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An Overview of Patient Safety and Accreditation: A Literature Review Study

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Abstract: Patient safety is one of the most important points to consider in healthcare. As such, various programs are entered by healthcare institutions to monitor their services including patient safety procedures. One of these programs is accreditation. Accreditation is an internationally recognized evaluation process used to assess, promote and guarantee efficient and effective quality of patient care and patient safety. This study will provide valuable information regarding the impact and limitations of the accreditation process found by other researchers as well as the experience of King Abdul-Aziz University Hospital in Saudi Arabia. The 28 out of 81 (34.57%) patient safety indicators significantly improved during accreditation process at King Abdulaziz University Hospital. Survey results show that the overall average of relative improvement percent is 34.43%. Both results are similar to other findings. The accreditation process as experienced by King Abdulaziz University Hospital has significantly improved 1/3 of patient safety indicators and perception of nursing staffs is correlated with statistical findings. Those findings are supported by international literature.

Key words: Patient safety, accreditation, indicators, health care, perception, Saudi Arabia

INTRODUCTION

From the time of Hippocrates, the dictum First, do no harm has prodded healthcare providers to ensure safe patient care. The Institute of Medicine (IM, 1999) report, To Err is Human: Building a Safer Health System brought to light how far the American healthcare system had strayed from this edict (Kohn *et al.*, 1999). In response to the report, the Joint Commission on Accreditation for Healthcare Organizations (JCAHO), the leading healthcare accrediting body in the nation, revised its standards so that 50% of the hospital accreditation standards focused on patient safety (JCAHO, 2003).

Determining the factors that are associated with the provision of safe patient care is crucial for today's healthcare environment. Such efforts are necessary as research demonstrates that the majority of medical errors or adverse events are preventable (Brennan *et al.*, 1991a, b; Thomas and Brennan, 2000; Lehman *et al.*, 2005).

Since 1999, the hospital accreditation process is seen to focus more on risk management and patient safety rather than on the previous measuring of degree of compliance with quality standards. However, the effect of implementing patient safety practices and their resultant impact on patient outcomes remain relatively unexplained in healthcare (Shojania *et al.*, 2001).

Patient safety is conceptualized as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care (Cooper *et al.*, 2000). Patient safety management is the establishment of operational systems and processes designed to minimize the likelihood of errors and maximize the likelihood of intercepting errors when or before they occur (Institute of Medicine, 2001).

Accreditation of health care organizations has been increasingly utilized as a tool for governmental regulations to guarantee quality (El-Jardali et al., 2008). Accreditation is generally viewed as a formal process by which an authorized body either governmental or nongovernmental, assesses and determines whether a healthcare organization meets applicable, predetermined and published standards. Accreditation standards are intended to be optimal and achievable and they are designed to encourage continuous quality improvement efforts within accredited organizations. Accreditation is usually a voluntary process where organizations choose to participate rather than are required to do so by law or regulation (Rooney and van Ostenberg, 1999). Accreditation bodies have responded to pressure for greater knowledge of clinical effectiveness and indicators of clinical performance. They have systemized and brought change upon the health care approach as well as governmental roles as regulatory bodies.

It appears clear that accreditation focuses on reducing the hospitals risk factors as is shown in the initial metric of JCAHO monitoring. This showed the status of the organization with regards to patient safety goals and if their participation in patient safety initiatives were met or not at the time of accreditation. The second metric introduced in 2006 had an aim to reduce morbidity and mortality rates in Health Care Institutions. Different terms may be used by different accreditation organizations Accreditation Canada describes the approach to maximize patient safety in the health care organization as ROP (Required Organizational Practice). JCAHO approaches it as a Patient Safety Programme or Risk Management Programme. The Joint Commission has introduced the idea that quality of care and accreditation should focus on improving risk management in hospitals as well as patient safety. Quality should then address safety issues in medication use, infection control, surgery and anaesthesia, transfusions, restraint and seclusion, staffing and staffing competencies, fire and safety, medical equipment, emergency management and security etc. The prevention of accidental harm through analysis and redesign of vulnerable patient systems such as ordering, preparation and dispensing of medications, infection control, falls, patient identification, accidents or incidents involving injury, sentinel events etc. should also be closely monitored. The term complication implies that the underlying condition of the patient plays a part in the development of the adverse event.

The oft cited statistics released within the 1999 Institute of Medicine report estimated that as many as 44,000-98,000 people die in hospitals each year as a result of medical errors making such errors the eight leading cause of death in the USA (Kohn et al., 1999). These figures are based on extrapolated data from landmark studies conducted during the early 1990s that were among the first to demonstrate that the majority of medical errors or adverse events were preventable. In these initial studies, investigators identify 1,133 adverse events in a sample of 30, 195 records. About 70% of the errors were preventable; 6% were potentially preventable and 24% were not preventable. Errors in management were identified for 58% of the adverse events among which nearly half were attributed to negligence (Brennan et al., 1991a, b; Leape et al., 1991). More recent studies reveal similar results. Thomas and Brennan (2000) reviewed 15,000 medical records in Colorado and Utah, finding that 54% of surgical errors were preventable with death following 6.6% of the adverse events. In a study of iatrogenic events resulting in ICU admission, Lehman et al. (2005) assessed that 34% of the events were preventable.

In a large national study using the 2000 HCUP Nationwide Inpatient Sample and patient safety outcome indicators, Romano et al. (2003) identified that 1.12 million potential safety-related events occurred in 1.07 million hospitalizations at non-federal acute care facilities. The national sample represented over 36 million hospitalizations with approximately 34% of the safety related events occurring in surgical hospitalizations, 31% in obstetric hospitalizations and 35% in medical hospitalizations. Approximately 24% of the events represented deaths either affecting patients in low-mortality DRGs (DRGs with <0.5% inpatient mortality in 1997) or reflecting failure to rescue after a major complication (e.g., shock, cardiac arrest).

CHAPTER 1

Adverse event sequelae: Adverse events often result in a longer lengths of stay, higher costs and poorer outcomes even death. In a study of 1,047 patients admitted to a large urban teaching hospital, 17.7% of patients were found to have suffered at least one serious adverse event that led to longer hospital stays and increased (Andrews et al., 1997). The likelihood of experiencing an adverse event will be increased by about 6% for each day of hospital stay. Similarly, a study by Nordgren et al. (2004) found that patients who had been at the receiving end of care involving a medical error had longer hospital stays and greater costs when compared to controls. Likewise, Zhan and Miller (2003a) found that postoperative bloodstream infections or sepsis, resulted in hospital stays of almost 11 days longer, costing an additional \$57,727 per stay and resulting in a 21.9% increased risk of death after surgery. Rojas et al. (2005) found that length of stay nearly doubled for patients who experienced an adverse event.

Often, a first complication begins the cascade of complications that ends in death. Such cascade iatrogenesis or the serial development of multiple medical complications (Rothschild et al., 2000) can be set in motion by a seemingly innocuous first event. For example, an older patient with post-operative pain is over sedated, leading to respiratory failure that requires mechanical ventilation, culminating in the development of ventilator associated pneumonia (Rothschild et al., 2000). Such a cascade of complications is not uncommon. Silber et al. (2005) found that the odds of dying within 60 days of admission increased 3.4 fold in Medicare patients with post-operative complications as compared to those without complications. A first complication of respiratory compromise was associated with a 7.2 fold increase in the odds of dying within 60 days whereas first complications of pneumonia or congestive heart failure were associated,

respectively with 5 fold and 5.1 fold increases in the odds of dying within 60 days as compared with no complication.

