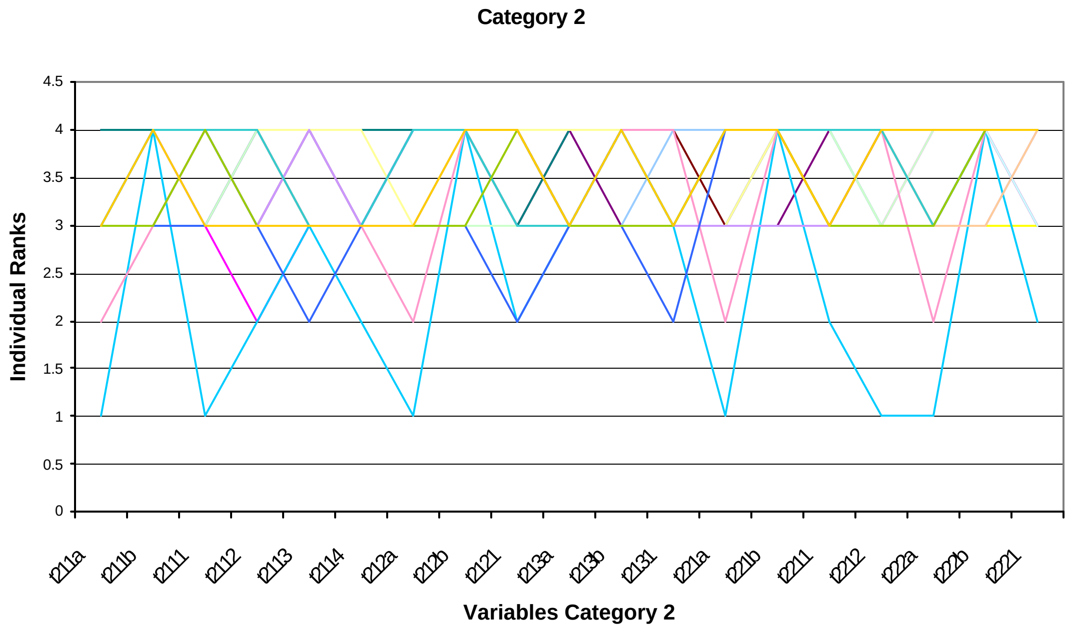

FIGURE 5. Distribution of Individual Participant Ratings for Variables in Category 2

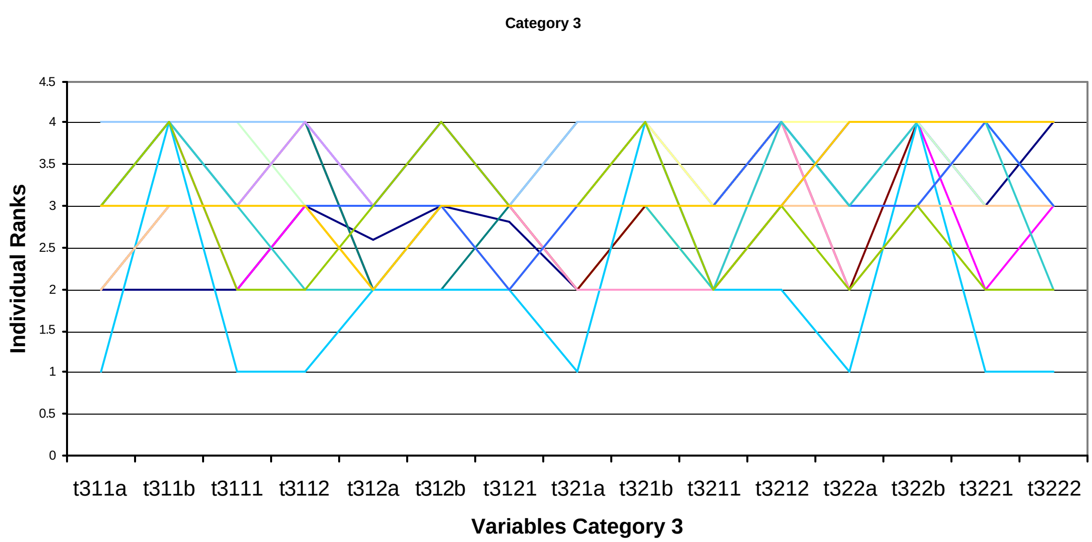

FIGURE 6. Distribution of Individual Participant Ratings for Variables in Category 3

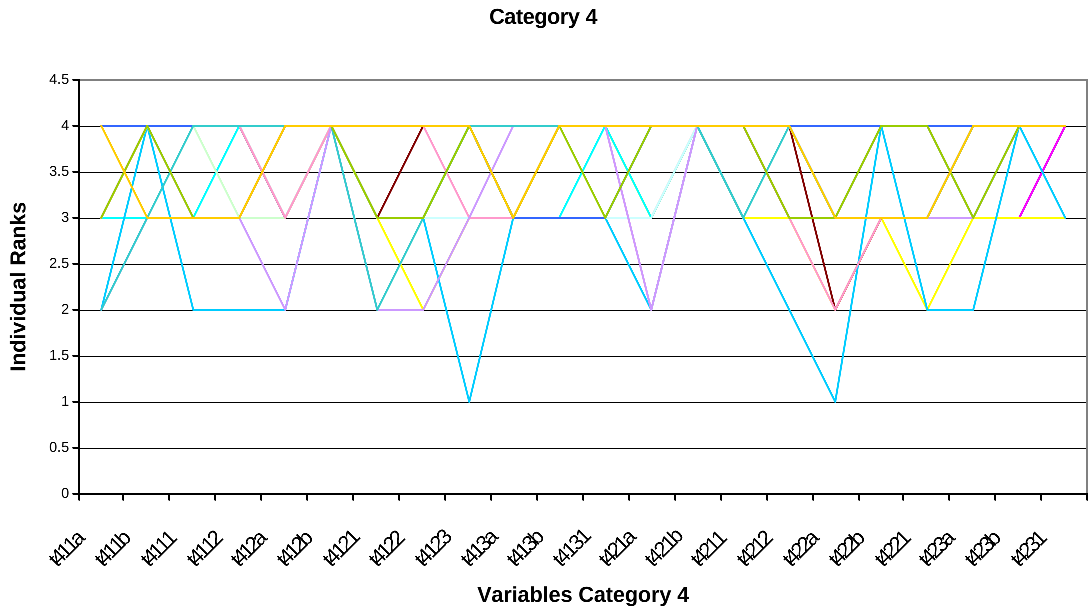

FIGURE 7. Distribution of Individual Participant Ratings for Variables in Category 4

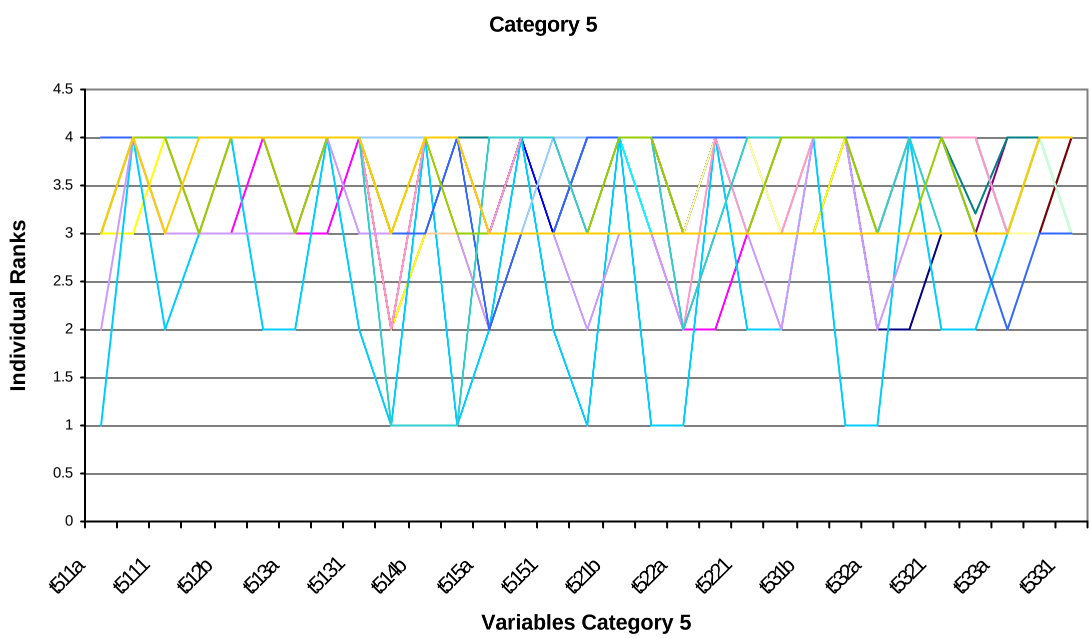

FIGURE 8. Distribution of Individual Participant Ratings for Variables in Category 5

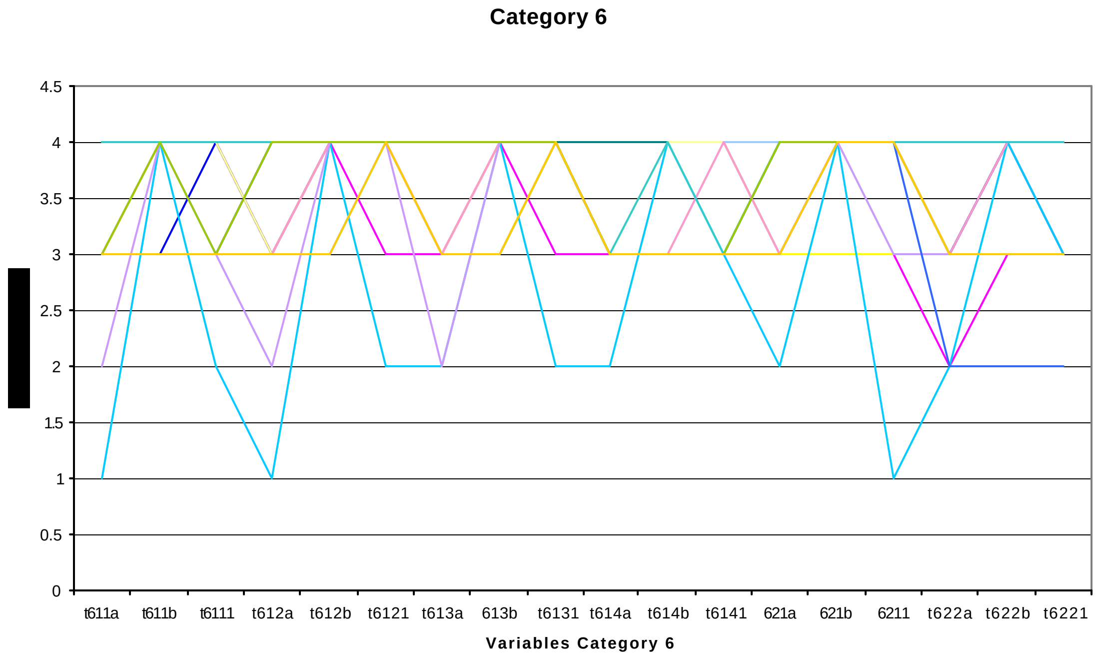

FIGURE 9. Distribution of Individual Participant Ratings for Variables in Category 6

New and Corrected Critical Processes and Performance Measures

The Delphi experts added a total of eight new critical processes and 12 new performance measures to the first round patient safety questionnaire. Eight of the new performance measures corresponded to the eight added critical processes, and four complemented critical processes from the initially suggested framework. The Delphi experts also corrected the wording of three critical processes and six performance measures with consecutive iterations of the questionnaire.

Research Question One

The first researched question for this study asked, “What are the critical processes that should be included in healthcare patient safety systems?” To answer this question, the Delphi experts were asked to (1) review the suggested critical processes for each of the seven Malcolm Baldrige National Quality Award Categories, (2) edit all suggested patient safety critical processes, and (3) add new critical processes related to improving the healthcare quality and patient safety in healthcare institutions. The emphasis was on institution-wide (system-wide) patient safety critical processes rather than on clinical processes reflecting issues related to a particular disease or separate healthcare service only. All critical processes ranked 2.5 or higher were considered to be “important” to healthcare patient safety systems and are included in the final patient safety framework.

Category 1, Leadership

A total of seven critical processes for the two items in category 1 were approved by the study participants as reflecting the institutional leadership and the social responsibility of healthcare institutions in regard to patient safety systems (Table 2). The seven critical processes covered six areas to address: Senior leadership direction, Institutional governance, Institutional performance, Responsibilities to the public, Ethical behavior, and Support of key communities. The Delphi experts ranked all seven critical processes as “important” or “very important.” Thus, all patient safety critical processes in Category 1, Leadership are included in the final patient safety framework.

TABLE 2. Patient Safety Critical Processes, Category 1, Leadership

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
1.1. Institutional leadership	1.1.1.a. Senior Leadership Direction: How senior leaders communicate the priority of patient safety to all stakeholders	3.6	3.7	0.581	0.571
	1.1.2.a. Institutional Governance: How senior leaders create an environment for development and improvement of patient safety systems in the institution	3.6	3.7	0.581	0.571
	1.1.3.a. Institutional Performance Review: How patient safety findings are translated into institutional short- and long-term goals and priorities.	3.4	3.5	0.800	0.761
1.2. Social responsibility	1.2.1.a. Responsibilities to the Public: How the institution incorporates patient safety accreditation and legal requirements as integral parts of its performance improvement.	3.2	3.1	0.619	0.587
	1.2.2.a. Ethical Behavior: How the institution ensures ethical communication with stakeholders in regard to patient safety issues.	3.1	3.2	0.548	0.550
	1.2.3.a. Support of Key Communities: How the institution proactively responds to current and future public concerns in regard to patient safety.	3.2	3.1	0.671	0.587
	1.2.4.a. Responsibilities to the Public: How the institution monitors its medication error rate.	3.1	3.1	0.657	0.447

Figure 10 visually presents the ranks as assigned by individual experts to the critical processes in Category 1. One of the participants had assigned low ranks to all patient safety critical processes in this category, and two other participants assigned a rank of 2, Not very important to the critical processes reflecting the incorporation of accreditation and legal requirements as integral parts of institutional performance improvement, and the institutional proactive response to public concerns about patient safety. Thus, these two critical processes may not be on the radar of all healthcare institutions in the current healthcare environment.

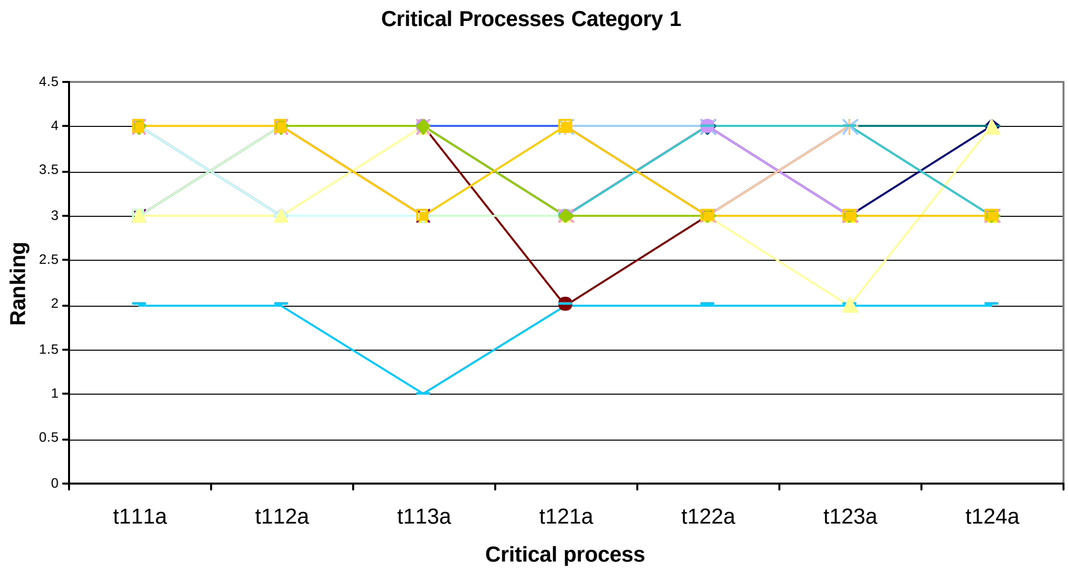

FIGURE 10. Distribution of Individual Ranks for Critical Processes in Category 1

For the three critical processes addressing the institutional leadership item of Category 1, the group means increased from round one to round three (Figure 11). At the end of the study the experts reached consensus about the increased importance of communicating the priority of patients to all stakeholders, creating an environment for development and improvement of patient safety systems, and translating the patient safety data into institution's short- and long-term goals and priorities. The Delphi panel perceived the importance of attention to legal and accreditation requirements and the proactive response to public patient safety concerns as less important at the end of the study than in the first round.

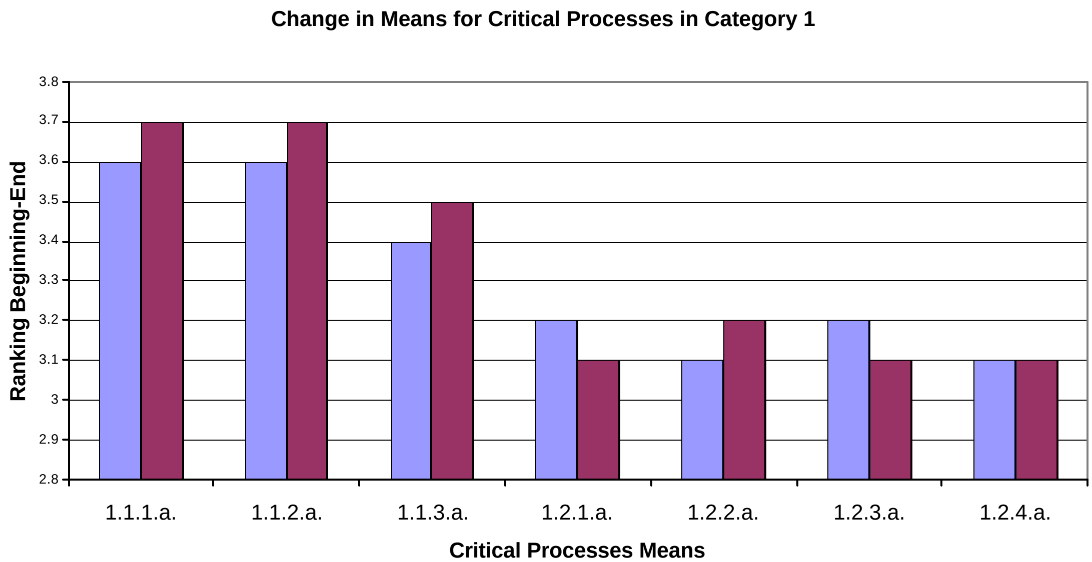

FIGURE 11. Change of the Group Mean for Critical Processes in Category 1: Beginning - End of Study (blue – beginning, maroon – end)

Greatorex and Dexter (2000) argued that stability of group mean across Delphi study rounds is a measure of the stability of the panel opinion across rounds, while the stability of the panel agreement in the consensus is presented by the standard deviation. Similarly, the decrease in the standard deviation for the critical process ranks in Category 1 between the first and last round in this study confirms stabilization of the group opinion, i.e. the variability in the ranks distribution decreased (Figure 12). For example, the group mean for the importance of monitoring the medication error rate within healthcare institutions yielded the same group rank in the beginning and at the end of the study, but there was a dramatic decrease in its standard deviation, from 0.657 to 0.447 (critical process 1.2.4.a.).

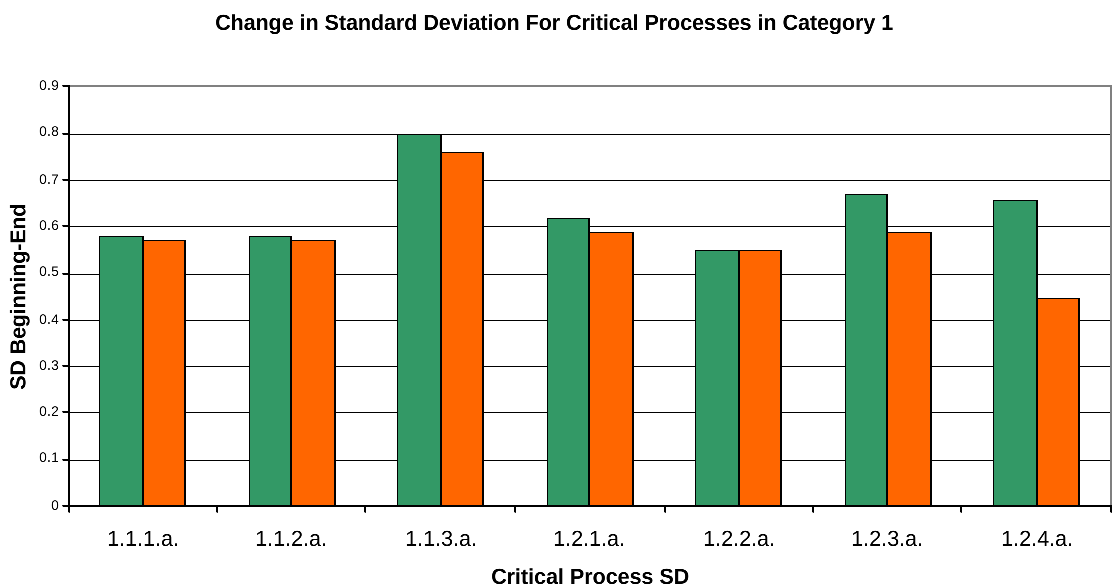

FIGURE 12. Change in the Group Standard Deviation for Critical Processes in Category 1: Beginning-End of Study (green – beginning, orange – end)

Category 2, Strategic Planning

The critical processes in Category 2 reflected the importance of patient safety strategy development and deployment. The five critical processes in this category covered four institutional areas to address: Strategic development process, Strategic objectives, Action plan development and deployment, and Performance projection (Table 3).

TABLE 3. Patient Safety Critical Processes, Category 2, Strategic Planning

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
2.1. Strategy Development	2.1.1.a. Strategic Development Process: How the healthcare institution develops its view of the future and sets directions and policies to communicate, implement and monitor its patient safety systems.	3.1	3.0	0.774	0.686
	2.1.2.a. Strategic Objectives: How patient safety practices are identified and translated to institutional goals.	3.1	3.2	0.795	0.447
	2.1.3.a. Strategic Objectives: How the institution achieves realistic evaluation of technology capability for improving safety (present and future).	3.1	3.1	0.618	0.366
2.2. Strategy Deployment	2.2.1.a. Action Plan Development and Deployment: How the institution develops, monitors and improves action plans to ensure patient safety.	3.2	3.3	0.822	0.813
	2.2.2.a. Performance Projection: How leaders achieve consistency and improvement of healthcare delivery.	3.0	3.2	0.792	0.768

The majority of the Delphi experts considered the critical processes in Category 2 either “important,” or “very important” and assigned ranks of 3 and 4 respectively. Two of the study participants ranked four of the processes in this category lower than 3 (Figure 13). However, all five patient safety critical processes in Category 2 had a group mean equal to or higher than 3; thus, all critical processes in this category are included in the patient safety framework.

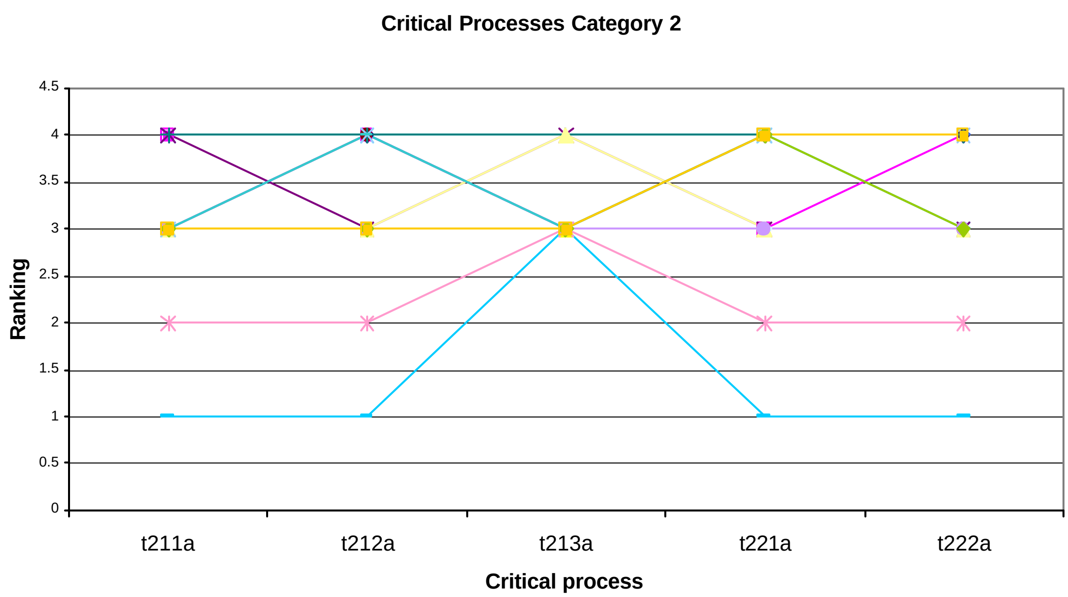

FIGURE 13. Distribution of Individual Ranking of Critical Processes in Category 2

Two of the critical processes in this category did not change their group mean across study rounds, and the change in the other three was slight, with minor increase or decrease in the respective group means (Figure 14). However, all five critical processes had a decrease in their standard deviation between the first and third study round (Figure 15), which measures the tightened variability in the assigned ranks (i.e. stabilized consensus).

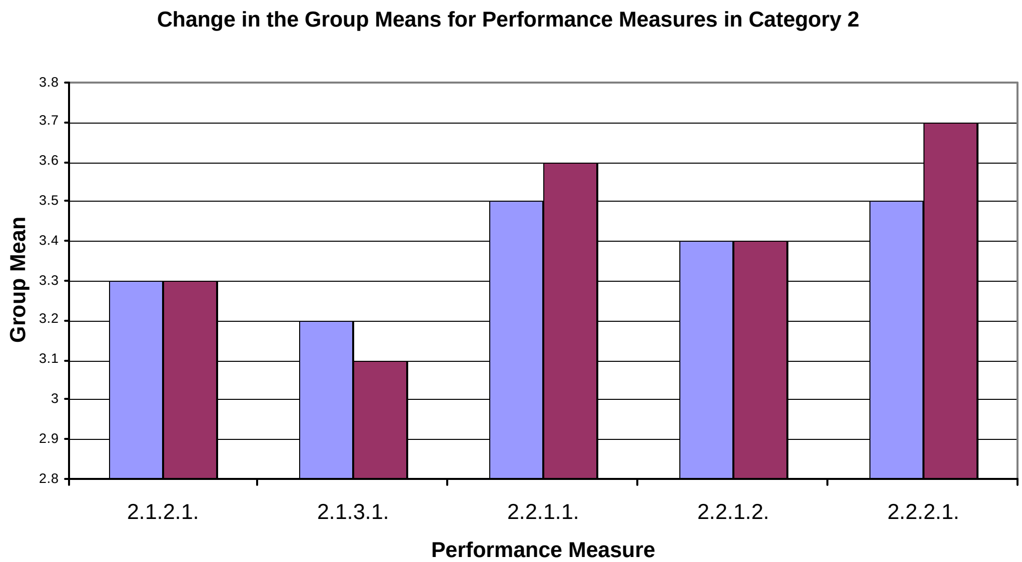

FIGURE 14. Change in Group Means for Critical Processes in Category 2: Beginning-End of Study (blue – beginning, maroon – end)

Two of the critical processes, process 2.1.2.a., How patient safety practices are identified and translated to institution’s goals, and 2.1.3.a., How the institution achieves realistic evaluation of technology capability for improving safety, had significant decreases in their standard deviation, from 0.795 to 0.447 and from 0.618 to 0.366 respectively. The stability of the group mean across study rounds, coupled with the decrease in the standard deviation for all five critical processes in Category 2, define the panel perception that patient safety strategy and deployment are important in building and maintaining patient safety systems in healthcare institutions.

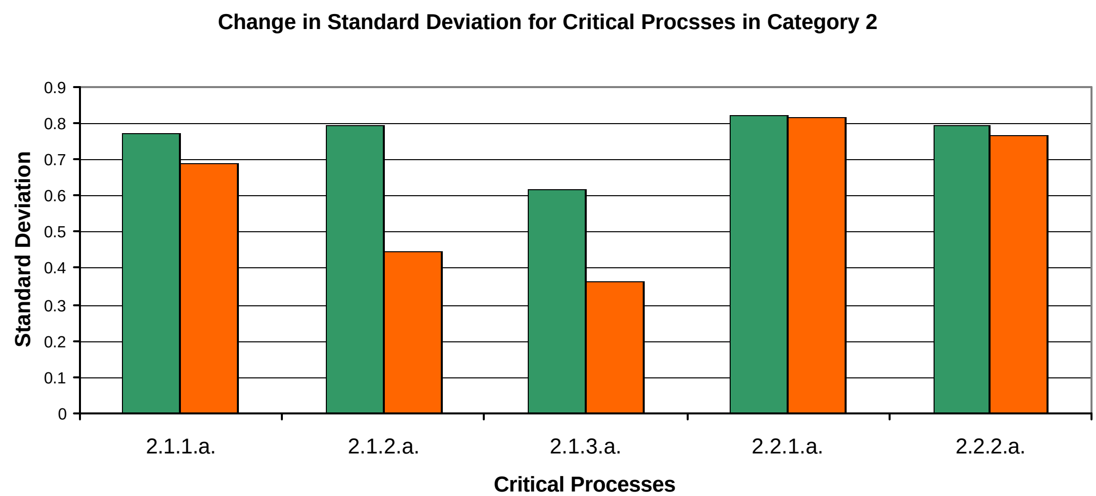

FIGURE 15. Change in Group Standard Deviation for Critical Processes in Category 2: Beginning - End of Study (green – beginning, orange – end)

Category 3, Focus on Patients, Other Customers and Markets

The Delphi panel assessed four critical processes in this category (Table 4). The four processes defined two items: (1) Patient, other customer and market knowledge, and (2) Patients and other customer relationships and satisfaction. The critical processes for Category 3 covered three areas to address: Patient safety market knowledge, Patient/customer relationship building, and Satisfaction determination.

TABLE 4. Patient Safety Critical Processes, Category 3, Focus on Patients, Other Customers and Markets

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
3.1. Patient, Other Customer and Healthcare Market Knowledge	3.1.1.a. Patient Safety Market Knowledge: How the healthcare institution determines patients' expectations and appropriate knowledge in regard to patient safety.	2.8	2.7	0.757	0.716
	3.1.2.a. Patient Safety Market Knowledge: How the institution helps set the expectations of patients and infuses realistic goals and expectations into the marketplace.	2.5	2.6	0.799	0.496
3.2. Patient and Other Customer Relationships and Satisfaction	3.2.1.a. Patient/Customer Relationship Building: How the healthcare institution gathers and analyzes information about patients' and community's expectations in regard to safety of healthcare delivery, and how the results and interpretations are used for improvement of institution's patient safety systems.	2.8	2.8	0.777	0.696
	3.2.2.a. Satisfaction Determination: How the institution obtains information and feedback from patients on patient safety issues to improve the delivery of healthcare.	3.2	3.0	0.751	0.795

Although all four critical processes in this category qualified for inclusion in the final patient safety framework, three of them yielded ranks lower than 3.0. Critical process 3.1.1.a., How the healthcare institution determines patients' expectations and appropriate knowledge in regard to patient safety, had a consensus group rank of 2.7; the importance of critical process 3.1.2.a., how the institution helps set the expectations of patients and infuses realistic goals and expectations into the marketplace, was ranked by the study participants as 2.6; and critical process 3.2.1.a., How the institution gathers and analyzes information about patients' and community's expectations in regard to safety of healthcare delivery, and how the results and interpretations are used for improvement of institution's patient safety systems, had a group rank of 2.8. Obviously, while customer expectations are considered important to patient safety systems, healthcare patient safety and quality improvement experts assign them less importance than other critical processes in the realms of leadership and strategic planning (Categories 1 and 2 respectively).

The diversity of experts' opinions regarding the importance of focusing on patients, other customers and markets is visually presented on Figure 16. There are no clear clusters around a given rank, rather, ranks are dispersed across the scale. The Delphi experts assigned more ranks of 2, Not very important, and 3, Important, than 4, "Very important."

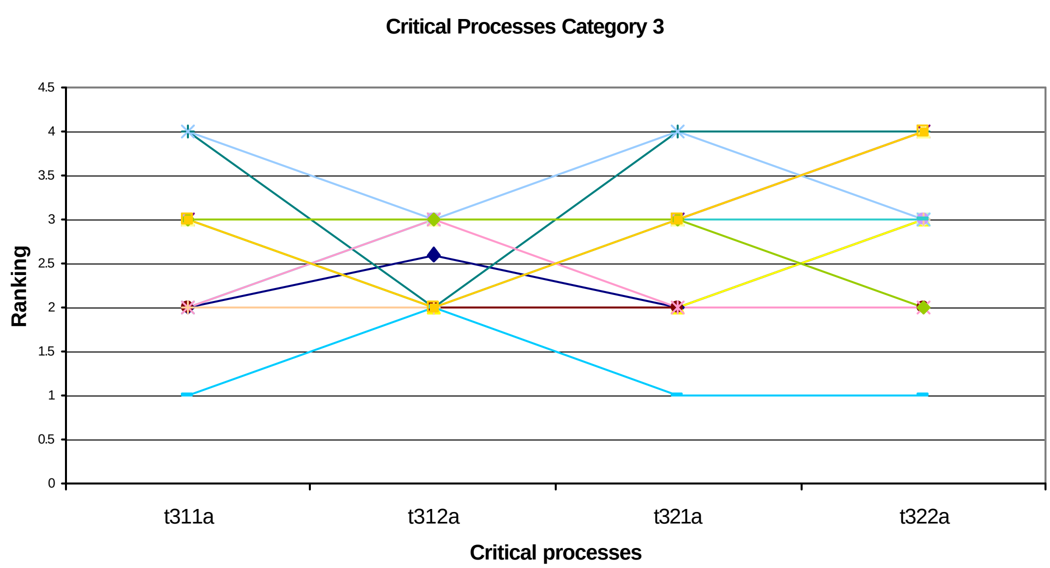

FIGURE 16. Distribution of Individual Ranking of Critical Processes in Category 3

The diversity of participants' perceptions led to slight increase of the group mean for one of the critical processes in Category 3, decrease of the group mean for two of the processes, and one process had no change in its group mean at the end of the study (Figure 17).

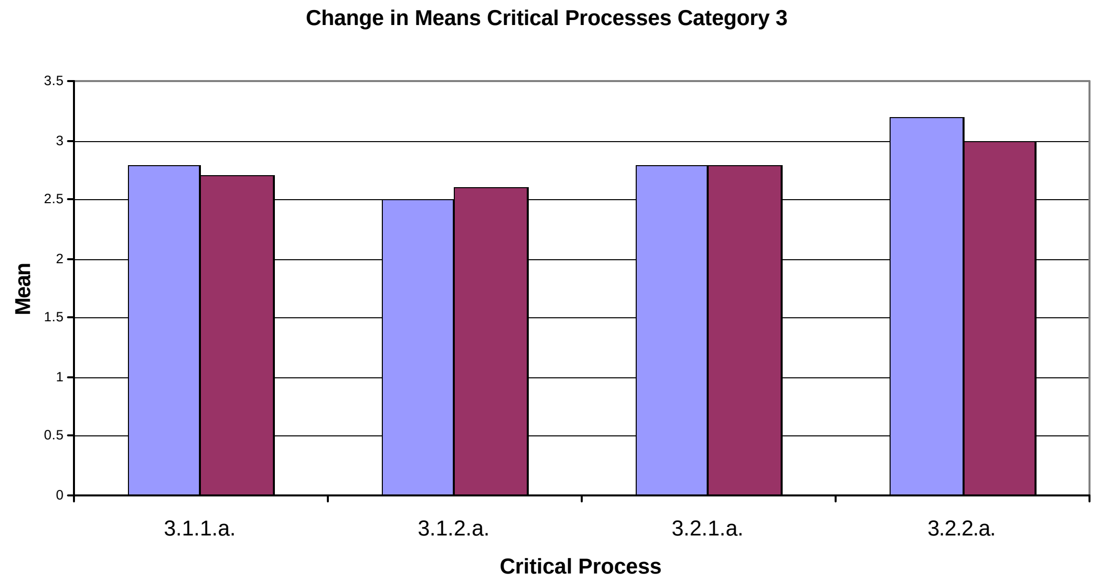

FIGURE 17. Change in Group Means for Critical Processes in Category 3: Beginning-End of Study (blue – beginning, maroon – end)

Furthermore, while two critical processes had a decrease and one of the critical processes had a significant decrease in its standard deviation, one critical process 3.2.2.a., How the institution obtains information and feedback from patients on patient safety issues to improve the delivery of healthcare, increased its standard deviation (Figure 18). Apparently, the Delphi panel, although in consensus (as defined in Chapter I, Introduction, section "Operational definitions") could have further explored this issue.

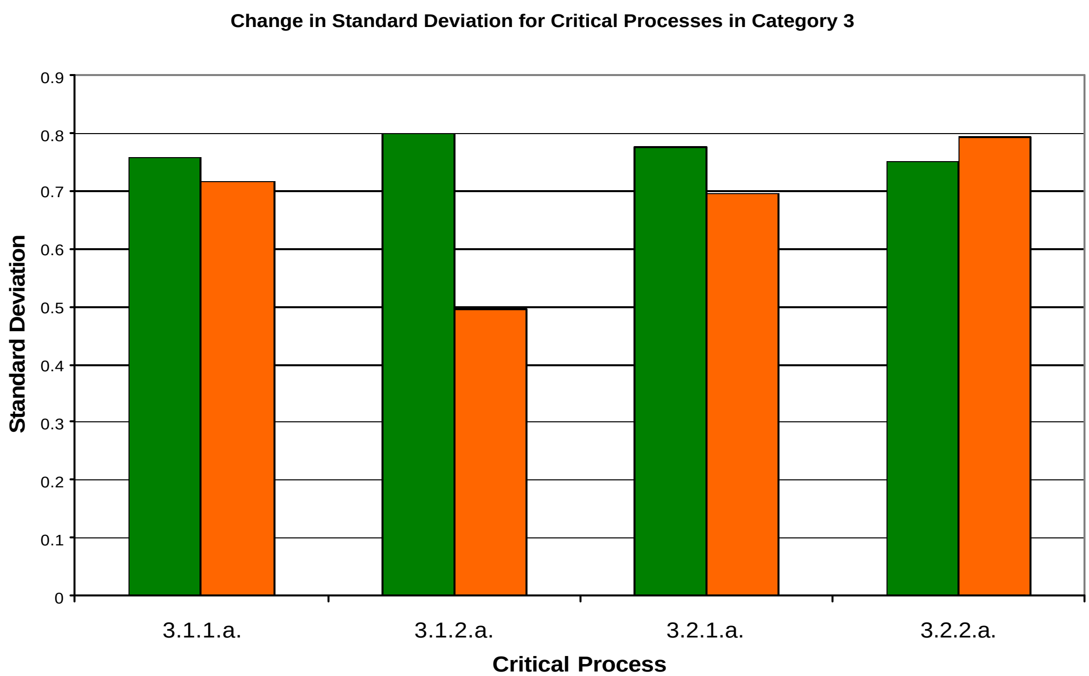

FIGURE 18. Change in Standard Deviation for Critical Processes in Category 3: Beginning - End of Study (green – beginning, orange - end)

Category 4, Measurement, Analysis and Knowledge Management

In Category 4, Measurement, analysis and knowledge management, two items were discussed: (1) Measurement and analysis of institutional performance, and (2) Information and knowledge management (Table 5). The six critical processes in Category 4 encompassed three areas to address: Performance measurement, Data and information availability, and Institutional knowledge. Only one of the patient safety critical processes in Category 4 (critical process 4.2.1.a., How the institution ensures that its clinical information technology is reliable, secure and friendly) obtained a group mean for its importance of 3.5, i.e. qualified to be “very important” to patient safety systems in healthcare institutions. Patient safety critical process 4.2.2.a., How stakeholders’ satisfaction, dissatisfaction and expectations in regard to patient safety are determined and used for improvement of patient safety systems, was ranked lowest in this category. This critical process was the only one in the category considering stakeholders in regard to patient safety measurement and analysis. As a whole, all critical processes in Category 4 obtained ranks above 2.5. Thus, all processes qualified for inclusion in the final patient safety framework.

TABLE 5. Patient Safety Critical Processes, Category 4, Measurement, Analysis and Knowledge Management

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
4.1. Measurement and Analysis of Institutional Performance	4.1.1.a. Performance Measurement: How the institution selects and implements into its patient safety systems patient safety benchmarks.	3.3	3.2	0.775	0.696
	4.1.2.a. Performance Measurement: How the institution collects, tracks and analyzes patient safety data.	3.3	3.4	0.722	0.681
	4.1.3.a. Performance Measurement: How the institution monitors the occurrence of near misses and how uses this information for process improvement.	3.3	3.3	0.840	0.489
4.2. Information and Knowledge Management	4.2.1.a. Data and Information Availability: How the institution ensures that its clinical information technology (Computerized Physician's Order Entry – CPOE, infusion pumps, alarm systems, etc) is reliable, secure and user-friendly.	3.5	3.5	0.662	0.761
	4.2.2.a. Data and Information Availability: How stakeholders' satisfaction, dissatisfaction and expectations in regard to patient safety are determined and used for improvement of patient safety systems.	2.9	2.9	0.705	0.718
	4.2.3.a. Institutional Knowledge: How patient safety information is shared with all stakeholders in support of overall institution's goals and action plans for performance improvement.	3.4	3.4	0.656	0.605

The individual participant ranks for the critical processes in Category 4 are presented on Figure 19. The assigned ranks for the critical processes in this category varied widely throughout the rank scale, with the majority clustered at rank 3. One critical process, the one regarding the reliability, security and user-friendliness of clinical information technology, had only ranks of 3, Important, and 4, Very important.

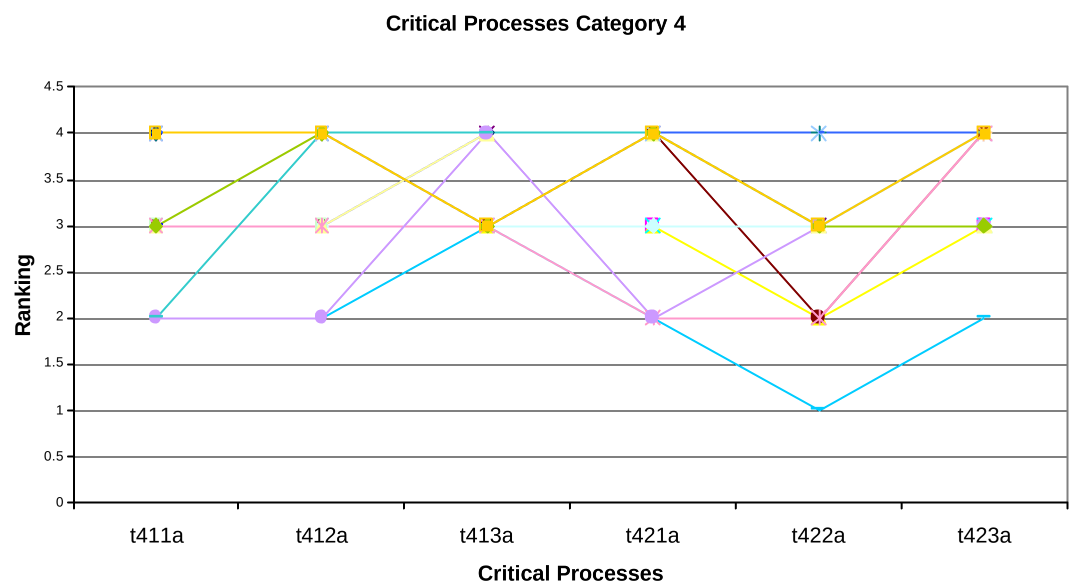

FIGURE 19. Distribution of Individual Ranking of Critical Processes in Category 4

Four of the six critical processes in Category 4 did not change their group mean throughout the Delphi process (Figure 20). The group mean for critical process 4.1.2.a., How the institution collects, tracks and analyzes patient safety data, slightly increased its group mean, while critical process 4.1.1.a., How the institution selects and implements into its patient safety systems patient safety benchmarks, decreased its group mean. This result is in contrast to the focus on measuring clinical patient safety outcomes and implementing quality and safety benchmarks, as required by regulating bodies and emphasized in the literature.

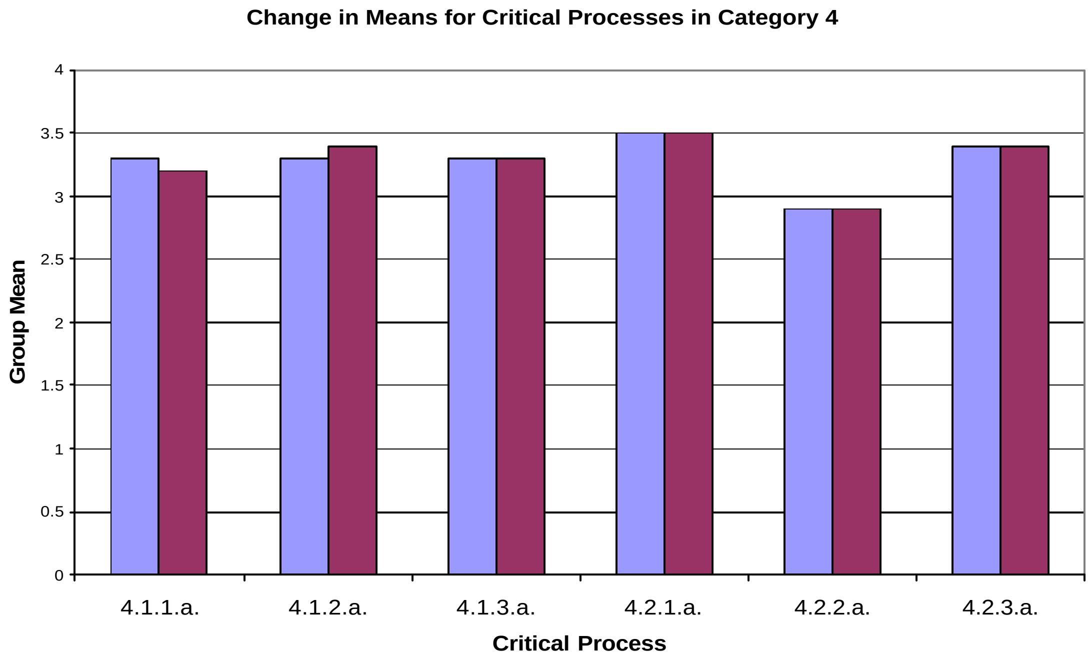

FIGURE 20. Change in Group Means for Critical Processes in Category 4: Beginning - End of Study (blue – beginning, maroon – end)

For four of the critical processes there was a decrease in the standard deviation (and for critical process 4.1.3.a., How the institution monitors the occurrence of near misses and how it uses this information for process improvement, this increase was dramatic, with a drop from 0.840 to 0.489). For two of the critical processes in Category 4, there was an increase in their standard deviation, while their group mean remained the same (Figure 21). These findings do not follow the trend identified by Greatorex and Dexter (2000) that with consecutive Delphi rounds variable standard deviations decrease.