Patient safety taxonomy: In studying adverse events and patient safety, the lack of universal nomenclature and taxonomy is the first challenge to be faced (Zhan et al., 2005). Many terms are used to describe unintended injuries to patients in the process of delivering care including adverse events, medical errors, medical injuries, iatrogenic conditions, sentinel events, health care associated risks and hazards. The terms are not clearly defined and overlap. While no standard definition of the term adverse event exists (Kellogg and Havens, 2003), the term is most often defined as injuries caused by medical management (rather than by the underlying disease) that result in either prolonged length of stay, disability at discharge or both (Thomas and Brennan, 2000). A serious adverse event or sentinel event is an unexpected occurrence involving death or serious physical or psychological injury. Serious injury specifically includes loss of limb or function. Such events are called sentinel because they signal the need for immediate investigation and response (JCAHO, 2003).

Patient safety has been conceptualized as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care (Cooper et al., 2000). A goal of patient safety, therefore is to reduce the risk of injury or harm to patients from the structures or processes of care (Battles and Lilford, 2003). Patient safety management is the establishment of operational systems and processes designed to minimize the likelihood of errors and maximize the likelihood of intercepting errors when or before they occur (Institute of Medicine, 2001).

Hospital systems associated with patient safety outcomes:

Various structural and organizational factors have been shown to correlate with patient safety outcomes although, many of the findings reported in the literature on this topic are somewhat dissonant (Thornlow, 2007). For example, synthesized reviews of studies examining the relationship between teaching status and morbidity and mortality reveal inconsistencies (Mitchell and Shortell, 1997; Ayanian and Weissman, 2002; Kupersmith, 2005) with some researchers reporting lower mortality rates in non-teaching hospitals (Fleming *et al.*, 1991; Pollack *et al.*, 1994; Yuan *et al.*, 2000), some reporting lower risk-adjusted mortality rates in teaching hospitals (Allison *et al.*, 2000; Keeler *et al.*, 1992; Rosenthal *et al.*, 1997; Silber *et al.*, 1995) others demonstrating no difference in risk-adjusted in hospital mortality rates

between teaching and non-teaching hospitals (Rogowski *et al.*, 2004; Cunningham *et al.*, 1999; Schultz *et al.*, 1999) and still others demonstrating inconsistencies depending on the outcome measured (Romano *et al.*, 2003; Thornlow and Stukenborg, 2006).

Similarly, Baker et al. (2002)'s review of the association of hospital ownership with patient outcomes found mixed or inconclusive evidence regarding hospital ownership and its relationship to access to care, morbidity and mortality. Investigators conducting a subsequent meta-analysis of 15 observational studies involving >26,000 hospitals and 38 million patients (Devereaux et al., 2002) concluded however that private for profit ownership of hospitals (i.e., hospitals owned by corporations or partnerships and operated for profit) in comparison with private not for profit ownership resulted in a higher risk of death for patients. Studies also yield inconsistent associations between hospital location (urban versus rural) and mortality rates and patient outcomes (Al-Haider and Wan, 1991; Baldwin et al., 2004; Glenn and Jijon, 1999; Maynard et al., 2000). Keeler et al. (1992) demonstrated that rural versus urban differences even varied markedly between states.

In a research conducted to independently analyze the relationship between hospital size and patient outcomes, investigators found that larger facility size was associated with adequacy of hemodialysis in chronic dialysis patients (Frankenfield *et al.*, 2000). In a national study of preventable adverse events, Romano *et al.* (2003) found mixed results with large hospitals demonstrating higher incidence of most patient safety events but lower incident rates for others. In an earlier study, hospital size and specialization were not statistically associated with hospital mortality when controlling for the effects of other organizational factors (Al-Haider and Wan, 1991).

From a nursing perspective, certain hospital systems and processes have been shown to influence patient safety outcomes. In a recent study of 18,142 patients discharged from 49 acute care hospitals in Canada, Estabrooks *et al.* (2005) demonstrated that hospital nursing characteristics such as higher nurse education level, higher skill mix, lower proportion of temporary employees and higher scores on collaborative nurse-physician relationships were associated with lower rates of 30 days patient mortality. These findings are similar to those of other studies which documented that patient safety outcomes are related to nurse staffing (Aiken *et al.*, 2002; Cho *et al.*, 2003; Kovner and Gergen, 1998; Lichting *et al.*, 1999; McCue *et al.*, 2003; Needleman *et al.*, 2002; Person *et al.*, 2004).

Higher nurse staffing intensity, expressed as proportion of hours of care delivered by registered nurses in relation to other nursing personnel and patient census has been associated with lower mortality in US hospitals (Aiken et al., 2002; Person et al., 2004) as well as with lower rates of failure to rescue (Aiken et al., 2002; Needleman et al., 2002), lower rates of pressure sore development (Blegen et al., 1998; Lichting et al., 1999) and lower rates of post surgical complications such as pneumonia (Cho et al., 2003; Kovner and Gergen, 1998; Needleman et al., 2002) and urinary tract infections (Kovner and Gergen, 1998; Lichting et al., 1999; Needleman et al., 2002). Further, Aiken et al. (2003) demonstrated that surgical patients experienced lower mortality and failure to rescue rates in hospitals with higher proportions of nurses educated at the baccalaureate level and higher. While the studies that examined the relationship of nurse staffing to patient outcomes appear more consistent in strength and direction of association than those analyzing other organizational characteristics, healthcare is complex and additional research is needed to further elucidate the relationship between acute care hospital systems, patient safety practices and patient outcomes.

Hospital processes associated with patient safety outcomes: Organizations and investigators alike are searching for ways to improve delivery and safety of patient care. Many are intent on embedding patient safety practices into healthcare. A patient safety practice has been defined by the Evidence-based Practice Center as a type of process whose application reduces the probability of an adverse event however, evidence for the incorporation of various safety practices including incident reporting, root cause analysis and the promise of promoting a culture of safety comes from domains other than medicine or nursing. Although, these safety practices herald longstanding success in commercial aviation, nuclear safety and aerospace, many possess a weak evidentiary base in the healthcare literature (Shojania et al., 2001). When evidence does exist, organizations have made attempts to translate such evidence into practice. For example, in 2002 the National Quality Foundation (NQF) published a list of 30 evidence based practices deemed ready for implementation (Kizer and Blum, 2005; Leape et al., 2002; Shojania et al., 2002). JCAHO has since required at least ten of these practices be implemented in its accredited hospitals.

Several studies have been conducted to analyze accreditation. One of which was of Greenfield and Braithwaite (2008) where 66 studies were retrieved and analyzed. The results, examining the impact or effectiveness of accreditation were classified into 10 categories: professions' attitudes to accreditation, promote change, organizational impact, financial impact, quality measures, program assessment, consumer views or patient satisfaction, public disclosure, professional development and surveyor issues.

The analysis reveals a complex picture. In two categories consistent findings were recorded: promote change and professional development. Inconsistent findings were identified in five categories: professional attitudes to accreditation, organizational impact, financial impact, quality measures and program assessment. The remaining three categories-consumer views or patient satisfaction, public disclosure and surveyor issues did not have sufficient studies to draw any conclusion. The search identified a number of national health care accreditation organizations engaged in research activities.

One potential model to consider in improving safety in healthcare comes from the field of anaesthesiology which some consider to be a medical field with a safety record that rivals that of other high-reliability fields such as aviation and nuclear power (Clancy, 2003; Shojania et al., 2001). Since the 1960s, Anesthesia has been incorporating core patient safety practices into care delivery. Adapted from high-reliability industries, these practices include a non-punitive approach to safety that emphasizes systems-based learning, the accurate reporting and detection of adverse events, the active seeking out of near misses or close calls which are then viewed as opportunities for learning and interdisciplinary investigation of adverse events through root cause analyses (Heget et al., 2002). While this field has made tremendous strides in improving patient safety, it is difficult to discern a particular isolated practice that accounts for the improvement (Lagasse, 2002). Instead, bundles of changes such as those proposed by the Institute of Medicine (2004) and those surveyed by the JCAHO are more likely responsible for the improvement in anesthesia safety.

Patient outcomes: In selecting patient safety outcome variables, experts contend that the event in must be deemed preventable and the measures must be clinically meaningful (Zhan et al., 2005). Additionally, nursing-sensitive measures should be included as patients are hospitalized because they require nursing care and strong evidence suggests that focusing on nursing would improve patient safety (Aiken, 2005). Maas et al. (1996) coined the phrase nursing-sensitive to reflect patient outcomes that are affected by nursing practice. Examples of patient safety outcomes include nosocomial infections such as central line infections,

post-operative complications such as post-operative respiratory failure and even death. Examples of nursing sensitive patient safety outcome include central line infections, pressure ulcers and failure to rescue or failing to rescue a patient from complications such as cardiac arrest or shock.

To address the need for standardized patient safety outcome measures, the Agency for Health Care Research and Quality (AHRQ) developed criteria for comparing risk-adjusted hospital rates for several types of preventable adverse events in studies administrative data especially data used in conjunction w ith the Healthcare Cost and Utilization Project (HCUP). These Patient Safety Indicators (PSIs) consist of 20 hospital based indicators for medical conditions and surgical procedures that have been shown to have adverse event rates that vary substantially across institutions and for which evidence suggest may be associated with deficiencies in the provision of care. In essence, the twenty accepted PSIs represent a selective list of potential safety-related events deemed amenable to detection using administrative data, adequately coded in previous studies and sensitive to the quality of care (Romano et al., 2003).

As noted, the PSIs are designed to screen administrative data. Although, hospital administrative data are readily available, inexpensive and cover large populations (Zhan and Miller, 2003b), administrative data are not without limitations. Most administrative data were initially collected for other purposes (Zhan *et al.*, 2005).

Despite its limitations, the release by AHRQ of the Patient Safety Indicators (PSIs) opened a new era for patient safety research using administrative data. Measures have been developed by governmental or regulatory agencies and by individual investigators for use in their own studies. Further evaluation of the reliability and validity of the measures developed and deployed in patient safety research is warranted (Merwin and Thornlow, 2006). Likewise, additional research is needed to support the validity of the patient safety indicators including nursing-sensitive measures, in detecting errors due to substandard hospital care. Recent analysis of data from the Hospital Quality Alliance national reporting system demonstrates that performance varies among hospitals and across indicators (Jha et al., 2005).

Concerns over cost and quality have created a climate where decision makers at all levels are seeking objective data for evaluating healthcare organizations (Salmon *et al.*, 2003). Quality of care is now prominent on the agendas of health policy makers of the governments of several countries in the East Mediterranean region

(El-Jardali *et al.*, 2008). In the United States, 95% of urban hospitals are accredited by the Joint Commission but fewer than 60% of rural hospitals seek their accreditation. There is no doubt that hospitals in developing countries and rural hospitals in developed countries have seen outcomes of improvement by the accreditation process.

While the degree of compliance to standards could be more easily measured, some researchers have however expressed their reservations on the methods used to measure the real impact of accreditation on risk management and patient safety.

While the number of countries implementing hospital accreditation is mounting because the process is generally believed to be beneficial to date there is little conclusive evidence that the accreditation process actually improves the quality of care offered in hospitals (Walsh, 1995; Viswanathan and Salmon, 2000; Shaw, 2001).

Significance and purpose: Significant series of reports from the IOM on patient safety has encouraged public arguments and generated anthology of regional and nationwide efforts to evaluate and address the issue of patient safety. Considering the growing importance attributed to patient safety and the developing complex nature of healthcare, it becomes imperative to find out if disparities in preventable adverse events among acute care hospitals are reflective of differences in structural methodology. Because strong evidence suggests that focusing on nursing would improve patient safety (Aiken, 2005), any focus on acute patient safety must include a focus on nursing.

Nurses bring considerable expertise and leadership to the field of patient safety research. As point of care providers, nurses are well poised to design systems and processes that protect patients and accomplish the goals of patient safety management: to minimize the likelihood of errors and maximize the likelihood of intercepting errors when or before they occur (Battles and Lilfold, 2003; Institute of Medicine, 2001). Therefore, nurses should be involved in evaluating patient safety practices to improve care delivery. Detecting patient safety outcomes that are sensitive to nursing care in acute settings is crucial given that nurses represent the largest component of the health care workforce (Hall, 2002; Savitz et al., 2005).

Statement of the problem: Wherein the concept of patient safety is considered, it is important to consider the status of the hospital systems and processes either directly or indirectly linked to adverse events such as staffing shortage in the units, blaming culture, lack of quality improvement programs, the existence of Risk Management

Units or Patient Safety Committees and others. Although, studies have demonstrated the association between hospital systems such as hospital teaching status, ownership status and nurse staffing to patient safety outcomes (Ayanian and Weissman, 2002; Devereaux *et al.*, 2002; Kupersmith, 2005; Stanton, 2004).

Few studies have compared or examined the relationship between hospital systems with utilization of patient safety practices and risk management.

The role of accreditation of hospitals will address the issue of patient safety and risk management as a part of quality improvement and hospital performance (76 Canada Accreditation Report 2009; 128 JCI Accreditation 2009 etc.). A study by Romano *et al.* (2003) focused on the relationship of patient systems to patient safety indicators but did not address patient safety practices.

There is very little evidence that actually suggests that the patient safety practices commonly used in other fields confer any benefit in acute care hospitals especially on patient safety outcomes. When evidence does exist, organizations have made attempts to translate such evidence into practice (Kizer and Blum, 2005; Leape et al., 2002; Shojania et al., 2002) to include incorporating patient safety standards and goals into the hospital accreditation process. Two previous studies that examined the association between JCAHO accreditation scores and quality measures and mortality (Chen et al., 2003) and inpatient quality and patient safety indicators (Miller et al., 2005) found no significant association between JCAHO accreditation decisions and performance. A major limitation, however was the fact that data were captured before the incorporation of quality measures and patient safety standards into the JCAHO accreditation process. Analysis and clear understanding of the association among hospital systems and processes is a necessary prerequisite to designing patient safety solutions, especially as evidence of incorporating various safety practices currently comes from domains outside of healthcare (Shojania et al., 2001).