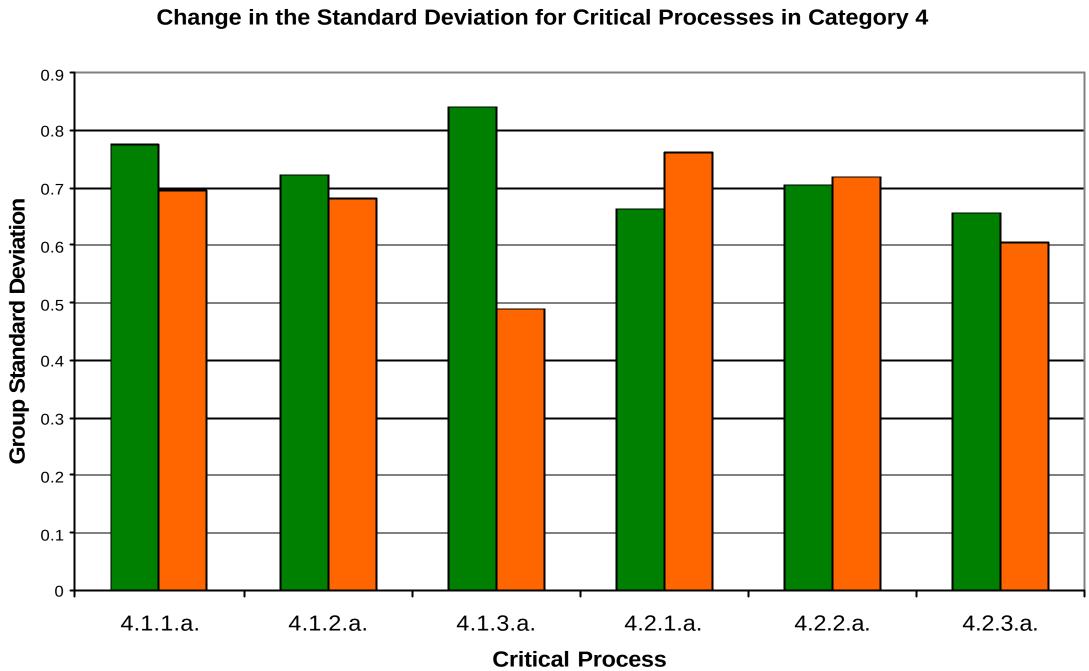

FIGURE 21. Change in Group Standard Deviation for Critical Processes in Category 4: Beginning - End of Study (green – beginning, orange – end)

Category 5, Staff Focus

There were ten patient safety critical processes in Category 5 (Table 6). These critical processes were organized in three category items (Work systems, Staff learning and motivation, and Staff well-being and satisfaction) and reflected seven areas to address:

- Organization and management of work;
- Staff performance management system;
- Recruitment and career progression;
- Staff education, training and development;
- Motivation and career development;

- Work environment;
- Staff support and satisfaction.

All ten critical processes in Category 5 received a rank of “important” and qualified for inclusion in the final patient safety framework. The changes of group means for the variables in Category 5 between survey rounds were slight and their ranks were either preserved or changed by 0.1.

TABLE 6. Patient Safety Critical Processes, Category 5, Staff Focus

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
5.1. Work Systems	5.1.1.a. Organization and Management of Work: How healthcare delivery is organized to promote patient safety systems establishment and innovation.	3.3	3.2	0.822	0.786
	5.1.2.a. Staff Performance Management System: How the institution supports high clinical performance standards and alignment with national clinical performance measures and best case-management practices.	3.4	3.4	0.499	0.503
	5.1.3.a. Staff Performance Management System: How the institution identifies, deploys and monitors patient safety practices.	3.5	3.4	0.593	0.605
	5.1.4.a. Recruitment and Career Progression: How the institution identifies requirements and recognition for patient safety officers.	2.8	2.7	0.936	0.801
	5.1.5.a. Recruitment and Career Progression: How the institution includes safety compliance and attitudes in staff recruitment, selection and promotion.	2.8	2.9	0.737	0.553

TABLE 6. (cont.)

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
5.2. Staff Learning and Motivation	5.2.1.a. Staff Education, Training and Development: How the institution structures and promotes effective education and training of professionals in developing and improving patient safety systems.	3.2	3.3	0.810	0.801
	5.2.2.a. Motivation and Career Development: How the institution supports the role of the patient safety officer and the patient safety role of the whole workforce.	2.8	2.8	0.886	0.745
5.3. Staff Well-being and Satisfaction	5.3.1.a. Work Environment: How the institution maintains a conductive environment in regard to patient safety.	3.4	3.4	0.727	0.686
	5.3.2.a. Staff Support and Satisfaction: How the institution determines staff satisfaction in implementation of patient safety systems.	3.0	3.0	0.792	0.725
	5.3.3.a. Staff Support and Satisfaction: How the institution includes medical staff attitudes and satisfaction in implementation of patient safety systems.	3.0	3.0	0.802	0.394

The individual expert ranks for critical processes in Category 5 exhibited a diverse pattern, with lowest group rank mean of 2.7 for critical process 5.1.4.a., How the institution identifies requirements and recognition for patient safety officers, and highest rank mean of 3.4 for critical process 5.1.2.a., How the institution supports high clinical performance standards and alignment with national clinical performance measures and best case management practices (Figure 22).

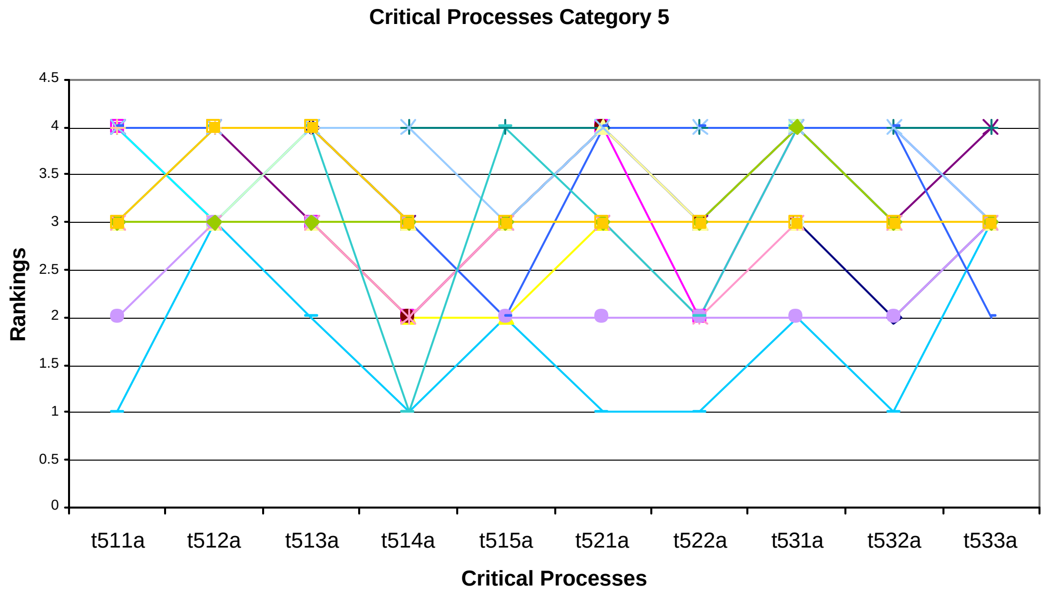

FIGURE 22. Distribution of Individual Ranking for Critical Processes in Category 5

Five of the ten critical processes in Category 5, Staff focus, had no change in group rank mean throughout the study (Figure 23) and most of the variable standard deviations decreased from the beginning to the end of the study (Figure 24). Two of the variable standard deviations did not follow the expectation to decrease with consecutive survey rounds and slightly increased while remaining within a consensus range. Eight of the ten critical processes had lower individual rank variability as expressed by their lowered standard deviation.

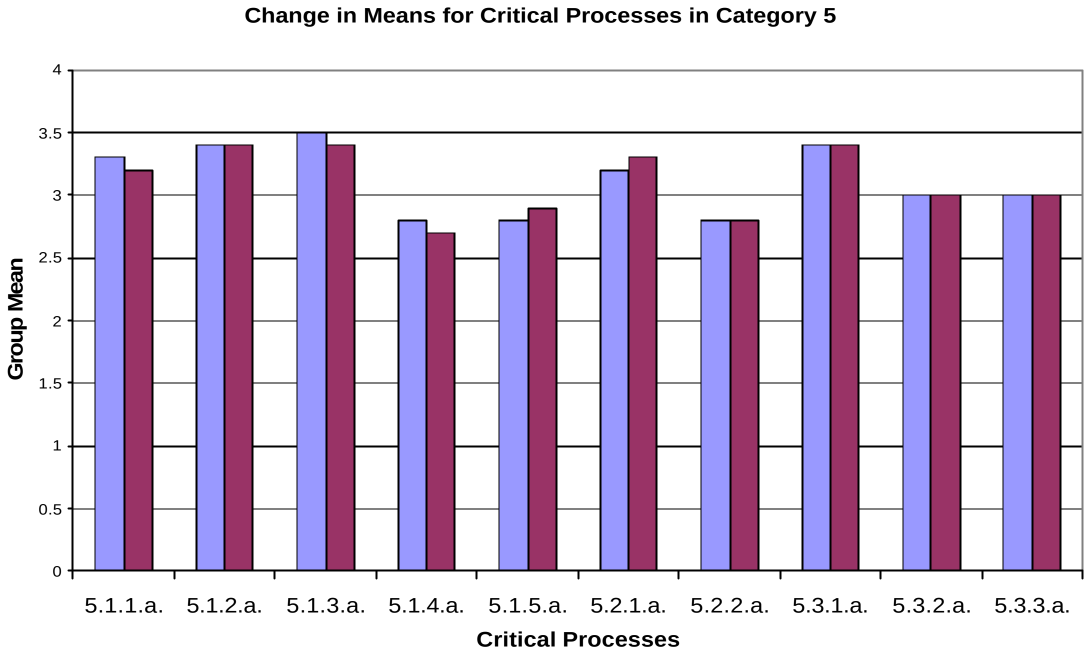

FIGURE 23. Change in Group Means for Critical Processes in Category 5: Beginning - End of Study (blue – beginning, maroon – end)

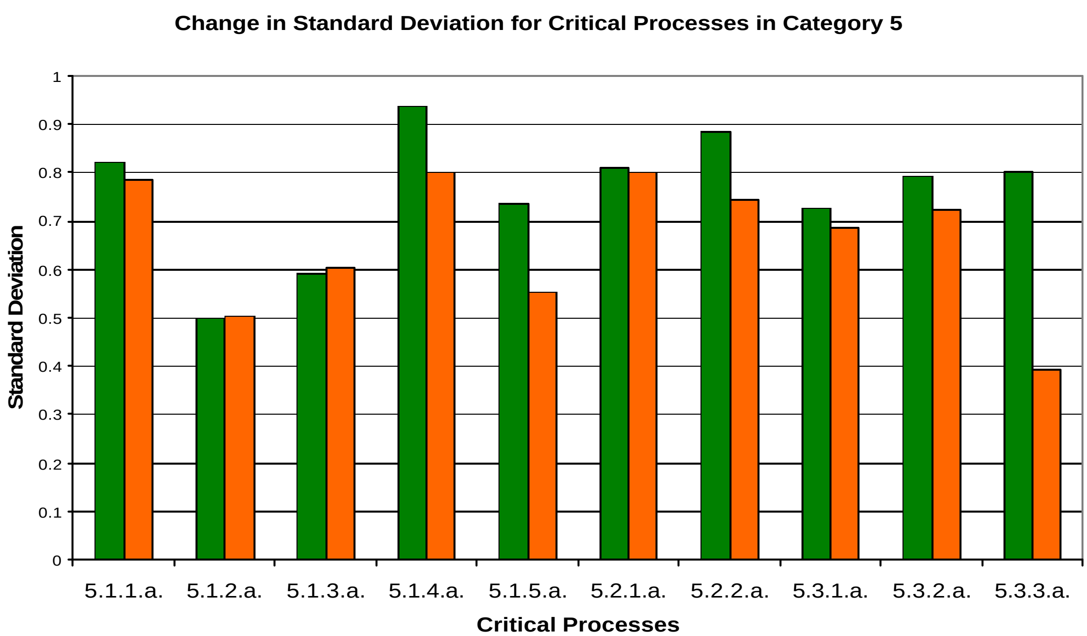

FIGURE 24. Change in Group Standard Deviation for Critical Processes in Category 5 (green – beginning, orange – end)

Category 6, Process Management

Category 6, Process management, consisted of two category items (Patient safety system and Support processes) and its six processes addressed three areas: Patient safety system, Campus security, and Patient safety support processes (Table 7).

TABLE 7. Patient Safety Critical Processes, Category 6, Process Management

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
6.1. Patient Safety System	6.1.1.a. Patient Safety System: How the institution determines patient safety process requirements and involves patients and other stakeholders in design and redesign of patient safety processes.	3.1	3.1	0.777	0.718
	6.1.2.a. Patient Safety System: How the institution designs patient safety systems.	3.2	3.2	0.751	0.786
	6.1.3.a. Patient Safety System: How the institution ensures that patient safety requirements are met at the "sharp end" of the healthcare delivery system.	3.3	3.3	0.656	0.671
	6.1.4.a. Campus security: How the institution ensures that patients feel secure arriving for and leaving appointments for care.	3.0	3.1	0.539	0.447
6.2. Support Processes	6.2.1.a. Patient Safety Support Processes: How the institution coordinates departmental and interdepartmental patient safety infrastructures to reduce variability in healthcare delivery and improve performance.	3.2	3.3	0.646	0.470
	6.2.2.a. Patient Safety Support Process: How the institution includes suppliers and partners in safety initiatives and process development	2.8	2.9	0.758	0.510

The majority of the study participants ranked the patient safety critical processes in Category 6 as “important” or “very important,” while three Delphi experts assigned lower ranks to some of the critical processes (Figure 25).

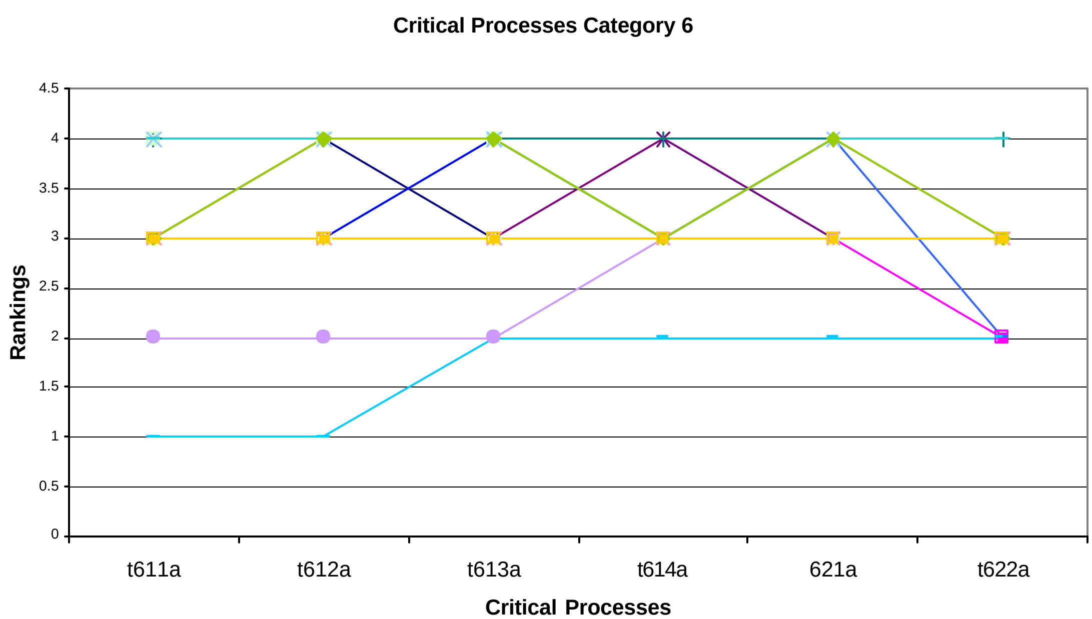

FIGURE 25. Distribution of Individual Rankings of Critical Processes in Category 6

One of the participants that had assigned low ranks (Figure 25) was the “outlier” panelist who diverted from the study ranking criteria and considered the feasibility of applying the critical process in the current healthcare environment for his rank assignments, rather than assessing the criticality of the patient safety process for introducing, managing and improvement of healthcare patient safety systems in an institutional level.

For the critical processes in Category 6, the group rank mean either remained the same or increased with consecutive study rounds (Figure 26). Critical process 6.1.4.a., How the institution ensures that patients feel secure arriving for and leaving appointments for care, was suggested during the first study round and was found “important” by the other panelists, with a consensus rank of 3.1.

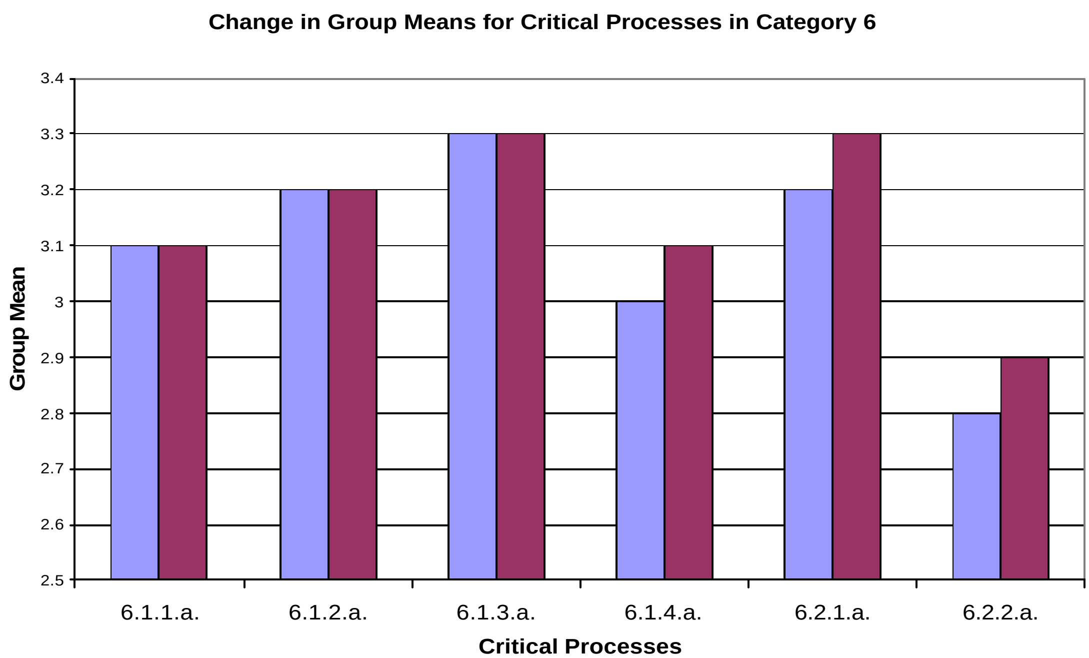

FIGURE 26. Change in Group Mean for Critical Processes in Category 6: Beginning - End of Study (blue – beginning, maroon – end)

The group rank standard deviation slightly increased for two of the six patient safety critical processes and the variability of the panel ranks decreased for four critical processes (Figure 27). All critical processes in Category 6 ranked above 2.5. Therefore, all six processes in this category are included in the patient safety framework.

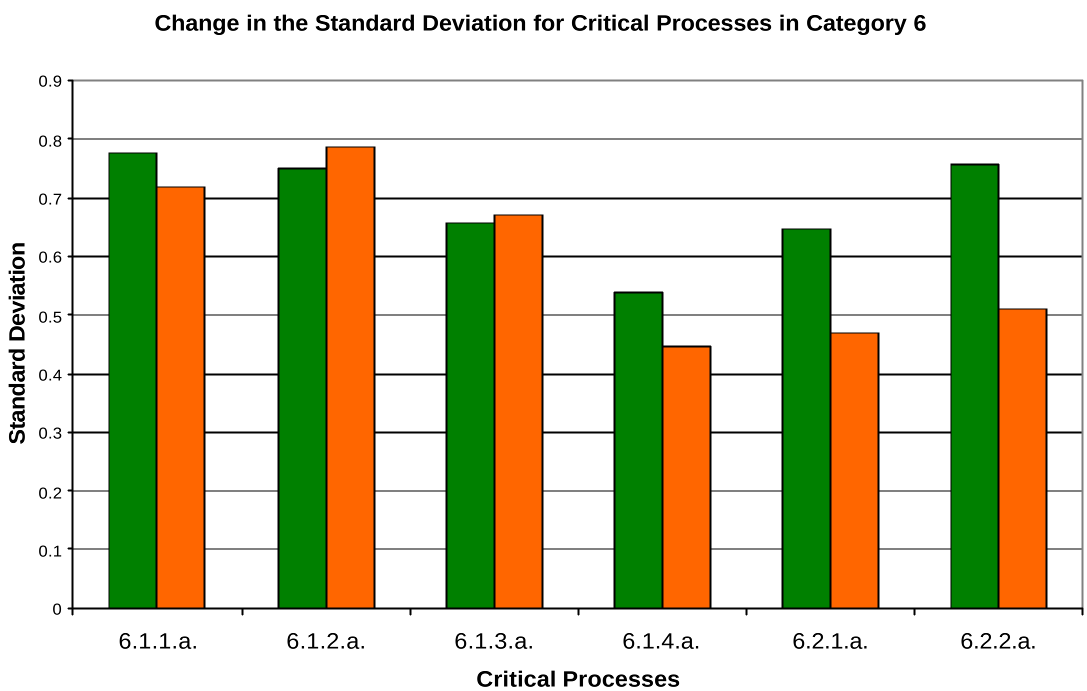

FIGURE 27. Change in Group Standard Deviation for Critical Processes in Category 6: Beginning - End of Study (green – beginning, orange – end)

Category 7, Institutional Performance

Category 7, Institutional performance, consisted of one item (Patient safety institutional performance), one area to address (Patient safety results) and one critical process (How the institution ensures patient safety). There were 16 performance measures to assess the effectiveness of institutional performance in regard to patient safety. Fourteen of the performance measures were extracted from the literature and accreditation requirements, and two were suggested by Delphi experts.

The ranks of the current importance of patient safety performance measures, as assigned by individual panelists are presented on Figure 28. Only three experts gave ranks lower than 3 to several of the performance measures in Category 7. The majority of the Delphi experts considered performance measures for this category ‘important" or “very important.” Three of the performance measures addressed the non-punitive approach and the culture of learning in regard to identifying, reporting and decreasing both medical adverse events and near misses. The study participants identified as most important clinical safety issues as proper marking of surgery sites, attention in application of high-alert medications, and proper use of infusion pumps. The issue of changing the “blame and shame” culture in healthcare to a non-punitive culture allowing for creation of learning environment, was identified by the Delphi experts as a “very important” patient safety performance measure. The Delphi experts added two performance measures regarding the importance of providing ongoing education of healthcare institutional leadership and clinical staff on patient safety related issues. The changes in group ranks and standard deviations for performance measures in Category 7 are discussed in section “Research Question Two.”

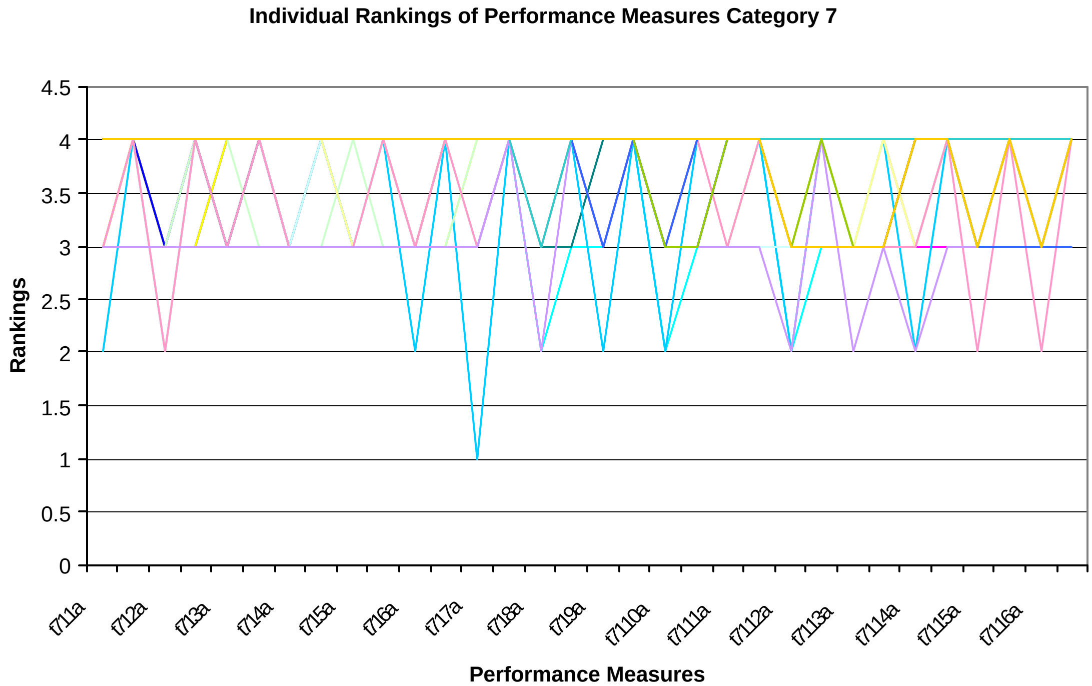

FIGURE 28. Distribution of Individual Rankings of Performance Measures in Category 7

Research Question Two

The second research question in this study was, “What are the performance measures that can serve as indicators of quality for the processes critical for ensuring patient safety?” To answer this question, the Delphi experts were asked to (1) review the suggested performance measures for each of the critical processes in the seven study categories, (2) edit all suggested patient safety performance measures, and (3) add new performance measures where deemed appropriate. As with the assessment of the current importance of the patient safety critical processes, the emphasis was on institution-wide (system-wide) patient safety performance measures rather than narrowly tailored clinical performance measures reflecting the quality of care in regard to a certain disease or one singular healthcare service. All performance measures with consensus group rank means of 2.5 or higher were considered to be “important” to healthcare patient safety systems and are included in the final patient safety framework.

Category 1, Leadership

Seven of the performance measures included in Category 1, Leadership, received a group rank mean above 3.5, i.e. these performance measures were perceived by the Delphi experts to be “very important” to patient safety systems in healthcare institutions (Table 8).

TABLE 8. Patient Safety Performance Measures, Category 1, Leadership

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
1.1.1.1. Functioning institutional systems for communicating patient safety policies, issues and activities to all stakeholders, actively seeking feedback and use of the information for improvement and creating a culture of safety.	3.6	3.6	0.726	0.745
1.1.1.2. Provision and use of real time adverse event reporting tool that alerts leadership automatically to events as they happen, thereby improving real-time communication and stressing the importance of performance improvement in real time.	3.3	3.3	0.607	0.489
1.1.2.1. A patient safety plan and institutional policies support non-punitive reporting environment and disclosure of adverse events.	3.6	3.6	0.726	0.745
1.1.2.2. Systems are in place on different institutional levels for collection and analysis of relevant data used for institutional improvement of patient safety.	3.7	3.8	0.538	0.523
1.1.3.1. There is an institutional structure that takes the lead in continuous internal assessment of patient safety, review of current patient safety research findings and translation of research and developed clinical guidelines in institution’s clinical practices, strategic planning and priorities.	3.7	3.8	0.428	0.366

TABLE 8. (cont.)

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
1.2.1.1. Institutional patient safety plans and policies are developed, carried forward and improved in accordance with the regulations and recommendations of legislative bodies, patient safety agencies and accreditation bodies, such as but not limited to JCAHO, OSHA, NRA, IHI, NCQA, URAC, AAHP, AHA, etc.	3.2	3.2	0.810	0.639
1.2.1.2. Requirements in the areas of patient identification, healthcare communications, administration of high-alert medications, wrong-site surgery, use of infusion pumps and clinical alarm systems are adequately addressed.	3.6	3.7	0.634	0.571
1.2.2.1. Ongoing monitoring of quality issues and appropriate procedures are in place for reporting and analysis of adverse events and improvement of institution's patient safety systems.	3.5	3.7	0.499	0.444
1.2.2.2. Adopting guidelines and monitoring healthcare staff and professionals compliance with patient safety policies and procedures and effective communication of these policies and procedures to patients and their families.	3.3	3.3	0.657	0.587
1.2.3.1. Institutional plan and support systems are in place for proactive collecting and analysis of patient safety information and utilization of the review results for improvement of the patient safety systems.	3.6	3.6	0.656	0.587
1.2.4.1. Independent medication error review team is identified and educated in regard to the medication usage cycle and is engaged in developing and monitoring medication safety system.	3.1	2.9	0.764	0.324

Two of the patient safety performance measures in this category (measures 1.1.1.2. and 1.2.4.1.) were added by the Delphi panelists in the first survey round. The Delphi experts ranked as “very important” performance measures related to establishing institutional systems for collection and analysis of patient safety data, communication of patient safety findings to all healthcare stakeholders, utilization of the patient safety findings in institutional policies and safety plans, and establishment of an institutional body to take the lead in improving patient safety. Furthermore, the panelists considered highly important monitoring quality and patient safety and establishing appropriate reporting systems, as well as support systems for patient safety data analysis. While high priority was assigned to compliance with the JCAHO patient safety goals, the inclusion of patient safety accreditation and legislation recommendations and requirements in the institutional patient safety plan was assigned a lower importance rank by the Delphi panel.

Two of the experts assigned a rank lower than 3 to several of the performance measures in this category (Figure 29). One of these experts was the expert that diverged from the ranking criteria. The majority of the experts ranked the performance measures in Category 1, Leadership either as “very important” or “important.”

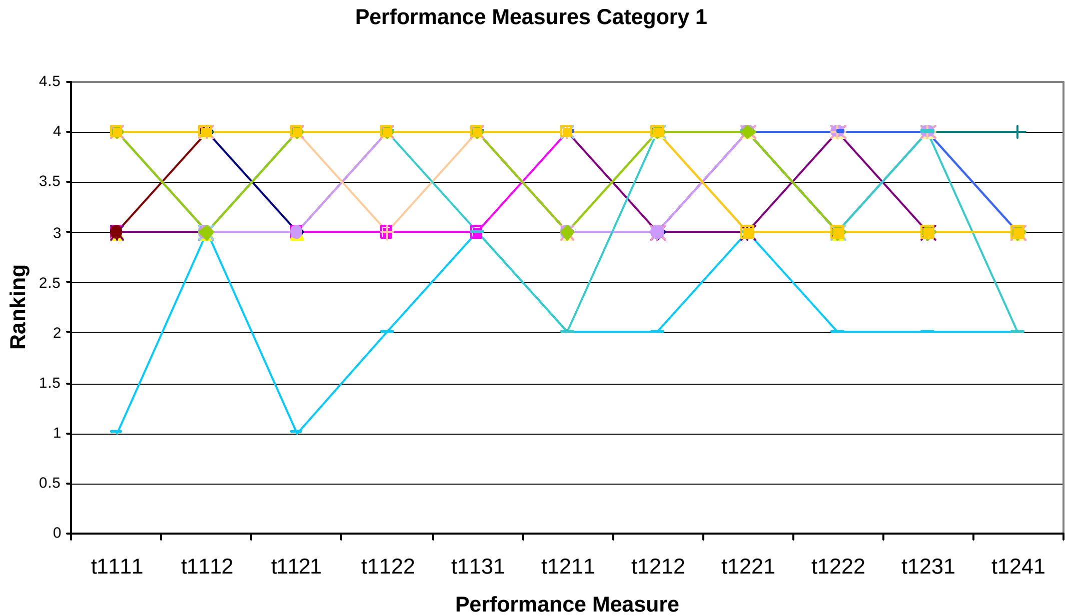

FIGURE 29. Distribution of Individual Ranks of Performance Measures, Category 1, Leadership

Four of the performance measures in Category 1, Leadership, increased their group rank mean across the questionnaire iterations (Figure 30). These four performance measures scored high on the importance scale with group rank means of 3.7 or 3.8. Six of the leadership performance measures did not change their group rank means with iterations of the survey, and one performance measure (related to establishment of an independent medication error review team to monitor institution's medication safety system) had a decrease in its group rank mean.

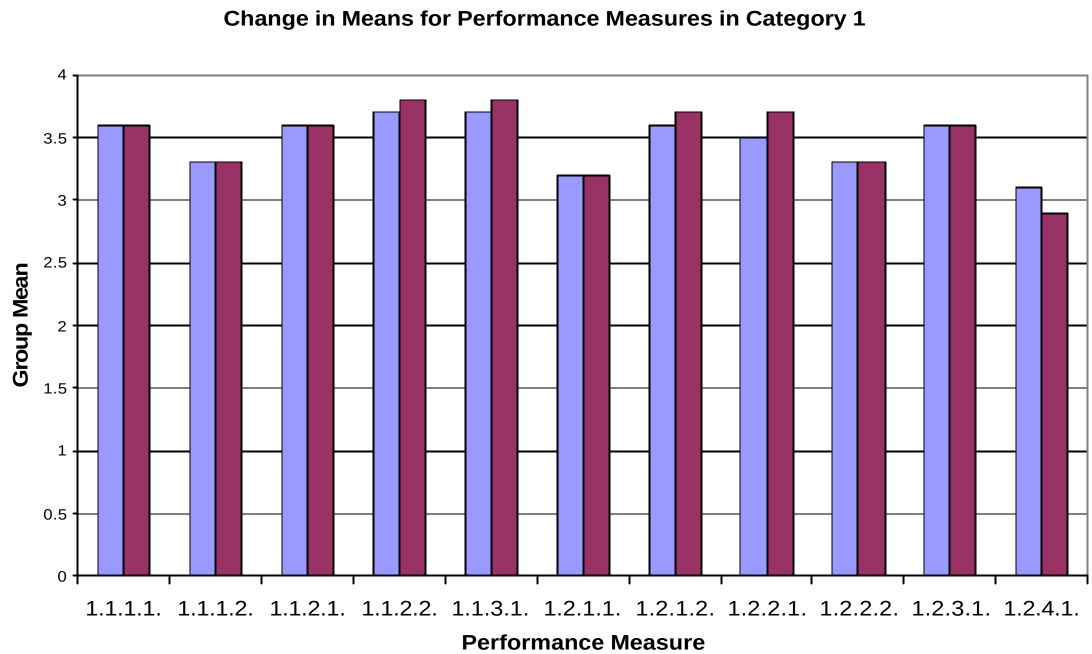

FIGURE 30. Change in Group Means for Performance Measures in Category 1: Beginning - End of Study (blue – beginning, maroon – end)

The group rank mean for performance measure 1.2.4.1. (related to establishment of independent medication error review team) decreased; also, its group standard deviation dramatically decreased (Figure 31). Obviously, the Delphi experts identified the medication safety system with the sharp end of the healthcare delivery system (where the medications are administered) and failed to recognize the importance of institution-wide systems approach to medication safety. With the iterations of survey rounds, there was a slight increase in the group standard deviation for two of the performance measures and decrease for the remaining nine measures, showing the decreased variability of opinions.

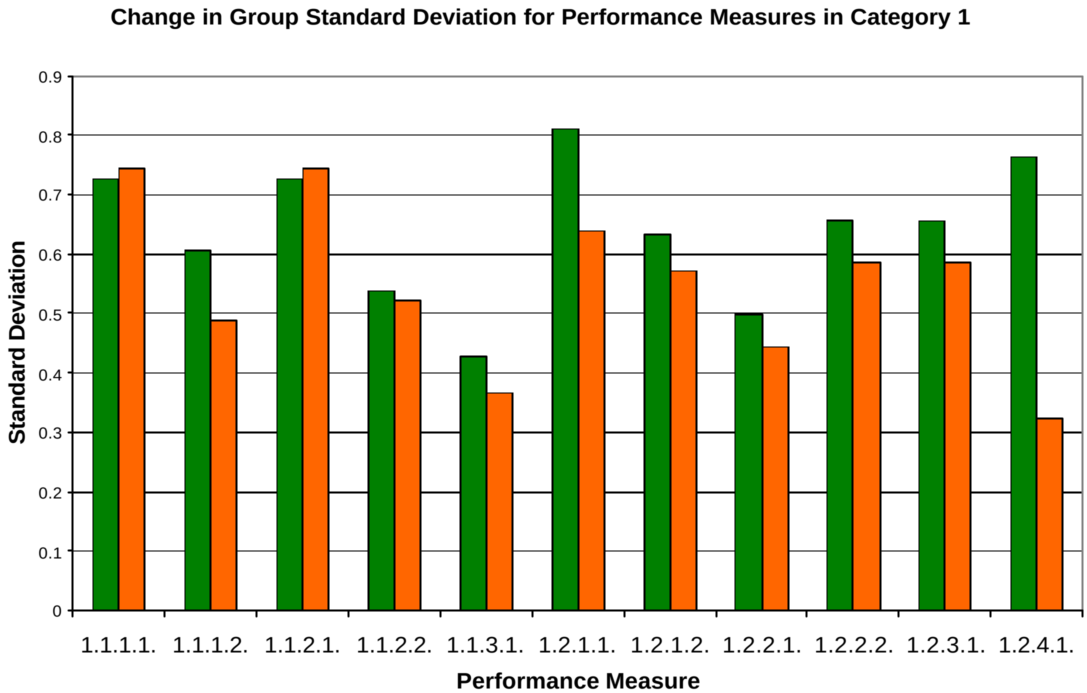

FIGURE 31. Change in Group Standard Deviation for Performance Measures in Category 1: Beginning - End Of Study (green – beginning, orange – end)

Category 2, Strategic Planning

In Category 2, two of the strategic planning performance measures had an increased consensus group rank mean compared to their rank mean after the first study round. These performance measures (2.2.1.1. and 2.2.2.1.) were also ranked as "very important" to patient safety systems in healthcare institutions. These "very important" performance measures assessed institution's patient systems action plans and the incorporation of healthcare benchmarks in institutional plans and quality assessment activities (Table 9).

TABLE 9. Patient Safety Critical Processes, Category 2, Strategic Planning

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
2.1.1.1. Patient safety action plans and systems for sustaining achieved improvements are in accordance with national best practices and performance measures guidelines and provide for optimal matching of healthcare needs and service delivery capabilities.	3.4	3.4	0.740	0.759
2.1.1.2. Ongoing, planned and regularly monitored effort in creation, adaptation and adoption of clinical guidelines and best practices based on clinical patient safety research.	3.4	3.4	0.666	0.681
2.1.1.3. Comprehensive and ongoing proactive approach in seeking stakeholder expectations in setting goals for short- and long-term patient safety planning.	3.2	3.2	0.550	0.523
2.1.1.4. The capabilities of modern technologies and database access are taken into consideration in setting goals for short- and long-term planning.	3.2	3.1	0.550	0.447
2.1.2.1. Data from national databanks and practice guidelines from professional organizations are incorporated in institution's patient safety goals, plans and patient care practices.	3.3	3.3	0.590	0.671
2.1.3.1. Cost-benefit analysis of safety technology with accumulation of data to evaluate the accuracy of such estimates over time and life of safety technology projects.	3.2	3.1	0.669	0.489
2.2.1.1. Institutional and unit patient safety action plans and systems for sustaining achieved improvements are in place and are revised and improved on a regular basis.	3.5	3.6	0.593	0.598
2.2.1.2. System-wide processes are used for communication and alignment of patient safety planned efforts.	3.4	3.4	0.727	0.759
2.2.2.1. National, regional and specialty standards (best practices, clinical performance measures, etc.) are incorporated as benchmarks in institution's short- and long-term plans and are used in the assessment of institution's and individual's quality of healthcare delivery.	3.5	3.7	0.510	0.571

The majority of the Delphi experts assigned ranks of 3 or 4 to the performance measures in this category. However, three of the study participants assigned lower ranks to most of the strategic planning performance measures (Figure 32).

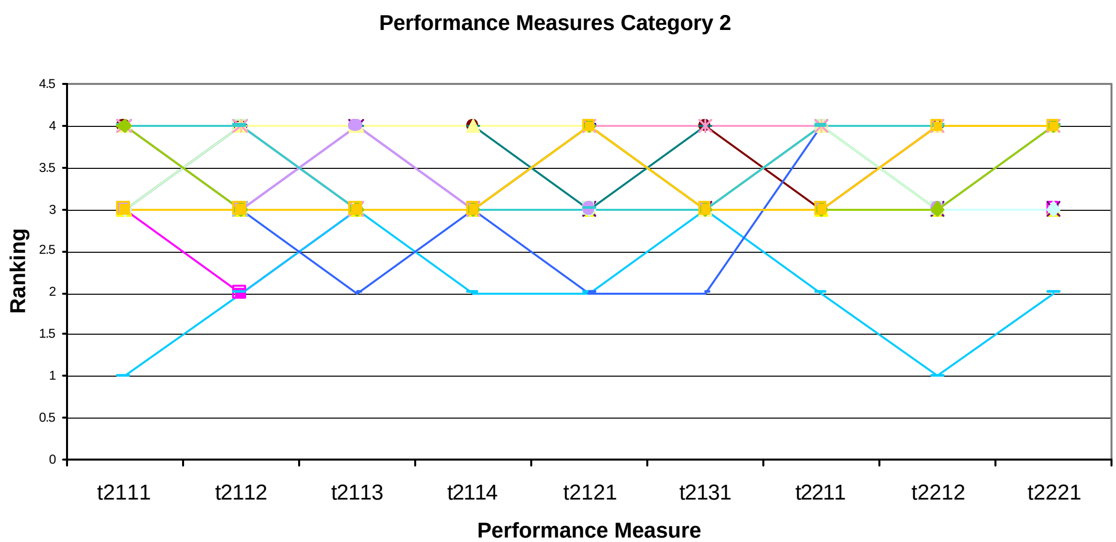

FIGURE 32. Distribution of Individual Ranks, Performance Measures, Category 2

One of the strategic planning performance measures, 2.1.3.1, regarding performing of cost-benefit analysis of safety technology with accumulation of data to evaluate the accuracy of such estimates over time, was added by the Delphi panel after the first survey round. This new performance measure measured the new patient safety critical process 2.1.3, also added by the panelists during the first study round to assess how the institution achieves realistic evaluation of its technology capabilities for improvement of patient safety in the present and in the future. The consensus group rank mean for that performance measure showed a slight decrease compared to the panelist ranks after the new performance measure was initially introduced to them (Figure 33).

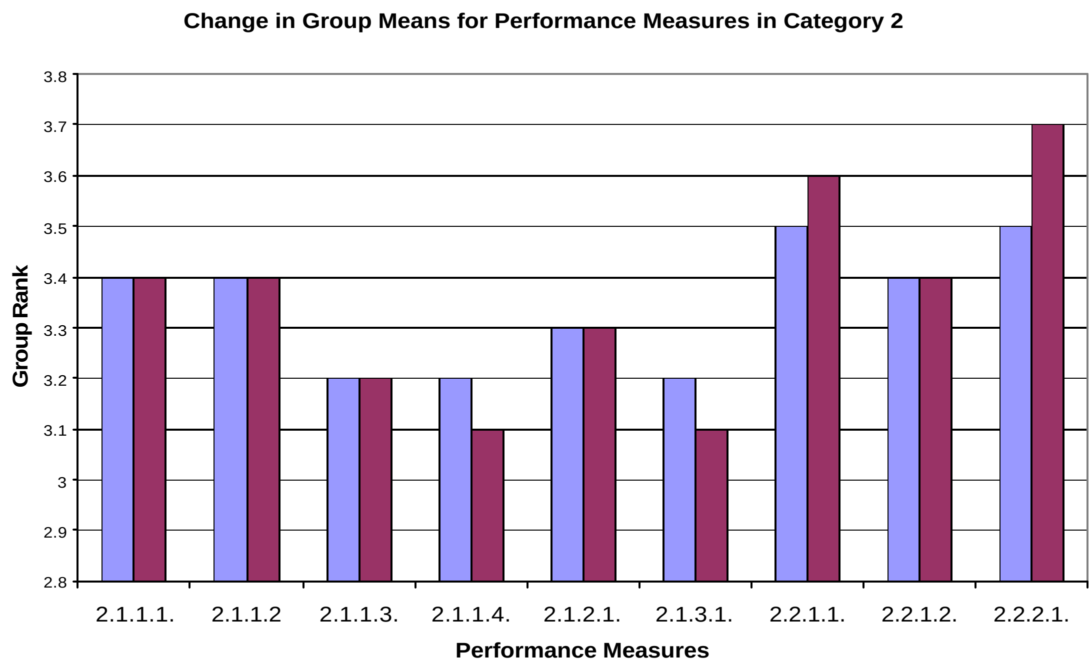

FIGURE 33. Change in Group Means for Performance Measures in Category 2: Beginning - End of Study (blue – beginning, maroon – end)

Five of the performance measures in Category 2, Strategic planning, did not change their group rank mean throughout the survey iterations. Two of the performance measures increased their group mean, and another two measures had a decrease in their group mean. In the cases of mean change, the new group ranks moved closer to the whole integer of their importance rank, as observed in other Delphi studies (Greatorex & Dexter, 2000). The majority of the changes in the standard deviation of strategic planning performance measures did not follow the expected pattern of decreasing the standard deviation (Figure 34) with consecutive survey rounds (Greatorex & Dexter, 2000).

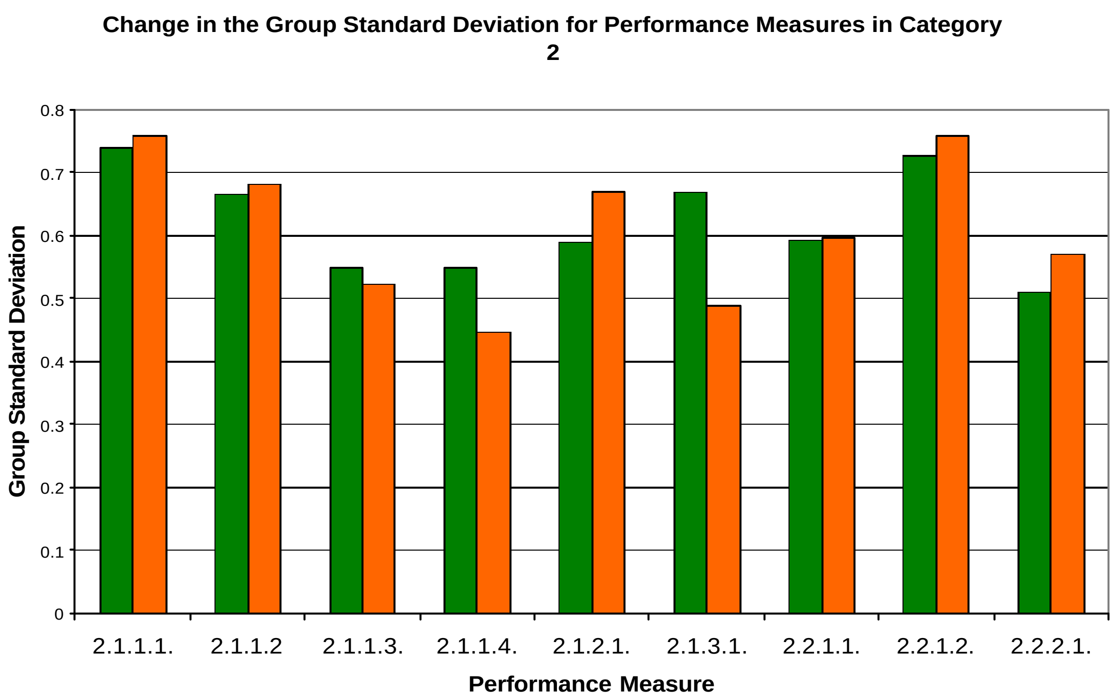

FIGURE 34. Change in Group Standard Deviation for Performance Measures in Category 2: Beginning - End of Study (green – beginning, orange – end)

Six of the performance measures in this category had greater standard deviation at the end of the study compared to the study beginning. Although the changes in the variable standard deviation were small enough to remain within consensus range, the opinions of the experts continued to vary at the end of the study. Thus, the performance measures in the category of strategic planning (even those ranked as “very important”) deserve further exploration. The issue of strategic planning in regard to patient safety in healthcare institutions may be regarded as a novel approach and although consensus was reached, its underlying issues remain to be explored.

Category 3, Focus on Patients, Other Customers and Markets

The patient safety performance measures in Category 3 focused on planned institutional activities to serve diverse patient populations, proactive alliance building with patients and community groups, provision of patient safety information to patients and their families and their inclusion as active team players in the process of healthcare delivery, in the reporting of medical errors, and ensuring appropriate patient education to enhance patient safety knowledge (Table 10). The Delphi panel suggested one new performance measure, Outcome determination of patient expectations and efforts to influence the development of realistic [customer] expectations. This measure was introduced to assess how healthcare institutions set realistic patient and marketplace expectations.

TABLE 10. Patient Safety Performance Measures, Category 3, Focus on Patients, Other Customers and Markets

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
3.1.1.1. Coordinated and planned interdepartmental activities to ensure effective team effort for determining the requirements and expectations of culturally and linguistically diverse patient populations in regard to patient safety and use of this information for improvement of institution's patient safety systems.	3.0	2.9	0.824	0.759
3.1.1.2. Planned coordinated and aligned institutional activities to ensure patient education and providing of useful information to the intended audiences in regard to patient safety issues, institutional policies and practices.	3.1	3.1	0.867	0.788
3.1.2.1. Outcome determination of patient expectations and efforts to influence the development of realistic expectations.	2.5	2.7	0.704	0.419
3.2.1.1. Proactive alliance building with patient safety groups and local communities for continuous collection, analysis and interpretation of data about patient and other customer expectations.	2.9	2.7	0.814	0.639
3.2.1.2. Designing, aligning, monitoring and improving of the procedures for inclusion of patients and their families as active team players in the process of professional healthcare delivery.	3.5	3.4	0.510	0.605
3.2.2.1. Design and implementation of comprehensive and accessible systems for adverse events reporting from patients and their families, and continuous analysis of the obtained data.	3.4	3.3	0.831	0.865
3.2.2.2. Proactive planned effort to enhance patients' knowledge and information in regard to patient safety issues.	3.3	3.2	0.810	0.834

The Delphi experts ranked all performance measures in Category 3, Focus on patients, other customers and markets, as “important.” However, none of the performance measures earned a rank of “very important.” Furthermore, over 40% of the performance measures in this category, although ranked as “important,” scored below 3. The traditionally clinical orientation of the healthcare professionals at all clinical levels might have prevented some of the participants from giving a high importance rank to issues that have been historically left outside the main focus of clinician’s interests and responsibilities. Focusing on the healthcare customers and market is a new skill, borrowed from the trade and industry markets; this skill is yet to be mastered by the healthcare professionals and administrators. The confusion about the importance of focusing on healthcare customers and markets is visually presented by the individual expert ranks for the performance measures in Category 3, spreading all over the rank spectrum (Figure 35).

There was no clear point of clustering of experts’ opinions, while the individual panelist ranks changed just slightly across the study. Thus, the group opinion remained stable as a whole with continuing lack of uniformly centered rank position. Figure 33 presents the change in the group rank mean for the performance measures in Category 3. For five of the measures, the group rank regarding their importance to patient safety systems decreased, while the rank for one performance measure increased and for another remained unchanged (Figure 36).

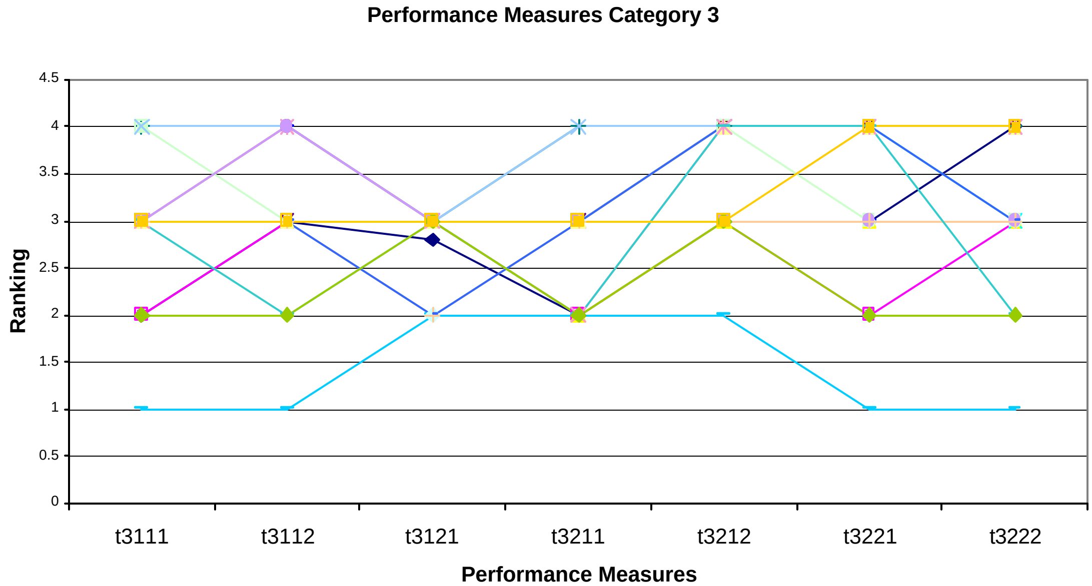

FIGURE 35. Distribution of Individual Ranks, Performance Measures, Category 3

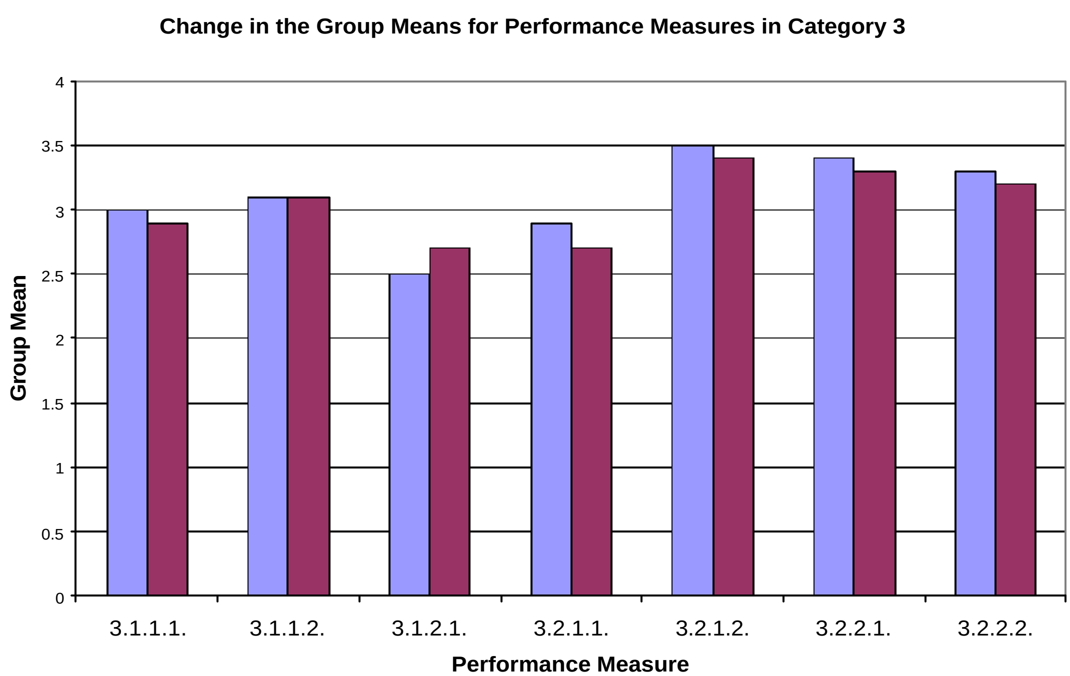

FIGURE 36. Change in Group Means for Performance Measures, Category 3: Beginning - End of Study (blue – beginning, maroon – end)

The diversity of expert opinions on four of the Category 3 variables decreased, as shown by the decrease in their standard deviations, and for three of the variables the group standard deviation increased (Figure 37).

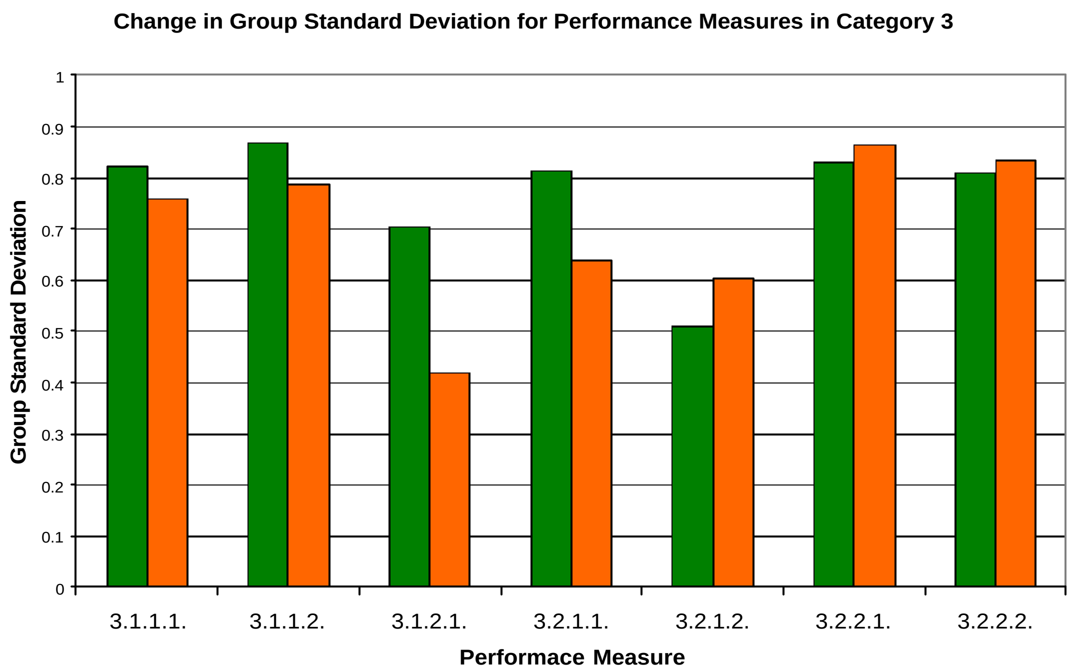

FIGURE 37. Change in Group Standard Deviation for Performance Measures in Category 3: Beginning - End of Study (green – beginning, orange – end)

Category 4, Measurement, Analysis and Knowledge Management

Category 4 (Measurement, analysis and knowledge management) included ten performance measures (Table 11). The Delphi panel ranked seven of the ten performance measures in this category as "very important." The "very important" performance measures related to:

- Applying a systematic, planned, and aligned effort to monitor developments of patient safety standards and implement national, regional, and specialty standards as benchmarks for institution's clinical practice;
- Implementation of clinical performance measures as developed by national, regional or professional institutions (as applicable) in the everyday clinical practice, i.e. at the "sharp end" of healthcare service delivery;
- Development of non-punitive reporting systems to enhance recording, monitoring, tracking and analysis of adverse events and near misses and the results from this analysis are used in institution's improvement plans;
- Recording, monitoring, tracking and analysis of near misses and use of the feedback from this process for further process improvement;
- Facilitation of information transfer and clear communications through a planned, aligned and monitored institution-wide process of clinical technology use;
- Implementation of a process to ensure that technology implementation is in compliance with patient safety requirements;
- Ensuring that processes are in place to secure integrity, timeliness, reliability, security, accuracy and confidentiality of patient safety related data and analyses of such data, as data is shared with all stakeholders, and data are used to positively affect institution's performance improvement and action planning (Table 11).

All performance measures in Category 4 were ranked above 3. Thus, all performance measures for Category 3 were included in the final patient safety framework.

TABLE 11. Patient Safety Performance Measures, Category 4, Measurement, Analysis and Knowledge Management

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
4.1.1.1. A systematic, planned and aligned effort is made to monitor developments of patient safety standards and implement regional, national and specialty standards as benchmarks for institution's clinical practices.	3.6	3.5	0.583	0.605
4.1.1.2. Clinical performance measures as developed by national, regional or professional institutions (as applicable) are implemented in the everyday clinical practice, i.e. at the "sharp end" of healthcare service delivery.	3.5	3.5	0.593	0.605
4.1.2.1. Root Cause Analysis (RCA) and Failure Modes and Effects Analysis (FMEA) training is available to healthcare providers.	3.2	3.3	0.688	0.657
4.1.2.2. RCA and/or FMEA approach is used on a customary basis by the healthcare providers in analysis of patient safety issues and improvement of healthcare delivery and patient safety.	3.4	3.3	0.722	0.671
4.1.2.3. Non-punitive reporting systems are in place for recording, monitoring, tracking and analysis of adverse events and near misses and the results from this analysis are used in institution's improvement plans.	3.5	3.6	0.727	0.754
4.1.3.1. A process exists for recording, monitoring, tracking and analysis of near misses and feedback is used for process improvement.	3.5	3.7	0.772	0.470
4.2.1.1. A planned, aligned and monitored institution-wide process of clinical technology use facilitates information transfer and clear communication.	3.6	3.8	0.558	0.410
4.2.1.2. A process is in place for assurance that technology implementation is in compliance with patient safety requirements.	3.6	3.6	0.583	0.587

TABLE 11. (cont.)

4.2.2.1. Data from comprehensive, accessible and user-friendly systems for tracking stakeholder reports, comments and complaints in regard to patient safety satisfaction, dissatisfaction and expectations is used to improve patient safety systems and update patient safety action plans.	3.2	3.2	0.634	0.616
4.2.3.1. Processes are in place to secure integrity, timeliness, reliability, security, accuracy and confidentiality of patient safety related data and analyses of such data, as it is shared with all stakeholders, are used to positively affect institution's performance improvement and action planning.	3.8	3.9	0.387	0.308

Four of the Delphi experts assigned a rank lower than 3, Important, to performance measures in category 3 (including one particular participant who diverted from the ranking instructions). The majority of the panelists assigned ranks of "important" or "very important" (Figure 38) and all performance measures in Category 4 had modes of 3 or 4.

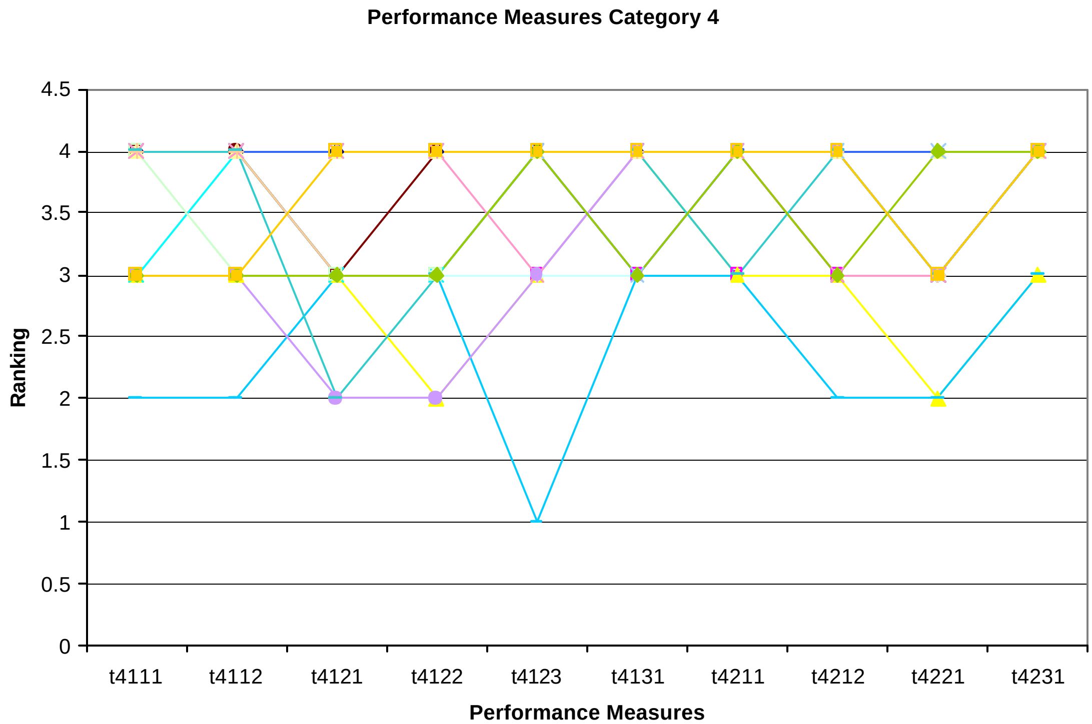

FIGURE 38. Distribution of Individual Ranks, Performance Measures, Category 4

Compared to the beginning of the study, five of the performance measures in Category 4, Measurement, analysis and knowledge management, had increased group rank means. For three of the performance measures, the score got closer to the highest rank of 4, Very important, and for one performance measure the increased group rank mean remained in the realm of "important." The Delphi panel suggested one new performance measure, related to the use of feedback from tracking of near misses for process improvement, and corrected the wording of two other performance measures to include use of tracking and analysis of both, adverse events and near misses for institutional improvement (4.1.2.3.), and sharing of patient safety related data with all stakeholders (4.2.3.1.).

Three of the performance measures had no change in their group rank means throughout the study, and for two performance measures the group rank means slightly decreased (Figure 39). However, all performance measures in group 4 had a consensus rank above 3, and seven of the performance measures were ranked above 3.5, including one rank of 3.9 for the measure related to securing the integrity, timeliness, reliability, security and accuracy of patient safety data that are further used in institutional improvement and action planning.

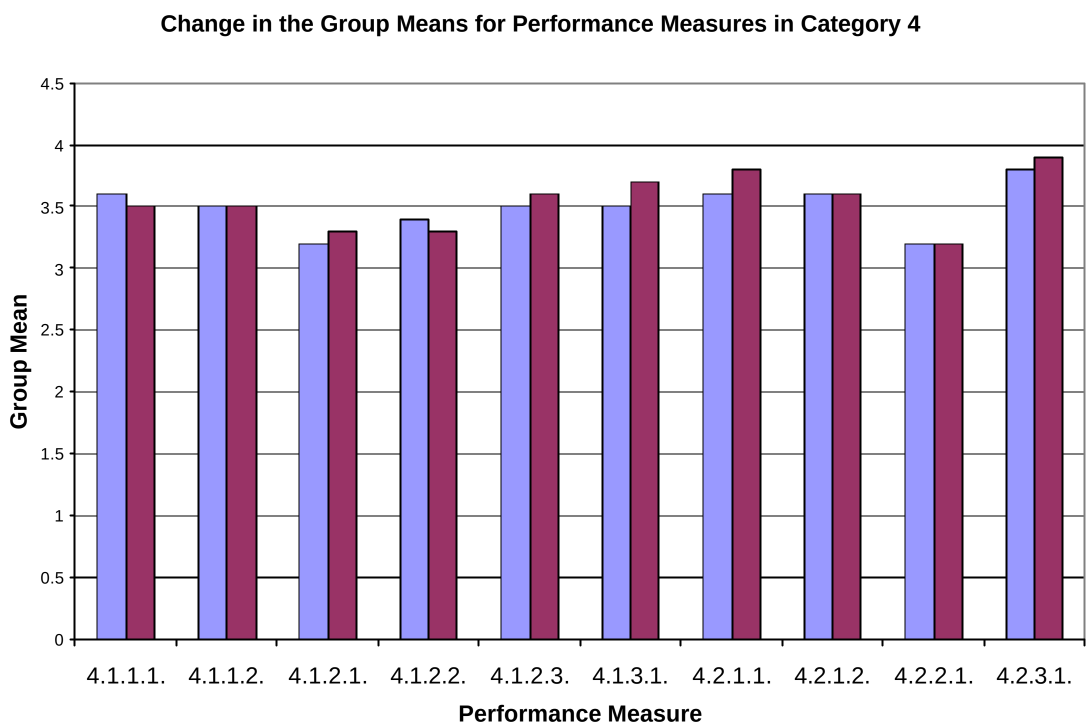

FIGURE 39. Change in Group Means for Performance Measures in Category 4: Beginning - End of Study (blue – beginning, maroon – end)

While most of the performance measures in Category 4 received ranks of “very important” and the rest were ranked as “important,” the variability in the opinions of the Delphi experts showed dramatic decrease from 0. 772 to 0.470 for only one of the performance measure, 4.1.3.1., A process exists for recording, monitoring, tracking and analysis of near misses and feedback is used for process improvement. While for six of the performance measures the group standard deviation decreased with iterations of the survey, for four of the performance measures it increased (Figure 40).

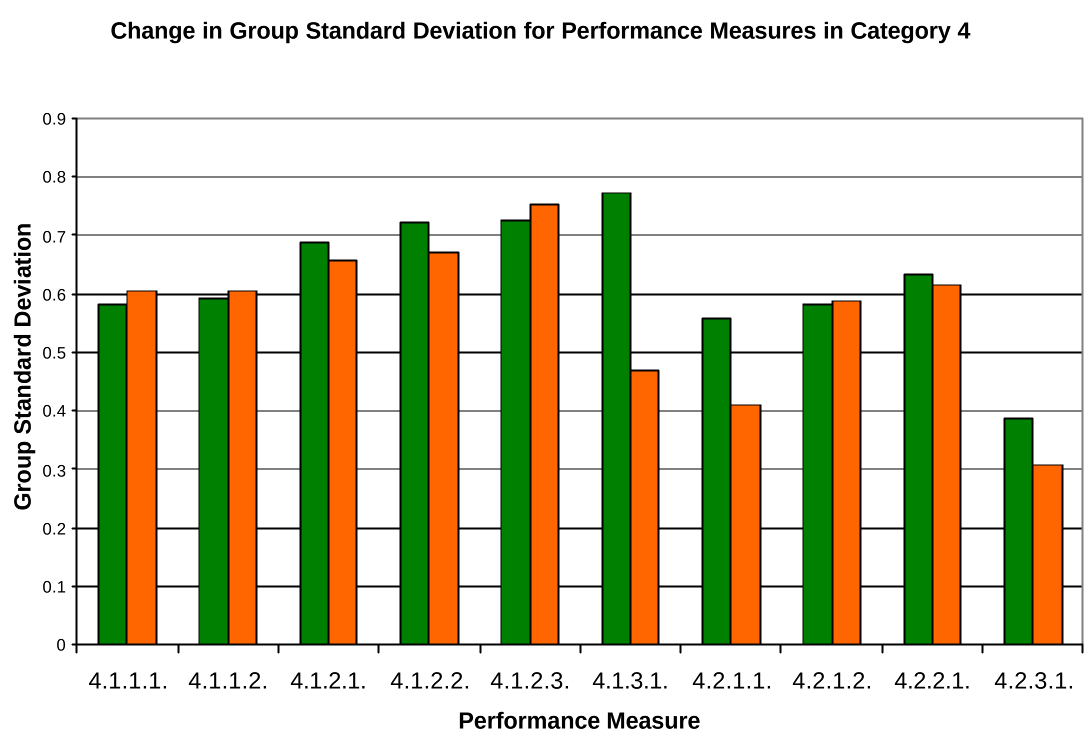

FIGURE 40. Change in Group Standard Deviation for Performance Measures in Category 4: Beginning - End of Study (green – beginning, orange – end)

Although the changes in the group standard deviation for the variables with increase in the variability of expert opinions were less than 0.1, the failure of the group standard deviation for those variables to decrease and for individual opinions to tightly cluster around one rank, speaks of the still unsettled nature of the importance of patient safety measurement, data analysis and knowledge management in the mindset of healthcare professionals and administrators.

Category 5, Staff Focus

There were 11 performance measures included in Category 5, Staff focus (Table 12). Three of the performance measures were added by the Delphi panel after the first study round. The panel identified three important aspects of assessing the staff focus in continuous quality improvement in patient safety institutions related to patient safety:

- General staff knowledge and safe practices should be rewarded and considered in recruitment, selection and promotion;
- Active feedback on safety system implementation should be provided to hospital staff;
- Medical staff participation and support of safety environment within the institution should be recognized and supported.

All performance measures for Category 5 were rated at least as “important,” and five of them were considered “very important” for building and improvement of patient safety systems in healthcare institutions. The “very important” performance measures were related to:

- Promotion of consistency in the safety of healthcare delivery through improved patient safety processes at all institutional levels;
- Adoption of patient safety practices and clinical guidelines to serve as a basis for clinicians’ performance evaluation;

- Seamless healthcare delivery across all institutional departments that is consistent with national, regional and specialty best practices and standards for patient safety and healthcare delivery;
- Integration of institution's patient safety goals into healthcare delivery functions with continuous monitoring of progress toward their achievement and improvement;
- Institution safety environment is supported by the medical staff (Table 12).

TABLE 12. Patient Safety Performance Measures, Category 5, Staff Focus

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
5.1.1.1. How patient safety issues are communicated, data is collected and analyzed, and existing processes are improved at different institutional levels to promote consistency in the safety of healthcare delivery.	3.5	3.6	0.583	0.587
5.1.2.1. Best patient safety practices and clinical guidelines are adopted, monitored and clinician performance is evaluated for consistency with these adopted standards.	3.7	3.8	0.518	0.489
5.1.3.1. Interdepartmental systems for ensuring seamless healthcare delivery and patient safety are consistent with national, regional or specialty best practices and standards for patient safety and healthcare delivery.	3.6	3.8	0.558	0.489
5.1.4.1. Development, implementation, revision and improvement of institution's plan for hiring, retaining and recognition of patient safety staff.	3.0	3.2	0.949	0.894
5.1.5.1. General staff knowledge and practice of safe activities is rewarded and taken into consideration for recruitment, selection and promotion.	3.1	3.2	0.809	0.523

TABLE 12. (cont.)

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
5.2.1.1. Institutional mechanism for determining of and acting on patient safety educational and training needs for individuals, teams, departments and different categories of professional caregivers.	3.4	3.4	0.787	0.754
5.2.2.1. Development, implementation and improvement of internal patient safety policies, practices and activities.	3.3	3.3	0.634	0.587
5.3.1.1. Institution's patient safety goals are integrated in institution's everyday healthcare delivery functions and are regularly reviewed and improved, and progress towards them is continuously monitored and evaluated.	3.7	3.8	0.688	0.696
5.3.2.1. Institutional mechanisms for periodic gathering of information on healthcare providers' opinions and expectations in regard to factors enhancing or inhibiting communication of sentinel events and using the results of the analysis of all collected data for institutional patient safety improvement.	3.3	3.4	0.647	0.598
5.3.2.2. Staff satisfaction is promoted by actively providing feedback on patient safety system implementation.	3.1	3.1	0.750	0.501
5.3.3.1. Medical staff participation and support of safety environment within the institution.	3.5	3.7	0.785	0.470

Figure 41 presents the individual ranks of the Delphi experts for the performance measures in Category 5. Clearly, one of the participants had an outlier ranking behavior with assigned ranks below the group ranks of 3 and 4. One more study participant assigned a rank of 1, Unimportant, to the performance measure 5.1.4.1 related to the importance of development, implementation, revision and improvement of institution's plan for hiring, retaining, and recognition of patient safety staff.

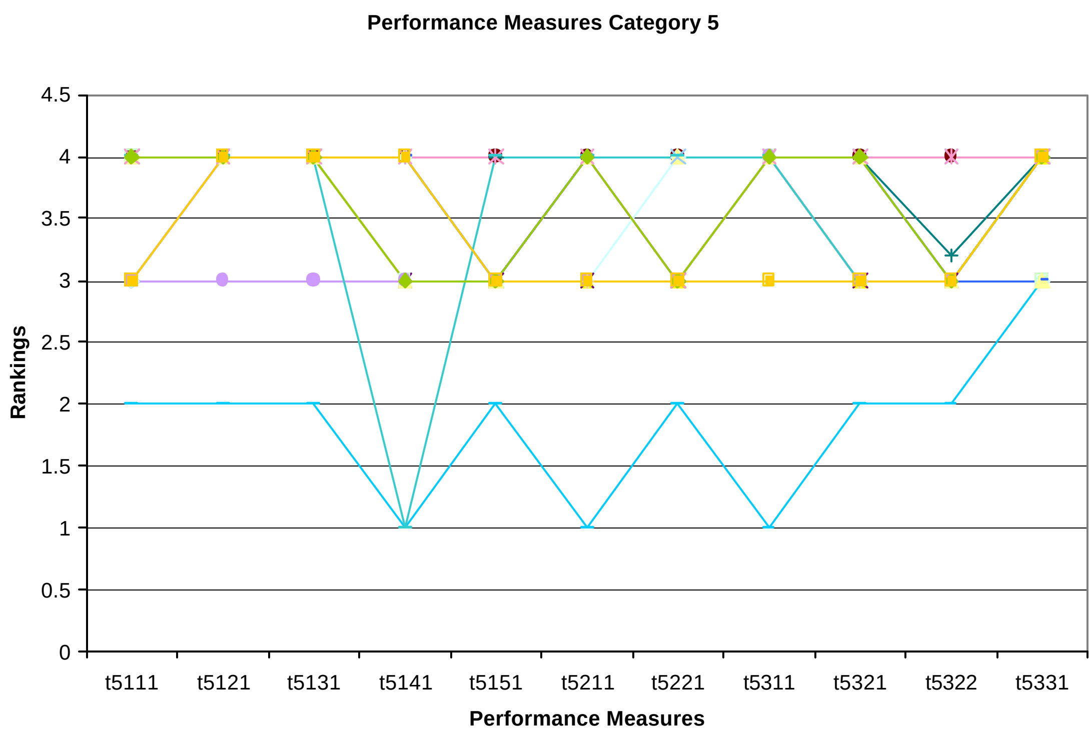

FIGURE 41. Distribution of Individual Ranks, Performance Measures, Category 5

Eight of the performance measures had an increase in their consensus group rank means compared to the experts' ranks at the beginning of the study (Figure 42). Three of the performance measures did not have any change in the group means. Since all performance measures in Category 5 had a group rank mean above 3, Important, and five of them were perceived to be "very important" for healthcare patient safety systems, all performance measures in this category were included in the final patient safety framework.

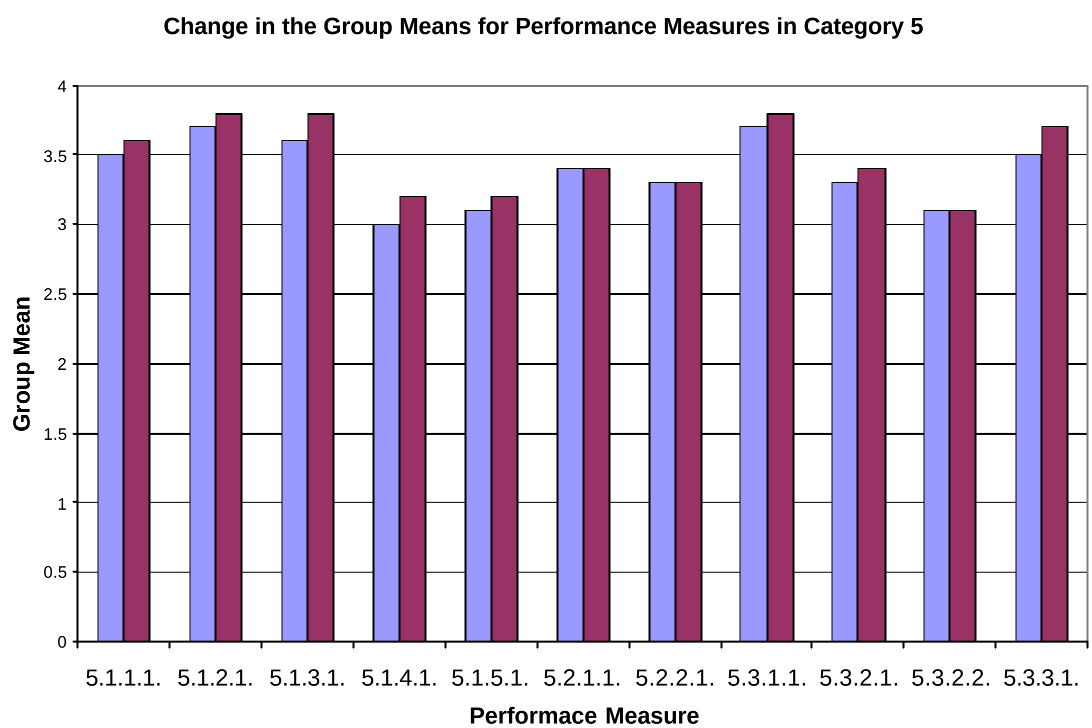

FIGURE 42. Change in Group Means for Performance Measures in Category 5: Beginning - End of Study (blue – beginning, maroon – end)

Nine of the eleven performance measures in this category had a decrease in their group standard deviation (Figure 43) at the end of the study compared to the initial variability in experts' opinions in the study start and three of the performance measures standard deviations had a significant decrease in their values (measures 5.1.5.1., 5.3.2.2, and 5.3.3.1.). All three measures with significant decrease in their group standard deviations were suggested by the Delphi panel during the first study round. Two of the performance measures had a slight increase in their group standard deviation of 0.004 and 0.012 respectively. Thus, the level of agreement for the performance measures in Category 5 was high.

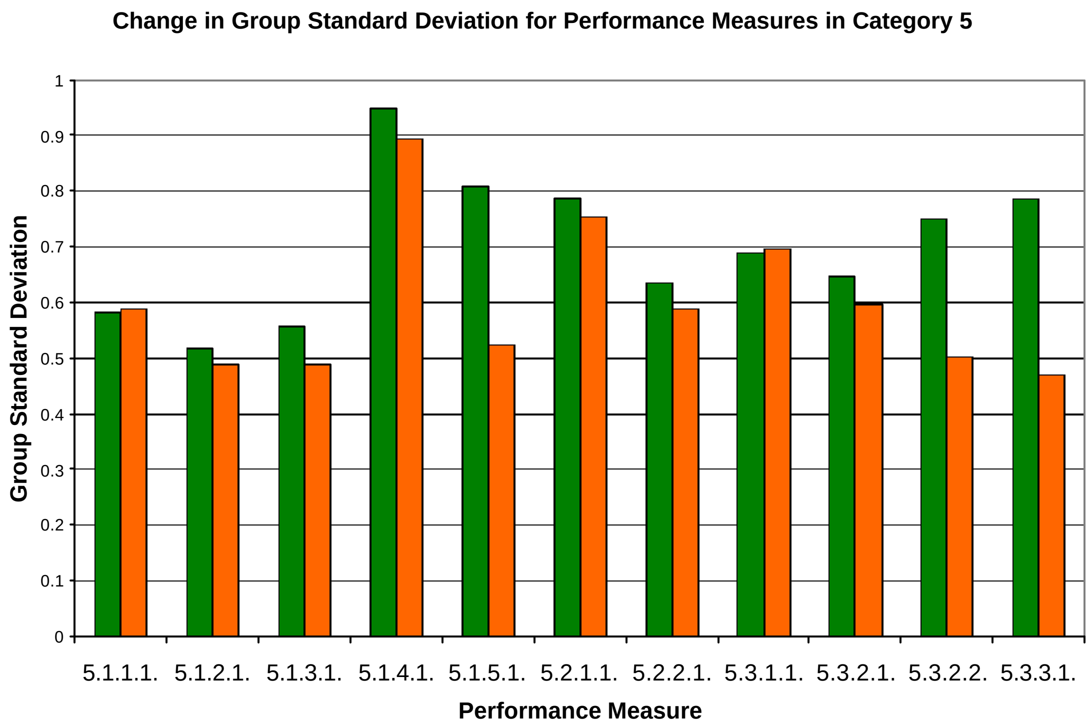

FIGURE 43. Change in Group Standard Deviation for Performance Measures in Category 5: Beginning - End of Study (green – beginning, orange – end)

Category 6, Process Management

The Delphi experts assessed six performance measures included in Category 6, Process management (Table 13). Two of the performance measures related to improvement and sustainability of safe and secure campus environment that supports the healing process and evaluation of safety compliance of suppliers, partners and medical staff, were added by the panelists during the first survey round. All performance measures in Category 6 had a group rank mean above 3, Important, and were included in the final patient safety framework.

Three of the performance measures were ranked as “very important.” These “very important measures were:

- Evidence that Quality Improvement methodology, clinical performance measures and best practices are used to decrease variability of healthcare delivery and improve patient safety outcomes;
- An institutional mechanism exists for continuous monitoring, improvement and sustainability of patient safety outcomes in healthcare delivery;
- Systems for departmental and interdepartmental communications, collaborations and aligned effort in regard to seamless implementation of best practices and clinical guidelines in patient identification, medication and continuous case management are assessed and improved on an ongoing basis.

TABLE 13. Patient Safety Performance Measures, Category 6, Process Management

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
6.1.1.1. Accreditation, professional and legal requirements as well as improvements resulting from stakeholder surveys and reporting systems results analyses are incorporated in institution's patient safety systems and processes on a regular basis.	3.5	3.4	0.589	0.605
6.1.2.1. Evidence that Quality Improvement (QI) methodology, including but not limited to RCA, FMEA, Plan-Do-Study-Act Cycle (PDSA, Rapid Cycle Change), clinical performance measures and best practices are used to decrease variability of healthcare delivery and improve patient safety outcomes.	3.6	3.8	0.558	0.489
6.1.3.1. An institutional mechanism exists for continuous monitoring, improvement and sustainability of patient safety outcomes in healthcare delivery.	3.6	3.8	0.470	0.489
6.1.4.1. An institutional mechanism exists for continuous monitoring, improvement and sustainability of a campus environment that promotes a feeling of safety and security, and supports the healing process without adding stress regarding personal safety.	3.2	3.3	0.574	0.470
6.2.1.1. Systems for departmental and interdepartmental communications, collaborations and aligned effort in regard to seamless implementation of best practices and clinical guidelines in patient identification, medication and continuous case management are assessed and improved on an ongoing basis.	3.5	3.6	0.590	0.754
6.2.2.1. Safety compliance evaluations of suppliers and partners (including medical staff).	3.2	3.1	0.732	0.489

The study experts consistently assigned importance ranks of 3 or 4 to all performance measures in this category, with two exceptions (Figure 44). One of the experts also considered the feasibility of the required changes related to the respective variables (in departure from the rank assignment criteria). That expert doubted that seamless and aligned interdepartmental communications and collaboration in implementation of best practices and clinical guidelines are realistic in the current healthcare environment. Another expert considered the evaluation of safety compliance of suppliers, partners and medical staff as “not very important.”

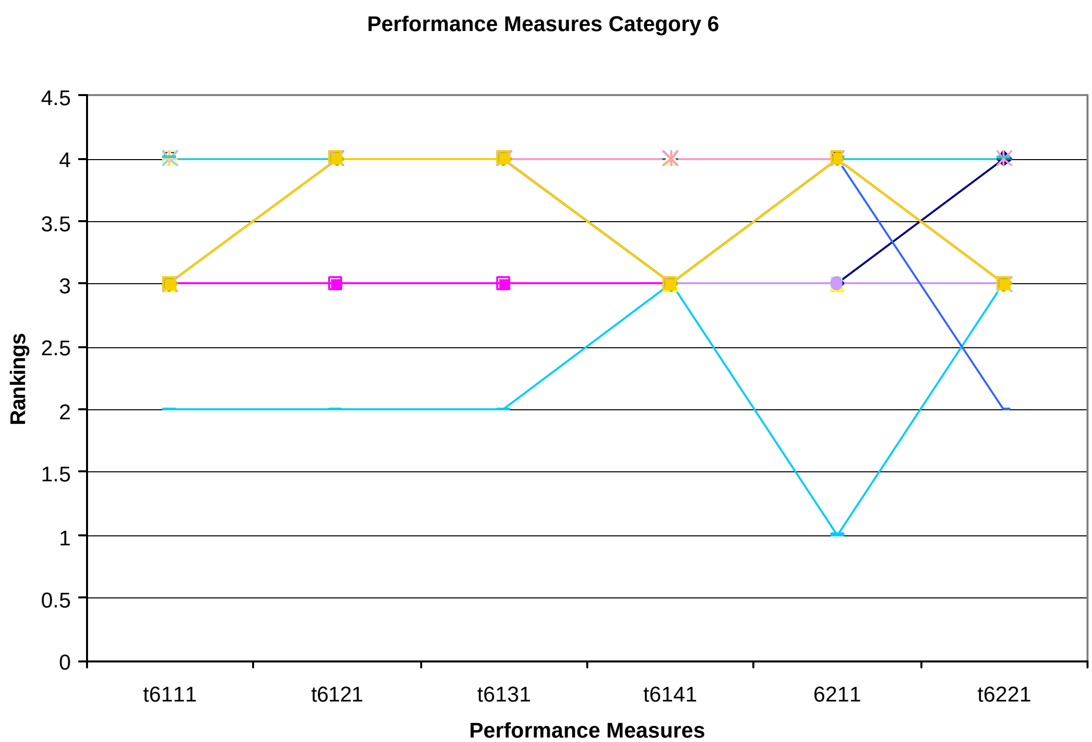

FIGURE 44. Distribution of Individual Ranks, Performance Measures, Category 6

For four of the performance measures in this category the consensus group rank mean at the end of the study was higher than the group mean for the respective variables after the first study round (Figure 45). However, the panel perceived two of the variables to have slightly lower importance at the end of the study in comparison with the first study round.

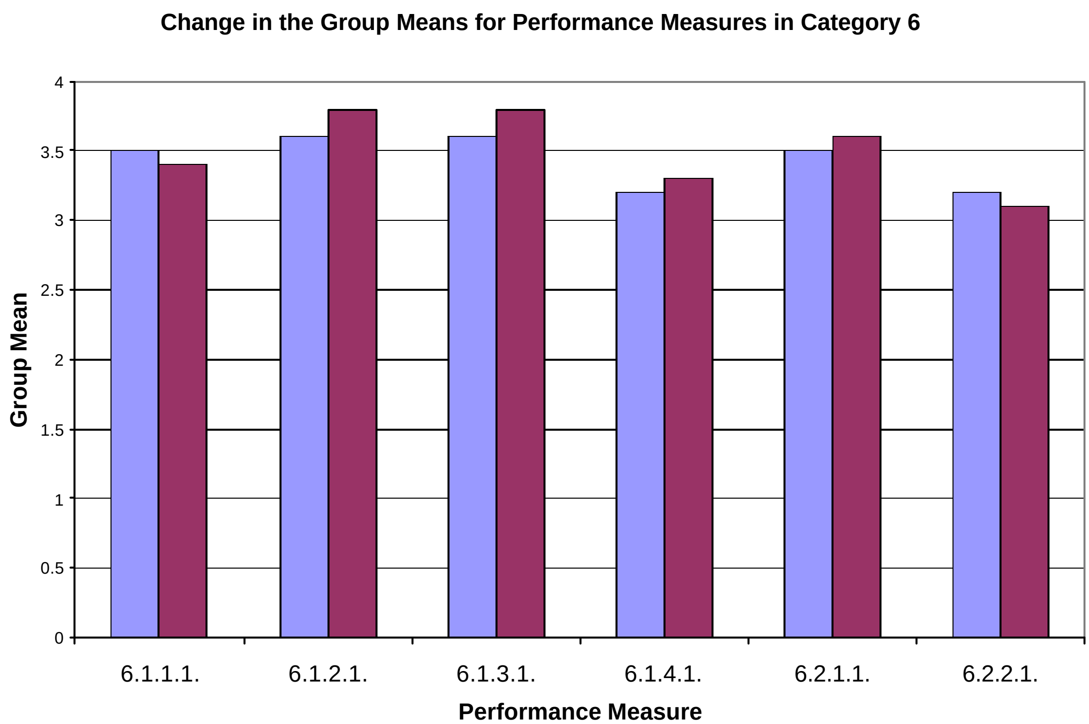

FIGURE 45. Change in Group Means for Performance Measures in Category 6: Beginning - End of Study (blue – beginning, maroon – end)

The group standard deviation (Figure 46) did not uniformly decrease for the variables in this category, and for one variable, 6.2.1.1., related to the interdepartmental collaboration in seamless implementation of best practices and clinical guidelines, significantly increased. This increase was attributed to the divergent opinion of the expert who did not follow the study criteria for assignment of importance ranks.