CHAPTER 2

Health care providers' accountability for the services that they render is increasingly a subject of concern to regulators, advocates and consumers (Epstein, 1998). As efforts to contain costs while increasing competition in the health care field have advanced, concerns about deteriorating quality of care now receive even more attention than health care costs. Measuring health care quality and comparing providers performance has emerged as the most hopeful strategy for holding them accountable for the care they provide (Jencks, 1994).

Quality measurement, performance monitoring quality improvement are constant refrain among health care sectors. Hospitals produce statistics regarding their performance in selected clinical areas and most are now surveying their patients about their satisfaction with the care they receive (Edgman-Levitan and Cleary, 1996; Rosenthal et al., 1998). Managed care companies are routinely compared with how well they ensure that preventive health services are delivered to their subscribers (Scanlon et al., 2001). The performance of surgeons is routinely monitored in terms of mortality and complication rates whereas ambulatory practice' performance in holding down waiting times is touted, particularly in highly competitive markets in the US (Hannan et al., 1995).

Key nursing care quality indicators in conjunction with hospital measurements have gone from in-house measurements to public information with performance scores and comparisons accessible to all health care consumers. In this time of heightened awareness, the staff of the Department of Nursing Quality strives to improve patient care by communicating evidence-based standards and by monitoring and reporting the progress of key nursing quality indicators.

In developing countries, accreditation is increasingly being used as a tool for government regulation to guarantee quality of care (El-Jardali *et al.*, 2008). Although, Saudi Arabia is one of the countries in the East Mediterranean region to develop and implement accreditation standards, little is known yet on its impact on quality of care. Quality of care is now prominent on health policy agendas of governments of several countries in the East Mediterranean region. A study conducted in 2000 by the World Health Organization revealed that there were no accreditation programs in the Eastern Mediterranean (WHO, 2003).

Accreditation is a process whereby an organization is assessed on a set of pre-determined standards (Klazinga, 2000; Montagu, 2003). It intends to promote quality improvement through diverse approaches; they are either mandated by the government, voluntary or initiated by independent agencies (Montagu, 2003). health-care Although many organizations developing countries are undergoing or considering accreditation, there is little research on its impact (Buetow and Wellingham, 2003) and consequently no conclusive evidence that it improves quality of care (Viswanathan and Salmon, 2000; Salmon et al., 2003; Shaw, 2001).

Accreditation is an internationally recognized evaluation process used in many countries to assess the quality of health services provided. There are many countries in the world currently embarking on the

development of organizations and programs that offer accreditation. It is a means of publicly recognizing that a healthcare organization has met national standards of quality (Pomey *et al.*, 2005).

Accreditation of health care organizations is defined as an external assessment of the entire organization's performance against a pre-determined set of standards that are objective and measurable to the extent possible. Unlike licensing which tends to focus on the capability the organization may have to deliver health care services, accreditation standards focus attention on the quality and safety of the services. Licensing generally is not time limited. On the other hand, accreditation is time limited and the organization must periodically be re-evaluated to ensure that it continues to meet the standards in order to maintain its accreditation status. Therefore, accreditation not only fosters but requires, a process of continuous improvement (Schwark and Thomas, 2005).

Overview of accreditation processes: Accreditation is a 3 years learning and continuous quality improvement process. Participating organizations are required to undertake self-assessment against a set of internationally recognized standards, followed by an on-site survey. The survey aims to validate the self-assessment and includes provision for documentation review, interviews with Self-Assessment Teams, patients/clients, staff and tours of the relevant facilities (IHSAB, 2007).

Accreditation is the process whereby a designated accreditation body assesses the competence of the berification body to carry out its functions according to relevant standards/guidelines and applicable legislation (if relevant); it is an ongoing cyclical process.

Accreditation is not new to the health system. The first initiative towards accreditation was taken in the United States of America as early as 1910. Over a period of time after several experiments, the Joint Commission on Accreditation of Healthcare Organisation (JCAHO), a national accreditation programme established itself as an esteemed accreditation body by 1987. JCAHO has high standards of quality assurance and rigorous process of evaluation which makes it a much-esteemed agency for accreditation. Health services certified by JCAHO are given deemed status (Chandrima, 2005).

Patient safety: Patient safety has become a major concern of the general public and of policymakers at the State and Federal levels. This interest has been fueled in part by news coverage of individuals who were the victims of serious medical errors and by the publication in 1999 of the Institute Of Medicine's (IOM's) report To Err is Human: Building a Safer Health System. In its report, IOM

highlighted the risks of medical care in the United States and shocked the sensibilities of many Americans, in large part through its estimates of the magnitude of medical errors-related deaths (44,000-98,000 deaths per year) and other serious adverse events (AHRQ, 2001).

The report prompted a number of legislative and regulatory initiatives designed to document errors and begin the search for solutions. But Americans who now wondered whether their next doctor's or hospital visit might harm rather than help them began to demand concerted action (AHRQ, 2001).

System approaches such as improving working conditions have been advocated to improve patient safety. However, the independent effect of many working condition variables on patient outcomes is unknown (Stone *et al.*, 2007).

Patient safety continues to concern consumers, health professionals, policymakers, insurers and researchers. Organizations at the local, state and national levels are developing policies and implementing strategies to improve patient safety. To Err is Human advocated a systems approach to improving patient safety. Its companion report, Crossing the Quality Chasm, emphasized that the non-system in which patients see multiple providers, in multiple settings and where no one has complete information, affects both the safety and quality of health care. Many types of process errors have been attributed to this non-system including medication errors, administrative mistakes, treatment delivery problems and miscommunication.

Harris and Associates (1997) stated that until recently, systematic analyses of provider and public perceptions regarding the impact of the health care system on patient safety have been missing from the literature. Recent surveys have found that overworked health professionals, the nursing shortage, poor supervision, lack of teamwork, poor handwriting, insurer influence on care decisions, varying definitions of errors, lack of training and fear of litigation are viewed as barriers to patient safety by both physicians and the public. These studies also found support for greater legal safeguards, better training, improved staffing, improved error reporting, computerized medical records and spending more time with patients as potential strategies for improving patient safety. Although, these studies begin to address parts of the non-system that contribute to unsafe care, they fail to explore perceptions among providers practicing in a variety of settings (Durbin et al., 2006).

When sick people enter into hospital facilities they expect to receive high quality care and they hope to leave in a better condition than when they arrived. Yet, far too often mistakes are made, patients become injured from falling or they acquire infections while in the hospital that they would not otherwise have been exposed to. While it is impossible to design a facility in which errors are never made and patients never fall, the design of acute care facilities can enhance patient safety. Appropriate lighting may reduce medication errors, non-slip floors may reduce falls and the proximity of the nursing stations to the patient rooms may improve safety. Patient safety is more than risk management it is a moral obligation for those professionals who are dedicated to improving health. Achieving desired improvements in the safety of hospitalized patients requires a long-term commitment to research. education and evidence-based design. Unfortunately, we do not yet have a thorough understanding of how the built environment affects patient safety and we are often ineffective at disseminating the information we do have to the right audience. To address these problems, three Patient Safety groups at the HER Summit (HER) developed a list of research needs, a set of issues regarding the pipeline of information flow among various stakeholders concerning evidence-based design and a set of action items that will improve patient safety in the hospitals that will be built or renovated in the years to come (HER, 2006).