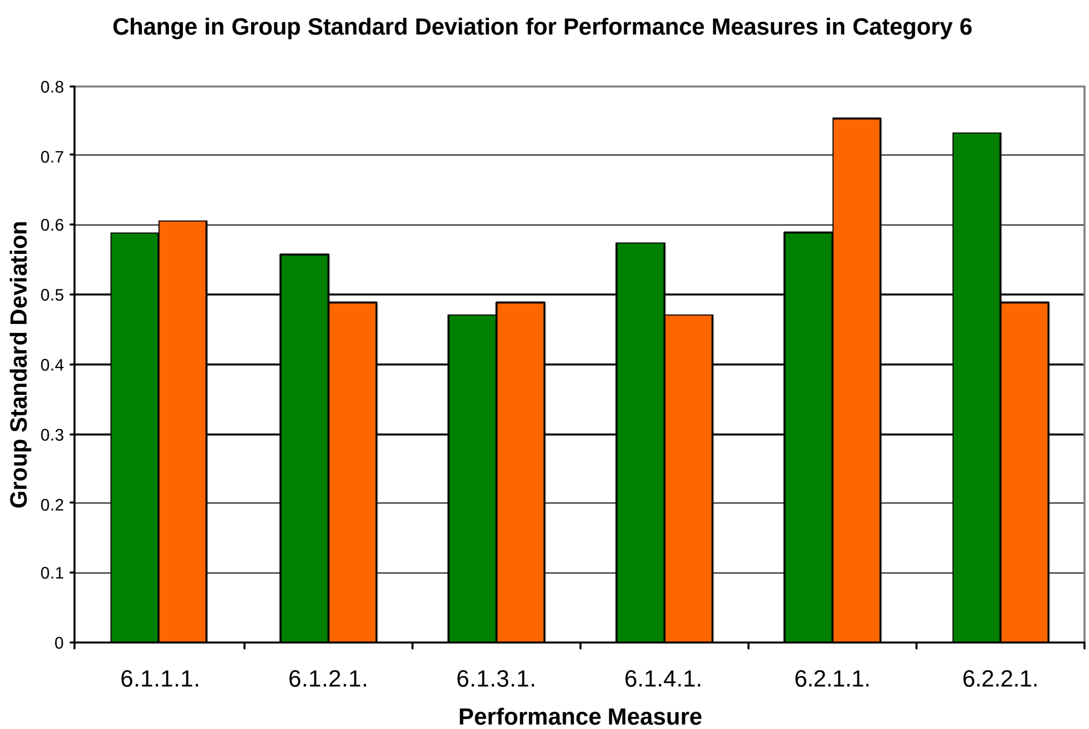

FIGURE 46. Change in Group Standard Deviation for Performance Measures in Category 6: Beginning - End of Study (green – beginning, orange – end)

Category 7, Institutional Performance

There were 16 performance measures in Category 7, Institutional performance (Table 14). The majority of these performance measures directly reflected patient safety requirements of healthcare accreditation agencies. Seven of the performance measures in this category were considered "very important" to patient safety systems in healthcare institutions:

- A two-identifier system for patient identification is in place and is consistent in the continuity of healthcare throughout the institution;
- The institution monitors the administration of high-alert medications;
- Proper marking of surgery sites is established as a precaution to decrease incidents of wrong-site surgery (where applicable);
- The institution ensures adequate professional staff preparation for proper and safe use of infusion pumps (where applicable);
- The institution ensures a non-punitive approach for reporting all adverse events and near misses;
- The institution ensures that an accessible, confidential and adequately functioning reporting system is in place for reporting all adverse events and near misses;
- The institution proactively works towards changing the traditional culture of "blame and shame."

TABLE 14. Patient Safety Performance Measures, Category 7, Institutional Performance

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
7.1.1.a. A 2-identifier system for patient identification is in place and is consistent in the continuity of healthcare throughout the institution.	3.4	3.5	0.730	0.607
7.1.2.a. Healthcare departmental and interdepartmental communications are accurate and reliable at different institutional levels.	3.3	3.2	0.722	0.716
7.1.3.a. The institution monitors the administration of high-alert medications.	3.6	3.7	0.486	0.444
7.1.4.a. Proper marking of surgery sites is established as a precaution to decrease incidents of wrong-site surgery (where applicable).	3.5	3.6	0.656	0.489
7.1.5.a. The institution ensures adequate professional staff preparation for proper and safe use of infusion pumps (where applicable).	3.5	3.5	0.499	0.513
7.1.6.a. The institution ensures adequate professional staff preparation for proper and safe use of clinical alarm systems (where applicable).	3.2	3.3	0.702	0.587
7.1.7.a. The institution ensures a non-punitive approach for reporting all adverse events and near misses.	3.4	3.5	0.843	0.761
7.1.8.a. The institution ensures proper staff is dedicated to support and conduct RCA, FMEA, and implement QI methodology in analyzing multidimensional patient safety practices at different institutional levels.	3.3	3.4	0.656	0.681

TABLE 14. (cont.)

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
7.1.9.a. The institution ensures that an accessible, confidential and adequately functioning reporting system is in place for reporting all adverse events and near misses.	3.4	3.5	0.510	0.607
7.1.10.a. The institution ensures that a uniform, unambiguous and comprehensive nomenclature for reporting of adverse events and near misses is adopted throughout the healthcare institution.	3.2	3.2	0.735	0.616
7.1.11.a. The institution proactively works towards changing the traditional culture of "blame and shame."	3.5	3.6	0.499	0.489
7.1.12.a. The institution ensures safe healthcare delivery through utilization of modern technology.	3.2	3.2	0.751	0.696
7.1.13.a. The institution ensures that professional, accreditation and legal requirements in the area of patient safety are adequately addressed.	3.3	3.3	0.634	0.571
7.1.14.a. The institution ensures that national benchmarks in healthcare delivery (best practices, clinical performance measures, etc.) are used to decrease variability of healthcare delivery and improve patient safety outcomes.	3.3	3.4	0.656	0.686
7.1.15.a. The institution assures that appropriate leadership development and education in the area of patient safety is provided on an ongoing basis.	3.1	3.2	0.882	0.523
7.1.16.a. The institution assures that appropriate staff development and education in the area of patient safety is provided on an ongoing basis.	3.1	3.2	0.882	0.523

The distribution of individual expert ranks for the variables in Category 7 is presented on Figure 47. Four of the experts assigned ranks lower than 3, Important, to several of the category performance measures, while the majority of the Delphi experts agreed that the variables in this category are either “very important” or “important” to patient safety systems in healthcare institutions.

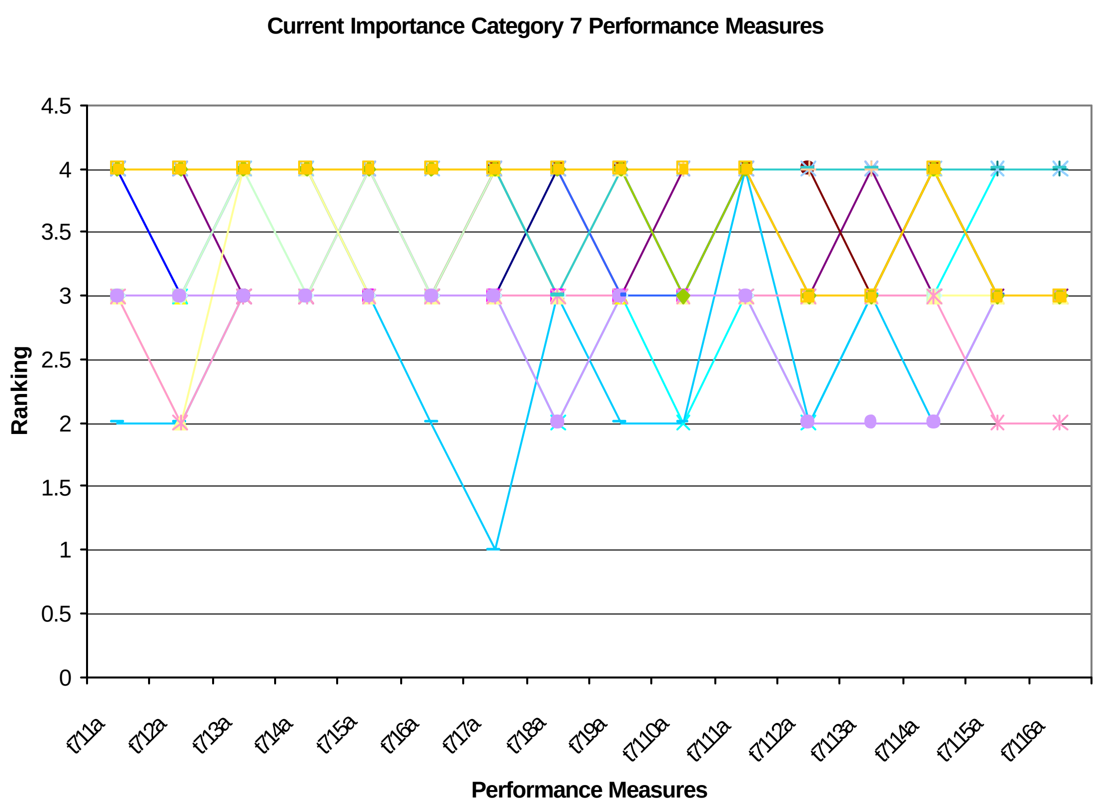

FIGURE 47. Distribution of Individual Ranks for Performance Measures, Category 7

Only one of the 16 performance measures in Category 7 had a lower group rank mean at the end of the study compared to the results after the first study round (Figure 48). Fifteen of the performance measures had a higher group rank mean at the end of the study. Twelve of the performance measures in this category had a decrease in the variability of experts' opinions expressed by lower standard deviation (Figure 49).

Four of the performance measures had higher group standard deviation at the point of reaching consensus than after the first study round. The Delphi experts suggested two new performance measures to this category related to the importance of providing patient safety education to both, hospital leadership and staff (measures 7.1.15. and 7.1.16.). For both of the performance measures added to the framework by the study participants, there was a dramatic decrease in the variability with a drop of the group standard deviation from 0,882 to 0.523 for both variables.

The performance measures suggested for Category 7 are intended to measure healthcare institutional performance in the area of patient safety. The performance measures included in Category 7 should not be assessed separately from the first six categories of the patient safety framework, based on the Malcolm Baldrige National Quality Award Criteria for Performance Excellence in Healthcare. Since all performance measures in Category 7 had group rank means higher than 3, Important, all performance measures in this category were included in the final patient safety framework.

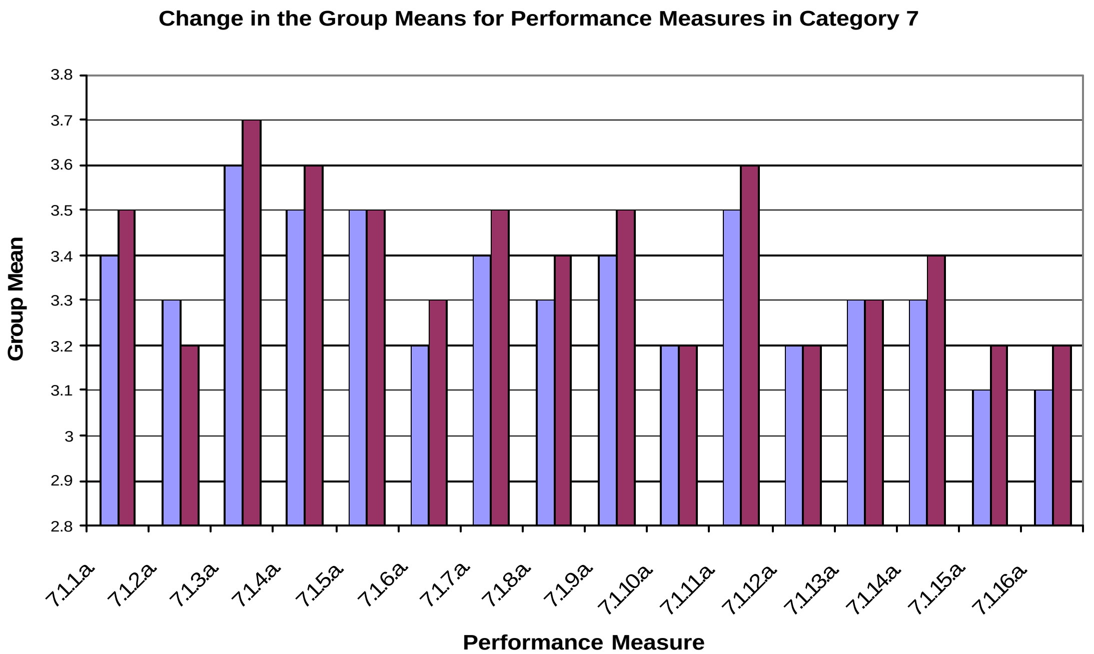

FIGURE 48. Change in Group Means for Performance Measures in Category 7: Beginning - End of Study (blue – beginning, maroon – end)

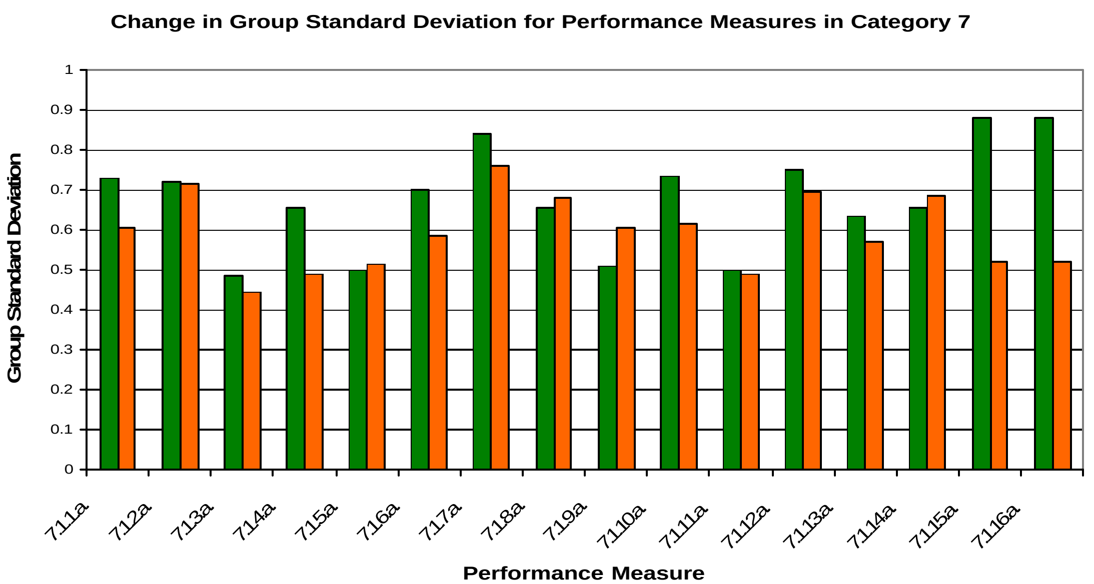

FIGURE 49. Change in Group Standard Deviation for Performance Measures in Category 7: Beginning - End of Study (green – beginning, orange – end)

Research Question Three

The third research question for this study explored what processes will be critical for patient safety in the future as forecasted by healthcare administrators on the Delphi panel. The Delphi experts assessed the already identified patient safety critical processes (see section “Research Question One” above) with respect to their importance in the future. While the assessment of the current importance of the identified patient safety critical processes was marked with suffix of “a” behind the process number (e.g. 1.1.1.a. as shown in the tables and figures), for identification of the future importance of the same critical processes, a suffix of “b” was added to the process number (e.g. 1.1.1.b.).

For each category, a table presents the change in the experts’ opinions about the importance of the variables in the respective category through displaying the initial and consensus group rank means and standard deviations. The individual consensus opinions of the future importance of the critical processes (for categories 1-6) and performance measures (for category 7) are visually presented in a following figure. Last, a comparison is made between the importance of the critical processes and performance measures for the current (as discussed in section “Research Question One”) and for the future based on the expert opinion of the Delphi panelists.

Future Importance of the Critical Processes in Category 1, Leadership

The values of the group means and consensus numbers for the future importance of the critical processes in Category 1 are presented on Table 15. The future importance of six of the critical processes in this category, both in the beginning and at the end of the study, was ranked as “very important.” Only one critical process, related to how the institution monitors its medication error rate, was given a rank of “important.” The opinions of the panelists changed little over the course of the study. For five of the seven critical processes in Category 1, Leadership, there was an increase in the group rank mean of 0.1, and for two processes the group ranks remained the same. The group standard deviations increased for the two critical processes with no change in the group ranks and decreased for all processes with increased rank mean.

TABLE 15. Future Importance of Patient Safety Critical Processes in Category 1, Leadership

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
1.1. Institutional leadership	1.1.1.b. Senior Leadership Direction: How senior leaders communicate the priority of patient safety to all stakeholders	3.9	4.0	0.213	0.000
	1.1.2.b. Institutional Governance: How senior leaders create an environment for development and improvement of patient safety systems in the institution	3.9	3.9	0.213	0.224
	1.1.3.b. Institutional Performance Review: How patient safety findings are translated in institutional short- and long-term goals and priorities.	3.8	3.8	0.351	0.366
	1.2.1.b. Responsibilities to the public: How the institution incorporates patient safety accreditation and legal requirements as integral parts of its performance improvement.	3.5	3.6	0.589	0.503
	1.2.2.b. Ethical Behavior: How the institution ensures ethical communication with stakeholders in regard to patient safety issues.	3.5	3.6	0.510	0.503
	1.2.3.b. Support of key communities: How the institution proactively responds to current and future public concerns in regard to patient safety.	3.6	3.7	0.572	0.470
	1.2.4.b. Responsibilities to the Public: How the institution monitors its medication error rate.	3.3	3.4	0.582	0.503

Critical process 1.1.1.b., How senior leaders communicate the priority of patient safety to all stakeholders, received a unanimous rank of 4, Very important, from all Delphi experts. The unanimous vote on the great importance of this critical process is visualized in Figure 50. There were no outlier ranks for the future importance of the processes in the leadership category of the patient safety framework. The Delphi panel placed a considerable weight on the role of healthcare institutions' leadership in promoting patient safety, and achieving and sustaining patient safety results.

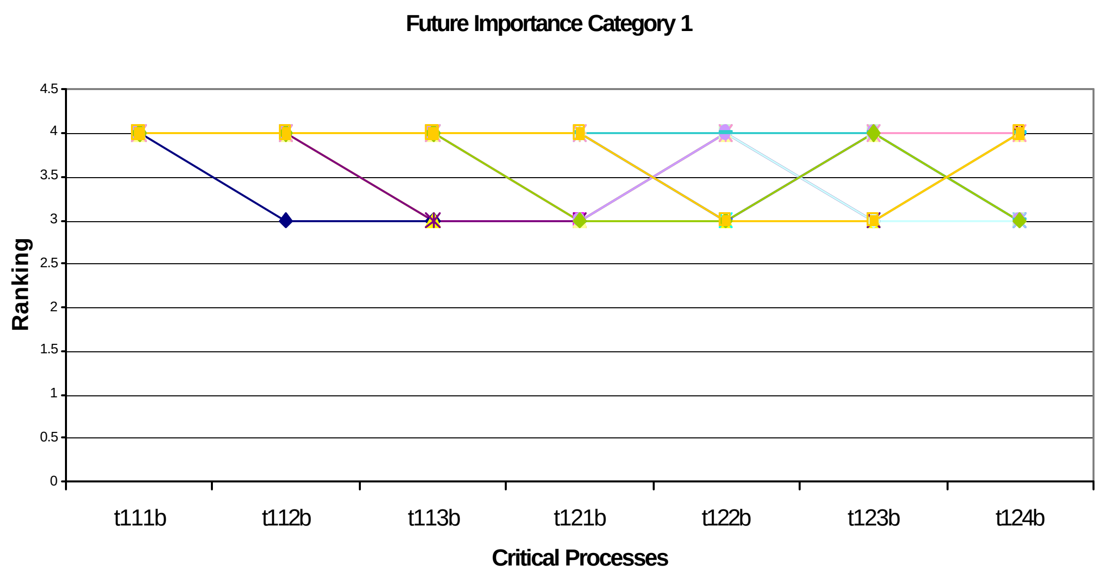

FIGURE 50. Distribution of the Individual Ranks of the Future Importance of Critical Processes in Category 1

The comparison between the importance for the current and for the future of the patient safety critical processes showed that all critical processes in the leadership category will have higher importance for the future patient safety performance of U.S. healthcare institutions (Figure 51). Thus, senior healthcare leadership will play a central role for the patient safety outcomes of their respective healthcare institutions.

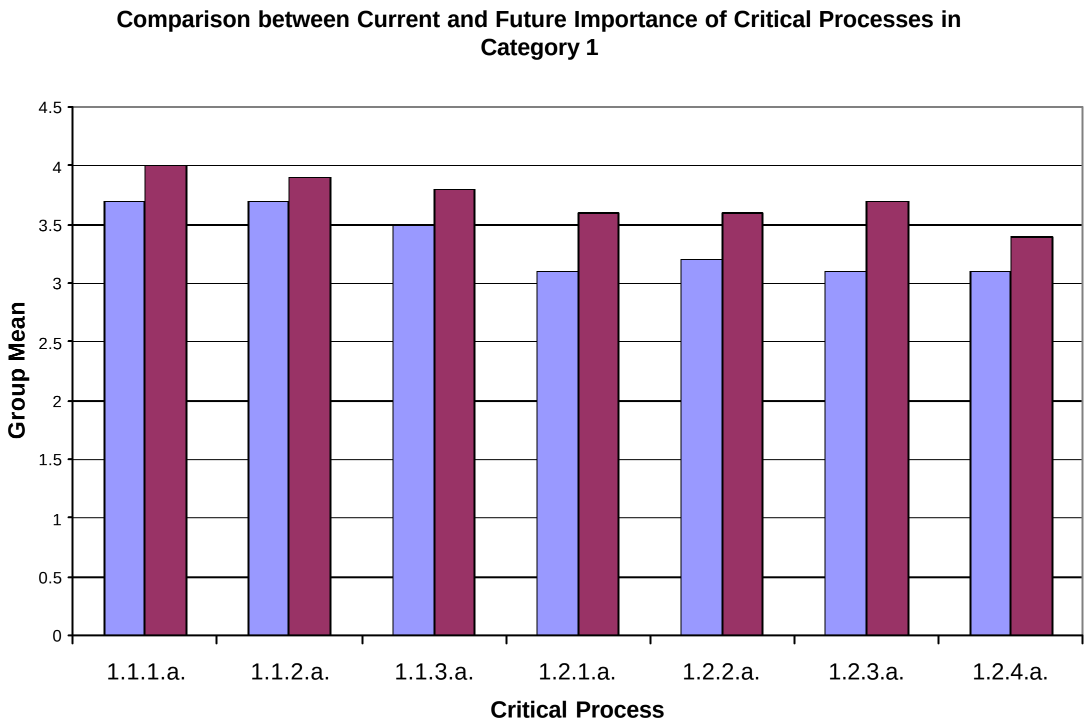

FIGURE 51. Comparison between Current and Future Importance of Patient Safety Critical Processes in Category 1 (blue – current, maroon – future)

Future Importance of the Critical Processes in Category 2, Strategic Planning

All five critical processes in Category 2, Strategic planning, were perceived by the Delphi panel to be "very important" for healthcare patient safety systems in the future both at the beginning and at the end of the study (Table 16).

TABLE 16. Future Importance of Patient Safety Critical Processes in Category 2, Strategic Planning

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
2.1. Strategy Development	2.1.1.b. Strategic Development Process: How the healthcare institution develops its view of the future and sets directions and policies to communicate, implement and monitor its patient safety systems.	3.5	3.5	0.511	0.510
	2.1.2.b. Strategic Objectives: How patient safety practices are identified and translated to institution's goals.	3.6	3.7	0.503	0.470
	2.1.3.b. Strategic Objectives: How the institution achieves realistic evaluation of technology capability for improving safety (present and future).	3.6	3.7	0.485	0.470
2.2. Strategy Deployment	2.2.1.b. Action Plan Development and Deployment: How the institution develops, monitors and improves action plans to ensure patient safety.	3.7	3.8	0.421	0.366
	2.2.2.b. Performance Projection: How leaders achieve consistency and improvement of healthcare delivery.	3.6	3.8	0.470	0.366

One critical process had no change in its group rank mean, while four critical processes were perceived more important at the end of the study with slight increase in the group rank means of 0.1 or 0.2. The variability in the opinions of the Delphi panelists regarding the future importance of the strategic planning critical processes decreased throughout the study, shown by the decrease in the group standard deviation with achieving consensus. The individual ranks of the Delphi experts for this framework category were either 3 or 4 (Figure 52).

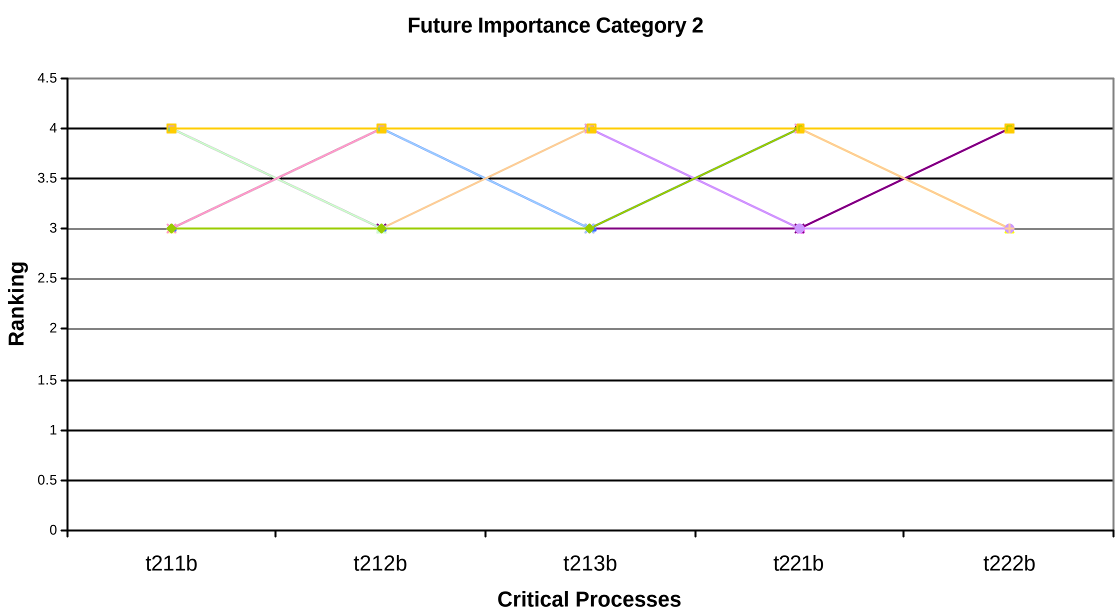

FIGURE 52. Distribution of the Individual Ranks of Future Importance of Patient Safety Critical Processes in Category 2

As was the case in Category 1, the comparison between the current and future importance of the critical processes in Category 2 revealed that the Delphi panelists perceived the critical processes in Category 2 as more important for the future than in the present (Figure 53). Thus, Category 2, Strategic planning, was identified as a whole as very important for the success of patient safety systems in the future.

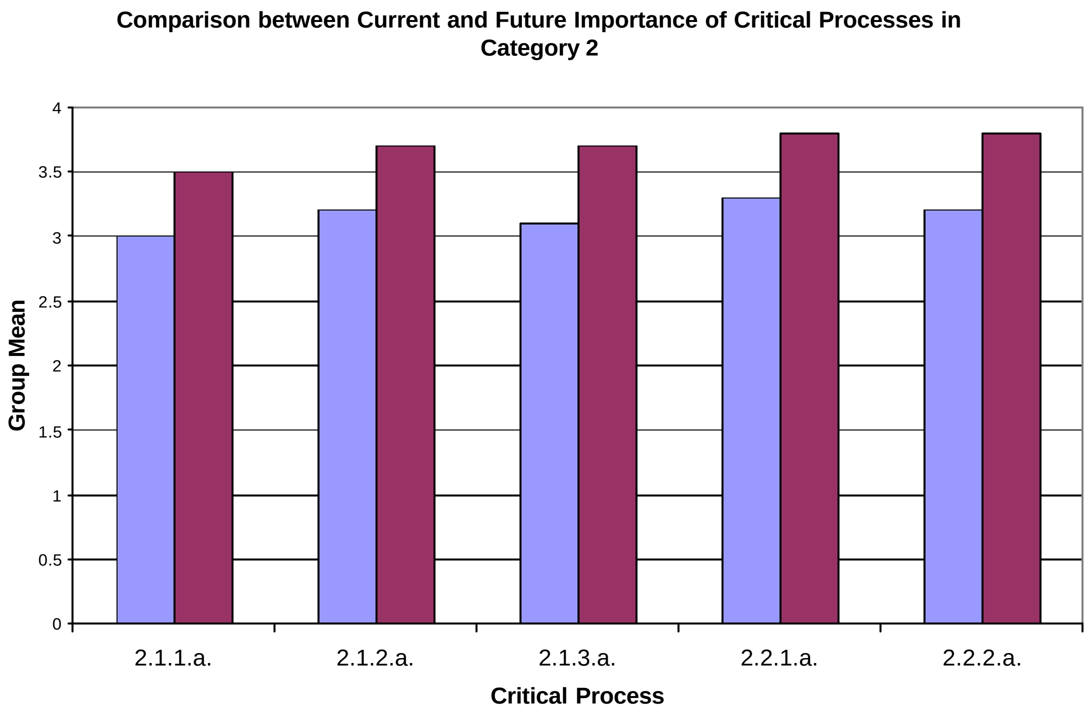

FIGURE 53. Comparison between Current and Future Importance of Patient Safety Critical Processes in Category 2, Strategic Planning (blue – current, maroon – future)

Future Importance of the Critical Processes in Category 3, Focus on Patients, Other Customers and Markets

The group rank means and standard deviations for the future importance of the critical processes in Category 3, Focus on patients, other customers and markets are presented in Table 17. For the future importance of two of the critical processes on Category 3 there was no change of the group rank mean with iterations of the study questionnaire. For these two critical processes the steady group rank mean was accompanied by a decrease in the standard deviation, i.e. the Delphi panelists' opinions were less diverse. The group rank mean for the other two critical processes in this category slightly decreased and this change lead to an increase in the group standard deviation for these variables, i.e. the Delphi panelists' ranks varied more.

As it is evident on Figure 54, three of the experts assigned a rank of 2, Not very important, to some of the variables in this category. To a great extent the diversity of the opinions of the panelists on the future importance of the critical processes in Category three reflects the results about the current importance of the critical processes in this category. However, the Delphi panel perceived all patient safety critical processes in this category as more important in the future than in the present (Figure 55).

TABLE 17. Future Importance of Patient Safety Critical Processes in Category 3, Focus on Patients, Other Customers and Markets

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
3.1. Patient, Other Customer and Healthcare Market Knowledge	3.1.1.b. Patient Safety Market Knowledge: How the healthcare institution determines patients' expectations and appropriate knowledge in regard to patient safety.	3.4	3.4	0.665	0.605
	3.1.2.b. Patient Safety Market Knowledge: How the institution helps set the expectations of patients and infuses realistic goals and expectations into the marketplace.	3.0	3.0	0.816	0.471
3.2. Patient and Other Customer Relationships and Satisfaction	3.2.1.b. Patient/Customer Relationship Building: How the healthcare institution gathers and analyses information about patients' and community's expectations in regard to safety of healthcare delivery, and how the results and interpretations are used for improvement of institution's patient safety systems.	3.4	3.3	0.589	0.657
	3.2.2.b. Satisfaction Determination: How the institution obtains information and feedback from patients on patient safety issues to improve the delivery of healthcare.	3.7	3.5	0.470	0.510

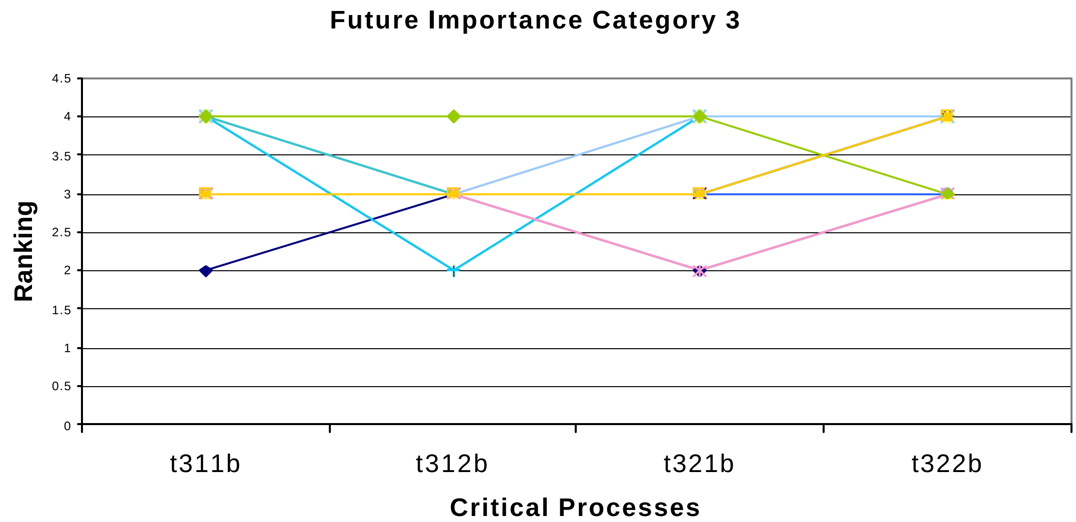

FIGURE 54. Distribution of the Individual Ranks of Future Importance, Critical Processes, Category 3

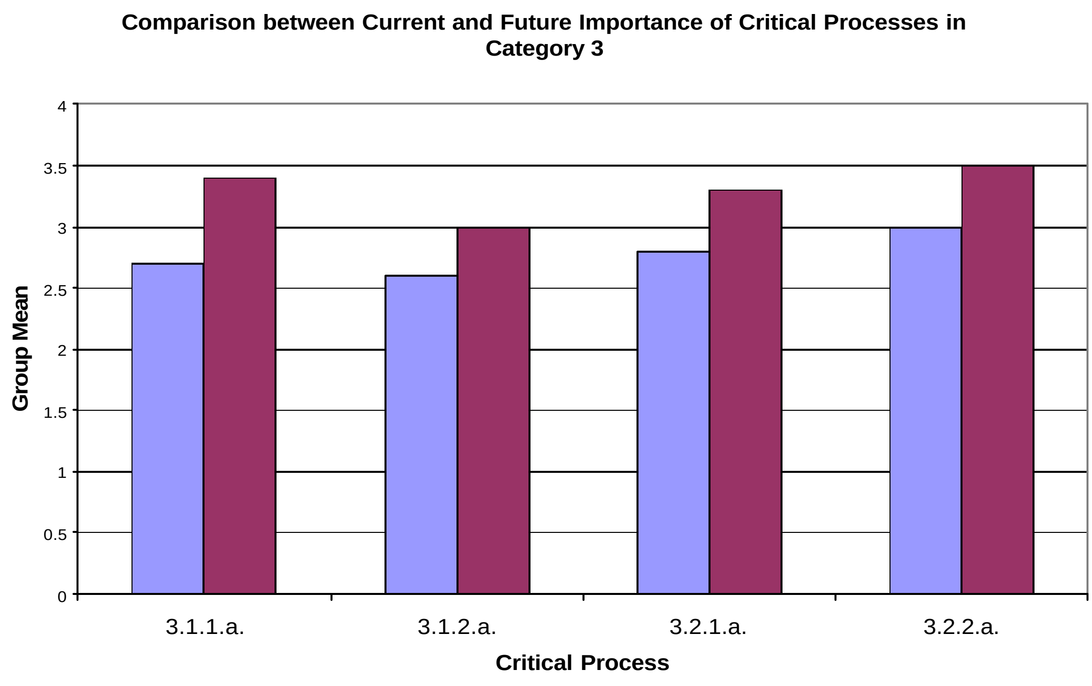

FIGURE 55. Comparison between the Current and Future Importance of Patient Safety Critical Processes in Category 3, Focus on Patients, Other Customers and Markets (blue – current, maroon – future)

Future Importance of the Critical Processes in Category 4, Measurement, Analysis and Knowledge Management

The Delphi experts ranked five of the six patient safety critical processes as “very important” to patient safety systems in the future (Table 18). Importantly, two of the critical processes, related to collection, tracking and analysis of patient safety information at institutional level and ensuring that clinical information technology is reliable, secure and user friendly, received an unanimous rank of 4, Very important, and there was no variation in the expert opinions (i.e. their standard deviation was zero). The group rank means for the future importance of two of the patient safety critical processes (4.1.1.b. and 4.1.3.b.) did not change with questionnaire iterations, and increased for three of the critical processes. The group rank mean for critical process 4.2.2.b., the only process related to customer feedback, decreased.

As pictorially presented on Figure 56, there was little variability in the individual panelist ranks for the variables in Category 4. This finding is strongly supported by the fact that the group standard deviation decreased for all critical processes in this category, as presented in Table 18.

As was the case with the first three categories, the Delphi panelists perceived the future importance of the critical processes in Category 4 as greater than their current importance (Figure 57). Furthermore, the two categories with group mean ranks of 4 and zero standard deviation (critical processes 4.1.2.b. and 4.2.1.b., see Table 18) were expected to be an integral part of any patient safety system in the future.

TABLE 18. Future Importance of Patient Safety Critical Processes, Category 4, Measurement, Analysis and Knowledge Management

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
4.1. Measurement and Analysis of Institutional Performance	4.1.1.b. Performance Measurement: How the institution selects and implements into its patient safety systems patient safety benchmarks.	3.7	3.7	0.470	0.444
	4.1.2.b. Performance Measurement: How the institution collects, tracks and analyzes patient safety data.	3.7	4.0	0.448	0.000
	4.1.3.b. Performance Measurement: How the institution monitors the occurrence of near misses and how uses this information for process improvement.	3.7	3.7	0.574	0.470
4.2. Information and Knowledge Management	4.2.1.b. Data and Information Availability: How the institution ensures that its clinical information technology (Computerized Physician's Order Entry – CPOE, infusion pumps, alarm systems, etc) is reliable, secure and user-friendly.	3.9	4.0	0.208	0.000
	4.2.2.b. Data and Information Availability: How stakeholders' satisfaction, dissatisfaction and expectations in regard to patient safety are determined and used for improvement of patient safety systems.	3.4	3.3	0.506	0.489
	4.2.3.b. Institutional Knowledge: How patient safety information is shared with all stakeholders in support of overall institution's goals and action plans for performance improvement.	3.7	3.8	0.448	0.366

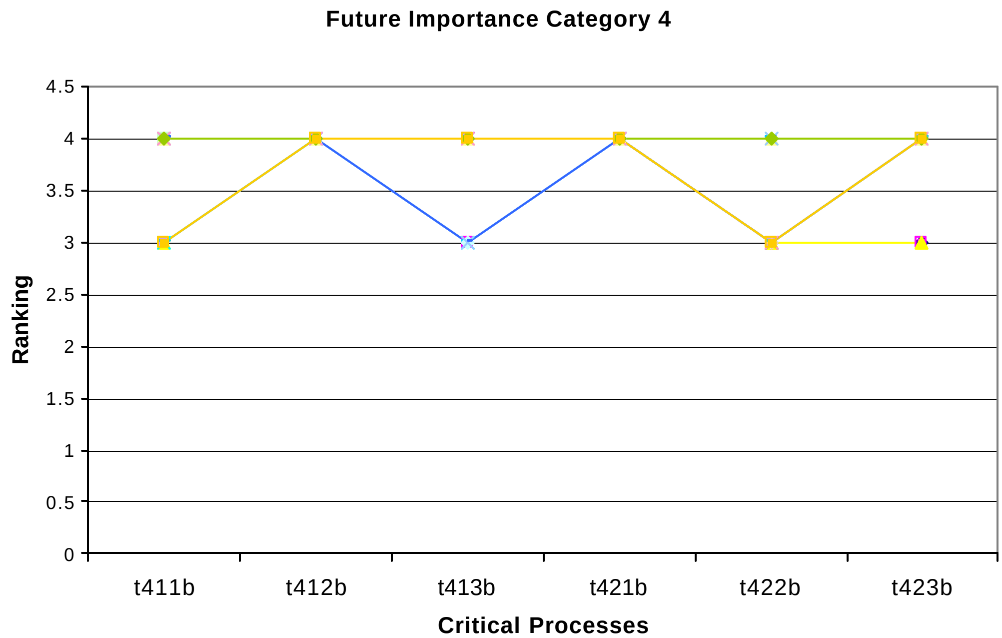

FIGURE 56. Distribution of Individual Ranks of Future Importance, Critical Processes, Category 4

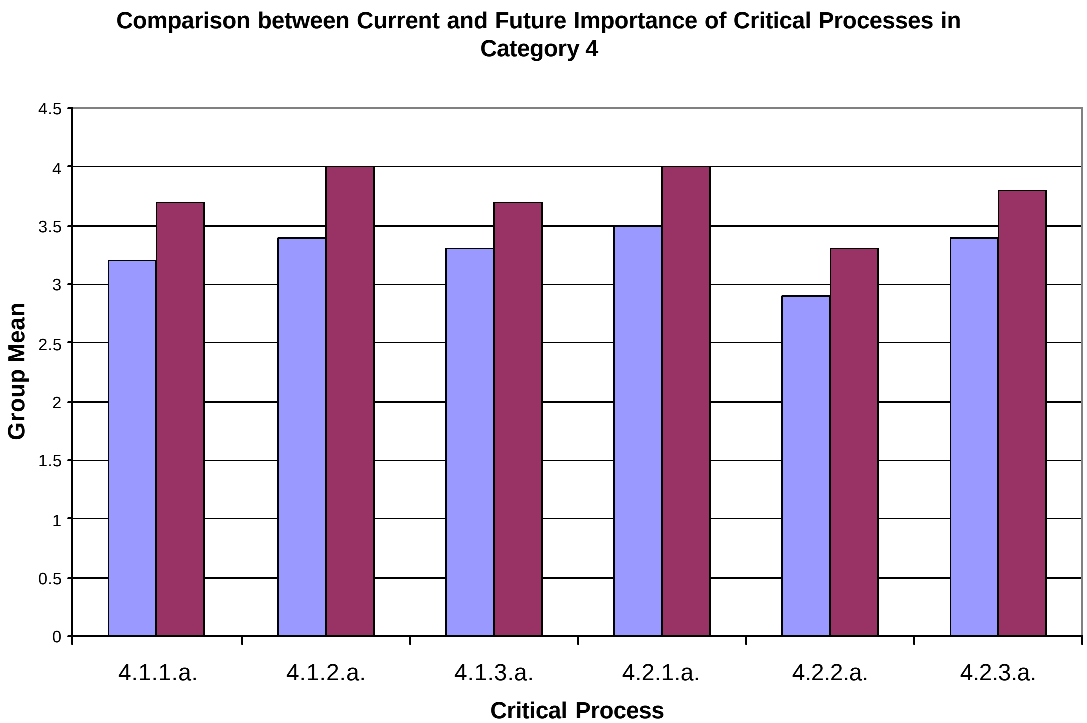

FIGURE 57. Comparison between the Current and Future Importance of Patient Safety Critical Processes in Category 4, Measurement, Analysis and Knowledge Management (blue – current, maroon – future)

Future Importance of the Critical Processes in Category 5, Staff Focus

Table 19 presents the group rank means and standard deviations for patient safety critical processes in Category 5, Staff focus.

TABLE 19. Future Importance of Patient Safety Critical Processes, Category 5, Staff Focus

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
5.1. Work Systems	5.1.1.b. Organization and Management of Work: How healthcare delivery is organized to promote patient safety systems establishment and innovation.	3.8	3.9	0.387	0.224
	5.1.2.b. Staff Performance Management System: How the institution supports high clinical performance standards and alignment with national clinical performance measures and best case-management practices.	3.7	3.9	0.448	0.308
	5.1.3.b. Staff Performance Management System: How the institution identifies, deploys and monitors patient safety practices.	3.9	3.9	0.288	0.224
	5.1.4.b. Recruitment and Career Progression: How the institution identifies requirements and recognition for patient safety officers.	3.2	3.3	0.822	0.733
	5.1.5.b. Recruitment and Career Progression: How the institution includes safety compliance and attitudes in staff recruitment, selection and promotion.	3.3	3.3	0.671	0.470

TABLE 19. (cont.)

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
5.2. Staff Learning and Motivation	5.2.1.b. Staff Education, Training and Development: How the institution structures and promotes effective education and training of professionals in developing and improving patient safety systems.	3.5	3.6	0.499	0.489
	5.2.2.b. Motivation and Career Development: How the institution supports the role of the patient safety officer and the patient safety role of the whole workforce.	3.2	3.4	0.875	0.598
5.3. Staff Well-being and Satisfaction	5.3.1.b. Work Environment: How the institution maintains conductive environment in regard to patient safety.	3.7	3.8	0.727	0.366
	5.3.2.b. Staff Support and Satisfaction: How the institution determines staff satisfaction in implementation of patient safety systems.	3.4	3.4	0.589	0.605
	5.3.3.b. Staff Support and Satisfaction: How the institution includes medical staff attitudes and satisfaction in implementation of patient safety systems.	3.6	3.7	0.485	0.470

Six of the patient safety critical processes in category 5 received a rank of “very important” and four of the critical processes in this category were ranked as “important” for patient safety systems in the future. Three Delphi experts assigned ranks lower than 3 to the future importance of critical processes in this category (Figure 58). As was the case with the previous four framework categories, all patient safety critical processes in Category 5 were considered to have increased importance in the future compared to their importance in the present healthcare environment (Figure 59).

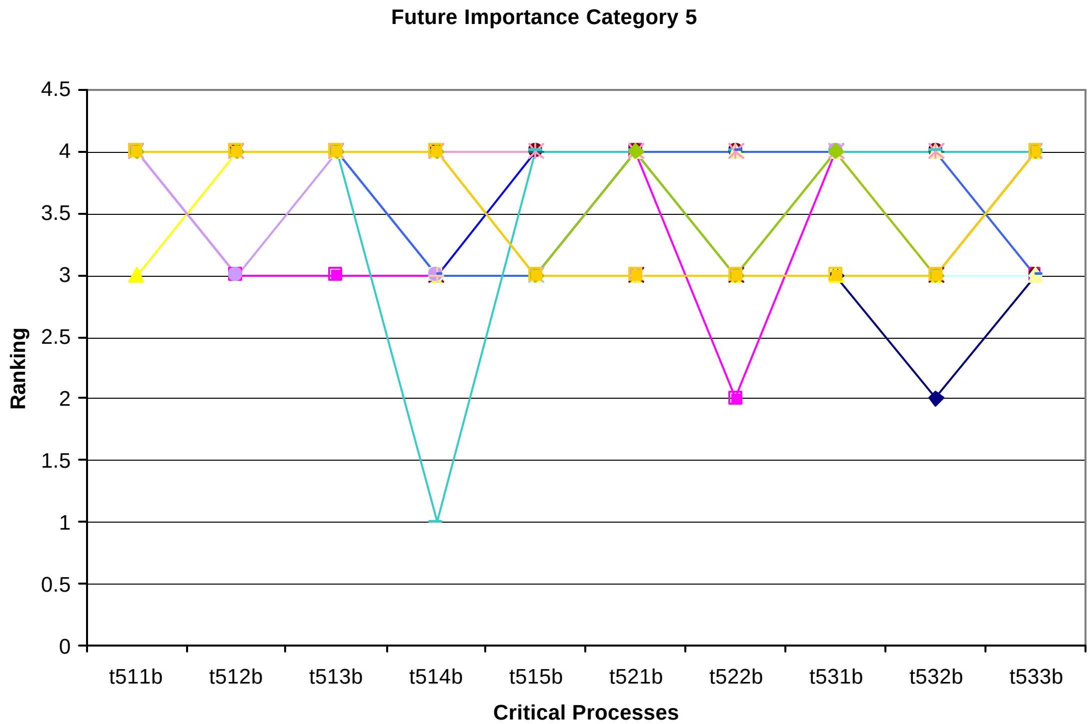

FIGURE 58. Distribution of the Individual Ranks of the Future Importance of Critical Processes, Category 5

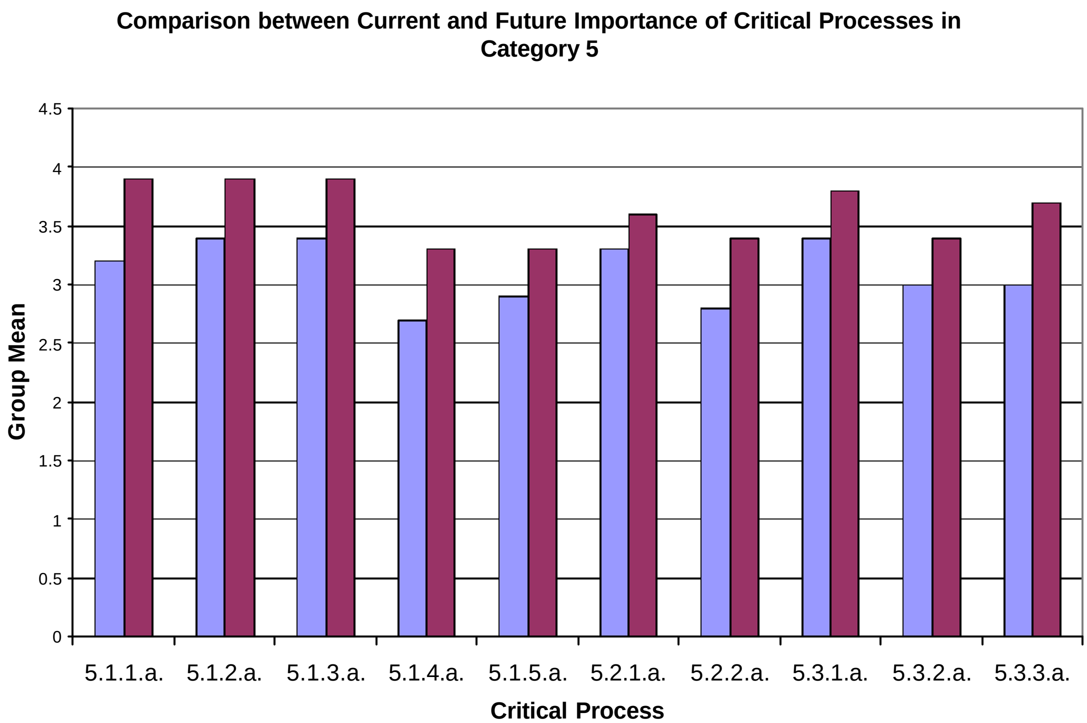

FIGURE 59. Comparison between the Current and Future Importance of Patient Safety Critical Processes in Category 5, Staff Focus (blue – current, maroon – future)

Future Importance of the Critical Processes in Category 6, Process Management

The Delphi panel assessed the future importance of six patient safety processes included in Category 6, Process management (Table 20). How the institution coordinates departmental and interdepartmental patient safety infrastructures to reduce variability and improve performance, how the institution ensures that patient safety requirements are met at the “sharp end” of the healthcare delivery system, how the institution determines patient safety process requirements and involves stakeholders in process design, and how the institution designs patient safety systems – these four critical processes were considered “very important” for patient safety systems in the future. Two processes related to ensuring campus security and including suppliers and partners in safety initiatives and process development, received ranks of “important” to patient safety systems in the future.

TABLE 20. Future Importance of Patient Safety Critical Processes, Category 6, Process Management

Item	Area to address: Critical process	Initial Mean	Consensus Mean	Initial SD	Consensus SD
6.1. Patient Safety System	6.1.1.b. Patient Safety System: How the institution determines patient safety process requirements and involves patients and other stakeholders in design and redesign of patient safety processes.	3.5	3.7	0.593	0.470
	6.1.2.b. Patient Safety System: How the institution designs patient safety systems.	3.7	3.8	0.421	0.410
	6.1.3.b. Patient Safety System: How the institution ensures that patient safety requirements are met at the “sharp end” of the healthcare delivery system.	3.8	3.8	0.387	0.366
	6.1.4.b. Campus security: How the institution ensures that patients feel secure arriving for and leaving appointments for care.	3.2	3.3	0.460	0.470
6.2. Support Processes	6.2.1.b. Patient Safety Support Processes: How the institution coordinates departmental and interdepartmental patient safety infrastructures to reduce variability in healthcare delivery and improve performance.	3.6	3.8	0.476	0.366
	6.2.2.b. Patient Safety Support Process: How the institution includes suppliers and partners in safety initiatives and process development	3.3	3.2	0.607	0.550

The individual panelist ranks for variables in category 6 are presented on Figure 60. Only one expert assigned a rank lower than 3 to one of the critical processes. The fact that the Delphi panelists rated the future importance of the patient safety critical processes in Category 6 higher than their current importance is consistent with observations in previously discussed patient safety framework categories (Figure 61).

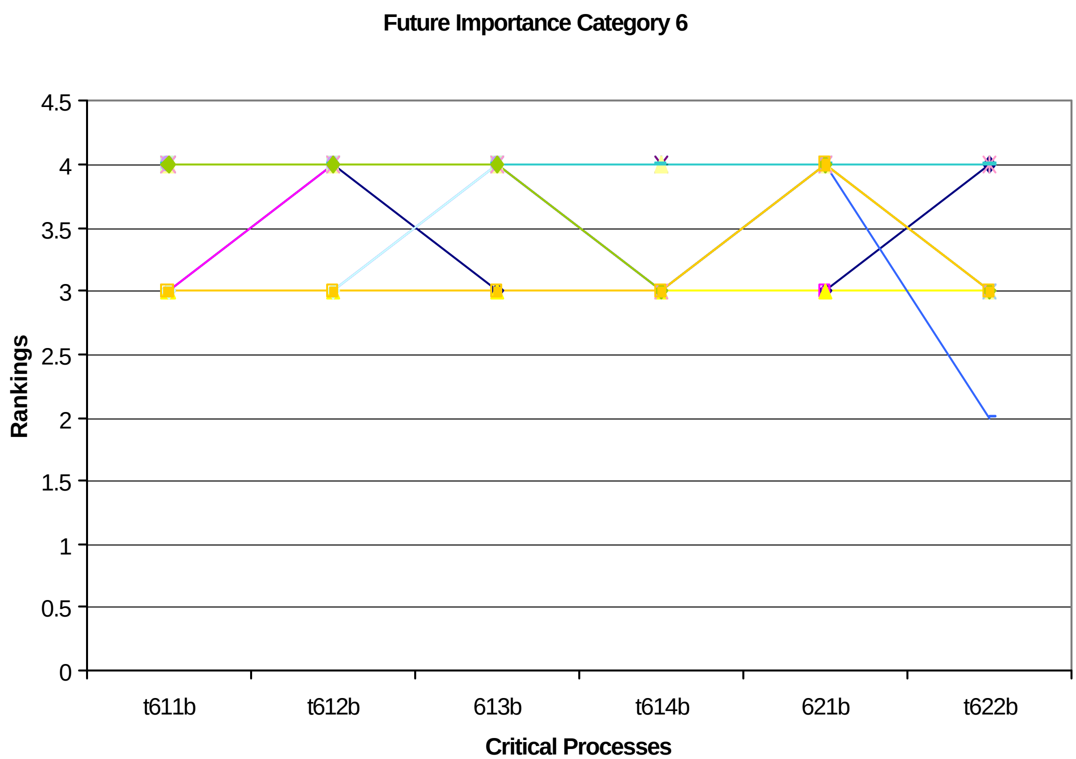

FIGURE 60. Distribution of the Individual Ranks of Future Importance of Critical Processes, Category 6

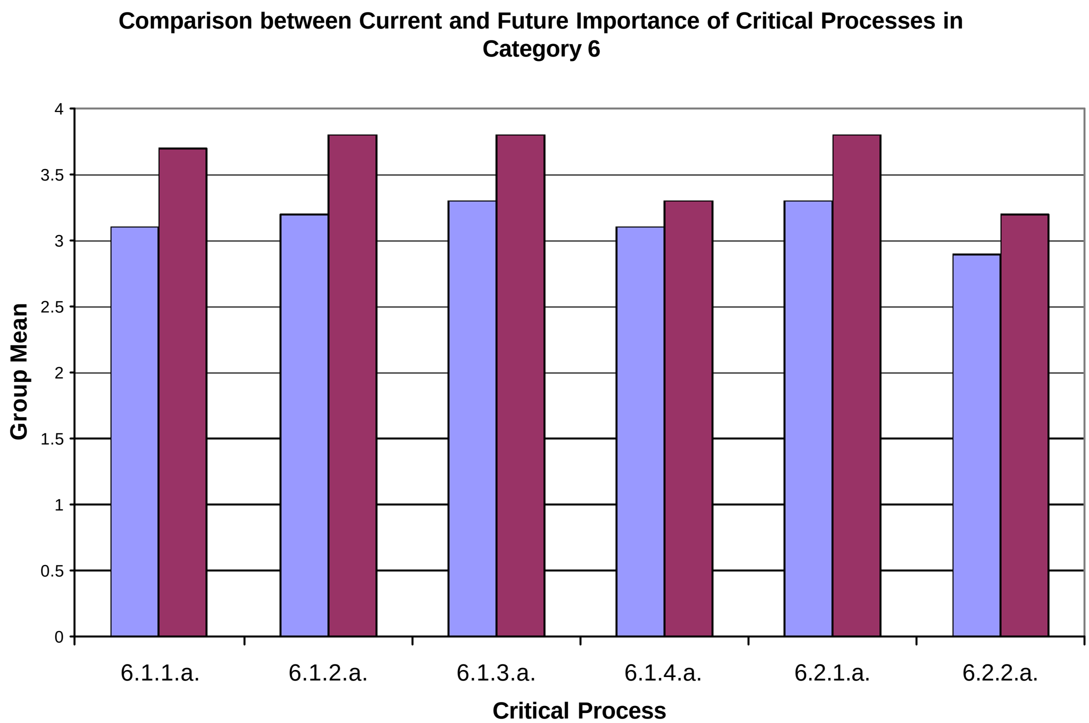

FIGURE 61. Comparison between the Current and Future Importance of Patient Safety Critical Processes in Category 6, Process Management (blue – current, maroon – future)

Future Importance of the Performance Measures in Category 7, Institutional Performance

The Delphi experts assessed the future importance of the 16 performance measures, whose current importance was discussed earlier in this chapter in sections *Research question one* and *Research question two.* All performance measures in Category 7 had increased group consensus rank means for their future importance as compared to their initial group rank mean at the beginning of the study. Furthermore, all performance measures in this category were ranked by the experts as "very important" to patient safety systems in the future. Moreover, two performance measures, related to non-punitive approach to adverse event and near miss reporting and ensuring that reporting systems are accessible, reliable and adequately functioning, received an unanimous rank of 4, Very important, without any variability in expert opinions (i.e. their standard deviation was zero). Additionally, the increase of consensus rank means for all patient safety performance measures in this category was accompanied by a decrease in the group standard deviation for 15 of the measures, and no change for one.

TABLE 21. Future Importance of Patient Safety Performance Measures for Category 7, Institutional Performance

Item 7.1. Patient Safety Institutional Performance Area to Address: Patient Safety Results: How the institution ensures patient safety				
Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
7.1.1.b. A 2-identifier system for patient identification is in place and is consistent in the continuity of healthcare throughout the institution.	3.5	3.8	0.662	0.410
7.1.2.b. Healthcare departmental and interdepartmental communications are accurate and reliable at different institutional levels.	3.7	3.8	0.421	0.366
7.1.3.b. The institution monitors the administration of high-alert medications.	3.7	3.9	0.619	0.308
7.1.4.b. Proper marking of surgery sites is established as a precaution to decrease incidents of wrong-side surgery (where applicable).	3.7	3.8	0.619	0.410
7.1.5.b. The institution ensures adequate professional staff preparation for proper and safe use of infusion pumps (where applicable).	3.5	3.7	0.656	0.470
7.1.6.b. The institution ensures adequate professional staff preparation for proper and safe use of clinical alarm systems (where applicable).	3.5	3.7	0.656	0.444
7.1.7.b. The institution ensures a non-punitive approach for reporting all adverse events and near misses.	3.6	4.0	0.572	0.000

TABLE 21. (cont.)

Item 7.1. Patient Safety Institutional Performance
Area to Address: Patient Safety Results: How the institution ensures patient safety

Performance Measure	Initial Mean	Consensus Mean	Initial SD	Consensus SD
7.1.8.b. The institution ensures proper staff is dedicated to support and conduct RCA, FMEA, and implement QI methodology in analyzing multidimensional patient safety practices at different institutional levels.	3.8	3.9	0.387	0.308
7.1.9.b. The institution ensures that an accessible, confidential and adequately functioning reporting system is in place for reporting all adverse events and near misses.	3.6	4.0	0.558	0.000
7.1.10.b. The institution ensures that a uniform, unambiguous and comprehensive nomenclature for reporting of adverse events and near misses is adopted throughout the healthcare institution.	3.4	3.5	0.589	0.510
7.1.11.b. The institution proactively works towards changing the traditional culture of "blame and shame."	3.7	3.8	0.540	0.366
7.1.12.b. The institution ensures safe healthcare delivery through utilization of modern technology.	3.6	3.7	0.470	0.470
7.1.13.b. The institution ensures that professional, accreditation and legal requirements in the area of patient safety are adequately addressed.	3.5	3.6	0.593	0.503
7.1.14.b. The institution ensures that national benchmarks in healthcare delivery (best practices, clinical performance measures, etc.) are used to decrease variability of healthcare delivery and improve patient safety outcomes.	3.7	3.9	0.518	0.308
7.1.15.b. The institution assures that appropriate leadership development and education in the area of patient safety is provided on an ongoing basis.	3.7	3.8	0.437	0.366
7.1.16.b. The institution assures that appropriate staff development and education in the area of patient safety is provided on an ongoing basis.	3.7	3.8	0.437	0.366

The consensus of the panelists regarding the future importance of the performance measures for category 7 is pictorially presented on Figure 62. All experts assigned ranks of 3 or 4 for the measures in this category and the mode for all variables was 4. The observed trend of expert expectations that the assessed variables will be more important for patient safety in the future than currently was also true for the performance measures in Category 7 (Figure 63).

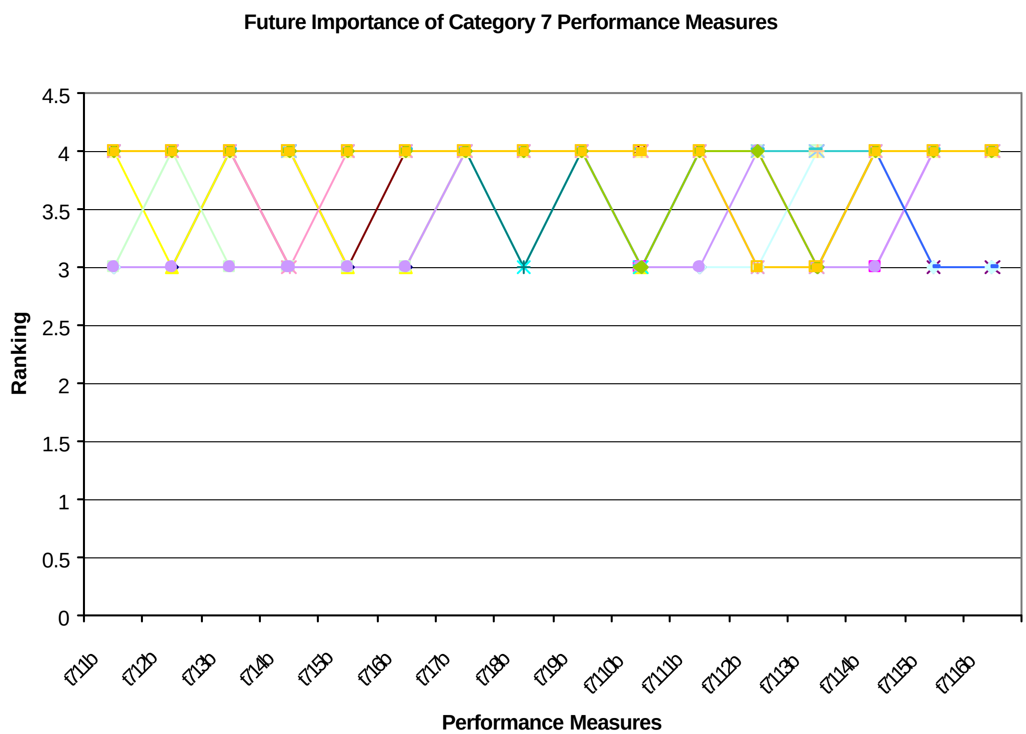

FIGURE 62. Distribution of the Individual Ranks of the Future Importance of Patient Safety Performance Measures, Category 7

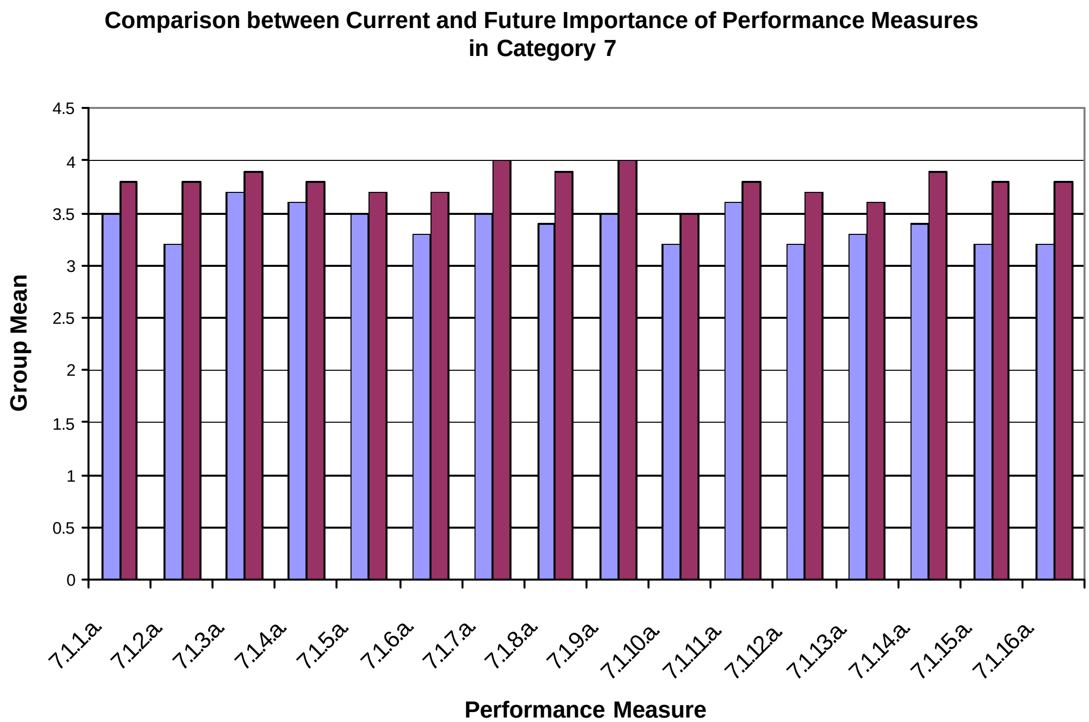

FIGURE 63. Comparison between the Current and Future Importance of Patient Safety Performance Measures in Category 7 (blue – current, maroon – future)

Non-representative Outlier Effects on the Study Results

Communication with one of the study participants, who had assigned the majority of ranks of "1" (unimportant), revealed that the expert had considered the feasibility of applying the variables to the present environment rather than their importance to implementation of patient safety systems in healthcare institutions. Although the outlier's results were correctly recorded, they may be considered unique because of the deviant interpretation of the ranking scale applied by that expert. Since the outlier's ranks were included in the calculation of the group means and standard deviations fed back to the Delphi panel in rounds two and three, it is important to identify and analyze the possible effects of the outlier ranks on the timing of consensus reaching as well as on the consensus variable group means and standard deviations. Table 22 presents study variable consensus group means and standard deviations with the outlier ranks included in the group results compared to the study results with exclusion of the outlier ranks.

TABLE 22. Comparison between Consensus Means and Standard Deviations with and without the Rankings of the Outlier Participant (for variable identification see tables 2 through 21)

Variable	Group Consensus with All Ranks Included		Group Consensus with Outlier Excluded	
	Mean	SD	Mean	SD
111a	3.7	0.571	3.7	0.418
111b	4.0	0.000	4.0	0.000
1111	3.6	0.745	3.7	0.418
1112	3.3	0.489	3.3	0.495
112a	3.7	0.571	3.7	0.418
112b	3.9	0.223	3.9	0.229
1121	3.6	0.745	3.7	0.418
1122	3.8	0.523	3.8	0.315
113a	3.5	0.760	3.6	0.495
113b	3.8	0.366	3.8	0.374

TABLE 22. (cont.)

Variable	Group Consensus with All Ranks Included		Group Consensus with Outlier Excluded	
	Mean	SD	Mean	SD
1131	3.8	0.366	3.8	0.315
121a	3.1	0.587	3.2	0.535
121b	3.6	0.502	3.5	0.507
1211	3.2	0.638	3.3	0.582
1212	3.7	0.571	3.7	0.418
122a	3.2	0.550	3.3	0.477
122b	3.6	0.502	3.5	0.507
1221	3.7	0.444	3.7	0.418
1222	3.3	0.587	3.4	0.507
123a	3.1	0.587	3.2	0.535
123b	3.7	0.470	3.6	0.477
1231	3.6	0.587	3.7	0.452
124a	3.1	0.447	3.1	0.374
124b	3.4	0.502	3.3	0.495
1241	2.9	0.394	3.0	0.333
211a	3.0	0.686	3.1	0.501
211b	3.5	0.510	3.5	0.512
2111	3.4	0.759	3.5	0.507
2112	3.4	0.680	3.4	0.611
2113	3.2	0.523	3.2	0.535
2114	3.1	0.447	3.1	0.374
212a	3.2	0.786	3.3	0.597
212b	3.7	0.470	3.6	0.477
2121	3.3	0.670	3.4	0.606
213a	3.1	0.366	3.1	0.374
213b	3.7	0.470	3.6	0.477
2131	3.1	0.489	3.1	0.501
221a	3.3	0.812	3.4	0.611
221b	3.8	0.366	3.8	0.374
2211	3.6	0.598	3.6	0.477
2212	3.4	0.759	3.5	0.507
222a	3.2	0.767	3.3	0.582
222b	3.8	0.366	3.8	0.374
2221	3.7	0.571	3.7	0.418
311a	2.7	0.716	2.8	0.602
311b	3.4	0.604	3.4	0.606
3111	2.9	0.759	3.0	0.621
3112	3.1	0.788	3.2	0.630
312a	2.6	0.495	2.6	0.485
312b	3.0	0.471	3.0	0.416
3121	2.7	0.418	2.8	0.383
321a	2.8	0.695	2.8	0.567
321b	3.3	0.656	3.2	0.653
3211	2.7	0.638	2.7	0.630
3212	3.4	0.604	3.5	0.512

TABLE 22. (cont.)

Variable	Group Consensus with All Ranks Included		Group Consensus with Outlier Excluded	
	Mean	SD	Mean	SD
322a	3.0	0.794	3.1	0.657
322b	3.5	0.510	3.5	0.512
3221	3.3	0.864	3.4	0.692
3222	3.2	0.833	3.3	0.671
411a	3.2	0.695	3.2	0.653
411b	3.7	0.444	3.7	0.452
4111	3.5	0.604	3.6	0.495
4112	3.5	0.604	3.6	0.495
412a	3.4	0.680	3.4	0.611
412b	4.0	0.000	4.0	0.000
4121	3.3	0.656	3.3	0.671
4122	3.3	0.670	3.3	0.683
4123	3.6	0.753	3.7	0.452
413a	3.3	0.489	3.3	0.495
413b	3.7	0.470	3.7	0.452
4131	3.7	0.470	3.7	0.452
421a	3.5	0.760	3.5	0.692
421b	4.0	0.000	4.0	0.000
4211	3.8	0.410	3.8	0.374
4212	3.6	0.587	3.7	0.452
422a	2.9	0.718	3.0	0.577
422b	3.3	0.489	3.3	0.477
4221	3.2	0.615	3.2	0.561
423a	3.4	0.604	3.5	0.512
423b	3.8	0.366	3.8	0.374
4231	3.9	0.307	3.9	0.229
511a	3.2	0.786	3.3	0.597
511b	3.9	0.223	3.9	0.229
5111	3.6	0.587	3.7	0.452
512a	3.4	0.502	3.4	0.507
512b	3.9	0.307	3.8	0.315
5121	3.8	0.489	3.9	0.229
513a	3.4	0.604	3.5	0.512
513b	3.9	0.223	3.9	0.229
5131	3.8	0.489	3.9	0.229
514a	2.7	0.801	2.7	0.713
514b	3.3	0.732	3.2	0.733
5141	3.2	0.894	3.3	0.749
515a	2.9	0.552	2.9	0.524
515b	3.3	0.470	3.2	0.452
5151	3.2	0.523	3.2	0.452

TABLE 22. (cont.)

Variable	Group Consensus with All Ranks Included		Group Consensus with Outlier Excluded	
	Mean	SD	Mean	SD
521a	3.3	0.801	3.4	0.606
521b	3.6	0.489	3.6	0.495
5211	3.4	0.753	3.5	0.512
522a	2.8	0.745	2.9	0.621
522b	3.4	0.598	3.3	0.597
5221	3.3	0.587	3.4	0.507
531a	3.4	0.686	3.5	0.611
531b	3.8	0.366	3.8	0.374
5311	3.8	0.695	3.9	0.229
532a	3.0	0.725	3.1	0.567
532b	3.4	0.604	3.4	0.606
5321	3.4	0.598	3.4	0.512
5322	3.1	0.501	3.2	0.427
533a	3.0	0.394	3.0	0.404
533b	3.7	0.470	3.6	0.477
5331	3.7	0.470	3.7	0.452
611a	3.1	0.718	3.2	0.535
611b	3.7	0.470	3.6	0.477
6111	3.4	0.604	3.6	0.512
612a	3.2	0.786	3.3	0.597
612b	3.8	0.410	3.7	0.418
6121	3.8	0.489	3.9	0.229
613a	3.3	0.670	3.4	0.606
613b	3.8	0.366	3.8	0.374
6131	3.8	0.489	3.9	0.229
614a	3.1	0.447	3.1	0.374
614b	3.3	0.470	3.2	0.452
6141	3.3	0.470	3.3	0.477
621a	3.3	0.571	3.3	0.495
621b	3.8	0.366	3.8	0.374
6211	3.6	0.753	3.7	0.452
622a	2.9	0.510	3.0	0.471
622b	3.2	0.550	3.2	0.535
6221	3.1	0.489	3.1	0.501

TABLE 22. (cont.)

Variable	Group Consensus with All Ranks Included		Group Consensus with Outlier Excluded	
	Mean	SD	Mean	SD
711a	3.5	0.606	3.5	0.507
711b	3.8	0.410	3.7	0.418
712a	3.2	0.716	3.3	0.671
712b	3.8	0.366	3.8	0.374
713a	3.7	0.444	3.7	0.418
713b	3.9	0.307	3.8	0.315
714a	3.6	0.489	3.6	0.477
714b	3.8	0.410	3.7	0.418
715a	3.5	0.512	3.5	0.512
715b	3.7	0.470	3.6	0.477
716a	3.3	0.587	3.2	0.507
716b	3.7	0.444	3.7	0.452
717a	3.5	0.760	3.6	0.495
717b	4.0	0.000	4.0	0.000
718a	3.4	0.680	3.4	0.692
718b	3.9	0.307	3.8	0.315
719a	3.5	0.606	3.5	0.507
719b	4.0	0.000	4.0	0.000
7110a	3.2	0.615	3.2	0.561
7110b	3.5	0.510	3.5	0.512
7111a	3.6	0.489	3.6	0.495
7111b	3.8	0.366	3.8	0.374
7112a	3.2	0.695	3.2	0.653
7112b	3.7	0.470	3.6	0.477
7113a	3.3	0.571	3.3	0.582
7113b	3.6	0.502	3.5	0.507
7114a	3.4	0.686	3.5	0.611
7114b	3.9	0.307	3.8	0.315
7115a	3.2	0.523	3.2	0.535
7115b	3.8	0.366	3.8	0.374
7116a	3.2	0.523	3.2	0.535
7116b	3.8	0.366	3.8	0.374

The comparison between the study results with and without the outlier ranks revealed the following effects of the non-representative outlier ranks:

1. Effects on the group consensus means:

- Thirty-four percent of the group consensus means were higher when the outlier ranks were excluded. Fifty-five variable ranks went up with 0.1 and one variable rank increased with 0.2.
- For five percent of the variables (four critical processes and five performance measures), the minimal change in the group ranks with exclusion of the outlier responses was sufficient to change their rank from “important” to “very important.” For six of the nine variables that changed their importance rank, the outlier participant did not assign a rank of “1.” Thus, the outlier participant’s decision to assign ranks of “1” to critical processes and performance measures that were deemed not to be feasible under the present healthcare environment, did not play a role for the change. Furthermore, all critical processes and performance measures that changed their importance rank were assessing the *present* importance of those processes and measures and not their *future* importance.
- Approximately fifteen percent of the group consensus means decreased by 0.1. This decrease in the consensus group rank did not lead to change in the importance rank for any of the variables. Twenty-three of the variables with decreased importance rank related to the variable importance in the *future* and only one of the variables related to the variable importance in the *present*.

2. Effects on the variable standard deviations:

- With exclusion of the non-representative outlier ranks, the group consensus standard deviation remained the same for six (3.7%) of the variables. Five of the six variables without change in their standard deviation were variables with consensus means of 4.0 and standard deviation of 0.0. The sixth variable with no change in its group consensus standard deviation was related to the current importance of assuring that appropriate leadership development and education in the area of patient safety is provided on an ongoing basis (performance measure 7.1.15.a).

- Thirty-four percent of the variables slightly increased their standard deviation, i.e. there was more disagreement present in the group after excluding the outlier participant. However, all variables with increased standard deviation had an increase of less than 0.01.
- Over sixty-one percent of the study variables showed decrease in their standard deviation, i.e. a tighter consensus. Approximately seven percent of these variables (ten performance measures and one critical process assessed in the present) showed a drastic decrease in their standard deviation. However, a comparison of the changes in the standard deviation for the variables with and without the outlier ranks between study rounds showed that this change did not affect the timing of reaching consensus.

3. Overall effects on the study results:

- The analysis of the means and standard deviations between rounds with and without the unique outlier responses revealed that the outlier responses *did not* affect the timing of consensus reaching;
- The exclusion of the outlier responses changed the rank for the current importance of nine variables (5% of the study variables) from “important” to “very important.”
- The exclusion of the outlier responses did not change the priority of the importance of the patient safety framework categories in the present and in the future, as discussed in Chapter V.

Importantly, the participant that assigned ranks of “1” based on the great difficulty of applying specific patient safety processes and measures in the present healthcare environment recognized their importance by assigning ranks of 4, Very important, to the importance of those processes in the future. Thus, for a number of critical processes that participant had assigned “1” to the current importance and “4” to the future importance of the respective patient safety critical process. As deviant from the ranking instructions this expert’s behavior may have been, it raised the issue about two different ways of administrative thinking, decision-making and approaching resource allocation. There are two different approaches to the target of achieving patient safety in healthcare institutions. One approach is to target what *should* be achieved as suggested by evidence-based medicine or what *must* be achieved as required by regulatory agencies. Another approach is to target what *could* be achieved given the present healthcare environment and resource pool. Thus, the success of designing, implementing, maintaining and improving patient safety systems is directly related to the priority assigned by senior healthcare administrators and policy-makers to achieving institution’s patient safety goals and improving the quality of healthcare services.

As discussed above, the effects of the non-representative outlier responses on the overall study results were minimal. The inclusion of the outlier did not change the timing of reaching consensus and affected the importance ranking of only five percent of the study variables. Therefore, the study model was robust enough to allow discussion of the study results in Chapter IV based on the original raw dataset including the outlier responses.

Barriers to Implementation of Patient Safety Systems in Healthcare Institutions

At the end of the first survey, an open-ended question explored the perceptions of the Delphi experts regarding which are the most important barriers to implementation of patient safety systems in healthcare institutions. The researcher's dissertation committee, while discussing the dissertation proposal, suggested this question to be added to the first round questionnaire. The dissertation committee felt that the responses to this question might shed additional light on the importance of the identified critical processes and performance measures. Thus, the open question regarding the most important barriers to implementation of patient safety systems was added to the questionnaire.

The first iteration of the survey 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. All suggested barriers were grouped thematically and 29 different groups were formed. There was no prioritization in the sequence of presentation of the barrier groups neither in the barrier group differentiation process, nor in further presentation of the barrier groups to the Delphi panel.

The Delphi panelists were asked to rank the importance of each barrier group from 1 to 4, where:

- Rank of 4 represented a "very important" barrier, i.e. patient safety systems cannot be implemented unless this barrier is eliminated or modified;
- Rank of 3 represented an "important" barrier, i.e. 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, i.e. 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, i.e. patient safety systems can be implemented in the presence of this barrier.

Furthermore, based on their perception whether a given barrier was related to the individual healthcare institutional context (i.e. to a "local issue") or was common to the national healthcare system (i.e. related to a "system issue"), the experts were asked to classify each barrier as "local" or "system" in origin. The results of expert opinions on how important is the elimination of each barrier for successful implementation of patient safety systems in healthcare institutions, as well as their perceptions whether a given barrier is systematic or locally nested, are presented on Table 23 below. The overwhelming majority of the barriers to implementation of patient safety systems – 26 out of a total of 29 barriers – were perceived as systematic, and only three of the barriers were classified as "local." These local barriers were related to healthcare professionals' fear that a non-punitive reporting system may miss an individual's pattern of errors, lack of positive feedback after reporting of errors with no evident changes in the system, and lack of operational planning for and deployment of patient safety systems.

The Delphi experts perceived four of the barriers as "not very important," i.e. in the presence of these barriers patient safety systems could be implemented, although their functioning might be limited. These four "not very important" barriers were:

- Difficulties in creating patient safety peer review for healthcare professionals;
- Difficulties in finding a patient safety approach that smoothly integrates into existing systems without creating added costs and complexity;
- Over expectations of potential and capability of technology to solve healthcare safety problems;
- Fear that a non-punitive system will miss an individual's pattern of errors.

TABLE 23. Barriers to Implementation of Patient Safety Systems in Healthcare Institutions

Barrier group	Mean	SD	Origin: System/local
1. Competing priorities for scarce resources in a system where patient safety is not considered a top priority.	3.6	0.502	System
2. Lack of resources: inadequate staffing and work overloads.	3.4	0.502	System
3. Availability and cost of patient safety technology.	3.3	0.587	System
4. Resistance to change (the assumption that providers are already providing safe care).	3.2	0.444	System
5. Culture of blame (current healthcare culture is punitive in nature).	3.2	0.523	System
6. Lack of senior leadership understanding and involvement with patient safety issues.	3.2	0.523	System
7. Culture of healthcare workforce perceptions, attitudes and behaviors of error "cover up."	3.0	0.510	System
8. Reliance on measurement systems that depend on voluntary reporting of errors.	2.9	0.825	System
9. Inadequate education of staff, professionals, management and leadership in regard to patient safety.	2.9	0.394	System
10. Current legal system: fear of litigation.	2.9	0.510	System
11. Complexity of healthcare systems.	2.9	0.686	System
12. Insufficient data about institutional performance and benchmarking.	2.9	0.510	System
13. Communication: lack of transparency and openness in regard to patient safety issues.	2.9	0.686	System
14. Reliance on human capabilities for ensuring safety.	2.9	0.686	System
15. Lack of positive feedback: no change occurs after reporting.	2.9	0.640	Local
16. Culture of physicians considered the ultimate authority.	2.8	0.745	System
17. Research-driven best healthcare practices are not adopted.	2.8	0.695	System
18. Lack of operational planning and deployment skills regarding implementation of patient safety systems.	2.8	0.695	Local
19. Culture of quality "inspection" (regulatory oversight is sufficient, no further effort is needed).	2.8	0.695	System
20. Disbelief, denial, and lack of knowledge about the ubiquitous nature of errors.	2.7	0.638	System
21. Cumbersome, complicated and time-consuming error reporting processes.	2.7	0.656	System
22. Cumbersome, complicated and time-consuming healthcare safety processes.	2.6	0.598	System

TABLE 23. (cont).

Barrier group	Mean	SD	Origin: System/local
23. Bureaucracy.	2.5	0.686	System
24. Culture of hesitancy of healthcare organizations to allow consumers to participate in decision-making.	2.5	0.686	System
25. Need of standardization of patient safety terminology, technology and approaches.	2.5	0.827	System
26. It is difficult to find an approach that smoothly integrates into existing systems without creating added costs and complexity.	2.4	0.825	System
27. Over expectations of potential and capability of technology to solve healthcare safety problems.	2.3	0.670	System
28. Difficulties in creating patient safety peer review for healthcare professionals.	2.2	0.786	System
29. Fear that a non-punitive system will miss an individual's pattern of errors.	2.0	0.561	Local

Twenty-four of the barriers were classified as "important," i.e. in their presence patient safety systems may begin but could not be continued unless the barrier is eliminated or modified. Only one barrier was classified as "very important," i.e. patient safety systems cannot be implemented unless this barrier is modified or eliminated. Seven of the barriers received a rank of 3.0 or higher. These "top seven" barriers were as follows (presented in descending order of their group consensus ranks):

1. Competing priorities for scarce resources in a system where patient safety is not considered a top priority;
2. Lack of resources: inadequate staffing and work overloads;
3. Availability and cost of patient safety technology;
4. Resistance to change (the assumption that providers are already providing safe care);

5. Culture of blame (current healthcare culture is punitive in nature);
6. Lack of senior leadership understanding of and involvement with patient safety issues;
7. Culture of healthcare workforce perceptions, attitudes and behaviors of error "cover up."

Importantly, all barriers included in the "top seven" list relate to critical processes and performance measures identified as "important" or "very important" for patient safety systems in the present and in the future. For example, the first patient safety critical process in Category 1, Leadership, asked how senior leaders communicate the priority of patient safety to all stakeholders. The first performance measure to this critical process looked into the institutional patient safety communication systems and whether the information feedback from those systems was used for creating a culture of safety. Thus, this critical process and its first performance measure are related to two of the "top seven" patient safety barriers: (a) lack of senior leadership and understanding of and involvement with patient safety issues, and (b) the existing culture nurtures the assumption that healthcare providers are already providing safe healthcare. Therefore, the identified "top seven" barriers to implementation of patient safety systems carry a great potential of enhancing the implementation of safety healthcare systems. Importantly, all "top seven" barriers are systematic in nature. Thus, the efforts of individual institutions will be less successful than a broader approach across the U.S. healthcare system.

"Non-punitive" versus "Just" Reporting Systems

During the first and second survey iterations, several Delphi panelists raised the question whether completely non-punitive reporting systems may allow reckless or malicious behavior of healthcare providers to remain unaccountable. One of the panelists suggested to replace the term "non-punitive culture" with "just culture," i.e. providing for learning from mistakes and at the same time recognizing the need for accountability and disciplinary or enforcement actions as discussed in *Patient safety and the "just culture": A primer for health care executives* (Marx, 2001). An open-ended question was included in the third survey round asking the panelists about their opinion whether the terminology of "non-punitive" medical error reporting in the patient safety framework should be changed to "just" reporting. Sixty-five percent of the Delphi experts recommended the use of the term "non-punitive" reporting culture to be continued based on its important message that healthcare professionals should not feel threatened when reporting medical errors or near misses.

Summary

The consensus results from the third, final round of this study indicated that virtually all identified patient safety critical processes and performance measures within the seven categories of the Malcolm Baldrige framework were considered by this panel of experts important or very important for implementation of patient safety systems in healthcare institutions. The patient safety critical processes and performance measures in five of the categories of the framework (Leadership, Strategic planning, Measurement, analysis and knowledge management, Staff focus, and Process management) had consensus group rank means of 3 or higher. One category (Category 3, Focus on patients, other customers and markets) was a clear exception from the overall consensus results of the survey. The patient safety critical processes and performance measures for this category, although generally considered "important," received group rank means of 3 or lower. Patient safety performance measures for Category 7, Institutional performance, were well accepted by the Delphi panel and ranked as "important" or "very important." The Delphi panel forecasted that all critical processes will have increased importance in the future.

The Delphi panel also identified 29 groups of barriers to implementation of patient safety systems in healthcare institutions. The experts in this study ranked seven of the barriers as ”very important” or “important” with a consensus group rank mean of 3 or higher. All “top seven” barriers were considered to have system origins.

A series of conclusions for each of the three research questions have been reached based on the outcomes of this study. The following chapter summarizes the results of the data analysis and the conclusions made from the study results. A patient safety framework, based on the seven Malcolm Baldrige categories for performance excellence in healthcare and the consensus results from this study, is presented. Three levels of practical application of the patient safety framework and further implications of this study are discussed.

CHAPTER V

SUMMARY OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

Introduction

Jones and Hunter (1995) emphasized that the output from consensus approaches, such as Delphi, is not an end in itself; rather, dissemination and implementation of the study findings are the ultimate aims of consensus activities and are intended to guide health policy decision-making, clinical practice and research. Although measurement is essential to patient safety improvement efforts, concerns have been raised for using quality measurement as a basis for rewarding physicians and healthcare institutions because measurement may lead to reallocation of both organizational resources and physician time towards activities that are measured; thus, the measured aspects would become important and other areas, equally important for the overall quality and safety of healthcare may be ignored (Casalino, 1999).

Voices have been raised calling for a stronger leadership role of the U.S. Government in support of the quality improvement efforts and patient safety accountability throughout the healthcare system, coordination and institutionalization of the healthcare quality priorities, implementation of clinical performance measures and development of standards of care. Moreover, there have been strong recommendations for establishment of performance-based payment policies, removal of major financial barriers to quality improvement, and investments in quality and safety infrastructure, research and training (Schoenbaum, Audet, & Davis, 2003).

Summary of Study Methodology and Procedures

In this study, the Delphi method was used to gather a consensus of healthcare quality improvement and patient safety experts. The study included two major phases:

(1). Creation of the original survey instrument, and

(2). Conducting the survey with the identified experts.

The first phase utilized three quality improvement and patient safety experts to validate the questionnaire instrument. The second phase was completed by a panel of 23 experts and was conducted in three iterations.

The original instrument consisted of 31 critical processes and 58 performance measures structured in the framework of the Malcolm Baldrige National Quality Award Healthcare Criteria for Performance Excellence. Each performance measure was linked to a critical process, and each critical process had one or more associated performance measures. The critical processes and performance measures included in the initial instrument were identified through an extensive literature review of professional publications on patient safety and healthcare quality improvement. The current importance of all patient safety critical processes and performance measures included in the first round instrument as well as the future importance of 30 critical processes and 14 performance measures was assessed by the Delphi experts during the first survey iteration. An additional study question was designed as an open-ended request for the panel member's perceptions regarding the most important barriers to implementation of patient safety systems in healthcare institutions. The Delphi experts were asked to rate the critical processes and performance measures on a Likert-type scale indicating a degree of importance from very important to unimportant. Panelists were also asked to add any critical process or performance measure they believed should be included in the questionnaire and were given the opportunity to edit all processes and measures as they deemed appropriate.

The second round questionnaire included all original critical processes and performance measures along with additional critical processes and performance measures suggested by panelists in the first round. Three critical processes and six performance measures were corrected and eight new critical processes and 12 performance measures were added. For each critical process and performance measure the group rank mean from the first round was included, along with the individual participant rank for each variable. Each expert was then asked to review the group scores and re-evaluate their individual original responses. Changes of ranks were permitted in the process of building consensus. In the second questionnaire, the identified 29 barriers to implementation of patient safety systems in healthcare institutions were also included. The Delphi experts were asked to rank the importance of each barrier based on a 4-point Likert-type scale similar to the Likert scale used for evaluation of the importance of the critical processes and performance measures, as well as to define whether each barrier was local or systematic in origin (i.e. whether a barrier should be dealt with at a local, or at a broader, system level).

All critical processes and performance measures about which consensus was not reached during the second survey round were included in the third survey iteration. All critical processes and performance measures suggested by the study participants during the first survey iteration were also included in the third questionnaire. The third questionnaire presented to the study experts the initial group means and perceptions about the importance and origin of the barriers to implementation of patient safety systems in healthcare institutions. The experts were given the opportunity to review and change as deemed appropriate their initial ranks and perceptions. At the conclusion of the third survey iteration, consensus was reached about the current and future importance of patient safety critical processes and performance measures as well as about the importance and the nature (system or local) of the barriers to implementation of patient safety systems in healthcare institutions.

Summary of Findings

The following findings were discovered in review and analysis of the study results:

1. Key findings regarding the current importance of identified patient safety critical processes:
    - All identified patient safety critical processes were perceived to be at least “important” to patient safety systems in healthcare institutions. Four of the

critical processes received a rank of “very important” for implementation of patient safety systems in healthcare institutions in the present.

- Three of the critical processes considered to be “very important” are within Category 1, Leadership, Item 1.1, Institutional Leadership. Healthcare senior leadership direction, institutional governance and setting of institutional goals for performance review are milestones for implementation of patient safety systems in healthcare institutions.
- The fourth “very important” patient safety critical process identified by the Delphi panel is related to securing data and information availability, and in particular, ensuring that healthcare information technology is reliable, secure and user-friendly.
- All critical processes that facilitate the leadership system and the strategic planning process in healthcare institutions were regarded as “important” or “very important” in a substantial manner (the group rank means for all processes in these two categories were 3.0 or higher).
- The critical processes for three of the framework categories (Category 4 – Measurement, analysis and knowledge management, Category 5 – Staff focus, and Category 6 – Process management), although considered “important,” received mixed responses from study participants as to processes’ relative importance. One of the six critical processes in both Category 4 and Category 6 had a consensus group rank mean of 2.9, and three of the 10 processes in Category 5 received group rank means between 2.7 and 2.9.
- Three of the four critical processes in Category 3, Focus on patients, other customers and markets were considered “important” with group rank means between 2.6 and 2.8. The critical processes in this framework category received the lowest group rank mean as a whole.