In 1998 Veteran Affairs formed the Expert Advisory Panel for Patient Safety System Design to obtain expert advice to enhance the design of Veteran Affairs reporting systems. These experts in the safety field included Dr. Charles Billings, one of the founders of the Aviation Safety Reporting System (ASRS) as well as other experts from NASA and the academic community. They advised us that an ideal reporting system must be non-punitive, voluntary, confidential and de-identified; must make extensive use of narratives have interdisciplinary review teams and most importantly, focus on identifying vulnerabilities rather than be a counting exercise. Veteran Affairs has used these principles to design the patient safety reporting systems we have in use or in development. Based on the expert advice and on lessons learned from the datory adverse event reporting pilot, the National Center for Patient Safety (NCPS) has developed and rolled out a comprehensive adverse event, close call analysis and corrective action program and computer assisted tool that includes an end-to-end handling of event reports. This system not only allows for the determination of the root causes but also captures the corrective actions as well as the concurrence and support of local management for implementation. The system includes a number of innovations such as human factors

decision support tools and computer-aided report tools to determine the root cause of adverse events and close calls.

In 1999, Veteran affairs established four Patient Safety Centers of Inquiry. These centers conducted research on critical patient safety challenges. Activities at the Centers of Inquiry range from fall prevention and operating room simulators to understanding the role of poor communication in patient safety. The Center in Palo Alto, California which is affiliated with Stanford University is a recognized leader in the area of simulation and has been featured prominently in the media. Their simulated operating room allows surgeons and anesthesiologists to train and do research without endangering a patient.

Another Center at White River Junction, Vermont is partnering with the Institute for Healthcare Improvement (IHI) to build learning collaborative aimed at reducing medication errors, a major issue identified in the IOM report. IHI collaborative will affect several hundred VHA personnel each year. Other IHI collaborative have resulted in measurable improvements and similar results are anticipated with medication errors.

In November 1999, the new event and close call reporting system was first pilot tested in Veteran Affairs' VISN 8 (Florida, South Georgia and Puerto Rico). Extensive training and constant mentoring and feedback were provided to assure full understanding of the search for the root cause and redesign of the system. The quality managers, risk managers and clinicians using the system believe that the new methods analysis of error will make a significant improvement in the care of veterans. Independently, Veteran Health Administration's Patient Safety Improvement Oversight Committee has stated that the reports and corrective actions that are the product of this new approach are superior in numerous ways to the ones from the previous system.

Veteran affairs sought to design reporting systems that would identify adverse events that might be preventable now or in the future. In addition, they sought systems to identify and analyze situations or events that would have resulted in an adverse event if not for either luck or the quick action of a health care provider they call such events close calls. Close calls provide the best opportunity to learn and institute preventive strategies as they unmask system weaknesses before a patient is injured thus enabling preventive actions to be taken. This emphasis on close calls has been employed by organizations outside of health care with great success. It has been said that experience is the best teacher however, it is also the most expensive. In the case of medically

related experience that cost can be expressed in terms of tragic consequences. lose calls enable us to learn and institute preventive actions without first having to pay the costly tuition born of human tragedy.

To complement VA's internal system, an agreement to establish the Patient Safety Reporting System (PSRS), a complementary, de-identified voluntary reporting system was finalized in May 2000. It is external to Veteran Affairs and allows all physicians, nurses, pharmacists, laboratory personnel and others to report unsafe occurrences without fear of administrative or other action being taken against them.

Another key Veteran affairs strategy to reduce medical errors involved the development of a new curriculum on safety. Veteran affairs is moving forward with plans to provide education and training relevant to patient safety not only to those already in practice but also at the medical, nursing and health professional school levels. Veteran affairs is particularly well situated to lead the educational effort due to the extensive role it plays in the education of health care professionals in the United States. Veteran affairs is affiliated with 105 medical schools and up to one-half of all physicians in the country train in a Veteran affairs facility during medical school or residency.

Based on lessons learned from the review of adverse events, actions are taken at both the local level and nationally. Examples of national level actions are as follows:

- Restricting access to concentrated potassium chloride on patient care units
- Requiring use of barcode technology for patient identification and blood transfusions in operating rooms
- Establishing new procedures for missing patient searches
- Enhancing violent behavior prevention efforts
- Enhanced procedures to ensure safe injection of Radio-Labeled Blood Products
- Enhanced requirements for protective fencing around construction sites

They believed that patient safety can only be achieved by working towards a culture of safety. Patient safety improvement requires a new mindset that recognizes that real solutions require an understanding of the hidden opportunities behind the more obvious errors. Unfortunately, systems thinking is not historically rooted in medicine. On the contrary, the field of medicine has typically ascribed errors to individuals and embraced the name-blame-shame and train approach to error reduction.

Such an approach by its very nature forecloses the opportunity to find systems solutions to problems. Other industries such as aviation have recognized the failings of this approach and over many years have succeeded in transitioning from a similar blame and fault finding approach to a system-based approach that seeks the root causes of errors to guide them in preventive actions. Veteran Affairs realized how pivotal culture is to improving safety and in 1998 conducted a culture survey of a sample of employees. Of interest, the shame of making an error appeared a more powerful inhibitor of reporting than was fear of punishment. The surveys provided information that indicated that employees were intolerant of their own errors and ashamed if others knew that an error had been made. People who have expressed strong feelings of shame are less likely to exchange learning experiences with others thus thwarting the opportunity for the entire institution to learn from the experience.

Environment of patient safety

Definition of patient safety terms: A definition of terms is helpful in understanding patient safety concerns and developing programs to improve care. Unfortunately, the lines between Qality Iprovement (QI) and patient safety are indistinct. While patient safety can be assumed under the umbrella of QI not all quality efforts are considered patient safety improvements. While reduction in medical errors and Averse Eents (AEs) are important factors in improving patient safety, access to care, overuse and under-use of services are also safety concerns. The IOM used the following definitions in addressing patient safety concerns.

- Medical error: The failure to complete a planned action as intended or the use of a wrong plan to achieve an aim:
 - Medical errors can be categorized as acts of omission or commission. An example of an error of omission is not giving the patient the prescribed medication or not performing a procedure. Errors of commission include giving the patient the wrong drug dose. Medical errors usually infer a certain level of patient harm
- Adverse event: An injury caused by medical management rather than by the underlying disease or condition of the patient
- Patient safety: Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur

This report uses the term patient safety in discussing a range of practices that could be used by UM (Utilization Management) to systematically decrease errors of commission and omission and to maximize the likelihood of intercepting errors.

A great deal of recent research has focused on the relationship between nurse staffing and patient outcomes while little addresses the nursing work environment (Hall, 2002).

Quality work settings for nursing are those that emphasize:

- Workplace safety
- Personal satisfaction
- Teamwork
- Reasonable workload
- Adequate physical surroundings (McGillis, 2005)

Defining patient safety practices: Working closely with AHRQ and the National Forum for Quality Measurement and Reporting (the National Quality Forum or NQF) a public-private partnership formed in 1999 to promote a national health care quality agenda the EPC began its work by defining a patient safety practice as:

A type of process or structure whose application reduces the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures.

This definition is consistent with the dominant conceptual framework in patient safety which holds that systemic change will be far more productive in reducing medical errors than targeting and punishing individual providers. The definition's focus on actions that cut across diseases and procedures also allowed the research team to distinguish patient safety activities from the more targeted quality improvement practices (e.g., practices designed to increase the use of beta-blockers in patients who are admitted to the hospital after having a myocardial infarction). The editors recognize, however that this distinction is imprecise (AHRQ, 2001).

This evidence-based review also focuses on hospital care as a starting point because the risks associated with hospitalization are significant, the strategies for improvement are better documented there than in other health care settings and the importance of patient trust is paramount (AHRQ, 2001).

Patient safety is an important concern of many health care stakeholders including patients, providers, employers, health plans and insurers. This qualitative study was designed to examine the current role of Utilization Management (UM) programs in promoting patient safety and to identify strategies through which

UM could enhance patient safety in the health care system. URAC received a grant from the Robert Wood Johnson Foundation to examine a cross section of UM companies to better understand their approaches to systematically identifying and investigating potential patient safety concerns. URAC presented preliminary findings to a group of industry leaders to solicit recommendations on future UM research and industry development needed to enable a UM role in patient safety (URAC, 2003).

Goals of accreditation: Accreditation and standards setting initially emerged in response to unacceptable variations in the quality of educational institutions (Lewis, 2007). These methods were eventually adopted in other sectors, notably health care. Today, accreditation is affirmed as a process designed to improve the quality, efficiency and effectiveness of a healthcare organization including its structures, processes and outcomes. Simply put, accreditation is based on the premise that adherence to evidence-based standards will reliably produce higher quality health services in a safer environment than would be the case without them. The resultant decreased variation in administrative and clinical structures and processes, similar to the contribution of clinical practice guidelines is thus a powerful mechanism to improve the quality of health care and ultimately healthcare outcomes (Accreditation Canada, 2009).

The accreditation is the process of competence assessment, quality control and regulation of the independent auditor much as the Public Company Accounting Oversight Board in the United States or the Canadian Public Accountability Board, supervises financial auditors for public trading. Accreditation is perceived as a key component in strengthening quality improvement and enabling patient safety initiatives. For organizations and programs that participate in accreditation, they are confirming their commitment to quality improvement, patient safety, improved efficiency and the demonstration of accountability. This is a powerful message to key decision-makers and the public in today's dynamic healthcare environment (Accreditation Canada, 2009).

Accreditation organizations are uniquely positioned to provide a comprehensive look at the challenges and successes healthcare organizations experience and to identify prevalent themes in the provision and delivery of healthcare services. Equally important, the data collected through accreditation can be leveraged as a valuable resource for healthcare providers, governments and policy-makers thus contributing to effective decision making and ongoing quality improvement on a national basis (Accreditation Canada, 2009).

Identified benefits of accreditation: The identified benefits of accreditation are often viewed as:

- Enhancing patient safety by effectively managing and mitigating clinical and safety-related risks (Rene et al., 2006; Salmon et al., 2003; Mays, 2004)
- Ensuring an acceptable level of quality among health care providers (Rene et al., 2006; Mays, 2004; Montagu, 2003)
- Stimulating sustainable Quality Improvement (QI) and continuously raising the bar with regards to QI initiatives (Salmon et al., 2003; Mays, 2004; Montagu, 2003; Sutherland and Leatherman, 2006)
- Enhancing organizations' understanding of the continuum of care by focusing on performance improvement and outcomes of care
- Increasing reputation among end-users and enhancing their awareness and perception of quality care (Rene et al., 2006; Mays, 2004; Montagu, 2003; Chair et al., 2005; El-Jardali et al., 2008; Greenfield et al., 2008)
- Promoting capacity-building and organizational learning (Rene *et al.*, 2006; Mays, 2004)
- Providing a framework that assists in the creation and implementation of systems and processes which improve operational effectiveness and enhance positive health outcomes (Rene et al., 2006; Salmon et al., 2003; Greenfield and Braithwaite, 2008)

These benefits reflect the current expectations by healthcare organizations and systems, clients and the public as a whole. They result from the impacts of an organization's self-assessment which allows a close look at its strengths and areas for improvement and modification of its priorities and the accreditation survey and reports which provide recommendations from surveyors who represent their peer group and have significant experience in the healthcare field as well as assisting organizations to focus on outcomes measurement to allow them to benchmark themselves with other healthcare organizations. The question then becomes are these benefits validated by current research (Accreditation Canada, 2009).

Furthermore, there are many strengths concerning accreditation as it provides external and objective evaluation, uses consensus standards involves the health professions, proactive not reactive, organization wide, focus on systems not individuals, stimulates quality culture in the organization and periodic re-evaluation against standards. Accreditation is intended to stimulate continuous improvement in patient care processes and outcomes, increase efficiency/reduce costs, strengthen the public's confidence, improve the management of health services, provide education on better/best

practices, enhance staff recruitment, retention and satisfaction, improve or expand sources of payment for patient care, increase chances to enter networks and new provider arrangements provide greater independence from government oversight, build a quality measurement database, provide comparison with self, others and best practices and provide a framework to improve patient safety (JCI, 2003).

Accreditation benefits medical and nursing staff as it improves professional staff development, provides education on consensus standards provides leadership for quality improvement within medicine and nursing, increases satisfaction with working conditions, leadership and accountability. Also, benefits for hospital employees include values employee opinions, measures employee satisfaction, involvement in quality activities, improved employee safety and security, clearer lines of authority and accountability and promotes teamwork (JCI, 2003).

The benefits of accreditation for patients include access to a quality and safety focused organization, rights are respected and protected, understandable education and communication, satisfaction is evaluated, involvement in care decisions and care process and focus on patient safety (JCI, 2003).

While a number of positive benefits regarding the value and impact of accreditation have been highlighted above, many of the articles published on the subject call for more research in this area. It is encouraging to see a number of Canadian and International researchers focusing in this area. Until empirical, evidence-based research on accreditation is complete, there will continue to be questions raised, regarding the value and impact of accreditation (Accreditation Canada, 2009).

There are mixed views and inconsistent findings regarding the impact of accreditation on client outcomes. Existing research lacks rigorous in-depth analysis of the accreditation process and the relationship between accreditation and performance, outcomes, quality improvement and patient safety (Braithwaite et al., 2006; Greenfield et al., 2007; Greenfield and Braithwaite, 2008). While there is no conclusive evidence on the direct impact of accreditation on client outcomes, there is some indication if accreditation that strengthens interdisciplinary team effectiveness, communication and enhanced use of indicators leading to evidence-based decision making then accreditation contributes to improving health outcomes.