2. Key findings regarding the current importance of identified patient safety performance measures:

    - All performance measures were considered either “very important” or “important” for implementation of patient safety systems in healthcare institutions.
    - Thirty-one (31) of the performance measures in the patient safety framework received a rank of “very important” to patient safety systems in the present. These 31 “very important” performance measures were distributed throughout the framework categories with one exception: Category 3.
    - Forty-three percent (43%) of the performance measures in Category 3, Focus on patients, other customers and markets had a consensus rank mean below 3.0. Although within the range defining the performance measures as “important,” combined with the results about the current importance of the critical processes in this category, it is obvious that healthcare experts have not adopted a customer’s market focus.
    - The results for performance measures in Category 3 are in sync with the traditional service model in healthcare. Healthcare professionals have been accustomed to a service model where the customer has been narrowly defined to include patients and their families, or even more narrowly defined as including only the patients. In this old service model the customers have been more “recipients’ of care than active participants in the process of care. In the new marketplace such a service model is not only unsuitable but also inappropriate if the healthcare institutions want to re-focus on striving for quality and safety of care and providing patient-centered services.
    - As reflected by the group rank means for performance measures in Category 7, Institutional performance, performance measures based on accreditation

standards are considered important for implementation of patient safety systems in healthcare institutions.

3. Key findings regarding the future importance of identified patient safety critical processes in the patient safety framework:

   - The Delphi experts expected that all critical processes identified in the patient safety framework will have higher importance in the future than in the present. One hundred percent (100%) of the patient safety critical processes had increased consensus group rank mean in comparison with the group rank means for their current importance. Thus, patient safety critical processes within a patient safety system framework are perceived as important for healthcare institutions in the future.
   - Three of the patient safety critical processes received a perfect score of 4.0 regarding their future importance to implementation of patient safety systems in the future. These processes were:
     - Critical process 1.1.1, How senior leaders communicate the priority of patient safety to all stakeholders;
     - Critical process 4.1.2, How the institution collects, tracks and analyzes patient safety data;
     - Critical process 4.2.1, How the institution ensures that its clinical information technology is reliable, secure and user-friendly.
   - Seventy-two percent (72%) of the identified patient safety critical processes were considered “very important” to future patient safety systems implementation. The rest 28% were ranked as “important” to patient safety systems in the future. The “important” critical processes received a rank of 3.0 or above (i.e. none of the critical processes’ future importance rank was between 2.5 and 2.9).

- Eighty-eight percent (88%) of the critical processes in Category 1, Leadership, were perceived to be "very important" to implementation of patient safety systems in the future. The critical processes in both category items, Institutional leadership and Social responsibility, will play a significant role in establishing patient safety systems in healthcare institutions in the future.
- All critical processes in Category 2, Strategic planning, were considered "very important" for future patient safety systems by the experts in the Delphi panel. Patient safety strategy development and deployment will lead the process of implementation of patient safety systems in the future.
- Both critical processes regarding patient, other customer and market knowledge in Category 3 were considered to be "important" for future patient safety systems. While customer relationship building was also perceived to be an important area to address, the only process that was considered "very important" in Category 3 was related to obtaining information and feedback from patients on patient safety issues in order to improve healthcare delivery.
- Eighty-three percent (83%) of the identified critical processes in Category 4 were considered "very important" for future patient safety systems and two of the processes received a perfect score of 4.0. This study results are in support of the findings identified in the literature review that more aggressive use of quality measurement, data analysis and knowledge management is needed in healthcare settings.
- The results for the future importance of the critical processes within the three items in Category 5 (Work systems, Staff learning and motivation, and Staff well-being and satisfaction) were mixed. Sixty percent (60%) of the processes in this category were identified as "very important" and 40% were considered "important" for implementation of patient safety systems in the future. The

Delphi experts considered “very important” processes related to patient safety systems establishment and improvement, alignment with national performance standards, patient safety education and providing institutional environment conducive of patient safety.

- Sixty-seven percent (67%) of the critical processes in Category 6, Process management, were considered to be of high importance for future patient safety systems. The way healthcare institutions design and determine process requirements for their patient safety systems, along with how the healthcare institutions enhance patient safety at the “sharp end” of their healthcare delivery systems were considered by the Delphi panelists as “very important” for future patient safety systems in healthcare. Additionally, building departmental patient safety infrastructure and interdepartmental coordination of patient safety activities will be crucial for introducing and improving patient safety.

4. Key findings about the future importance of patient safety performance measures included in Category 7, Institutional performance:
    - All performance measures included in Category 7 received a rank of “very important” regarding their role in patient safety systems in the future.
    - Two measures received a perfect score of 4.0. These two performance measures related to ensuring a non-punitive approach for reporting all adverse events and near misses, and ensuring that an accessible, confidential and adequately functioning reporting system is in place for reporting all adverse events and near misses. The importance of the non-punitive reporting culture was additionally emphasized by the Delphi panelists in the third study round when they answered the question whether the reporting approach should be “non-punitive” or “just” (see Chapter IV, Analysis of data, section Barriers to

implementation of patient safety systems in healthcare institutions, sub-section "Non-punitive" versus "just" reporting systems).

- Patient safety performance measures in category 7 reflected requirements of national healthcare accreditation organizations. Healthcare accreditation requirements regarding implementation of patient safety systems and measures enhance and promote the necessary understanding of healthcare administrators and professionals about the importance of quality results in healthcare delivery. Being a part of the quality measurement in healthcare, patient safety measures are widely recognized by healthcare institutions as areas that should be adequately addressed.

Criteria for Inclusion of Critical Processes and Performance Measures in the Final Patient Safety Framework

The purpose of this dissertation study was to identify critical processes and performance measures of quality that could serve as a framework for healthcare institutions implementing continuous quality improvement programs and patient safety systems. This study created a patient safety framework for institution-wide systems approach to introducing, maintaining and improving healthcare patient safety systems. The criteria for inclusion of critical processes and performance measures in the patient safety framework were based on the 4-point Likert scale for ranking of the importance of the items in the Delphi surveys:

- Critical processes and performance measures with a consensus group mean equal to or lower than 1.4 were considered "unimportant" for patient safety systems in healthcare institutions and were not included in the final patient safety framework. None of the critical processes or performance measures in this study fell in this category.

- Critical processes and performance measures with a consensus group mean between 1.5 and 2.4 were considered “not very important” for patient safety systems in healthcare institutions and were not included in the final patient safety framework. None of the critical processes or performance measures in this study fell in this category.
- Critical processes and performance measures with a consensus group mean between 2.5 and 3.4 were considered “important” for patient safety systems in healthcare institutions and were included in the final patient safety framework.
- Critical processes and performance measures with a consensus group mean equal to or higher than 3.5 were considered “very important” for patient safety systems in healthcare institutions and were included in the final patient safety framework.

The patient safety framework that resulted from this study is presented on Table 24. Each Malcolm Baldrige category is presented with its respective items, areas to address, critical processes and performance measures.

Three Levels of Patient Safety Framework

The researcher continued contacts and consultations with the three members of the Instrument Review Panel throughout the study. They were an invaluable source of support during the survey iterations. At the end of the study, the representative from the Malcolm Baldrige National Quality Award office raised concerns that a detailed framework may be difficult to implement, especially by healthcare organizations “beginners” in the area of quality improvement and patient safety, and recommended that multi-level framework be considered. Thus, a three-level patient safety framework was designed to fit three levels of familiarity of healthcare administrators with patient safety and quality improvement. Starting at “beginners” level with the most important critical processes and performance measures for each of the seven Malcolm Baldrige categories, every higher level adds more critical processes and performance measures, following a hierarchy model based on the consensus group rank means of the current importance of the study variables. The criteria for inclusion of critical processes and performance measures in the different levels of the patient safety framework were as follows:

- Level One, *Beginners.* The critical processes and performance measures included in this framework level are intended to help healthcare institutions to start their patient safety programs. The processes and measures at this level reflect basic design requirements for patient safety systems at institutional level. For each item in each of the seven categories, only one patient safety critical process with the highest group rank mean for its current importance and one of its related performance measures with the highest group rank mean were included in the beginner's patient safety framework. Where two or more critical processes or related performance measures had equal group consensus rank means, the process/measure with the lower standard deviation was selected. In cases where the standard deviations of such processes/measures were equal, then the process/measure with the higher future importance rank mean was selected. The patient safety framework for "beginners" is presented on Table 25.
- Level Two, *Intermediate.* The critical processes and performance measures included in this framework level are intended to help healthcare administrators in institutions that have already started patient safety activities and need support in deciding which would be the best next step. The intermediate level framework builds upon the basic "beginners" level and adds essential processes for improvement of existing patient safety systems. To build this framework, to the critical processes in Level One were added all critical processes with a group rank mean equal to or higher than 3.5 (i.e. "very important") and their respective performance measures. The intermediate

level of the patient safety framework with its respective critical processes and performance measures is presented on Table 26.

- Level Three, *Advanced*. This is the full patient safety framework as presented on Table 24. This framework includes all critical processes and performance measures identified in the literature review and added by the Delphi experts in the survey iterations.

TABLE 24. Patient Safety Framework

Category 1: Leadership		
Item	**Area to address: Critical Process**	**Performance Measure**
1.1. Institutional Leadership	1.1.1. Senior Leadership Direction: How senior leaders communicate the priority of patient safety to all stakeholders.	1.1.1.1. Functioning institutional systems for communicating patient safety policies, issues and activities to all stakeholders, actively seeking feedback and use of the information for improvement and creating a culture of safety. 1.1.1.2. Provision and use of real time adverse event reporting tool that alerts leadership automatically to events as they happen, thereby improving real-time communication and stressing the importance of performance improvement in real time.
	1.1.2. Institutional Governance: How senior leaders create an environment for development and improvement of patient safety systems in the institution.	1.1.2.1. A patient safety plan and institutional policies support non-punitive reporting environment and disclosure of adverse events. 1.1.2.2. Systems are in place on different institutional levels for collection and analysis of relevant data used for institutional improvement of patient safety.
	1.1.3. Institutional Performance Review: How patient safety findings are translated in institutional short- and long-term goals and priorities.	1.1.3.1. There is an institutional structure that takes the lead in continuous internal assessment of patient safety, review of current patient safety research findings and translation of research and developed clinical guidelines in institution’s clinical practices, strategic planning and priorities.

TABLE 24. (cont.)

Category 1: Leadership		
Item	**Area to address: Critical Process**	**Performance Measure**
1.2. Social Responsibility	1.2.1. Responsibilities to the public: How the institution incorporates patient safety accreditation and legal requirements as integral parts of its performance improvement.	1.2.1.1. Institutional patient safety plans and policies are developed, carried forward and improved in accordance with the regulations and recommendations of legislative bodies, patient safety agencies and accreditation bodies, such as but not limited to JCAHO, OSHA, NRA, IHI, NCQA, URAC, AAHP, AHA, etc. 1.2.1.2. Requirements in the areas of patient identification, healthcare communications, administration of high-alert medications, wrong-site surgery, use of infusion pumps and clinical alarm systems are adequately addressed.
	1.2.2. Ethical Behavior: How the institution ensures ethical communication with stakeholders in regard to patient safety issues.	1.2.2.1. Ongoing monitoring of quality issues and appropriate procedures are in place for reporting and analysis of adverse events and improvement of institution's patient safety systems. 1.2.2.2. Adopting guidelines and monitoring healthcare staff and professionals compliance with patient safety policies and procedures and effective communication of these policies and procedures to patients and their families.
	1.2.3. Support of key communities: How the institution proactively responds to current and future public concerns in regard to patient safety.	1.2.3.1. Institutional plan and support systems are in place for proactive collecting and analysis of patient safety information and utilization of the review results for improvement of the patient safety systems.
	1.2.4. Responsibilities to the public: How the institution monitors its medication error rate.	1.2.4.1. Independent medication error review team is identified and educated in regard to the medication usage cycle and is engaged in developing and monitoring medication safety system.

TABLE 24. (cont.)

Category 2: Strategic Planning		
Item	**<u>Area to address</u>: Critical Process**	**Performance Measure**
2.1. Strategy Development	<u>2.1.1. Strategic Development Process</u>: How the healthcare institution develops its view of the future and sets directions and policies to communicate, implement and monitor its patient safety systems.	2.1.1.1. Patient safety action plans and systems for sustaining achieved improvements are in accordance with national best practices and performance measures guidelines and provide for optimal matching of healthcare needs and service delivery capabilities. 2.1.1.2. Ongoing, planned and regularly monitored effort in creation, adaptation and adoption of clinical guidelines and best practices based on clinical patient safety research. 2.1.1.3. Comprehensive and ongoing proactive approach in seeking stakeholder expectations in setting goals for short- and long-term patient safety planning. 2.1.1.4. The capabilities of modern technologies and database access are taken into consideration in setting goals for short- and long-term planning.
	<u>2.1.2. Strategic Objectives</u>: How patient safety practices are identified and translated to institution's goals.	2.1.2.1. Data from national databanks and practice guidelines from professional organizations are incorporated in institution's patient safety goals, plans and patient care practices.
	<u>2.1.3. Strategic Objectives:</u> How the institution achieves realistic evaluation of technology capability for improving safety (present and future).	2.1.3.1. Cost-benefit analysis of safety technology with accumulation of data to evaluate the accuracy of such estimates over time and life of safety technology projects.
2.2. Strategy Deployment	<u>2.2.1. Action Plan Development and Deployment</u>: How the institution develops, monitors and improves action plans to ensure patient safety.	2.2.1.1. Institutional and unit patient safety action plans and systems for sustaining achieved improvements are in place and are revised and improved on a regular basis. 2.2.1.2. System-wide processes are used for communication and alignment of patient safety planned efforts.
	<u>2.2.2. Performance Projection</u>: How leaders achieve consistency and improvement of healthcare delivery.	2.2.2.1. National, regional and specialty standards (best practices, clinical performance measures, etc.) are incorporated as benchmarks in institution's short- and long-term plans and are used in the assessment of institution's and individual's quality of healthcare delivery.

TABLE 24. (cont.)

Category 3: Focus on Patients, Other Customers and Markets		
Item	**<u>Area to address</u>: Critical Process**	**Performance Measure**
3.1. Patient, Other Customer and Healthcare Market Knowledge	<u>3.1.1. Patient Safety Market Knowledge</u>: How the healthcare institution determines patients' expectations and appropriate knowledge in regard to patient safety.	3.1.1.1. Coordinated and planned interdepartmental activities to ensure effective team effort for determining the requirements and expectations of culturally and linguistically diverse patient populations in regard to patient safety and use of this information for improvement of institution's patient safety systems. 3.1.1.2. Planned, coordinated and aligned institutional activities to ensure patient education and providing of useful information to the intended audiences in regard to patient safety issues, institutional policies and practices.
	<u>3.1.2. Patient Safety Market Knowledge</u>: How the institution helps set the expectations of patients and infuses realistic goals and expectations into the marketplace.	3.1.2.1. Outcome determination of patient expectations and efforts to influence the development of realistic expectations.
3.2. Patient and Other Customer Relationships and Satisfaction	<u>3.2.1. Patient/Customer Relationship Building</u>: How the healthcare institution gathers and analyses information about patients' and community's expectations in regard to safety of healthcare delivery, and how the results and interpretations are used for improvement of institution's patient safety systems.	3.2.1.1. Proactive alliance building with patient safety groups and local communities for continuous collection, analysis and interpretation of data about patient and other customers expectations. 3.2.1.2. Designing, aligning, monitoring and improving of the procedures for inclusion of patients and their families as active team-players in the process of professional healthcare delivery.
	<u>3.2.2. Satisfaction Determination</u>: How the institution obtains information and feedback from patients on patient safety issues to improve the delivery of healthcare.	3.2.2.1. Design and implementation of comprehensive and accessible systems for adverse events reporting from patients and their families, and continuous analysis of the obtained data. 3.2.2.2. Proactive planned effort to enhance patients' knowledge and information in regard to patient safety issues.

TABLE 24. (cont.)

Category 4: Measurement, Analysis and Knowledge Management		
Item	**Area to address: Critical Process**	**Performance Measure**
4.1. Measurement and Analysis of Institutional Performance	4.1.1. Performance Measurement: How the institution selects and implements into its patient safety systems patient safety benchmarks.	4.1.1.1. Systematic, planned and aligned effort to monitor developments of patient safety standards and implement regional, national and specialty standards as benchmarks for institution's clinical practices. 4.1.1.2. Clinical performance measures as developed by national, regional or professional institutions (as applicable) are implemented in the everyday clinical practice, i.e. at the "sharp end" of healthcare service delivery.
	4.1.2. Performance Measurement: How the institution collects, tracks and analyzes patient safety data.	4.1.2.1. Root Cause Analysis (RCA) and Failure Modes and Effects Analysis (FMEA) training is available to healthcare providers. 4.1.2.2. RCA and/or FMEA approach is used on a customary basis by the healthcare providers in analysis of patient safety issues and improvement of healthcare delivery and patient safety. 4.1.2.3. Non-punitive reporting systems are in place for recording, monitoring, tracking and analysis of adverse events and near misses and the results from this analysis are used in institution's improvement plans.
	4.1.3. How the institution monitors the occurrence of near misses and how uses this information for process improvement.	4.1.3.1. A process exists for recording, monitoring, tracking and analysis of near misses and feedback is used for process improvement.
4.2. Information and Knowledge Management	4.2.1. Data and Information Availability: How the institution ensures that its clinical information technology (Computerized Physician's Order Entry – CPOE, infusion pumps, alarm systems, etc) is reliable, secure and user-friendly.	4.2.1.1. A planned, aligned and monitored institution-wide process of clinical technology use facilitates information transfer and clear communication. 4.2.1.2. A process is in place for assurance that technology implementation is in compliance with patient safety requirements.
	4.2.2. Data and Information Availability: How stakeholders' satisfaction, dissatisfaction and expectations in regard to patient safety are determined and used for improvement of patient safety systems.	4.2.2.1. Data from comprehensive, accessible and user-friendly systems for tracking stakeholder reports, comments and complaints in regard to patient safety satisfaction, dissatisfaction and expectations is used to improve patient safety systems and update patient safety action plans.
	4.2.3. Institutional Knowledge: How patient safety information is shared with all stakeholders in support of overall institution's goals and action plans for performance improvement.	4.2.3.1. Processes are in place to secure integrity, timeliness, reliability, security, accuracy and confidentiality of patient safety related data and analyses of such data, as it is shared with all stakeholders, are used to positively affect institution's performance improvement and action planning.

TABLE 24. (cont.)

Category 5: Staff Focus		
Item	**Area to address: Critical Process**	**Performance Measure**
5.1. Work Systems	5.1.1. Organization and Management of Work: How healthcare delivery is organized to promote patient safety systems establishment and innovation.	5.1.1.1. How patient safety issues are communicated, data are collected and analyzed, and existing processes are improved at different institutional levels to promote consistency in the safety of healthcare delivery.
	5.1.2. Staff Performance Management System: How the institution supports high clinical performance standards and alignment with national clinical performance measures and best case-management practices.	5.1.2.1. Best patient safety practices and clinical guidelines are adopted, monitored and clinician performance is evaluated for consistency with these adopted standards.
	5.1.3. Staff Performance Management System: How the institution identifies, deploys and monitors patient safety practices.	5.1.3.1. Interdepartmental systems for ensuring seamless healthcare delivery and patient safety are consistent with national, regional or specialty best practices and standards for patient safety and healthcare delivery.
	5.1.4. Recruitment and Career Progression: How the institution identifies requirements and recognition for patient safety officers.	5.1.4.1. Development, implementation, revision and improvement of institution's plan for hiring, retaining and recognition of patient safety staff.
	5.1.5. Recruitment and Career Progression: How the institution includes safety compliance and attitudes in staff recruitment, selection and promotion.	5.1.5.1. General staff knowledge and practice of safe activities is rewarded and taken into consideration for recruitment, selection and promotion.
5.2. Staff Learning and Motivation	5.2.1. Staff Education, Training and Development: How the institution structures and promotes effective education and training of professionals in developing and improving patient safety systems.	5.2.1.1. Institutional mechanism for determining of and acting on patient safety educational and training needs for individuals, teams, departments and different categories of professional caregivers.
	5.2.2. Motivation and Career Development: How the institution supports the role of the patient safety officer and the patient safety role of the whole workforce.	5.2.2.1. Development, implementation and improvement of internal patient safety policies, practices and activities.

TABLE 24. (cont.)

Category 5: Staff Focus		
Item	**Area to address: Critical Process**	**Performance Measure**
5.3. Staff Well-being and Satisfaction	5.3.1. Work Environment: How the institution maintains conductive environment in regard to patient safety.	5.3.1.1. Institution's patient safety goals are integrated in institution's everyday healthcare delivery functions, regularly reviewed and improved and progress towards them is continuously monitored and evaluated.
	5.3.2. Staff Support and Satisfaction: How the institution determines staff satisfaction in implementation of patient safety systems.	5.3.2.1. Institutional mechanisms for periodic gathering of information on healthcare providers' opinions and expectations in regard to factors enhancing or inhibiting communication of sentinel events and using the results of the analysis of all collected data for institutional patient safety improvement. 5.3.2.2. Staff satisfaction is promoted by actively providing feedback on patient safety system implementation.
	5.3.3. Staff Support and Satisfaction: How the institution includes medical staff attitudes and satisfaction in implementation of patient safety systems.	5.3.3.1. Medical staff participation and support of safety environment within the institution.

TABLE 24. (cont.)

Category 6: Process Management		
Item	**<u>Area to address</u>: Critical Process**	**Performance Measure**
6.1. Patient Safety System	<u>6.1.1. Patient Safety System</u>: How the institution determines patient safety process requirements and involves patients and other stakeholders in design and redesign of patient safety processes.	6.1.1.1. Accreditation, professional and legal requirements as well as improvements resulting from stakeholder surveys and reporting systems results analyses are incorporated in institution's patient safety systems and processes on a regular basis.
	<u>6.1.2. Patient Safety System</u>: How the institution designs patient safety systems.	6.1.2.1. Evidence that Quality Improvement (QI) methodology, including but not limited to RCA, FMEA, Plan-Do-Study-Act Cycle (PDSA, Rapid Cycle Change), clinical performance measures and best practices are used to decrease variability of healthcare delivery and improve patient safety outcomes.
	<u>6.1.3. Patient Safety System</u>: How the institution ensures that patient safety requirements are met at the "sharp end" of the healthcare delivery system.	6.1.3.1. An institutional mechanism exists for continuous monitoring, improvement and sustainability of patient safety outcomes in healthcare delivery.
	<u>6.1.4. Campus security:</u> How the institution ensures that patients feel secure arriving for and leaving appointments for care.	6.1.4.1. An institutional mechanism exists for continuous monitoring, improvement and sustainability of a campus environment that promotes a feeling of safety and security, and supports the healing process without adding stress regarding personal safety.
6.2. Support Processes	<u>6.2.1. Patient Safety Support Processes</u>: How the institution coordinates departmental and interdepartmental patient safety infrastructures to reduce variability in healthcare delivery and improve performance.	6.2.1.1. Systems for departmental and interdepartmental communications, collaborations and aligned effort in regard to seamless implementation of best practices and clinical guidelines in patient identification, medication and continuous case management are assessed and improved on an ongoing basis.
	6.2.2. Patient Safety Support Process: How the institution includes suppliers and partners in safety initiatives and process development.	6.2.2.1. Safety compliance evaluations of suppliers and partners (including medical staff).

TABLE 24. (cont.)

Category 7: Institutional Performance		
Item	**<u>Area to address</u>: Critical Process**	**Performance Measure**
7.1. Patient Safety Institutional Performance	7.1.1. <u>Patient Safety Results:</u> How the institution ensures patient safety	7.1.1. A 2-identifier system for patient identification is in place and is consistent in the continuity of healthcare throughout the institution. 7.1.2. Healthcare departmental and interdepartmental communications are accurate and reliable at different institutional levels. 7.1.3. The institution monitors the administration of high-alert medications. 7.1.4. Proper marking of surgery sites is established as a precaution to decrease incidents of wrong-side surgery (where applicable). 7.1.5. The institution ensures adequate professional staff preparation for proper and safe use of infusion pumps (where applicable). 7.1.6. The institution ensures adequate professional staff preparation for proper and safe use of clinical alarm systems (where applicable). 7.1.7. The institution ensures a non-punitive approach for reporting all adverse events and near misses. 7.1.8. The institution ensures proper staff is dedicated to support and conduct RCA, FMEA, and implement QI methodology in analyzing multidimensional patient safety practices at different institutional levels. 7.1.9. The institution ensures that an accessible, confidential and adequately functioning reporting system is in place for reporting all adverse events and near misses. 7.1.10. The institution ensures that a uniform, unambiguous and comprehensive nomenclature for reporting of adverse events and near misses is adopted throughout the healthcare institution. 7.1.11. The institution proactively works towards changing the traditional culture of “blame and shame.” 7.1.12. The institution ensures safe healthcare delivery through utilization of modern technology. 7.1.13. The institution ensures that professional, accreditation and legal requirements in the area of patient safety are adequately addressed. 7.1.14. The institution ensures that national benchmarks in healthcare delivery (best practices, clinical performance measures, etc.) are used to decrease variability of healthcare delivery and improve patient safety outcomes. 7.1.15. The institution assures that appropriate leadership development and education in the area of patient safety is provided on an ongoing basis. 7.1.16. The institution assures that appropriate staff development and education in the area of patient safety is provided on an ongoing basis.

TABLE 25. Patient Safety Framework - Beginners

Item	Area to address: Critical Process	Performance Measure
Category 1: Leadership		
1.1. Institutional Leadership	Senior Leadership Direction: How senior leaders communicate the priority of patient safety to all stakeholders.	Functioning institutional systems for communicating patient safety policies, issues and activities to all stakeholders, actively seeking feedback and use of the information for improvement and creating a culture of safety.
1.2. Social Responsibility	Ethical Behavior: How the institution ensures ethical communication with stakeholders in regard to patient safety issues.	Ongoing monitoring of quality issues and appropriate procedures are in place for reporting and analysis of adverse events and improvement of institution's patient safety systems.
Category 2: Strategic Planning		
2.1. Strategy Development	Strategic Objectives: How patient safety practices are identified and translated to institution's goals.	Data from national databanks and practice guidelines from professional organizations are incorporated in institution's patient safety goals, plans and patient care practices.
2.2. Strategy Deployment	Action Plan Development and Deployment: How the institution develops, monitors and improves action plans to ensure patient safety.	Institutional and unit patient safety action plans and systems for sustaining achieved improvements are in place and are revised and improved on a regular basis.
Category 3: Focus on Patients, Other Customers and Markets		
3.1. Patient, Other Customer and Healthcare Market Knowledge	Patient Safety Market Knowledge: How the healthcare institution determines patients' expectations and appropriate knowledge in regard to patient safety.	Planned, coordinated and aligned institutional activities to ensure patient education and providing of useful information to the intended audiences in regard to patient safety issues, institutional policies and practices.
3.2. Patient and Other Customer Relationships and Satisfaction	Satisfaction Determination: How the institution obtains information and feedback from patients on patient safety issues to improve the delivery of healthcare.	Design and implementation of comprehensive and accessible systems for adverse events reporting from patients and their families, and continuous analysis of the obtained data.
Category 4: Measurement, Analysis and Knowledge Management		
4.1. Measurement and Analysis of Institutional Performance	Performance Measurement: How the institution collects, tracks and analyzes patient safety data.	Non-punitive reporting systems are in place for recording, monitoring, tracking and analysis of adverse events and near misses and the results from this analysis are used in institution's improvement plans.
4.2. Information and Knowledge Management	Data and Information Availability: How the institution ensures that its clinical information technology (Computerized Physician's Order Entry – CPOE, infusion pumps, alarm systems, etc) is reliable, secure and user-friendly.	A planned, aligned and monitored institution-wide process of clinical technology use facilitates information transfer and clear communication.

TABLE 25. (cont.)

Item	Area to address: Critical Process	Performance Measure
Category 5: Staff Focus		
5.1. Work Systems	Staff Performance Management System: How the institution supports high clinical performance standards and alignment with national clinical performance measures and best case- management practices.	Best patient safety practices and clinical guidelines are adopted, monitored and clinician performance is evaluated for consistency with these adopted standards.
5.2. Staff Learning and Motivation	Staff Education, Training and Development: How the institution structures and promotes effective education and training of professionals in developing and improving patient safety systems.	Institutional mechanism for determining of and acting on patient safety educational and training needs for individuals, teams, departments and different categories of professional caregivers.
5.3. Staff Well-being and Satisfaction	Work Environment: How the institution maintains conductive environment in regard to patient safety.	Institution's patient safety goals are integrated in institution's everyday healthcare delivery functions, regularly reviewed and improved and progress towards them is continuously monitored and evaluated.
Category 6: Process Management		
6.1. Patient Safety System	Patient Safety System: How the institution ensures that patient safety requirements are met at the "sharp end" of the healthcare delivery system.	An institutional mechanism exists for continuous monitoring, improvement and sustainability of patient safety outcomes in healthcare delivery.
6.2. Support Processes	Patient Safety Support Processes: How the institution coordinates departmental and interdepartmental patient safety infrastructures to reduce variability in healthcare delivery and improve performance.	Systems for departmental and interdepartmental communications, collaborations and aligned effort in regard to seamless implementation of best practices and clinical guidelines in patient identification, medication and continuous case management are assessed and improved on an ongoing basis.
Category 7: Institutional Performance		
7.1. Patient Safety Institutional Performance	Patient Safety Results: How the institution ensures patient safety	The institution monitors the administration of high-alert medications.

TABLE 26. Patient Safety Framework - Intermediate

Item	Area to address: Critical Process	Performance Measure
Category 1: Leadership		
1.1. Institutional Leadership	Senior Leadership Direction: How senior leaders communicate the priority of patient safety to all stakeholders.	Functioning institutional systems for communicating patient safety policies, issues and activities to all stakeholders, actively seeking feedback and use of the information for improvement and creating a culture of safety.
	Institutional Governance: How senior leaders create an environment for development and improvement of patient safety systems in the institution.	Systems are in place on different institutional levels for collection and analysis of relevant data used for institutional improvement of patient safety.
	Institutional Performance Review: How patient safety findings are translated in institutional short- and long-term goals and priorities.	There is an institutional structure that takes the lead in continuous internal assessment of patient safety, review of current patient safety research findings and translation of research and developed clinical guidelines in institution's clinical practices, strategic planning and priorities.
1.2. Social Responsibility	Ethical Behavior: How the institution ensures ethical communication with stakeholders in regard to patient safety issues.	Ongoing monitoring of quality issues and appropriate procedures are in place for reporting and analysis of adverse events and improvement of institution's patient safety systems.
Category 2: Strategic Planning		
2.1. Strategy Development	Strategic Objectives: How patient safety practices are identified and translated to institution's goals.	Data from national databanks and practice guidelines from professional organizations are incorporated in institution's patient safety goals, plans and patient care practices.
2.2. Strategy Deployment	Action Plan Development and Deployment: How the institution develops, monitors and improves action plans to ensure patient safety.	Institutional and unit patient safety action plans and systems for sustaining achieved improvements are in place and are revised and improved on a regular basis.
Category 3: Focus on Patients, Other Customers and Markets		
3.1. Patient, Other Customer and Healthcare Market Knowledge	Patient Safety Market Knowledge: How the healthcare institution determines patients' expectations and appropriate knowledge in regard to patient safety.	Planned, coordinated and aligned institutional activities to ensure patient education and providing of useful information to the intended audiences in regard to patient safety issues, institutional policies and practices.
3.2. Patient and Other Customer Relationships and Satisfaction	Satisfaction Determination: How the institution obtains information and feedback from patients on patient safety issues to improve the delivery of healthcare.	Design and implementation of comprehensive and accessible systems for adverse events reporting from patients and their families, and continuous analysis of the obtained data.

TABLE 26. (cont.)

Item	Area to address: Critical Process	Performance Measure
Category 4: Measurement, Analysis and Knowledge Management		
4.1. Measurement and Analysis of Institutional Performance	Performance Measurement: How the institution collects, tracks and analyzes patient safety data.	Non-punitive reporting systems are in place for recording, monitoring, tracking and analysis of adverse events and near misses and the results from this analysis are used in institution's improvement plans.
4.2. Information and Knowledge Management	Data and Information Availability: How the institution ensures that its clinical information technology (Computerized Physician's Order Entry – CPOE, infusion pumps, alarm systems, etc) is reliable, secure and user-friendly.	A planned, aligned and monitored institution-wide process of clinical technology use facilitates information transfer and clear communication.
Category 5: Staff Focus		
5.1. Work Systems	Staff Performance Management System: How the institution supports high clinical performance standards and alignment with national clinical performance measures and best case-management practices.	Best patient safety practices and clinical guidelines are adopted, monitored and clinician performance is evaluated for consistency with these adopted standards.
5.2. Staff Learning and Motivation	Staff Education, Training and Development: How the institution structures and promotes effective education and training of professionals in developing and improving patient safety systems.	Institutional mechanism for determining of and acting on patient safety educational and training needs for individuals, teams, departments and different categories of professional caregivers.
5.3. Staff Well-being and Satisfaction	Work Environment: How the institution maintains conductive environment in regard to patient safety.	Institution's patient safety goals are integrated in institution's everyday healthcare delivery functions, regularly reviewed and improved and progress towards them is continuously monitored and evaluated.

TABLE 26. (cont.)

Item	Area to address: Critical Process	Performance Measure
Category 6: Process Management		
6.1. Patient Safety System	Patient Safety System: How the institution ensures that patient safety requirements are met at the "sharp end" of the healthcare delivery system.	An institutional mechanism exists for continuous monitoring, improvement and sustainability of patient safety outcomes in healthcare delivery.
6.2. Support Processes	Patient Safety Support Processes: How the institution coordinates departmental and interdepartmental patient safety infrastructures to reduce variability in healthcare delivery and improve performance.	Systems for departmental and interdepartmental communications, collaborations and aligned effort in regard to seamless implementation of best practices and clinical guidelines in patient identification, medication and continuous case management are assessed and improved on an ongoing basis.
Category 7: Institutional Performance		
7.1. Patient Safety Institutional Performance	Patient Safety Results: How the institution ensures patient safety	A 2-identifier system for patient identification is in place and is consistent in the continuity of healthcare throughout the institution. The institution monitors the administration of high-alert medications. Proper marking of surgery sites is established as a precaution to decrease incidents of wrong-side surgery (where applicable). The institution ensures adequate professional staff preparation for proper and safe use of infusion pumps (where applicable). The institution ensures a non-punitive approach for reporting all adverse events and near misses. The institution ensures that an accessible, confidential and adequately functioning reporting system is in place for reporting all adverse events and near misses. The institution proactively works towards changing the traditional culture of "blame and shame."

Summary of Dissertation Study Conclusions

The following general conclusions can be made from a review and analysis of the findings of this dissertation study:

1. In the present, the leadership direction and support for patient safety in healthcare institutions is the most important aspect in building, maintaining and improving patient safety systems. How senior leaders communicate to all stakeholders is one of the most important issues to which leaders must attend.
2. Patient safety measurement, analysis and knowledge management will be the most important aspect for building patient safety systems in the future.
3. Traditional measurement approaches are more quantitative than qualitative. Some of the Delphi experts raised concerns about the quantitative measurability of several of the performance measures. The majority of the existing patient safety measures assess clinical results of healthcare, i.e. they measure infection rate, number of wrong-site surgeries, number of patient falls, number of medication mistakes, etc. Looking at performance measures at institutional level proved to be challenging. Although all performance measures in the suggested patient safety framework are quantifiable at a more detailed level, it is important to emphasize that the major objective of the variables in the framework is to help healthcare institutions implement working processes to foster a culture of safety. Each critical process and its related performance measures are designed to answer the question “so, what?” (i.e. not only to suggest what institutional processes are important to patient safety but also to check how these processes are used for implementation and/or improvement of institutional patient safety programs). Further quantification of the patient safety measures is desirable.

4. Strategic planning is one of the most important aspects in regard to implementing healthcare patient safety systems in the future. Strategic planning is necessary for healthcare institutions to become quality organizations.
5. There is a gap in the understanding of healthcare administrators and professionals about the importance of addressing healthcare customer and market requirements. The types of healthcare patient safety customers (internal, external, primary and secondary) are yet to be defined and the related performance requirements are yet to be determined. Similar to borrowing performance measurement approaches from the other industries (such as aviation, automotive industry, etc.), borrowing customer and market approaches from other industries (e.g. from other service industries) may prove beneficial for focusing healthcare institutions on better serving their customers and expanding their market share.
6. Healthcare institutions need to measure the satisfaction and dissatisfaction of both healthcare professionals and patients, to improve upon existing programs and services.
7. Utilization of national patient safety benchmarks and clinical protocols is an important aspect of patient safety. Standardization of healthcare devices, treatment approaches, and services is necessary in achieving patient safety.
8. Technology will be one of the leading change agents for improving patient safety in healthcare institutions. Patient safety approaches such as utilization of Computerized Physician's Order Entry, patient barcodes, computerized pharmacology dispensing systems, reliable infusion pumps and alarm systems, have a big potential for decreasing medical errors and making health care safer.
9. Patient safety education of healthcare leadership, clinical staff and patients is required for improving patient safety.
10. The importance of the patient safety framework categories in the present, based on the consensus group rank mean of all processes within each category, is as follows:

    # 1. Category 1, Leadership

2. Category 4, Measurement, analysis and knowledge management

3. Category 2, Strategic planning and Category 6, Process management

4. Category 5, Staff focus

5. Category 3, Focus on patients, other customers and markets.

11. The importance of the patient safety framework categories in the future, as identified by the Delphi experts and based on the compound group rank mean of all processes within each category, will be as follows:

    # 1. Category 4, Measurement, analysis and knowledge management

    # 2. Category 1, Leadership and Category 2, Strategic planning

    # 3. Category 5, Staff focus

    # 4. Category 6, Process management

    # 5. Category 3, Focus on patients, other customers and markets

12. The vast majority of barriers to implementation of patient safety systems in healthcare institution are systematic in nature. In order to achieve patient safety improvements in the future, healthcare administrators and policy makers should strive to eliminate or diminish the impact of the following "top seven" barriers:

    - Competing priorities for scarce resources in a system where patient safety is not considered a top priority;
    - Lack of resources: inadequate staffing and work overloads;
    - Availability and cost of patient safety technology;
    - Resistance to change (the assumption that providers are already providing safe care);
    - Culture of blame (current healthcare culture is punitive in nature);
    - Lack of senior leadership understanding of and involvement with patient safety issues;

- Culture of healthcare workforce perceptions, attitudes and behaviors of error “cover up.”

13. It is important to emphasize the “non-punitive” aspect of the medical error reporting systems based on the important message it carries that healthcare professionals should not feel threatened when reporting medical errors or near misses. Designing and utilizing non-punitive and reliable reporting systems that allow confidential or anonymous reporting of adverse events and near misses is essential for healthcare institutions to become learning organizations and use medical error and near miss data for improvement of their patient safety systems.
14. The patient safety performance results of healthcare institutions, addressed by Malcolm Baldrige Category 7, Institutional performance, reflect the institutional patient safety outcomes in Malcolm Baldrige categories 1-6 (Leadership, Strategic planning, Focus on patients, other customers and markets, Measurement, analysis and knowledge management, Staff Focus, and Process management). The categories in the Malcolm Baldrige framework are interrelated, and although institutions may be at a different stage of addressing each separate category, all patient safety framework categories should be addressed for achieving improvements in healthcare patient safety systems.

Recommendations for the Field

The data from this study suggest that for implementing, maintaining and improving of patient safety systems, healthcare administrators should do the following:

1. Effectively communicate the priority of patient safety to all stakeholders, actively seek feedback on patient safety and use the information for patient safety improvements.

2. Ensure ethical communication with stakeholders in regard to patient safety and utilize ongoing monitoring and analysis of patient safety outcomes for patient safety improvement.
3. Incorporate national databank data and clinical practice guidelines as patient safety performance benchmarks in institution's strategic plan and monitor staff performance against the adopted benchmarks.
4. Develop, monitor, regularly review and improve institution's patient safety action plans.
5. Plan, coordinate and align institutional patient safety activities to ensure patient safety education of institution's leadership, medical staff and patients at individual, team, departmental or institutional level as appropriate.
6. Design and implement comprehensive, accessible and user-friendly systems for recording, monitoring, tracking and analysis of adverse events and near miss reporting from both staff and patients, and use the results from the analysis of the obtained data for further patient safety improvement.
7. Plan, align and monitor institution-wide process(es) for facilitation of information transfer and communications through clinical information technology.
8. Integrate institution's patient safety goals into everyday healthcare delivery functions and protocols, regularly review and improve the healthcare delivery protocols and continuously monitor and evaluate institution's performance toward its safety goals.
9. Adopt clinical protocols for administration of high-alert medications.
10. Coordinate departmental and interdepartmental patient safety infrastructures to reduce variability in healthcare delivery and improve performance.
11. Design and implement an institutional mechanism for continuous monitoring, improvement and sustainability of patient safety outcomes in healthcare delivery.

Recommendations for Further Studies

This study used the Malcolm Baldrige National Quality Award Healthcare Criteria for Performance Excellence as the framework for identifying the patient safety processes and performance measures to be ranked by the Delphi experts. The Delphi technique was the methodology of choice and the expert panel consisted of 23 healthcare experts from 18 U.S. states. The issues related to the dissertation study methodology and Delphi panel selection drive the recommendations for further study. To enhance the results from this research, the author recommends the following aspects to be pursued in further studies:

1. A larger Delphi panel may return a different set of results. The panel for this study consisted of 23 healthcare experts from 18 U.S. states. Twenty of the experts (from 17 states) continued their participation through the second and third study round. There may have been limitations to the set of opinions based on the number and specific qualifications of the study experts. A larger expert sample may provide additional insights into the issues addressed in this study.
2. A larger panel size, or augmented (bootstrapped) data sets from a Delphi panel, will allow performing data reduction through exploratory and confirmatory factor analyses to determine the new constructs that the study variables are forming and to test whether there are seven areas of importance corresponding to the seven Malcolm Baldrige Quality Award areas.
3. A different panel make up may lead to different results of the research. The Delphi experts for this study were reviewers, senior reviewers and judges for the Malcolm Baldrige National Quality Award in healthcare and administrators in healthcare institutions that have won or applied for the Malcolm Baldrige award or have won State quality awards within the last 5-year period. Familiarity with the Malcolm Baldrige Healthcare Criteria for Performance Excellence either through a Malcolm Baldrige reviewer status or through being an administrator in a quality award winning or seeking

institution was a necessary prerequisite for inclusion in the Delphi panel. The majority of healthcare administrators on the panel represented larger hospitals in urban areas. Currently, the approach of continuous quality improvement is gaining momentum within the healthcare industry and patient safety has been brought to the forefront of the issue of healthcare quality improvement. However, the resources available to rural and urban hospitals are different, as are the resource pools for hospitals of varying sizes, healthcare clinics, practices and other healthcare institutions. The enormous variety of types of healthcare governing structures and resource availability makes it difficult to approach all healthcare institutions with a uniform formula for success in improvement of patient safety. More discretion is needed to address the specific needs of different healthcare organizations in building and maintaining patient safety systems. Thus, a new panel design employing sufficient numbers of representatives for different types of healthcare institutions may: (1) differentiate between measures which are more important for one certain healthcare institution type than for others; (2) suggest other critical processes and performance measures that have not been identified by the researcher and the experts for this study; (3) compare the results of a new study with the patient safety framework identified in this research and validate the level of agreement on the importance of mutual critical processes and performance measures; (4) validate the level of future importance of the patient safety critical processes and performance measures as identified in this study.

4. A different panel, by size or makeup, may identify different set of barriers to implementation of patient safety systems in healthcare institution or prioritize the importance of the barriers differently. Furthermore, with new legislative developments and accreditation requirements, the barrier set will continue to change over time. A follow-up on the most important barriers to patient safety will provide valuable information to healthcare policy-makers.

5. The critical processes and performance measures identified in the patient safety framework of this study should be further adapted to an easy-to-use patient safety tool, pilot-tested and deployed in order to determine their effectiveness to serve as a basis for continuous improvement of patient safety systems in healthcare institution. If validated, the outlined patient safety framework coupled with the Malcolm Baldrige Healthcare Criteria for Performance Excellence would make significant contributions to enhancing institutional patient safety capacity and enable healthcare institutions to better meet the needs of their customers and stakeholders.
6. As a recommendation for future Delphi studies, to avoid contamination of the group result by unique responses and influence of non-representative outlier responses on the overall study, researchers should be agile to identify possible outlier responses in the study raw data set and contact suspected outlier participants as early in the Delphi process as possible.

Summary: Dissertation Study Significance

This dissertation study identified 39 critical processes and 60 performance measures useful for assessing patient safety systems in healthcare institutions, especially patient safety programs and services in healthcare institutions that are utilizing the principles of continuous quality improvement and the Malcolm Baldrige framework for performance excellence. The number of identified patient safety critical processes and performance measures is substantial and provides a significant body of processes and measures at three levels of institutional familiarity with and progress in implementation of patient safety systems. All critical processes and performance measures carry substantial importance for healthcare patient safety systems, as demonstrated by the Delphi panel group rank means in reaching consensus. The Delphi panel also provided insight into the future and forecasted that patient safety measurement, analysis and knowledge management will be the leading factor in improving patient safety systems in the future.

Patient safety practices are multidimensional, difficult to assess and reach over all organizational levels. Implementation of patient safety systems based on the Malcolm Baldrige National Quality Award may ensure that healthcare institutions provide the systemic approach to quality services they intend to provide. The critical processes and performance measures identified in this research will be useful for healthcare institutions in designing, implementing and improving patient safety systems. The patient safety framework is intended to support senior healthcare administrators in achieving and sustaining improvement results. The patient safety framework may also serve as a means for evaluating existing patient safety initiatives or guiding the planning of new processes for better healthcare delivery. Moreover, the identified patient safety framework will assist healthcare institutions in using the Malcolm Baldrige National Quality Award Healthcare Criteria for Performance Excellence for self-assessment and quality improvement.

REFERENCES

Adler, M., & Ziglio, E. (Eds.). (1996). *Gazing into the oracle: The Delphi method and its application to social policy and public health.* Bristol, PA: Jessica Kingsley Publishers, Ltd.

Adoption of clinical information technology: Thought leadership research executive summary. (2002). San Francisco, CA: McKesson. Available: http://infosolutions.mckesson.com/ExecSummary.pdf

AHRQ quality indicators – Patient safety indicators. (2003, March 13). Software documentation, Version 2.1 – SAS. Rockville, MD: Agency for Healthcare Research and Quality. AHRQ Pub. No. 03-R203. Available: http://www.qualityindicators.ahrq.gov/data/hcup/psi.htm

American Medical Association, Physician's Consortium for Performance Improvement. (2002). *Taking the lead together.* Chicago, IL: Author. Pub. No. AP25:02-0103:2000:5/02. Available: http://www.ama-assn.org/ama/pub/category/3818.html

American Society for Hospital Pharmacists. (1993, February). ASHP guidelines on preventing medication errors in hospitals. *American Journal of Hospital Pharmacy, 50*(2): 305-314.

Andersen, B., & Fagerhaug T. (2000). *Root cause analysis: Simplified tools and techniques.* Milwaukee, WI: ASQ Quality Press.

Argys, L.M., Peters, H.E., & Waldman, D.M. (2001, Spring). Can the Family Support Act put some life back into deadbeat dads? *Journal of Human Resources, 36*(2): 226-252.

ASHRM keynote speaker examines root causes of medical errors. (2002). *ECRI's Healthcare Risk Control Weekly News,* October 2, 2002, p.1.

Baldrige National Quality Program. (2002). *Health care criteria for performance excellence*. Gaithersburg, MD: United States Department of Commerce. Technology Administration. National Institute of Standards and Technology.

Baldrige National Quality Program. (2003). *Health care criteria for performance excellence*. Gaithersburg, MD: United States Department of Commerce. Technology Administration. National Institute of Standards and Technology.

Baldrige National Quality Program. (2004). *Health care criteria for performance excellence*. Gaithersburg, MD: United States Department of Commerce. Technology Administration. National Institute of Standards and Technology.

Barker, K. N., Flynn, E. A., Pepper, G. A., Bates, D. W., & Mikeal, R. L. (2002, September). Medical errors observed in 36 care facilities. *Archives of Internal Medicine, 162*(16): 1897-1903.

Barker, K. N., & McConnell, W. E. (1962, August). Detecting errors in hospitals. *American Journal of Hospital Pharmacy, 19:* 360-369.

Barnett, V. (1994). Outliers in sample surveys. *Journal of Applied Statistics, 21*(5): 373-381.

Batalden, P., & Splaine, M. (2002). What will it take to lead the continual improvement and innovation of health care in the twenty-first century? *Quality Management in Health Care, 11*(1): 45-54.

Bates, D. W., Spell, N., Cullen, D. J., Burdick, E., Laird, N., Petersen, L. A., Small, S. D., Sweitzer, B. J., & Leape, L. L. (1997, January 22/29). The costs of adverse drug events in hospitalized patients. *Journal of the American Medical Association, 277*(4): 307-311.

Bernstein, S.J., Laouri, M., Hilborne, L.H., Leape, L.L., Kahan, J.P., Park, R.E., Kamberg, C.J., & Brook, R.H. (1992). *Coronary Angiography: A literature review and ratings of appropriateness and necessity.* The New York City Rand Institute, JRA-03. Santa Monica, CA: The Rand Corporation.

Bertin, G. (1996). Delphi techniques and the planning of social services: The prevention of dependency among the old. In M. Adler, & E. Ziglio, (Eds.), *Gazing into the oracle: The Delphi method and its application to social policy and public health* (pp.156-175). Bristol, PA: Jessica Kingsley Publishers, Ltd.

Berwick, D.M. (1989). Continuous improvement as an ideal in health care. *New England Journal of Medicine*. *320*: 53-56.

Berwick, D.M., Godfrey, A.B., & Roessner, J. (1991). *Curing health care: New strategies for quality improvement: A Report on the National Demonstration Project on Quality Improvement in Health Care.* San Francisco, CA: Jossey-Bass Publishers.

BHC Accreditation News. Issue 2, 2002. Available: http://www.jcaho.org/accredited+organizations/behavioral+health+care/bhc+news/2002issue/bhcnews_i202.pdf

Bing, M., Abel, R. L., Pendergrass, P., Sabharwal, K., & McCauley, C. (2000). Data used to improve quality of healthcare. *Texas Medicine: Symposium on Quality in Healthcare, 96*(10): 75-79.

Birkmeyer, J. D., Siewers, A. E., Finlayson, E. V. A., Stukel, T. A., Lucas, F. L., Batista, I., Welch, H. G., & Wennberg, D. E. (2002). Hospital volume and surgical mortality in the United States. *The New England Journal of Medicine, 346*(15): 1128-1137.

Black, N., Murphy, M., Lamping, D., McKee, M., Sanderson, C., Askham, J., & Marteau, T. (1999). Consensus development methods: A review of best practice in creating clinical guidelines. *Journal of Health Services Research and Policy, 4*(4): 236-248.

Bradbury, A. W., Bell, J., Lee, A. J., Prescott, R. J., Gillespie, I., Standsby, G., & Fowkes, F. G. (2002). Bypass or angioplasty for severe limb ischaemia? A Delphi consensus study. *European Journal of Vascular and Endovascular Surgery, 24*(5): 411-416.

Bradley, E. H., Holmboe, E. S., Mattera, J. A., Roumanis, S. A., Radford, M. J., & Krumholz, H. M. (2003, January/February). The roles of senior management in quality improvement efforts: What are the key components? *Journal of Healthcare Management, 48*(1): 15-28.

Brodell, R. T., Helms, S. E., KrishnaRao, I., & Bredle, D. L. (1997, May/June). Prescription errors: Legibility and drug name confusion. *Archives of Family Medicine, 6*: 296-298.

Calzone, K. A., Jenkins, J., & Masny, A. (2002). Core competencies in cancer genetics for advanced practice oncology nurses. *ONF, 29*(9): 1327-1333.

Carey, R. G., & Teeters, J. L. (1995, May). CQI case study: Reducing medication errors. *Joint Commission Journal on Quality Improvement., 21*(5): 232-237.

Casalino, L. P. (1999, October). The unintended consequences of measuring quality on the quality of medical care. *The New England Journal of Medicine, 341*(15): 1147-1150.

Catlin, A. J., & Carter, B.S. (2002). Creation of a neonatal end-of-life palliative care protocol. *Journal of Neonatal Nursing, 21*(4): 37-49.

Chambers, R.L. (1986). Outlier robust finite population estimation. *Journal of the American Statistical Association, 81*(396): 1063-1069.

Chrischilles, E. A., Fulda, T. R., Byrns, P. J., Winckler, S. C., Rupp, M. T., & Chui, M. A. (2002, May/June). The role of pharmacy computer systems in preventing medication errors. *Journal of the American Pharmaceutical Association, 42*(3): 439-448.

Classen, D. C., Pestotnik, S. L., Evans, R. S., Lloyd, J. F., & Burke, J. P. (1997, January 22/29). Adverse drug events in hospitalized patients. *Journal of the American Medical Association, 277*(4): 301-306.

Cobb, M. D. (1986). Evaluating medical errors. *Journal of Nursing Administration, 16*(4): 41-44.

Cohen, M. R., Senders, J., & Davis, N. M. (1994, February). 12 ways to prevent medication errors. *Nursing, 24*(2): 34-41.

Cooper, J. B. (2001). *Current research on patient safety in the United States.* Chicago, IL: National Patient Safety Foundation.

Cullen, D. J., Sweitzer, B. J., Bates, D. W., Burdick, E., Edmondson, A., & Leape, L. L. (1997). Preventable adverse drug events in hospitalized patients: A comparative study of intensive care and general care units. *Critical Care Medicine, 25*(8): 1289-1297.

Currell, R., Urquhart, C., Wainwright, P., & Lewis, R. (2000). Telemedicine versus face to face patient care: Effects on professional practice and health care outcomes (Cochrane Review). *The Cochrane Library*, Issue 2: p. CD002098. Oxford: Update Software Ltd.

Daley, J., Forbes, M.G., Young, G.L., Charms, M.P., Gibbs, J.O., Hur, K., Henderson, W., & Khuri, S.F. (1997). Validating risk-adjusted surgical outcomes: Site visit assessment of process and structure. National VA surgical risk study. *Journal of the American College of Surgeons, 185*(4): 341-351.

Daley, J., Vogeli, C., Blumenthal D., Kaushal. R., Landon B., & Normand S. (2002). *Physician clinical performance assessment: The state of the art. Issues, possibilities, and challenges for the future*. A report supported by the UnitedHealth Foundation. Boston, MA: Institute for Health Policy, Massachusetts General Hospital.

Davis, K., Schoenbaum, S. C., Collins, K. S., Tenney, K., Hughes, D. L., & Audet, A. J. (2002, April). *Room for improvement: Patients report on the quality of their healthcare.* A report of The Commonwealth Fund. Pub. No. 534. Available: http://www.cmwf.org.

DeCarlo, N. J., & Sterett, W. K. (1990, March). History of the Malcolm Baldrige National Quality Award. *Quality Progress, 23(3):* 21-27.

DeRosier, J., Stalhandske, E., Bacian, J. P., & Nudell, T. (May, 2002). Using Health Care Failure Mode and Effects Analysis™: The VA National Center for Patient Safety's prospective risk analysis system. *The Joint Commission Journal on Quality Improvement, 28*(5): 248-307.

Doolan, D. F., & Bates, D. W. (July/August, 2002). Computerized physician order entry: Mandates and incentives. *Health Affairs, 21*(4): 180-188.

Dovey, S. M., Meyers, D. S., Phillips, R. L., Jr., Green, L. A., Fryer, G. E., Galliher, J. M., Kappus, J., & Grob, P. (2002). A preliminary taxonomy of medical errors in family practice. *Quality and Safety in Health Care, 11*: 233-238.

Dunn, J. D. (2000). Patient safety in America: Comparison and analysis of national and Texas patient safety research. *Texas Medicine: Symposium on Quality in Healthcare, 96*(10): 66-74.

Edmondson, A., Roberto, M.A., & Tucker, A. (2003, August 1). *Children's Hospital and Clinics* (Case No. 9-302-050). Boston, MA: Harvard Business School.

Elnicki, D. M., Lescisin, D. A., & Case, S. (2002, June). Improving the National Board of Medical Examiners Internal Medicine Subject Exam for use in clerkship evaluation. *Journal of General Internal Medicine, 17*: 435-440.

Ernst, M. A., Buchanan, A., & Cox, C. (1991, April 3). A judgment of errors. *Nursing Times, 87*(14): 26-30.

Escobar, A., Qintana, J. M., Arostegui, I., Azkarate, J., Guenaga, J., I., Arenaza, J. C., Garai, I. (2003, Winter). Development of explicit criteria for total knee replacement. *International Journal of Technology Assessment in Health Care, 19*(1): 57-70.

Espositol, R., & Fox, J.K. (1994). ARIES: A visual path in the investigation of statistical data. *Journal of Computational and Graphical Statistics, 3*(2): 113-125.

Franke, J. (2000). It takes a team to treat a patient: The quest for quality. *Texas Medicine: Symposium on Quality in Healthcare, 96*(10): 35-42.

Getting started with the Baldrige National Quality Program Criteria for Performance Excellence: A guide to self-assessment and action. (2003). Milwakee, WI: American Society for Quality.

Graham, B., Regehr, G., Wright, J. G. (2003). Delphi as a method to establish consensus for diagnostic criteria. *Journal of Clinical Epidemiology, 56*(12): 1150-1156.

Greatorex, J., & Dexter, T. (2000, October). An accessible analytical approach for investigating what happens between the rounds in a Delphi study. *Journal of Advanced Nursing, 32*(4): 1016-1024.

Gwet, J., & Rivest, L. (1992). Outlier resistant alternatives to the ratio estimator. *Journal of the American Statistical Association, 87*(420): 1174-1182.

Hackel, R., Butt, L., & Banister, G. (1996, January). How nurses perceive medication errors. *Nursing Management, 27*(1): 31, 33-34.

Hanold, L. S., Koss, R. G., & Loeb, J. M. (2000). The ORYX initiative: goals and potential application to physician quality improvement efforts. *Texas Medicine: Symposium on Quality in Healthcare, 96*(10): 84-87.

Hart, C. W. L., & Bogan, C. E. (1992). *The Baldrige: What it is, how it's won, how to use it to improve quality in your company.* New York, NY: McGraw-Hill, Inc.

Hasson, F., Keeney, S., & McKenna, H. (2000, October). Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing, 32*(4):1008-1015.

Hatch, D. (2001). Incidence and acceptance of errors in medicine. *Bollettino dei Medici Svizzeri, 82*(25): 1339-1343.

Hertz, H. S., Reimann, C. W., & Bostwick, M. C. (1994). The Malcolm Baldrige National Quality Award concept: Could it help stimulate or accelerate healthcare quality improvement? *Quality Management in Healthcare, 2*(4): 63-72.

Holcomb, J. (2000). The role of administrative data in measurement and reporting of quality of hospital care. *Texas Medicine: Symposium on Quality in Healthcare, 96*(10): 48-52.

Horns, K. M., & Loper, D. L. (2002, May/June). Medication errors: Analysis, not blame. *Journal of Obstetric, Gynecologic, and Neonatal Nursing, 31*(3): 347-354.

House passes bill on medical mistakes. (2003, March 13). Washington, DC: CBS News. Available: http://www.cbsnews.com/stories/2003/03/12/health/main543668.shtml

Howanitz, P. J., Renner, S. W., & Walsh, M. K. (2002, July). Continuous wristband monitoring over 2 years decreases identification errors: A College of American Pathologists Q-Track study. *Archives of Pathology Laboratory in Medicine, 126*(7): 809-815.

Idealized design: Idealized design of medication systems. (2003). Institute of Healthcare Improvement. Available: http://www.ihi.org/idealized/idms/ci0401idms.asp.

Institute of Medicine Report. (2000). *To err is human: Building a safer health system.* Linda T. Kohn, Janet M. Corrigan, & Molla S Donaldson (Eds.). Washington, DC: National Academy Press.

Institute of Medicine Report. (2001). *Crossing the quality chasm: A new health system for the 21st century.* Committee on Quality Health Care in America, IOM. Washington, DC: National Academy Press.

JCAHO (Joint Commission on Accreditation of Healthcare Organizations). (2003). *2004 National Patient Safety Goals.* Available: http://www.jcaho.org/accredited+organizations/patient+safety/npsg/04_npsg.htm

JCAHO approves National Patient Safety Goals for 2003. (2002). *Joint Commission Perspectives, 22(9)*: 1-3. Available: http://www.jcrinc.com/subscribers/perspectives

JCAHO News Release. (2003, July 21). *Universal protocol established for preventing wrong site, wrong procedure, wrong person surgery*. Available: http://www.jcaho.org/news+room/news+release+archives/wss_7_21.htm

Joiner, G. A. (1994, March/April). Developing a proactive approach to medication error prevention. *Journal for Healthcare Quality, 16*(2): 35-40.

Joint Commission on Accreditation of Healthcare Organizations. (2002). *Performance Measurement: Setting the Standard for Quality in Health Care*. Available: http://www.jcaho.org/pms/index.htm

Joint Commission on Accreditation of Healthcare Organizations. (2004). *Comprehensive accreditation manual for hospitals: The official handbook*. Oakbrook Terrace, IL: Joint Commission Resources, Inc.

Joint Commission Resources. (2003) *Special Report: 2004 JCAHO national patient safety goals. Practical strategies and helpful solutions for meeting these goals.* Available: http://www.jcrinc.com/subscribers/patientsafety.asp

Jones, C.G. (1975). A Delphi evaluation of agreement between organizations. In Linstone, H.A., & Turoff, M. (Eds.)., *The Delphi method: Techniques and applications* (pp.160-167). Reading, MA: Addison-Wesley Publishing Company.

Jones, J., & Hunter, (1995). Consensus methods for medical and health services research. *British Medical Journal, 311*(7001): 376-380.

Kmetik, K.S., Williams, J. R., Hammons, T., & Rosof, B. M. (2000). The American Medical Association and physician performance measurement: Information for improving patient care. *Texas Medicine: Symposium on Quality in Healthcare, 96*(10): 80-83.

Korda, H. (1994, Summer). Utilization review for Medicaid diagnosis-related group systems: Practice, innovation, and lessons of experience. *American Journal of Medical Quality, 9*(2): 54-67.

Kost, G. J. (1991). Critical limits for emergency clinician notification at United States children's hospitals. *Pediatrics, 88*(3): 597-603.

Lawton, R., & Parker, D. (2002). Barriers to incident reporting in healthcare systems. *Quality and Safety in Health Care, 11*: 15-18.

Leape, L. L. (1994, December 21). Errors in medicine. *Journal of the American Medical Association, 272*(23): 1851-1857.

Leape, L. L. (1996, November/December). Out of the darkness: Hospitals begin to take mistakes seriously. *Health Systems Review, 29*(6): 21-24.

Leape, L. L., Bates, D. W., Cullen, D. J., Cooper, J., Demonaco, H. J., Gallivan, T., Hallisey, R., Ives, J., Laird, N., Laffel, G., Nemeskal, R., Petersen, L. A., Porter, K., Servi, D., Shea, B. F., Small, S. D., Sweitzer, B. J., Thompson, B. T., & Vliet, M. V. (1995, July 5). Systems analysis of adverse drug events. *Journal of the American Medical Association, 274*(1): 35-43.

Leape, L. L., Berwick, D. M., & Bates, D. W. (2002, July 24/31). What practices will most improve safety? Evidence-based medicine meets patient safety. *Journal of the American Medical Association, 288*(4): 501-507.

Leape, L. L., Brennan, T. A., Laird, N., Lawthers, A. G., Localio, A. R., Barnes, B. A., Hebert, L., Newhouse, J. P., Weiler, P. C., & Hiatt, H. (1991, February 7). The nature of adverse events in hospitalized patients: Results of the Harvard Medical Practice Study II. *The New England Journal of Medicine, 324*(6): 377-384.

Leeuwen van, D. H. (1994, April). Are medication error rates useful as comparative measures of organizational performance? *The Joint Commission Journal on Quality Improvement, 20*(4): 192-199.

Leite de Vasconcellos, M. T., Portela, M. C. (2001). Indice de Massa Corporal e sua rela?ão com variáveis nutricionais e sócio-econômicas: Um exemplo de uso de regressao linear para um grupo de adultos brasileiros. *Cadernos de Saude Publica, 17*(6): 1425-1436.

Leonard, M. (2003). Lessons from the sharp end: Critical components of successful patient safety work. *Focus on Patient Safety, 6*(2): 1-2.

Liang, B. A. (2002). A system of medical error disclosure. *Quality and Safety in Health Care, 11*: 64-68.

Lilley, L. L., & Guanci, R. (1995, November). Applying systems theory. *The American Journal of Nursing, 95*(11): 14-15.

Linstone, H. A., Turoff, M. (Eds.). (1975). *The Delphi method: Techniques and applications.* Reading, MA: Addison-Wesley Publishing Company.

Making health care safer: A critical analysis of patient safety practices. (2001, July). Evidence report 43, prepared for the Agency for Healthcare Research and Quality, Contract No. 290-97-0013. Available: http://www.ahcpr.gov/clinic/ptsafety

Marder, R & Sheff, R.A. (2002). *The step by step guide to Failure Modes and Effects Analysis*. Marblehead, MA: Opus Communications, Inc.

Marx, D. (2001, April 17). *Patient safety and the "just culture": A primer for health care executives.* A report prepared under a grant # R01-HL53772, National Heart, Lung, and Blood Institute, National Institutes of Health. New York, NY: Columbia University.

McBride, A. J., Pates, R., Ramadan, R., & McGowan, C. (2003). Delphi survey of experts' opinions on strategies used by community pharmacists to reduce over-the-counter drug misuse. *Addiction, 98*: 487-497.

McGlynn, E. A., Asch, S. M., Adams, J., Keesey, J., Hicks, J., DeCristofaro, A., & Kerr, E. A. (2003, June 26). The quality of health care delivered to adults in the United States. *The New England Journal of Medicine, 348*(26): 2635-2645.

Medical Records Institute. (2003). *MRI fifth annual survey of EHR trends and usage*. Available: http://www.medrecinst.com/resources/survey/results03/part1.shtml

Medication errors: High liability and price for hospitals. (1992, October). *Hospital Risk Management, 14*(10): 129-133.

Medications errors report and recommendations. (2000, December). Olympia, WA: Washington State Department of Health, Office of the Secretary.

MedMARx Data Reports. (2002). *Summary of information submitted to MedMARx in the Year 2000: Charting a course for change*. The United States Pharmacopeia Convention, Inc. USP Public Relations Department. Available: http://www.usp.org/medmarx/index1.htm

Meurier, C. E., Vincent, C. A., & Parmar, D. G. (1998). Nurses' responses to severity dependent errors: A study of the causal attributions made by nurses following an error. *Journal of Advanced Nursing, 27*: 349-354.

Mohr, J. J., & Batalden, P. B. (2002). Improving safety on the front lines: The role of clinical microsystems. *Quality and Safety in Health Care, 11*: 45-50.

Napper, C., Battles, J. B., Fargason, C. (April, 2003). Pediatrics and patient safety. *The Journal of Pediatrics, 142:* 359-360.

NASA. (2002) *National Aeronautics and Space Administration*. Available: http://www.nasa.gov

National Patient Safety Foundation. (2000). *Agenda for research and development in patient safety.* Chicago, IL: National Patient Safety Foundation.

National Quality Forum. (2002). *Serious reportable events in healthcare.* Washington, DC: Author. Available: http://www.qualityforum.org/neverteaser.pdf

Nauman, J. D., & Palvia, S. (March, 1982). A selection model for systems development tool. *MIS Quarterly, 6*(1):39-48.

NCQA. (2003). *National Committee for Quality Assurance*. Available: http://www.ncqa.org

NCQA. (2003). *Draft materials for 2004 standards: MCO, MBHO and PPO accreditation public comment.* Available: http://www.ncqa.org/Programs/Accreditation/2004/publiccomment.htm

NIST (National Institute of Standards and Technology). (2004). *Baldrige National Quality Program examiner application*. Milwakee, WI: American Society for Quality.

NQMC. (2003). *National Quality Measures Clearinghouse.* Available: http://www.qualitymeasures.ahrq.gov

Nursing's Safety and Quality Initiative. (1999). ANA item # PR-28. Available: http://nursingworld.org/readroom/fssafe99.htm

Pelonero, A.L., Elliott, R.L., Barber, J.W., & Best A. (1996). Physician caseloads at public mental hospitals. *American Journal of Psychiatry, 153*(3): 429-431.

Proulx, S., Wilfinger, R., & Cohen, M. R. (1997). Medication error prevention: Profiling one of pharmacy's foremost advocacy efforts for advice on error prevention. *Pharmacy Practice Management Quarterly, 17*(1): 1-9.

Reason, J. T. (1990). *Human error.* New York, NY: Cambridge University Press.

Reason, J. (2002). Combating omission errors through task analysis and good reminders. *Quality and Safety in Health Care, 11*: 40-44.

Reimann, C. W. (1988, January). The Malcolm Baldrige National Quality Improvement Award: The U.S. now has a national award for quality improvement and leadership. *Quality Progress, 21*(1): 71-73.

Reimann, C. W. (1989, October 11-13). Winning the race with manufacturing excellence. In *Proceedings of the Annual Conference for the Association for Manufacturing Excellence,* (pp.11-13). Louisville, KY: Association for Manufacturing Excellence.

Robinson, A. R., Hohmann, K. B., Rifkin, J. I., Topp, D., Gilroy, C. M., Pickard, J. A., & Anderson, R. J. (2002, October). Physician and public opinions on quality of health care and the problem of medical errors. *Archives of Internal Medicine, 162*(19): 2186-2190.

Rotondi, A., & Gustafson, D. (1996). Theoretical, methodological and practical issues arising out of the Delphi method. In M. Adler, & E. Ziglio, (Eds.), *Gazing into the Oracle: The Delphi method and its application to social policy and public health.* (pp. 34-55). Bristol, PA: Jessica Kingsley Publishers, Ltd.

Scheibe, M., Skutsch, M., & Schofer J. (1975). Experiments in Delphi methodology. In Linstone, H.A., Turoff, M. (Eds.). *The Delphi method: Techniques and applications* (pp.262-287). Reading, MA: Addison-Wesley Publishing Company.

Schoenbaum, S. C., Audet, A. J., & Davis, K. (November/December, 2003). Obtaining greater value from health care: The roles of the U.S. government. *Health Affairs, 22*(6): 183-190.

Semon, T.T. (1997). Outlier problem has no good practical solution. *Marketing News, 31*(13): 16.

Sentinel events: Approaches to error reduction and prevention. (1998, April). [Book excerpt from: Joint Commission on Accreditation of Healthcare Organizations. (1998). *Sentinel events: Evaluating cause and planning improvement*. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations]. *Joint Commission Journal on Quality Improvement, 24*(4): 175-186.

Sentinel event statistics. (2002, June). *Report on the sentinel events reviewed by the Joint Commission on Accreditation of Healthcare Organizations in the period January 1995-June, 2002.* Available: http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/se_stats.htm

Sexton, J.B., Helmreih, R.L., Rowan, K., Vella, K., Boyden, J., Neilands, T.B., Roberts, P.R., & Thomas E.J. (2003). *The safety attitude questionnaire: A psychometric validation*. Technical report, The University of Texas Center of Excellence for Patient Safety Research and Practice. Austin, TX. AHRQ Grants ## 1PO1HS1154401 and U18HS1116401.

Sharp, D., Liebenau, A., Stocks, N., Bennewith, O., Evans, M., Jones, W. B., Peters, T., Goldberg, D., & Gunnell, D. (2003). Locally developed guidelines for the aftercare of deliberate self-harm patients in general practice. *Primary Health Care Research and Development, 4*: 21-28.

Shojania, K. G., Duncan, B. W., McDonald, K. M., & Wachter, R. M. (2002, July). Safe but sound: Patient safety meets evidence-based medicine. *Journal of the American Medical Association, 288*(4): 508-513.

Shortell, S.M. (2000). *Remaking health care in America: Building organized delivery systems*. (2nd Ed.) San Francisco, CA: Jossey-Bass Publishers.

Smetzer, J. L. (1998, May). Lesson from Colorado: Beyond blaming individuals. *Nursing, 28(*5): 48-51.

Smetzer, J. L., Vaida, A. J., Cohen, M. R., Tranum, D., Pittman, M. A., & Armstrong, C. W. (2003, November), Findings from the ISMP Medication Safety Self-Assessment for hospitals. *Joint Commission Journal on Quality and Safety, 29*(11):586-597.

Spath, P. L. (Ed.). (2000). *Error reduction in health care.* San Francisco, CA: Jossey-Bass Publishers.

Spatz, C. (2001). *Basic statistics: Tales of distributions.* (7th ed.). Belmont, CA: Wadsworth/Thompson Learning.

Staker, Larry V. (2000). Practice-based learning for improvement: The pursuit of clinical excellence. *Texas Medicine, 96*: 53-60.

Stark, M. (2002). *Integrating theory and practice: Applying the Quality Improvement paradigm to product line engineering*. NASA's Information Systems Division. Available: http://isc.gsfc.nasa.gov/Papers/DOC/icse24stark.doc

Storzbach, D., Rohlman, D.S., Anger, W.K., Binder, L.M., Campbell, K.A. (2001). Neurobehavioral deficits in Persian Gulf veterans: Additional evidence from a population-based study. *Environmental Research, 85*(1): 1-13.

Subar, A.F., Midthune, D., Kulldorff, M., Brown, C.C., Thompson, F.E., Kipnis, V., & Schatzkin, A. (2000). Evaluation of alternative approaches to assign nutrient values to food groups in food frequency questionnaires. *American Journal of Epidemiology, 152*(3): 279-286.

Thompson, L.T. (1973, June). *A pilot application of Delphi techniques to the drug field: Some experimental findings.* The New York City Rand Institute, R-1124. Santa Monica, CA: The Rand Corporation.

Thomson O'Brien, M.A., Freemantle, N., Oxman, A.D., Wolf, F., Davis, D.A., & Herrin, J. (2001). Continuing education meetings and workshops: Effects on professional practice and health care outcomes (Cochrane Review). *The Cochrane Library*, Issue 2: p. CD003030. Oxford, OH: Update Software Ltd.

Thomson O'Brien, M.A., Oxman, A.D., Davis, D.A., Haynes, R.B., Freemantle, N., & Harvey, E.L. (2000). Audit and feedback: Effects on professional practice and healthcare outcomes (Cochrane Review). *The Cochrane Library*, Issue 2: p. CD000259. Oxford, OH: Update Software Ltd.

Thomson O'Brien, M.A., Oxman, A.D., Davis, D.A., Haynes, R.B., Freemantle, N., & Harvey, E.L. (2000). Educational outreach visits: Effects on professional practice and health care outcomes (Cochrane Review). *The Cochrane Library*, Issue 2: p. CD000409. Oxford, OH: Update Software Ltd.

Turoff, M. (1975). The policy Delphi. In: Linstone, H.A., Turoff, M. (Eds.), *The Delphi method: Techniques and applications* (pp. 84-101). Reading, MA: Addison-Wesley Publishing Company.

Turoff, M., & Hiltz, S. R. (1996). Computer-based Delphi process. In: M. Adler, & E. Ziglio, (Eds.), *Gazing into the Oracle: The Delphi method and its application to social policy and public health.* (pp.56-85). Bristol, PA: Jessica Kingsley Publishers, Ltd.

URAC (Utilization Review Accreditation Commission). (2003). *Draft accreditation 2004 changes*. Available: http://www.urac.org

U.S. Department of Health and Human Services, & Agency for Healthcare Research and Quality. (2003, December). *National Healthcare Quality Report.* Rockville, MD: AHRQ. AHRQ Pub. No. 04-RG003.

VanGeest, J. B., & Cummins, D. S. (2003). *Educational needs assessment for improving patient safety: Results of a national study of physicians and nurses*. Chicago, IL: National Patient Safety Foundation. White Paper Report No. 3: March 20, 2003. Available: http://www.npsf.org/download/EdNeedsAssess.pdf

Vincent, C., Taylor-Adams, S., Stanhope, N. (1998, April). Framework for analyzing risk and safety in clinical medicine. *British Medical Journal, 316:* 1154-1157.

Wang, C. C., Wang, Y., Zhang, K., Fang, J., Liu, W., Luo, S., Tang, S., Wang, S., & Li, V. C. (2003). Reproductive health indicators for China rural areas. *Social Science & Medicine, 57:* 217-225.

Weber, D. (2003, January/February). 25 health care trends: What's hot, what's not, and what does the future hold? *Physician Executive, 29*(1): 6-14.

White, S. V., & Savitsky, M. (2003, May/June). Sister Mary Jean Ryan on the first Baldrige award in healthcare. *Journal for Healthcare Quality, 25*(3): 24-25.

Williams, J. R. (2000). Information defines quality. *Texas Medicine: Symposium on Quality in Healthcare, 96*(10): 9-11.

Wolf, Z. R., McGoldrick, T. B., Flynn, E. R., & Warwick, F. (1996, March/April). Factors associated with a perceived harmful outcome from medication errors: A pilot study. *The Journal of Continuous Education in Nursing, 27*(2): 65-74.

Woods, D.D., & Cook, R.I. (2002). Nine steps to move forward from error. *Cognition, Technology & Work, 4:* 137-144.

Ziglio, E. (1996). The Delphi method and its contribution to decision making. In M. Adler, & E. Ziglio, (Eds.), *Gazing into the Oracle: The Delphi method and its application to social policy and public health.* (pp. 3-33). Bristol, PA: Jessica Kingsley Publishers, Ltd.

APPENDIX 1

DELPHI PANEL EXPERTS

Ann Allen, R.N., M.S.N., C.P.H.Q.
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Administrative Director, Rehabilitation, Mental Health, Privacy Official
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Cheryl Knapp
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Cynthia Miller Pellegrino
Director and CEO
Western Maryland Hospital Center
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Dana Rodrigue
Chief Quality Resource Officer
Thibodaux Regional Medical Center
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Jan Carson
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Villa Maria Continuum
Timonium, MD

Kathleen Jennison Goonan, M.D.
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Baldrige Quality/Senior Project Coordinator
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Pat Demarest, R.N., C.N.S.
Quality and Accreditation Coordinator
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Patricia M. Smith, R.N., B.S.N., M.S.
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Tom Lundquist, M.D., M.M.M.
Executive Vice President and Chief Medical Officer
DoctorQuality, Inc.
Conshohocken, PA

Wayne B. Wheeler, M.D., J.D., M.P.H.
Medical Director, Community Health and Wellness
Southern Ohio Medical Center
Portsmouth, OH

Delphi Expert – Requested Confidentiality of Name
Director of Financial Planning, MI

Delphi Expert – Requested Confidentiality of Name
Department Chairman, TX

APPENDIX 2

FIRST ROUND SURVEY INSTRUMENT

INFORMATION SHEET

for participation in a Delphi study and use of data in presentation or publication:

Critical Processes and Performance Measures for Patient Safety Systems in Healthcare Institutions: A Delphi Study

You understand that you agree to participate in a dissertation research study. You understand that the purpose of this study is to identify critical processes and performance measures of quality that can serve as a framework for healthcare institutions, which are implementing continuous quality improvement programs in patient safety systems. This study will identify critical processes and performance measures in the context of the Malcolm Baldrige Quality Award Health Care Criteria for Performance Excellence. In addition, the study will identify current patient safety trends and forecast future trends for healthcare institutions, which represent serious challenges or substantial change in healthcare delivery, services and programs. Twelve to 15 (and not less than 8 in any round) experts in the area of healthcare quality improvement and/or patient safety, recruited from healthcare institutions in different states, will serve on the study Delphi panel.

You understand that you are given an option to choose if you want to work with a hard copy of the questionnaire instrument (mailed), or prefer electronic copy sent via email. The time between survey rounds will depend on the way chosen for survey completion, timeliness of responses and time needed for data analysis. For each round, you would need approximately 30-45 min to fill in the questionnaire. It is estimated that one round will take approximately 4-6 weeks (time to reply and analyze the data), i.e. a questionnaire will come to you to fill in once a month 3 to 5 times (or more until consensus is reached). Consensus is usually reached by round five.

You understand that participation in this study is <u>*confidential*</u> during the study.

You understand that there will be no monetary or other compensation for your participation in this study.

You understand that your participation is voluntary and you may withdraw at any point or may refuse to answer any questions that make you feel uncomfortable.

You understand that this research study has been reviewed and approved by the Institutional Review Board-Human Subjects in Research, Texas A&M University. For research-related problems or questions regarding subjects' rights, you can contact the Institutional Review Board through Dr. Michael W. Buckley, Director of Support Services, Office of Vice President for Research at (979) 458 4067 or mwbuckley@tamu.edu.

You have read and understood the information provided to you. You have had all your questions answered to your satisfaction, and you voluntary agree to participate in this study. You agree your name and affiliated institution to be honored in the final dissertation and in any presentations and/or publications that might result from this study.

Investigator's contact details:
Ralitsa Akins
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Critical Processes and Performance Measures for Patient Safety Systems in Healthcare Institutions: A Delphi Study

INSTRUCTIONS:

Tables 1 to 6 present suggested items, areas to address, critical processes and performance measures for patient safety systems in healthcare institutions as identified in current literature on patient safety in healthcare and by national patient safety organizations and healthcare accreditation bodies. The organization of the items is consistent with the organization of the Malcolm Baldrige National Quality Award Criteria for Health Care.

Each table provides space for ranking of the importance of the relevant critical processes and performance measures for patient safety systems in healthcare institutions. The importance of critical processes is ranked twice: once in terms of its current importance and a second time in terms of its future importance. Performance measures are ranked only once in terms of their current importance.

Table 7 does not provide critical processes. It identifies performance measures relevant to assessing healthcare institution's patient safety results and their current and future importance to patient safety systems in healthcare.

For tables 1 to 7, please place a rank in each respective "Rank" column for each Critical Process and Performance Measure.
Rank each item from 1 to 4, in the context of its importance to patient safety systems in healthcare institutions, where

"**4**" represents "**very important**" to patient safety systems in healthcare institutions;
"**3**" represents "**important**" to patient safety systems in healthcare institutions;
"**2**" represents "**not very important**" to patient safety systems in healthcare institutions;
"**1**" represents "**unimportant**" to patient safety systems in healthcare institutions.

Each critical item, critical process and performance measure is numbered, where a two-digit identification refers to an item (e.g. 1.1.), a three-digit identification (e.g. 1.1.1.) refers to a critical process, and a four-digit identification (e.g. 1.1.1.1.) refers to a performance measure.

In the space provided after each item, please add any new critical process (you believe should be included for that particular item) in the space identified as "Critical process not included" and/or any new performance measure (you believe should be included for that particular critical process) in the space identified as "Performance measure not included" and score the ones you add using the same ranking scale. If you add a new critical process, please suggest a performance measure for its assessment. If you add a new performance measure only, please refer to the critical process (e.g. 1.1.1.) it addresses.

Additionally, in the space provided for comments at the end section for each table, please feel free to re-word any critical process and/or performance measure. Please, refer to the number of the critical process (e.g. 1.1.1.) or measure (e.g. 1.1.1.1.) you are addressing.

Additional space for comments is provided at the end of the questionnaire.

Please, return the filled-in questionnaire within two weeks of receipt.

Cordial thanks for your time and effort for filling in this questionnaire, ranking the suggested critical processes and performance measures and making improvements to them.

Expert's name:
Date:

Table 1: Leadership

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"					
Item	**<u>Area to address</u>: Critical Process**	**Rank current importance**	**Rank future importance**	**Performance Measure**	**Rank**
1.1. Institutional Leadership	<u>1.1.1. Senior Leadership Direction</u>: How senior leaders communicate the priority of patient safety to all stakeholders.			1.1.1.1. Functioning institutional systems for communicating patient safety policies, issues and activities to all stakeholders, actively seeking feedback and use of the information for improvement and creating a culture of safety.	
	<u>1.1.2. Institutional Governance</u>: How senior leaders create an environment for development and improvement of patient safety systems in the institution.			1.1.2.1. A patient safety plan and institutional policies support non-punitive reporting environment and disclosure of adverse events.	
				1.1.2.2. Systems are in place on different institutional levels for collection and analysis of relevant data used for institutional improvement of patient safety.	
	<u>1.1.3. Institutional Performance Review</u>: How patient safety findings are translated in institutional short- and long-term goals and priorities.			1.1.3.1. There is an institutional structure that takes the lead in continuous internal assessment of patient safety, review of current patient safety research findings and translation of research and developed clinical guidelines in institution's clinical practices, strategic planning and priorities.	
	Critical process not included (optional):			***Performance measure not included (optional):***	

Table 1: Leadership (cont.).

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"					
Item	**Area to address: Critical Process**	**Rank current importance**	**Rank future importance**	**Performance Measure**	**Rank**
1.2. Social Responsibility	1.2.1. Responsibilities to the public: How the institution incorporates patient safety accreditation and legal requirements as integral parts of its performance improvement.			1.2.1.1. Institutional patient safety plans and policies are developed, carried forward and improved in accordance with the regulations and recommendations of legislative bodies, patient safety agencies and accreditation bodies, such as but not limited to JCAHO, OSHA, NRA, IHI, NCQA, URAC, AAHP, AHA, etc.	
				1.2.1.2. Requirements in the areas of patient identification, healthcare communications, administration of high-alert medications, wrong-side surgery, use of infusion pumps and clinical alarm systems are adequately addressed.	
	1.2.2. Ethical Behavior: How the institution ensures ethical communication with stakeholders in regard to patient safety issues.			1.2.2.1. Ongoing monitoring of quality issues and appropriate procedures are in place for reporting and analysis of adverse events and improvement of institution's patient safety systems.	
				1.2.2.2. Adopting guidelines and monitoring healthcare staff and professionals compliance with patient safety policies and procedures and effective communication of these policies and procedures to patients and their families.	
	1.2.3. Support of key communities: How the institution proactively responds to current and future public concerns in regard to patient safety.			1.2.3.1. Institutional plan and support systems are in place for proactive collecting and analysis of patient safety information and utilization of the review results for improvement of the patient safety systems.	
	Critical process not included (optional):			***Performance measure not included (optional):***	
Additional Comments:					

Table 2. Strategic Planning.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**Area to Address: Critical Process**	**Rank current importance**	**Rank future importance**	**Performance Measure**	**Rank**
2.1. Strategy Development	2.1.1. Strategic Development Process: How the healthcare institution develops its view of the future and sets directions and policies to communicate, implement and monitor its patient safety systems.			2.1.1.1. Patient safety action plans and systems for sustaining achieved improvements are in accordance with national best practices and performance measures guidelines and provide for optimal matching of healthcare needs and service delivery capabilities.	
				2.1.1.2. Ongoing, planned and regularly monitored effort in creation, adaptation and adoption of clinical guidelines and best practices based on clinical patient safety research.	
				2.1.1.3. Comprehensive and ongoing proactive approach in seeking stakeholder expectations in setting goals for short- and long-term patient safety planning.	
				2.1.1.4. The capabilities of modern technologies and database access are taken into consideration in setting goals for short- and long-term planning.	
	2.1.2. Strategic Objectives: How patient safety practices are identified and translated to institution's goals.			2.1.2.1. Data from national databanks and practice guidelines from professional organizations are incorporated in institution's patient safety goals, plans and patient care practices.	
	Critical process not included (optional):			***Performance measure not included (optional):***	

Table 2. Strategic Planning (cont.)

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"					
Item	**Area to Address: Critical Process**	**Rank current importance**	**Rank future importance**	**Performance Measure**	**Rank**
2.2. Strategy Deployment	2.2.1. Action Plan Development and Deployment: How the institution develops, monitors and improves action plans to ensure patient safety.			2.2.1.1. Institutional and unit patient safety action plans and systems for sustaining achieved improvements are in place and are revised and improved on a regular basis.	
				2.2.1.2. System-wide processes are used for communication and alignment of patient safety planned efforts.	
	2.2.2. Performance Projection: How leaders achieve consistency and improvement of healthcare delivery.			2.2.2.1. National, regional and specialty standards (best practices, clinical performance measures, etc.) are incorporated as benchmarks in institution's short- and long-term plans and are used in the assessment of institution's and individual's quality of healthcare delivery.	
	Critical process not included (optional):			***Performance measure not included (optional):***	
Additional Comments:					

Table 3. Focus on Patients, Other Customers and Markets.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	Area to Address: Critical Process	Rank current importance	Rank future importance	Performance Measure	Rank
3.1. Patient, Other Customer and Healthcare Market Knowledge	3.1.1. Patient Safety Market Knowledge: How the healthcare institution determines patients' expectations and appropriate knowledge in regard to patient safety.			3.1.1.1. Coordinated and planned interdepartmental activities to ensure effective team effort for determining the requirements and expectations of culturally and linguistically diverse patient populations in regard to patient safety and use of this information for improvement of institution's patient safety systems.	
				3.1.1.2. Planned, coordinated and aligned institutional activities to ensure patient education and providing of useful information to the intended audiences in regard to patient safety issues, institutional policies and practices.	
	Critical process not included (optional):			***Performance measure not included (optional):***	

Table 3. Focus on Patients, Other Customers and Markets (cont.).

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	<u>**Area to Address**</u>**: Critical Process**	**Rank current importance**	**Rank future importance**	**Performance Measure**	**Rank**
3.2. Patient and Other Customer Relationships and Satisfaction	<u>3.2.1. Patient/Customer Relationship Building</u>: How the healthcare institution gathers and analyses information about patients' and community's expectations in regard to safety of healthcare delivery, and how the results and interpretations are used for improvement of institution's patient safety systems.			3.2.1.1. Proactive alliance building with patient safety groups and local communities for continuous collection, analysis and interpretation of data about patient and other customers expectations.	
				3.2.1.2. Designing, aligning, monitoring and improving of the procedures for inclusion of patients and their families as active team-players in the process of professional healthcare delivery.	
	<u>3.2.2. Satisfaction Determination</u>: How the institution obtains information and feedback from patients on patient safety issues to improve the delivery of healthcare.			3.2.2.1. Design and implementation of comprehensive and accessible systems for adverse events reporting from patients and their families, and continuous analysis of the obtained data.	
				3.2.2.2. Proactive planned effort to enhance patients' knowledge and information in regard to patient safety issues.	
	Critical process not included (optional):			***Performance measure not included (optional):***	
Additional Comments:					

Table 4. Measurement, Analysis and Knowledge Management

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	Area to Address: Critical Process	Rank current importance	Rank future importance	Performance Measure	Rank
4.1. Measurement and Analysis of Institutional Performance	4.1.1. Performance Measurement: How the institution selects and implements into its patient safety systems patient safety benchmarks.			4.1.1.1. Systematic, planned and aligned effort to monitor developments of patient safety standards and implement regional, national and specialty standards as benchmarks for institution's clinical practices.	
				4.1.1.2. Clinical performance measures as developed by national, regional or professional institutions (as applicable) are implemented in the everyday clinical practice, i.e. at the "sharp end" of healthcare service delivery.	
	4.1.2. Performance Measurement: How the institution collects, tracks and analyzes patient safety data.			4.1.2.1. Root Cause Analysis (RCA) and Failure Modes and Effects Analysis (FMEA) training is available to healthcare providers.	
				4.1.2.2. RCA and/or FMEA approach is used on a customary basis by the healthcare providers in analysis of patient safety issues and improvement of healthcare delivery and patient safety.	
				4.1.2.3. Non-punitive reporting systems are in place for recording, monitoring, tracking and analysis of sentinel events and the results from this analysis are used in institution's improvement plans.	
	Critical process not included (optional):			***Performance measure not included (optional):***	

Table 4. Measurement, Analysis and Knowledge Management (cont.).