The positive impacts of accreditation: The positive impacts of accreditation within the literature are noted as improves communication and collaboration, both

internally as well as with external, stakeholders and community partners (Rene et al., 2006; Werner and Asch, 2005; Greenfield et al., 2007; Gluck and Hassig, 2001; Heaton, 2000; El-Jardali et al., 2008), strengthens interdisciplinary team effectiveness, contributing to better patient outcomes (Pomey et al., 2005; Sutherland and Leatherman, 2006; NCQA, 2007; Simons et al., 2002; Shaw, 2003; El-Jardali et al., 2008), demonstrates commitment to quality, accountability as well as increased credibility of the healthcare organization (Salmon et al., 2003; Mays, 2004; Sutherland and Leatherman, 2006; Devers et al., 2004; Griffith et al., 2002; Baldi et al., 2000; Greenfield et al., 2008), strengthens professional development, organizational learning and capacity building (Pomey et al., 2005; Montagu, 2003; Gluck and Hassig, 2001; Shaw, 2003; Baldi et al., 2000; Newhouse, 2006; Pagliarulo, 1986; Touati and Pomey, 2009; Greenfield and Braithwaite, 2008), provides an opportunity for additional funding and decreased liability costs (Mays, 2004; Gluck and Hassig, 2001), increases effective risk management and mitigation including enhanced patient safety (Mays, 2004; Simons et al., 2002; Griffith et al., 2002; Pagliarulo, 1986; Grachek, 2003; Leatherman et al., 2003; Chen et al., 2003), sustains improvements in quality and organizational performance (Leatherman et al., 2003; Chen et al., 2003; Peer and Rakich, 2000; El-Jardali et al., 2008), enables ongoing self-analysis of performance in relation to standards (Mays, 2004; Montagu, 2003; Sutherland and Leatherman, 2006; Werner and Asch, 2005; Greenfield et al., 2007; Newhouse, 2006; Pagliarulo, 1986), codifies policies and procedures (Chair et al., 2005; Simons et al., 2002; Devers et al., 2004; Peer and Rakich, 2000; Touati and Pomey, 2009), decreases variances in practice between healthcare providers (Lewis, 2007; Salmon et al., 2003), provides consistency and meaning associated with the objective peer review process (Rene et al., 2006; Sutherland and Leatherman, 2006; Heaton, 2000; Pagliarulo, 1986; Gustafson et al., 1980) and provides an impetus for change and its effective management (Salmon et al., 2003; Gluck and Hassig, 2001; Devers et al., 2004; Peer and Rakich, 2000), Touati and Pomey, 2009; Greenfield and Braithwaite, 2009).

Concerns regarding accreditation: Achieving and maintaining accreditation status requires a significant investment of resources. For many organizations, there may be a question as to whether accreditation is worth the time, effort and cost as well as whether or not it demonstrates a quantifiable improvement in healthcare delivery and outcomes (Devers *et al.*, 2004).

Some of the common concerns identified include lack of research demonstrating a strong link between accreditation status and client outcomes (Lewis, 2007; Salmon et al., 2003; Mays, 2004; Shaw, 2003; Devers et al., 2004; Griffith et al., 2002; Chen et al., 2003; Beaulieu and Epstein, 2002; Barker et al., 2002; Greenfield and Braithwaite, 2009; Greenfield et al., 2008), not enough diversity in the results and results are too soft (resulting in excessively positive results) (Lewis, 2007; Mays, 2004; Miller et al., 2005) there are potentially other methods for assessing and ensuring quality (i.e., use of information technology and performance measures) (Lewis, 2007; Rene et al., 2006; Griffith et al., 2002; Miller et al., 2005), generally the process includes periodic as opposed to continuous assessment which leads to a more reactive than forward-looking focus and can be a factor in persistent quality deficiencies or critical adverse events (Lewis, 2007) being typically reliant on data collected through organizations' self-assessment which has the potential to be incomplete or inaccurate (Lewis, 2007; Pagliarulo, 1986) valuing uniformity and adherence to standards as opposed to individual organizations' performance and innovation (Lewis, 2007), the accreditation process being stressful, time consuming and require a serious investment of resources (Mays, 2004; Montagu, 2003; Touati and Pomey, 2009) there are risks involved (i.e., risk of attaining non-accreditation status) (Montagu, 2003) and accreditation may be slow to adapt to changing concepts of quality and performance (Lewis, 2007).

Characteristics of accreditation: Accreditation has three characteristics (Harvey, 2004).

- First, accreditation is a process applied to applicant organisations
- Second, accreditation is the label that institutions or programmes may acquire as a result of accreditation procedures
- Third, accreditation is an abstract notion of a formal authorising power' (Haakstad, 2001), enacted via official decisions about recognition (the accreditation process). It is this underpinning abstraction that gives accreditation its legitimacy. This abstraction, frequently taken for granted is not a traditionally intrinsic aspect of accreditation. As Jones (2002) has pointed out the original audience for accreditation was the academy itself. The process did not arise in response to concerns about quality expressed by external audiences

Proposed model of accreditation: In 1951, the American College of Surgeons, American College of Physicians, American Hospital Association and the American Medical Association cooperated to form the Joint Commission on Accreditation of Hospitals to address the need to improve the quality of care in the United States of America. Today it is the primary instrument used by the United States Health Care Financing Administration to approve the transfer of medical funds to hospitals. Only hospitals that have passed an accreditation process can receive payments. Countries in other WHO regions have also employed this method such as Egypt and Lebanon (EMR), Brazil and Argentina (AMR), Thailand, Taiwan and Indonesia (SEAR), England, France and Spain (EUR), South Africa (AFR) and Korea (WPR).

Accreditation has been defined as a system of external peer review for determining compliance with a set of standards. It is a procedure that evaluates the institutional resources periodically and confidentially, seeking to ensure the quality of care on the basis of previously accepted standards. Standards may be minimal, defining the bottom level or base or more detailed and demanding, defining various levels of achievement. A health care establishment is said to be accredited when the disposition and organization of its resources and activities make up a process which results in medical care of satisfactory quality. Accreditation implies confidence in a hospital by the population. In almost all cases this can be achieved without major investments infrastructure. There are three main purposes accreditation:

- Quality improvement using the accreditation process to bring about changes in practice that will improve the quality of care for patients
- Informing decision-making: providing data on the quality of health care that various stakeholders, policymakers, managers, clinicians and the public can use to guide their decisions
- Accountability and regulation making health care organizations accountable to statutory or other agencies such as professional bodies, government, patient groups and society at large and regulating their behavior to protect the interests of patients and other stakeholders

Standards are statements of expectation that define the structures, processes and results that must be firmly established in an organization so that it may provide quality care. For example, standard of structure refers to equipment, physical area, support services, personnel; standard of process includes admission, nursing procedures, medical procedures, operational manuals, norms, routines, flows and standard of outcomes covers mortality, morbidity, readmissions, complications, infections and client satisfaction (accessibility, information, personnel and facilities). All these standards require evidence of performance (or qualitative indicators) that are simple, inexpensive and easy to observe by the surveyors.

In the Eastern Mediterranean region there is often great diversity of hospitals within the same country. Although, there may be prominent public and private medical centers, comparable to the most advanced in any other region, many of these hospitals would not pass an evaluation review for a minimum level of quality in some services. Currently as well many hospitals have a great variation in quality among their services, independent of their size.

The major reasons for implementing accreditation are it stimulates the improvement of care delivered to patients, it strengthens community confidence in its hospital, it reduces unnecessary costs, it increases efficiency, it provides credentials for education, internships and residencies, it can protect against lawsuits and it facilitates acceptance by and funds from third-party payers.

From the World Health Organization-Regional Office for the Eastern Mediterranean in 2002, concepts that are important in accreditation methodology are as follows:

- Accreditation is not the goal; the goal is to improve the quality of each hospital service
- The emphasis is on the total hospital system (and its processes)
- Educational programmes are essential
- Standards for accreditation will evolve as the countries' hospital services progress
- The final verdict of accreditation is based on a consensus among the surveyors
- The standards should reflect the average status of hospitals in a country

In the draft manual of hospital accreditation (designed for the WHO/EMRO Intercountry workshop and is based on the document Standards and Indicators for Hospital Accreditation in Latin America by Drs. Humberto M. Novaes and Jose M. Paganini, standards are organized by increasing and related degrees of quality performance (or complexity) in such a way that to attain a superior level of quality for a specified hospital service, the standards for inferior levels must necessarily be satisfied. The standards seek to evaluate, within a single service, aspects of structure, processes and results through qualitative and dynamic evidence of performance or indicators that reflect the quality of services provided. To establish a given level for each item, the evaluation should begin at inferior levels until reaching the level where the requirements are not completely satisfied.