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"					
Item	**Area to Address: Critical Process**	**Rank current importance**	**Rank future importance**	**Performance Measure**	**Rank**
4.2. Information and Knowledge Management	4.2.1. Data and Information Availability: How the institution ensures that its clinical information technology (Computerized Physician's Order Entry – CPOE, infusion pumps, alarm systems, etc) is reliable, secure and user-friendly.			4.2.1.1. A planned, aligned and monitored institution-wide process of clinical technology use facilitates information transfer and clear communication.	
				4.2.1.2. A process is in place for assurance that technology implementation is in compliance with patient safety requirements.	
	4.2.2. Data and Information Availability: How stakeholders' satisfaction, dissatisfaction and expectations in regard to patient safety are determined and used for improvement of patient safety systems.			4.2.2.1. Data from comprehensive, accessible and user-friendly systems for tracking stakeholder reports, comments and complaints in regard to patient safety satisfaction, dissatisfaction and expectations is used to improve patient safety systems and update patient safety action plans.	
	4.2.3. Institutional Knowledge: How patient safety information is managed in support of overall institution's goals and action plans for performance improvement.			4.2.3.1. Processes are in place to secure integrity, timeliness, reliability, security, accuracy and confidentiality of patient safety related data and analyses of such data are used to positively affect institution's performance improvement and action planning.	
	Critical process not included (optional):			***Performance measure not included (optional):***	
Additional Comments:					

Table 5. Staff Focus.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"					
Item	**Area to Address: Critical Process**	**Rank current importance**	**Rank future importance**	**Performance Measure**	**Rank**
5.1. Work Systems	5.1.1. Organization and Management of Work: How healthcare delivery is organized to promote patient safety systems establishment and innovation.			5.1.1.1. How patient safety issues are communicated, data is collected and analyzed, and existing processes are improved at different institutional levels to promote consistency in the safety of healthcare delivery.	
	5.1.2. Staff Performance Management System: How the institution supports high clinical performance standards and alignment with national clinical performance measures and best case-management practices.			5.1.2.1. Best patient safety practices and clinical guidelines are adopted, monitored and clinician performance is evaluated for consistency with these adopted standards.	
	5.1.3. Staff Performance Management System: How the institution identifies, deploys and monitors patient safety practices.			5.1.3.1. Interdepartmental systems for ensuring seamless healthcare delivery and patient safety are consistent with national, regional or specialty best practices and standards for patient safety and healthcare delivery.	
	5.1.4. Recruitment and Career Progression: How the institution identifies requirements and recognition for patient safety officers.			5.1.4.1. Development, implementation, revision and improvement of institution's plan for hiring, retaining and recognition of patient safety staff.	
	Critical process not included (optional):			***Performance measure not included (optional):***	

Table 5. Staff Focus (cont.).

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	Area to Address: Critical Process	Rank current importance	Rank future importance	Performance Measure	Rank
5.2. Staff Learning and Motivation	5.2.1. Staff Education, Training and Development: How the institution structures and promotes effective education and training of professionals in developing and improving patient safety systems.			5.2.1.1. Institutional mechanism for determining of and acting on patient safety educational and training needs for individuals, teams, departments and different categories of professional caregivers.	
	5.2.2. Motivation and Career Development: How the institution supports the role of patient safety officer.			5.2.2.1. Development, implementation and improvement of internal patient safety policies, practices and activities.	

Table 5. Staff Focus (cont.).

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**<u>Area to Address</u>: Critical Process**	**Rank current importance**	**Rank future importance**	**Performance Measure**	**Rank**
5.3. Staff Well-Being and Satisfaction	<u>5.3.1. Work Environment</u>: How the institution maintains conductive environment in regard to patient safety.			5.3.1.1. Institution's patient safety goals are integrated in institution's everyday healthcare delivery functions, regularly reviewed and improved and progress towards them is continuously monitored and evaluated.	
	<u>5.3.2. Staff Support and Satisfaction</u>: How the institution determines staff satisfaction in implementation of patient safety systems.			5.3.2.1. Institutional mechanisms for periodic gathering of information on healthcare providers' opinions and expectations in regard to factors enhancing or inhibiting communication of sentinel events and using the results of the analysis of all collected data for institutional patient safety improvement.	
	Critical process not included (optional):			***Performance measure not included (optional):***	
Additional Comments:					

Table 6. Process Management.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"					
Item	**Area to address: Critical Process**	**Rank current importance**	**Rank future importance**	**Performance Measure**	**Rank**
6.1. Patient Safety System	6.1.1. Patient Safety System: How the institution determines patient safety process requirements.			6.1.1.1. Accreditation, professional and legal requirements as well as improvements resulting from stakeholder surveys and reporting systems results analyses are incorporated in institution's patient safety systems and processes on a regular basis.	
	6.1.2. Patient Safety System: How the institution designs patient safety systems.			6.1.2.1. Evidence that Quality Improvement (QI) methodology, including but not limited to RCA, FMEA, Plan-Do-Study-Act Cycle (PDSA, Rapid Cycle Change), clinical performance measures and best practices are used to decrease variability of healthcare delivery and improve patient safety outcomes.	
	6.1.3. Patient Safety System: How the institution ensures that patient safety requirements are met at the "sharp end" of the healthcare delivery system.			6.1.3.1. An institutional mechanism exists for continuous monitoring, improvement and sustainability of patient safety outcomes in healthcare delivery.	
	Critical process not included (optional):			***Performance measure not included (optional):***	

Table 6. Process Management (cont.).

Ranking: "4" represents "very important"; "3" represents "important"; "2" represents "not very important"; and "1" represents "unimportant."					
Item	**<u>Area to address</u>: Critical Process**	**Rank current importance**	**Rank future importance**	**Performance Measure**	**Rank**
6.2. Support Processes	<u>6.2.1. Patient Safety Support Processes</u>: How the institution coordinates departmental and interdepartmental patient safety infrastructures to reduce variability in healthcare delivery and improve performance.			6.2.1.1. Systems for departmental and interdepartmental communications, collaborations and aligned effort in regard to seamless implementation of best practices and clinical guidelines in patient identification, medication and continuous case management are assessed and improved on an ongoing basis.	
	Critical process not included (optional):			***Performance measure not included (optional):***	
Additional Comments:					

Table 7. Institutional Performance.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant**"

Item Area to address: Critical process	**Performance Measure**	**Rank** ***current importance***	**Rank** ***future importance***
7.1. Patient Safety Institutional Performance Area to Address: Patient Safety Results How the institution ensures patient safety	7.1.1. A 2-identifier system for patient identification is in place and is consistent in the continuity of healthcare throughout the institution.		
	7.1.2. Healthcare departmental and interdepartmental communications are accurate and reliable at different institutional levels.		
	7.1.3. The institution monitors the administration of high-alert medications.		
	7.1.4. Proper marking of surgery sites is established as a precaution to decrease incidents of wrong-side surgery (where applicable).		
	7.1.5. The institution ensures adequate professional staff preparation for proper and safe use of infusion pumps (where applicable).		
	7.1.6. The institution ensures adequate professional staff preparation for proper and safe use of clinical alarm systems (where applicable).		
	7.1.7. The institution ensures a non-punitive approach for reporting sentinel events.		
	7.1.8. The institution encourages utilization of RCA, FMEA, and QI methodology in analyzing multidimensional patient safety practices at different institutional levels.		
	7.1.9. The institution ensures that an accessible, confidential and adequately functioning reporting system is in place for sentinel events reporting. .		
	7.1.10. The institution ensures that a uniform, unambiguous and comprehensive nomenclature for sentinel events reporting is adopted throughout the healthcare institution.		
	7.1.11. The institution proactively works towards changing the traditional culture of "blame and shame."		
	7.1.12. The institution ensures safe healthcare delivery through utilization of modern technology.		
	7.1.13. The institution ensures that professional, accreditation and legal requirements in the area of patient safety are adequately addressed.		
	7.1.14. The institution ensures that national benchmarks in healthcare delivery (best practices, clinical performance measures, etc.) are used to decrease variability of healthcare delivery and improve patient safety outcomes.		
	Performance Measure not included (optional):		
Additional Comments:			

Please, list and briefly discuss which are the top five barriers to implementation of patient safety systems in healthcare organizations:

1.

2.

3.

4.

5.

Additional comments (optional):

Thank you!

APPENDIX 3

SECOND ROUND SURVEY INSTRUMENT

Critical Processes and Performance Measures for Patient Safety Systems in Healthcare Institutions: A Delphi Study

Second Round

GENERAL INFORMATION:

The Second Round questionnaire follows the organization of the First Round questionnaire. Tables 1 to 6 present suggested items, areas to address, critical processes and performance measures for patient safety systems in healthcare institutions. Each critical item, critical process and performance measure is numbered, where a two-digit identification refers to an item (e.g. 1.1.), a three-digit identification (e.g. 1.1.1.) refers to a critical process, and a four-digit identification (e.g. 1.1.1.1.) refers to a performance measure. Table 7 does not provide critical processes. It identifies performance measures relevant to assessing healthcare institution's patient safety results and their current and future importance to patient safety systems in healthcare. The importance of critical processes is ranked twice: once in terms of its current importance and a second time in terms of its future importance. Performance measures are ranked only once in terms of their current importance. Table 8 presents barriers to implementation of patient safety systems in healthcare institutions as suggested by the Delphi panel in the First Round survey.

INSTRUCTIONS FOR SECOND ROUND:

For each critical process and performance measure, the Second Round tables provide mean score for the group, individual panelist's score and space for change of rank, if deemed appropriate. Please, after considering the group mean and your previous rank, provide your new rank, when deemed appropriate, for each critical process and performance measure in tables 1 through 7. If no change of rank is deemed appropriate, please leave the space for "New rank" blank.

Critical processes and performance measures that have been re-worded by the Delphi panel are marked in bold with **"Corrected!"** Where more than one panelist suggested similar re-wording of a critical process and/or a performance measure, the new critical process or performance measure was included to accommodate all suggestions with the minimum possible modification to the original wording provided by the panelists. In light of the suggested modifications, please give a careful review to your original ranking for each corrected critical process/performance measure and the need for a new rank. Provide your new rank, when deemed appropriate, in the column labeled "New rank." If no change of rank is deemed appropriate, please leave the space for "New rank" blank.

New critical processes and performance measures suggested by the Delphi panelists are marked in bold with **"New!"** Where more than one panelist suggested similar new critical processes and/or performance measures, the new critical process or performance measure was included to accommodate all suggestions with the minimum possible modification to the original wording provided by the panelists. Please rank all new critical processes and performance measures in the column labeled "New rank."

The ranking is from 1 to 4, in the context of item's importance to patient safety systems in healthcare institutions, where:

"**4**" represents "**very important**" to patient safety systems in healthcare institutions;
"**3**" represents "**important**" to patient safety systems in healthcare institutions;
"**2**" represents "**not very important**" to patient safety systems in healthcare institutions;
"**1**" represents "**unimportant**" to patient safety systems in healthcare institutions.

Please, complete table 8, Barriers to implementation of patient safety systems, following the instructions immediately prior to table 8.

Please, return the filled-in questionnaire within two weeks of receipt.

Expert's name:
Date:

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Table 1: Leadership

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"											
Item	**Area to address: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
1.1. Institutional Leadership	1.1.1. Senior Leadership Direction: How senior leaders communicate the priority of patient safety to all stakeholders.							1.1.1.1. Functioning institutional systems for communicating patient safety policies, issues and activities to all stakeholders, actively seeking feedback and use of the information for improvement and creating a culture of safety.			
								1.1.1.2. New! Provision and use of real time adverse event reporting tool that alerts leadership automatically to events as they happen, thereby improving real-time communication and stressing the importance of performance improvement in real time.	N/A	N/A	
	1.1.2. Institutional Governance: How senior leaders create an environment for development and improvement of patient safety systems in the institution.							1.1.2.1. A patient safety plan and institutional policies support non-punitive reporting environment and disclosure of adverse events.			
								1.1.2.2. Systems are in place on different institutional levels for collection and analysis of relevant data used for institutional improvement of patient safety.			
	1.1.3. Institutional Performance Review: How patient safety findings are translated in institutional short- and long-term goals and priorities.							1.1.3.1. There is an institutional structure that takes the lead in continuous internal assessment of patient safety, review of current patient safety research findings and translation of research and developed clinical guidelines in institution's clinical practices, strategic planning and priorities.			

Table 1: Leadership (cont.).

Ranking: “**4**” represents “**very important**”; “**3**” represents “**important**”; “**2**” represents “**not very important**”; and “**1**” represents “**unimportant.**”

Item	<u>Area to address</u>: Critical Process	Current importance			Future importance			Performance Measure	Rank		
		Mean	Your rank	New rank	Mean	Your rank	New rank		Mean	Your rank	New rank
1.2. Social Responsibility	<u>1.2.1. Responsibilities to the public</u>: How the institution incorporates patient safety accreditation and legal requirements as integral parts of its performance improvement.							1.2.1.1. Institutional patient safety plans and policies are developed, carried forward and improved in accordance with the regulations and recommendations of legislative bodies, patient safety agencies and accreditation bodies, such as but not limited to JCAHO, OSHA, NRA, IHI, NCQA, URAC, AAHP, AHA, etc.			
								1.2.1.2. Requirements in the areas of patient identification, healthcare communications, administration of high-alert medications, wrong-site surgery, use of infusion pumps and clinical alarm systems are adequately addressed.			
	<u>1.2.2. Ethical Behavior</u>: How the institution ensures ethical communication with stakeholders in regard to patient safety issues.							1.2.2.1. Ongoing monitoring of quality issues and appropriate procedures are in place for reporting and analysis of adverse events and improvement of institution’s patient safety systems.			
								1.2.2.2. Adopting guidelines and monitoring healthcare staff and professionals compliance with patient safety policies and procedures and effective communication of these policies and procedures to patients and their families.			
	<u>1.2.3. Support of key communities</u>: How the institution proactively responds to current and future public concerns in regard to patient safety.							1.2.3.1. Institutional plan and support systems are in place for proactive collecting and analysis of patient safety information and utilization of the review results for improvement of the patient safety systems.			
	<u>1.2.4. New!</u> How the institution monitors its medication error rate.	N/A	N/A		N/A	N/A		**1.2.4.1. New!** Independent medication error review team is identified and educated in regard to the medication usage cycle and is engaged in developing and monitoring medication safety system.	N/A	N/A	

Table 2. Strategic Planning.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**Area to Address: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
2.1. Strategy Development	2.1.1. Strategic Development Process: How the healthcare institution develops its view of the future and sets directions and policies to communicate, implement and monitor its patient safety systems.							2.1.1.1. Patient safety action plans and systems for sustaining achieved improvements are in accordance with national best practices and performance measures guidelines and provide for optimal matching of healthcare needs and service delivery capabilities.			
								2.1.1.2. Ongoing, planned and regularly monitored effort in creation, adaptation and adoption of clinical guidelines and best practices based on clinical patient safety research.			
								2.1.1.3. Comprehensive and ongoing proactive approach in seeking stakeholder expectations in setting goals for short- and long-term patient safety planning.			
								2.1.1.4. The capabilities of modern technologies and database access are taken into consideration in setting goals for short- and long-term planning.			
	2.1.2. Strategic Objectives: How patient safety practices are identified and translated to institution's goals.							2.1.2.1. Data from national databanks and practice guidelines from professional organizations are incorporated in institution's patient safety goals, plans and patient care practices.			
	2.1.3. New! How the institution achieves realistic evaluation of technology capability for improving safety (present and future).	N/A	N/A		N/A	N/A		**2.1.3.1. New!** Cost-benefit analysis of safety technology with accumulation of data to evaluate the accuracy of such estimates over time and life of safety technology projects.	N/A	N/A	

Table 2. Strategic Planning (cont.)

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**Area to Address: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
2.2. Strategy Deployment	2.2.1. Action Plan Development and Deployment: How the institution develops, monitors and improves action plans to ensure patient safety.							2.2.1.1. Institutional and unit patient safety action plans and systems for sustaining achieved improvements are in place and are revised and improved on a regular basis.			
								2.2.1.2. System-wide processes are used for communication and alignment of patient safety planned efforts.			
	2.2.2. Performance Projection: How leaders achieve consistency and improvement of healthcare delivery.							2.2.2.1. National, regional and specialty standards (best practices, clinical performance measures, etc.) are incorporated as benchmarks in institution's short- and long-term plans and are used in the assessment of institution's and individual's quality of healthcare delivery.			

Table 3. Focus on Patients, Other Customers and Markets.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**Area to Address: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
3.1. Patient, Other Customer and Healthcare Market Knowledge	3.1.1. Patient Safety Market Knowledge: How the healthcare institution determines patients' expectations and appropriate knowledge in regard to patient safety.							3.1.1.1. Coordinated and planned interdepartmental activities to ensure effective team effort for determining the requirements and expectations of culturally and linguistically diverse patient populations in regard to patient safety and use of this information for improvement of institution's patient safety systems.			
								3.1.1.2. Planned, coordinated and aligned institutional activities to ensure patient education and providing of useful information to the intended audiences in regard to patient safety issues, institutional policies and practices.			
	3.1.2. New! Patient Safety Market Knowledge: How the institution helps set the expectations of patients and infuses realistic goals and expectations into the marketplace.	N/A	N/A		N/A	N/A		**3.1.2.1. New!** Outcome determination of patient expectations and efforts to influence the development of realistic expectations.	N/A	N/A	

Table 3. Focus on Patients, Other Customers and Markets (cont.).

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"											
Item	**<u>Area to Address</u>: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
3.2. Patient and Other Customer Relationships and Satisfaction	<u>3.2.1. Patient/Customer Relationship Building</u>: How the healthcare institution gathers and analyses information about patients' and community's expectations in regard to safety of healthcare delivery, and how the results and interpretations are used for improvement of institution's patient safety systems.							3.2.1.1. Proactive alliance building with patient safety groups and local communities for continuous collection, analysis and interpretation of data about patient and other customer expectations.			
								3.2.1.2. Designing, aligning, monitoring and improving of the procedures for inclusion of patients and their families as active team-players in the process of professional healthcare delivery.			
	<u>3.2.2. Satisfaction Determination</u>: How the institution obtains information and feedback from patients on patient safety issues to improve the delivery of healthcare.							3.2.2.1. Design and implementation of comprehensive and accessible systems for adverse events reporting from patients and their families, and continuous analysis of the obtained data.			
								3.2.2.2. Proactive planned effort to enhance patients' knowledge and information in regard to patient safety issues.			

Table 4. Measurement, Analysis and Knowledge Management

Ranking: “**4**” represents “**very important**”; “**3**” represents “**important**”; “**2**” represents “**not very important**”; and “**1**” represents “**unimportant.**”

Item	Area to Address: Critical Process	Current importance			Future importance			Performance Measure	Rank		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
4.1. Measurement and Analysis of Institutional Performance	4.1.1. Performance Measurement: How the institution selects and implements into its patient safety systems patient safety benchmarks.							4.1.1.1. Systematic, planned and aligned effort to monitor developments of patient safety standards and implement regional, national and specialty standards as benchmarks for institution’s clinical practices.			
								4.1.1.2. Clinical performance measures as developed by national, regional or professional institutions (as applicable) are implemented in the everyday clinical practice, i.e. at the “sharp end” of healthcare service delivery.			
	4.1.2. Performance Measurement: How the institution collects, tracks and analyzes patient safety data.							4.1.2.1. Root Cause Analysis (RCA) and Failure Modes and Effects Analysis (FMEA) training is available to healthcare providers.			
								4.1.2.2. RCA and/or FMEA approach is used on a customary basis by the healthcare providers in analysis of patient safety issues and improvement of healthcare delivery and patient safety.			
								4.1.2.3. Corrected! Non-punitive reporting systems are in place for recording, monitoring, tracking and analysis of **adverse events and near misses** and the results from this analysis are used in institution’s improvement plans.			
	4.1.3. New! How the institution monitors the occurrence of near misses and how uses this information for process improvement.	N/A	N/A		N/A	N/A		**4.1.3.1. New!** A process exists for recording, monitoring, tracking and analysis of near misses and feedback is used for process improvement.	N/A	N/A	

Table 4. Measurement, Analysis and Knowledge Management (cont.)

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**Area to Address: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
4.2. Information and Knowledge Management	4.2.1. Data and Information Availability: How the institution ensures that its clinical information technology (Computerized Physician's Order Entry – CPOE, infusion pumps, alarm systems, etc) is reliable, secure and user-friendly.							4.2.1.1. A planned, aligned and monitored institution-wide process of clinical technology use facilitates information transfer and clear communication.			
								4.2.1.2. A process is in place for assurance that technology implementation is in compliance with patient safety requirements.			
	4.2.2. Data and Information Availability: How stakeholders' satisfaction, dissatisfaction and expectations in regard to patient safety are determined and used for improvement of patient safety systems.							4.2.2.1. Data from comprehensive, accessible and user-friendly systems for tracking stakeholder reports, comments and complaints in regard to patient safety satisfaction, dissatisfaction and expectations is used to improve patient safety systems and update patient safety action plans.			
	4.2.3. Corrected! Institutional Knowledge: How patient safety information is **shared with all stakeholders** in support of overall institution's goals and action plans for performance improvement.							**4.2.3.1.Corrected!** Processes are in place to secure integrity, timeliness, reliability, security, accuracy and confidentiality of patient safety related data and analyses of such data**, as it is shared with all stakeholders,** are used to positively affect institution's performance improvement and action planning.			

Table 5. Staff Focus.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**<u>Area to Address</u>: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
5.1. Work Systems	<u>5.1.1. Organization and Management of Work</u>: How healthcare delivery is organized to promote patient safety systems establishment and innovation.							5.1.1.1. How patient safety issues are communicated, data is collected and analyzed, and existing processes are improved at different institutional levels to promote consistency in the safety of healthcare delivery.			
	<u>5.1.2. Staff Performance Management System</u>: How the institution supports high clinical performance standards and alignment with national clinical performance measures and best case- management practices.							5.1.2.1. Best patient safety practices and clinical guidelines are adopted, monitored and clinician performance is evaluated for consistency with these adopted standards.			
	<u>5.1.3. Staff Performance Management System</u>: How the institution identifies, deploys and monitors patient safety practices.							5.1.3.1. Interdepartmental systems for ensuring seamless healthcare delivery and patient safety are consistent with national, regional or specialty best practices and standards for patient safety and healthcare delivery.			
	<u>5.1.4. Recruitment and Career Progression</u>: How the institution identifies requirements and recognition for patient safety officers.							5.1.4.1. Development, implementation, revision and improvement of institution's plan for hiring, retaining and recognition of patient safety staff.			
	<u>5.1.5. New!</u> <u>Recruitment and Career Progression</u>: How the institution includes safety compliance and attitudes in staff recruitment, selection and promotion.	N/A	N/A		N/A	N/A		**5.1.5.1. New!** General staff knowledge and practice of safe activities is rewarded and taken into consideration for recruitment, selection and promotion.	N/A	N/A	

Table 5. Staff Focus (cont.).

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**<u>Area to Address</u>: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
5.2. Staff Learning and Motivation	<u>5.2.1. Staff Education, Training and Development</u>: How the institution structures and promotes effective education and training of professionals in developing and improving patient safety systems.							5.2.1.1. Institutional mechanism for determining of and acting on patient safety educational and training needs for individuals, teams, departments and different categories of professional caregivers.			
	<u>**5.2.2. Corrected!** Motivation and Career Development</u>: How the institution supports the role of the patient safety officer **and the patient safety role of the whole workforce.**							5.2.2.1. Development, implementation and improvement of internal patient safety policies, practices and activities.			

Table 5. Staff Focus (cont.).

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**<u>Area to Address</u>: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
5.3. Staff Well-being and Satisfaction	<u>5.3.1. Work Environment</u>: How the institution maintains conductive environment in regard to patient safety.							5.3.1.1. Institution's patient safety goals are integrated in institution's everyday healthcare delivery functions, regularly reviewed and improved and progress towards them is continuously monitored and evaluated.			
	<u>5.3.2. Staff Support and Satisfaction</u>: How the institution determines staff satisfaction in implementation of patient safety systems.							5.3.2.1. Institutional mechanisms for periodic gathering of information on healthcare providers' opinions and expectations in regard to factors enhancing or inhibiting communication of sentinel events and using the results of the analysis of all collected data for institutional patient safety improvement.			
								5.3.2.2. New! Staff satisfaction is promoted by actively providing feedback on patient safety system implementation.	N/A	N/A	
	<u>5.3.3. New!</u> <u>Staff Support and Satisfaction</u>: How the institution includes medical staff attitudes and satisfaction in implementation of patient safety systems.	N/A	N/A		N/A	N/A		**5.3.3.1. New!** Medical staff participation and support of safety environment within the institution.	N/A	N/A	

Table 6. Process Management.

Ranking: “**4**” represents “**very important**”; “**3**” represents “**important**”; “**2**” represents “**not very important**”; and “**1**” represents “**unimportant.**”

Item	**Area to address: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
6.1. Patient Safety System	**6.1.1. Corrected!** Patient Safety System: How the institution determines patient safety process requirements **and involves patients and other stakeholders in design and redesign of patient safety processes.**							6.1.1.1. Accreditation, professional and legal requirements as well as improvements resulting from stakeholder surveys and reporting systems results analyses are incorporated in institution’s patient safety systems and processes on a regular basis.			
	6.1.2. Patient Safety System: How the institution designs patient safety systems.							6.1.2.1. Evidence that Quality Improvement (QI) methodology, including but not limited to RCA, FMEA, Plan-Do-Study-Act Cycle (PDSA, Rapid Cycle Change), clinical performance measures and best practices are used to decrease variability of healthcare delivery and improve patient safety outcomes.			
	6.1.3. Patient Safety System: How the institution ensures that patient safety requirements are met at the “sharp end” of the healthcare delivery system.							6.1.3.1. An institutional mechanism exists for continuous monitoring, improvement and sustainability of patient safety outcomes in healthcare delivery.			
	6.1.4. New! Campus security: How the institution ensures that patients feel secure arriving for and leaving appointments for care.	N/A	N/A		N/A	N/A		**6.1.4.1. New!** An institutional mechanism exists for continuous monitoring, improvement and sustainability of a campus environment that promotes a feeling of safety and security, and supports the healing process without adding stress regarding personal safety.	N/A	N/A	

Table 6. Process Management (cont.)

Ranking: “**4**” represents “**very important**”; “**3**” represents “**important**”; “**2**” represents “**not very important**”; and “**1**” represents “**unimportant.**”

Item	**<u>Area to address</u>: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
6.2. Support Processes	<u>6.2.1. Patient Safety Support Processes</u>: How the institution coordinates departmental and interdepartmental patient safety infrastructures to reduce variability in healthcare delivery and improve performance.							6.2.1.1. Systems for departmental and interdepartmental communications, collaborations and aligned effort in regard to seamless implementation of best practices and clinical guidelines in patient identification, medication and continuous case management are assessed and improved on an ongoing basis.			
	<u>6.2.2. New!</u> <u>Patient Safety Support Process:</u> How the institution includes suppliers and partners in safety initiatives and process development	N/A	N/A		N/A	N/A		**6.2.2.1. New!** Safety compliance evaluations of suppliers and partners (including medical staff).	N/A	N/A	

Table 7. Institutional Performance.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant**"

Item Area to address: Critical process	**Performance Measure**	**Current importance**			**Future importance**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**
7.1. Patient Safety Institutional Performance Area to Address: Patient Safety Results How the institution ensures patient safety	7.1.1. A 2-identifier system for patient identification is in place and is consistent in the continuity of healthcare throughout the institution.						
	7.1.2. Healthcare departmental and interdepartmental communications are accurate and reliable at different institutional levels.						
	7.1.3. The institution monitors the administration of high-alert medications.						
	7.1.4. Proper marking of surgery sites is established as a precaution to decrease incidents of wrong-side surgery (where applicable).						
	7.1.5. The institution ensures adequate professional staff preparation for proper and safe use of infusion pumps (where applicable).						
	7.1.6. The institution ensures adequate professional staff preparation for proper and safe use of clinical alarm systems (where applicable).						
	7.1.7. Corrected! The institution ensures a non-punitive approach for reporting **all adverse events and near misses**.						
	7.1.8. Corrected! The institution **ensures proper staff is dedicated to support and conduct** RCA, FMEA, and **implement** QI methodology in analyzing multidimensional patient safety practices at different institutional levels.						
	7.1.9. Corrected! The institution ensures that an accessible, confidential and adequately functioning reporting system is in place for reporting **all adverse events and near misses**.						
	7.1.10. Corrected! The institution ensures that a uniform, unambiguous and comprehensive nomenclature for reporting **of adverse events and near misses** is adopted throughout the healthcare institution.						
	7.1.11. The institution proactively works towards changing the traditional culture of "blame and shame."						
	7.1.12. The institution ensures safe healthcare delivery through utilization of modern technology.						
	7.1.13. The institution ensures that professional, accreditation and legal requirements in the area of patient safety are adequately addressed.						
	7.1.14. The institution ensures that national benchmarks in healthcare delivery (best practices, clinical performance measures, etc.) are used to decrease variability of healthcare delivery and improve patient safety outcomes.						
	7.1.15. New! The institution assures that appropriate leadership development and education in the area of patient safety is provided on an ongoing basis.	N/A	N/A		N/A	N/A	
	7.1.16. New! The institution assures that appropriate staff development and education in the area of patient safety is provided on an ongoing basis.	N/A	N/A		N/A	N/A	

Barriers to implementation of patient safety systems

The First Round questionnaire returned a variety of barriers to implementing patient safety systems in healthcare institutions. All suggested barriers were grouped and 29 groups were formed. There is no prioritization in the sequence of presentation of the barrier groups. Please, rank the importance of each barrier group from 1 to 4, where:

4 = "**very important**": patient safety systems cannot be implemented unless this barrier is eliminated/modified
3 = "**important**": patient safety systems may begin but cannot be continued unless this barrier is eliminated/modified
2 = "**not very important**": patient safety systems may begin and continue, but at limited effectiveness unless this barrier is eliminated/modified
1 = "**unimportant**": patient safety systems can be implemented in the presence of this barrier

Based on your perception whether a given barrier is related to the individual healthcare institution context (local issue) or is common to the national healthcare system (system issue), please insert "local" or "system" in the column labeled "Local/System."

Table 8. Barriers to implementation of patient safety systems

Barrier group	Rank	Local/System
Competing priorities for scarce resources in a system where patient safety is not considered a top priority.		
Lack of senior leadership understanding and involvement with patient safety issues.		
Availability and cost of patient safety technology.		
Fear that a non-punitive system will miss an individual's pattern of errors.		
Cumbersome, complicated and time-consuming error reporting processes.		
Cumbersome, complicated and time-consuming healthcare safety processes.		
Culture of blame (current healthcare culture is punitive in nature).		
Culture of healthcare workforce perceptions, attitudes and behaviors of error "cover up."		
Culture of hesitancy of healthcare organizations to allow consumers to participate in decision-making.		
Culture of physicians considered the ultimate authority.		
Culture of quality "inspection" (regulatory oversight is sufficient, no further effort is needed).		
Complexity of healthcare systems.		
Current legal system: fear of litigation.		
Lack of resources: inadequate staffing and work overloads.		
Lack of positive feedback: no change occurs after reporting.		
Need of standardization of patient safety terminology, technology and approaches.		
Resistance to change (the assumption that providers are already providing safe care).		
Inadequate education of staff, professionals, management and leadership in regard to patient safety.		

Table 8. Barriers to implementation of patient safety systems (cont.)

Barrier group	Rank	Local/System
Difficulties in creating patient safety peer review for healthcare professionals.		
Reliance on measurement systems that depend on voluntary reporting of errors.		
Lack of operational planning and deployment skills regarding implementation of patient safety systems.		
Bureaucracy.		
Over expectations of potential and capability of technology to solve healthcare safety problems.		
Reliance on human capabilities for ensuring safety.		
Disbelief, denial, and lack of knowledge about the ubiquitous nature of errors.		
It is difficult to find an approach that smoothly integrates into existing systems without creating added costs and complexity.		
Communication: lack of transparency and openness in regard to patient safety issues.		
Research-driven best healthcare practices are not adopted.		
Insufficient data about institutional performance and benchmarking.		

Additional comments (optional):

Thank you!

APPENDIX 4

THIRD ROUND SURVEY INSTRUMENT

Critical Processes and Performance Measures for Patient Safety Systems in Healthcare Institutions: A Delphi Study

Third Round

GENERAL INFORMATION:

The Third Round questionnaire includes only those Critical Processes and Performance Measures for which consensus has not been reached during the previous rounds. In cases where consensus about the importance of a critical process has been reached but consensus for a related performance measure has not been reached, the performance measure is presented with the related critical process and the process importance is marked with "Consensus reached."

The Third Round questionnaire follows the organization and format of the two previous questionnaires. Tables 1 to 6 present suggested items, areas to address, critical processes and performance measures for patient safety systems in healthcare institutions. Each critical item, critical process and performance measure is numbered, where a two-digit identification refers to an item (e.g. 1.1.), a three-digit identification (e.g. 1.1.1.) refers to a critical process, and a four-digit identification (e.g. 1.1.1.1.) refers to a performance measure. Table 7 does not provide critical processes. It identifies performance measures relevant to assessing healthcare institution's patient safety results and their current and future importance to patient safety systems in healthcare. The importance of critical processes is ranked twice: once in terms of its current importance and a second time in terms of its future importance. Performance measures are ranked only once in terms of their current importance. Tables 8.1 and 8.2 present barriers to implementation of patient safety systems in healthcare institutions as ranked and defined by the expert panel in the Second Round survey.

INSTRUCTIONS FOR THIRD ROUND:

For each critical process and performance measure, for which consensus has not been reached during the previous rounds, the Third Round tables (1 through 7) provide mean score for the group, individual panelist's score and space for change of rank, if deemed appropriate. Please, after considering the group mean and your previous rank, provide your new rank, when deemed appropriate, for each critical process and performance measure in tables 1 through 7. If no change of rank is deemed appropriate, please leave the space for "New rank" blank.

The ranking is from 1 to 4, in the context of item's importance to patient safety systems in healthcare institutions, where:

"**4**" represents "**very important**" to patient safety systems in healthcare institutions;
"**3**" represents "**important**" to patient safety systems in healthcare institutions;
"**2**" represents "**not very important**" to patient safety systems in healthcare institutions;
"**1**" represents "**unimportant**" to patient safety systems in healthcare institutions.

Please, complete tables 8.1., Barriers to implementation of patient safety systems: Importance, and 8.2., Barriers to implementation of patient safety systems: System or local level, following the instructions immediately prior to the respective tables.

At the end of the survey, experts' opinion is sought whether the phrase "non-punitive culture" should be replaced by "just culture."

Please, return the filled-in questionnaire within two weeks of receipt.

Expert's name:
Date:

UPDATE:

Investigator's contact details:
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Table 1: Leadership

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"											
Item	**Area to address: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
1.1. Institutional Leadership	1.1.1. Senior Leadership Direction: How senior leaders communicate the priority of patient safety to all stakeholders.		Consensus reached			Consensus reached		1.1.1.2. Provision and use of real time adverse event reporting tool that alerts leadership automatically to events as they happen, thereby improving real-time communication and stressing the importance of performance improvement in real time.			
1.2. Social Responsibility	1.2.4. Responsibility to stakeholders: How the institution monitors its medication error rate.							1.2.4.1. Independent medication error review team is identified and educated in regard to the medication usage cycle and is engaged in developing and monitoring medication safety systems.			

Table 2. Strategic Planning.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"											
Item	**Area to Address: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
2.1. Strategy Development		**Mean**	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
	2.1.3. Strategic Objectives: How the institution achieves realistic evaluation of technology capability for improving safety (present and future).							2.1.3.1. Cost-benefit analysis of safety technology with accumulation of data to evaluate the accuracy of such estimates over time and life of safety technology projects.			

Table 3. Focus on Patients, Other Customers and Markets.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**<u>Area to Address</u>: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
3.1. Patient, Other Customer and Healthcare Market Knowledge	<u>3.1.2. Patient Safety Market Knowledge</u>: How the institution helps set the expectations of patients and infuses realistic goals and expectations into the marketplace.							3.1.2.1. Outcome determination of patient expectations and efforts to influence the development of realistic expectations.			

Table 4. Measurement, Analysis and Knowledge Management

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	**<u>Area to Address</u>: Critical Process**	**Current importance**			**Future importance**			**Performance Measure**	**Rank**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**		**Mean**	**Your rank**	**New rank**
4.1. Measurement and Analysis of Institutional Performance	<u>4.1.3. Performance Measurement:</u> How the institution monitors the occurrence of near misses and how uses this information for process improvement.							4.1.3.1. A process exists for recording, monitoring, tracking and analysis of near misses and feedback is used for process improvement.			

Table 5. Staff Focus.

Item	Area to Address: Critical Process	Current importance			Future importance			Performance Measure	Rank		
		Mean	Your rank	New rank	Mean	Your rank	New rank		Mean	Your rank	New rank
Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"											
5.1. Work Systems	5.1.5. Recruitment and Career Progression: How the institution includes safety compliance and attitudes in staff recruitment, selection and promotion.							5.1.5.1. General staff knowledge and practice of safe activities is rewarded and taken into consideration for recruitment, selection and promotion.			
5.3. Staff Well-being and Satisfaction	5.3.2. Staff Support and Satisfaction: How the institution determines staff satisfaction in implementation of patient safety systems.		Consensus reached			Consensus reached		5.3.2.2. Staff satisfaction is promoted by actively providing feedback on patient safety system implementation.			
	5.3.3. Staff Support and Satisfaction: How the institution includes medical staff attitudes and satisfaction in implementation of patient safety systems.							5.3.3.1. Medical staff participation and support of safety environment within the institution.			

Table 6. Process Management.

Ranking: "**4**" represents "**very important**"; "**3**" represents "**important**"; "**2**" represents "**not very important**"; and "**1**" represents "**unimportant.**"

Item	Area to address: Critical Process	Current importance			Future importance			Performance Measure	Rank		
		Mean	Your rank	New rank	Mean	Your rank	New rank		Mean	Your rank	New rank
6.1. Patient Safety System	6.1.4. Campus security: How the institution ensures that patients feel secure arriving for and leaving appointments for care.							6.1.4.1. An institutional mechanism exists for continuous monitoring, improvement and sustainability of a campus environment that promotes a feeling of safety and security, and supports the healing process without adding stress regarding personal safety.			
6.2. Support Processes	6.2.2. Patient Safety Support Process: How the institution includes suppliers and partners in safety initiatives and process development							6.2.2.1. Safety compliance evaluations of suppliers and partners (including medical staff).			

Table 7. Institutional Performance.

Ranking: “**4**” represents “**very important**”; “**3**” represents “**important**”; “**2**” represents “**not very important**”; and “**1**” represents “**unimportant**”

Item Area to address: Critical process	**Performance Measure**	**Current importance**			**Future importance**		
		Mean	**Your rank**	**New rank**	**Mean**	**Your rank**	**New rank**
7.1. Patient Safety Institutional Performance Area to Address: Patient Safety Results How the institution ensures patient safety	7.1.7. Corrected! The institution ensures a non-punitive approach for reporting all adverse events and near misses.		Consensus reached				
	7.1.9. Corrected! The institution ensures that an accessible, confidential and adequately functioning reporting system is in place for reporting all adverse events and near misses.		Consensus reached				
	7.1.15. New! The institution assures that appropriate leadership development and education in the area of patient safety is provided on an ongoing basis.						
	7.1.16. New! The institution assures that appropriate staff development and education in the area of patient safety is provided on an ongoing basis.						

Barriers to implementation of patient safety systems

The Second Round returned diverse opinions about the importance of the barriers to implementation of patient safety systems in healthcare institutions and variety of perceptions whether a given barrier is related to the individual healthcare institution context (local issue) or is common to the national healthcare system (system issue).

Table 8.1. Barriers to implementation of patient safety systems: Importance, presents the 29 barrier groups, the rank mean for the expert group and the rank mode (the most frequent rank assigned by the Delphi panelists) for each barrier. Five of the barrier groups showed a bimodal distribution.

Please, after considering the group mean, group mode and your previous rank, provide your new rank, when deemed appropriate, for each barrier. If no change of rank is deemed appropriate, please leave the space for "New rank" blank.

Please, rank the importance of each barrier group from 1 to 4, where:

4 = "**very important**": patient safety systems cannot be implemented unless this barrier is eliminated/modified
3 = "**important**": patient safety systems may begin but cannot be continued unless this barrier is eliminated/modified
2 = "**not very important**": patient safety systems may begin and continue, but at limited effectiveness unless this barrier is eliminated/modified
1 = "**unimportant**": patient safety systems can be implemented in the presence of this barrier.

Table 8. 1. Barriers to implementation of patient safety systems: Importance.

Barrier group	Mean	Mode	Your Rank	New Rank
Competing priorities for scarce resources in a system where patient safety is not considered a top priority.				
Lack of senior leadership understanding and involvement with patient safety issues.				
Availability and cost of patient safety technology.				
Fear that a non-punitive system will miss an individual's pattern of errors.				
Cumbersome, complicated and time-consuming error reporting processes.				
Cumbersome, complicated and time-consuming healthcare safety processes.				
Culture of blame (current healthcare culture is punitive in nature).				
Culture of healthcare workforce perceptions, attitudes and behaviors of error "cover up."				
Culture of hesitancy of healthcare organizations to allow consumers to participate in decision-making.				
Culture of physicians considered the ultimate authority.				
Culture of quality "inspection" (regulatory oversight is sufficient, no further effort is needed).				
Complexity of healthcare systems.				
Current legal system: fear of litigation.				
Lack of resources: inadequate staffing and work overloads.				
Lack of positive feedback: no change occurs after reporting.				
Need of standardization of patient safety terminology, technology and approaches.				
Resistance to change (the assumption that providers are already providing safe care).				
Inadequate education of staff, professionals, management and leadership in regard to patient safety.				
Difficulties in creating patient safety peer review for healthcare professionals.				
Reliance on measurement systems that depend on voluntary reporting of errors.				
Lack of operational planning and deployment skills regarding implementation of patient safety systems.				
Bureaucracy.				
Over expectations of potential and capability of technology to solve healthcare safety problems.				
Reliance on human capabilities for ensuring safety.				
Disbelief, denial, and lack of knowledge about the ubiquitous nature of errors.				
It is difficult to find an approach that smoothly integrates into existing systems without creating added costs and complexity.				
Communication: lack of transparency and openness in regard to patient safety issues.				
Research-driven best healthcare practices are not adopted.				
Insufficient data about institutional performance and benchmarking.				

Table 8.2. Barriers to implementation of patient safety systems: System or local level presents the mode (the most frequent relationship of a given barrier to its context, system or local) assigned by the Delphi panelists for each barrier. Three of the barriers to implementation of patient safety systems in healthcare institutions showed a 50/50 distribution.

After careful consideration of the group mode and your previous perception whether a given barrier is related to the individual healthcare institution context (local issue) or is common to the national healthcare system (system issue), please insert "local" or "system" in the column labeled "Local/System," when deemed appropriate. If no change of perception is deemed appropriate, please leave the space for "New Perception" blank.

Table 8.2. Barriers to implementation of patient safety systems: System or local level.

Barrier group	Mode	Your Perception	New Perception
Competing priorities for scarce resources in a system where patient safety is not considered a top priority.			
Lack of senior leadership understanding and involvement with patient safety issues.			
Availability and cost of patient safety technology.			
Fear that a non-punitive system will miss an individual's pattern of errors.			
Cumbersome, complicated and time-consuming error reporting processes.			
Cumbersome, complicated and time-consuming healthcare safety processes.			
Culture of blame (current healthcare culture is punitive in nature).			
Culture of healthcare workforce perceptions, attitudes and behaviors of error "cover up."			
Culture of hesitancy of healthcare organizations to allow consumers to participate in decision-making.			
Culture of physicians considered the ultimate authority.			
Culture of quality "inspection" (regulatory oversight is sufficient, no further effort is needed).			
Complexity of healthcare systems.			
Current legal system: fear of litigation.			
Lack of resources: inadequate staffing and work overloads.			
Lack of positive feedback: no change occurs after reporting.			
Need of standardization of patient safety terminology, technology and approaches.			
Resistance to change (the assumption that providers are already providing safe care).			
Inadequate education of staff, professionals, management and leadership in regard to patient safety.			
Difficulties in creating patient safety peer review for healthcare professionals.			
Reliance on measurement systems that depend on voluntary reporting of errors.			
Lack of operational planning and deployment skills regarding implementation of patient safety systems.			

Table 8.2. Barriers to implementation of patient safety systems: System or local level (cont.)

Barrier group	Mode	Your Perception	New Perception
Bureaucracy.			
Over expectations of potential and capability of technology to solve healthcare safety problems.			
Reliance on human capabilities for ensuring safety.			
Disbelief, denial, and lack of knowledge about the ubiquitous nature of errors.			
It is difficult to find an approach that smoothly integrates into existing systems without creating added costs and complexity.			
Communication: lack of transparency and openness in regard to patient safety issues.			
Research-driven best healthcare practices are not adopted.			
Insufficient data about institutional performance and benchmarking.			

"Non-punitive" or "just" culture

Several Delphi panelists raised the question whether completely non-punitive reporting systems may allow reckless or malicious behavior remain unaccounted for. A suggestion was made to replace the phrase "non-punitive culture" with "just culture" providing for learning from mistakes and at the same time recognizing the need for accountability and disciplinary or enforcement actions.

Please, provide your opinion.

Additional comments (optional):

Thank you!

VITA

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EDUCATION

2004	Doctor of Philosophy, Educational Administration, Texas A&M University, College Station, Texas
1999	Orthopedics and Traumatology Surgeon, Medical University, Varna, Bulgaria
1994	Medical Doctor, Medical University, Varna, Bulgaria

CERTIFICATION

2003	Certified Training Professional: Human Resource Training and Development, Professional Human Resource Training and Development Program, Texas A&M University, College Station, Texas
2003	Graduate Certificate in Business, Mays Business School, Texas A&M University, College Station, Texas
1997	Teacher in General Medicine, IFED-MG, Paris, France

PROFESSIONAL EXPERIENCE

2001-Present	Post-Doctoral Research Associate. Specialization in Rural Healthcare Quality and Patient Safety Consulting and Management, Rural and Community Health Institute: Quality and Patient Safety Initiatives, Office of the President, Texas A&M University System Health Science Center, College Station, Texas
2000	Governor’s Business Coordinator. Governor’s Office, Dobrich Region, Bulgaria
1998–2000	Faculty member, Assistant Professor, Department of General Medicine, Medical University, Varna, Bulgaria
1996–2000	Part-time Officer, International Relations Department, Medical University, Varna, Bulgaria
1995-2000	Staff, University Hospital, Varna, Bulgaria

LEADERSHIP EXPERIENCE

2003-Present	Leadership in rural network physician peer review for small rural and community hospitals
2002-Present	Member, A&M HSC Student Services Administrative Council
2002-2004	Member, A&M HSC Information Technology Advisory Committee
2001-Present	Member, A&M HSC Uniform Recruitment and Retention Steering Committee
2001-2002	Member, College of Medicine Curriculum Outcomes Analysis Subcommittee
2000	Member, International Relations Commission, Medical University, Varna
1998	One of the Founders of the Bulgarian Association of General Medicine Teachers. Elected Member of the Control Committee

MEMBERSHIP

Phi Kappa Phi, Chapter of Texas A&M University
Kappa Delta Pi, Chapter Mu Chi
Ron Brown Fellow

LANGUAGE CAPABILITY

Proficient in oral and written English, Russian, and Bulgarian; capable of interpreting all three