Qualitative indicators or evidence of performance are described for each standard and designed to ascertain the degree to which measures prescribed by standards are carried out and their effect on patient care. The data collection process for observing qualitative indicators is designed to be as simple as possible. The results should offer information useful to those in decision-making or managerial positions to help them make necessary changes. For countries that do not have sufficient valid or reliable information for statistical analysis or where adequate numerical data have not been collected, the indicator for each standard will be determined by qualitative observation using surveyor consensus. In the future and to the extent that data are collected and analyzed, one will be able to develop statistical interpretations to establish quantitative observation.

The evidence of performance of standards is not assessed through a checklist. Hospitals are unique entities each with its own tradition, culture and background. The surveyors will establish a tailor-made model of assessment for each hospital, defining how, when and what will be assessed first and this flexibility cannot exist in a rigid checklist. Accreditation is still a very subjective type of assessment. For this reason, highly competent surveyors must be selected The surveyors will establish a tailor-made model of assessment for each hospital, defining how, when and what will be assessed first and this flexibility cannot exist in a rigid checklist.

Currently, qualitative indicators point to sources where surveyors can seek evidence or where a hospital can show surveyors that it is or is not complying with the stated standard (s). These sources might be documents, interviews, medical reports or patient records etc.

Increasingly complex standards or those that evolve continually have been established for each hospital service from an initial threshold to more sophisticated levels. These standards represent the expected level of desired care, practice or methods defined by national experts and/or professional associations. In each situation, the initial standard is the required minimum level of quality. No country's hospital hopes to find itself below this level within a specified period of time for example. As these initial standards are met, subsequent steps are addressed to reach successive standards. Thus, when the standard for the basic level is met, the next step is to reach the second and then the third levels, progressively.

As a hospital is not comprised of independent or isolated services, it is necessary that all its services, from the laundry to the operating room or to staffing of the intensive care unit, for example, reach at least the basic level standard in order for the hospital to be accredited and receive the resulting public recognition for good quality medical care that accreditation brings. An isolated service is not accredited. Even if a hospital unit is fully equipped and of exceptional quality in some units or services, with sophistication levels at 3 or 4, the institution will continue to be accredited at the first level if other services do not exceed the first level.

This methodology attempts to reinforce the fact that hospital structures and processes are so integrated that poor functioning in one component interferes throughout and in the final result. Thus, a hospital is or is not accredited as a whole, indivisible unit. Distinct levels of accreditation are not established for secondary and tertiary care hospitals. It is commonly observed that hospitals perform complicated clinical procedures however, the surgical centre for example must interrupt its activities for lack of linens.

The methodology proposes that each service or hospital department standard reflects increasing performance of care. This promotes an environment of continuous improvement because there will always be standards of higher complexity to pursue. Before, during and after an evaluation for accreditation, administrators must gradually develop items to identify and distinguish discrepancies between practices and acceptable standards of quality, finding ways to correct or reduce deficiencies.

The draft manual of hospital accreditation recommends the use of levels of standards of accreditation of increasing complexity. The accreditation process may observe some specific principles. For example Level 1 should characterize the clients' safety (mainly structure component); Level 2 is more oriented at safety and organization of the hospital (mainly process component) and Level 3 is for safety, organization and management and quality (mainly outcome component).

Level 1: The demands of this level observe basic quality of care compatible with institutional resources. The services, units or sectors have responsible certified personnel, observe formal safety requirements and have appropriate infrastructure to implement activities within the corresponding rules and regulations.

At this level, surveyors should verify the following evidence of performance:

- Responsible certified personnel
- Functional personnel according to service needs
- Structural and operational conditions according to safety requirements for hospitalized and outpatient clients

Level 2: At this level, in addition to Level 1 standards, there should be evidence of organizational planning of care in relation to documentation, training, control and decisions making based on information and the internal audit. Services, units or sectors have documented process and procedure manuals that are up to date and available as well as clinical protocols and basic statistics continuous education programmes are offered for the improvement of processes, sentinel events and evidence of integration with other hospital services.

At this level, the surveyors should verify the following evidence of performance:

- Up to date and available process and procedure manuals
- Qualified professionals
- Groups for process improvement
- System of critical case assessment to control eventual problems or risks, procedure improvement
- Patient orientation
- Continuity of care and case follow up

Level 3: At this level, in addition to Level 2 standards, there should be evidence of institutional policies for continued improvement in terms of structures, processes, procedures, technology upgrades and outcomes or impacts. The services, units or sectors have measurement systems for client satisfaction; integration with the institutional quality and productivity programme; evidence of improvement cycles; data information systems and indicators that allow service evaluation and community impact.

At this level, the surveyors should verify the following evidence of performance:

- Planning and continued improvement systems relating to structure, processes and results; new technologies; refresher courses in clinical care actions and procedures
- Cycles of improvement with systemic impact
- Information systems based on indicators that allow analysis and comparisons
- Permanent system of satisfaction of inpatients and outpatients

Major challenges in implementing hospital accreditation (Novaes, 2002)

Legal considerations: Executive orders, laws or regulations of the Ministry of Health are important and useful but should not the paramount factor. In some cases, a change in Health Ministers can hinder implementation of the policy even if it has just been

announced by decree or through regulations, if the new Minister does not consider it a priority to encourage the national process of accreditation for political reasons. Thus, the initiative is delayed until another Minister presses the issue.

Lack of an inter-institutional and independent National Commission on Hospital Accreditation. Such a commission is always the goal to be reached although, it is not easy to achieve consensus among the different actors in the public and private health sectors to work together with a common goal. Another threat is the appearance of multiple accreditation entities, competing among each other and setting different standards, priorities and fees. This can affect the entire accreditation process negatively, leading to the possibility that if a hospital is not accredited by one entity, it may be accredited by another, under different standards. It is essential to have uniformity therefore there must be a National Commission that applies uniform accreditation standards to be followed by state or provincial entities.

Lack of participation by the insurance sector. The role of public or private social security and private health insurance is vital for implementation since, the inclusion of accredited hospitals in their list of providers characterizes the importance of hospital accreditation as an instrument to ensure quality of care for the clients of these institutions. Private insurance companies are beginning to analyse this situation however, many countries unfortunately do not yet have a process to tie national accreditation to contracts for hospital services.

The non-application of minimum standards as opposed to optimum standards. It is necessary to implement basic standards during the beginning of hospital accreditation development. This seems to be the most rational approach since no country would be likely to have adequate and sufficient human and financial resources to correct deficiencies throughout all of its hospitals, whether structural or process-related using optimum standards. Since the methodology anticipates that each hospital service will have increasingly complex standards, the highest level of standards would be considered ideal or optimal (Level 3). Generally, professional associations such as medical or nursing associations, always strive to establish optimum standards, although when starting to implement the accreditation process, they convince themselves that it is not possible to begin with very sophisticated levels. Consequently, very few hospitals in the short term, manage to be in a position to implement optimum standards.

Ensuring standards for all hospital services instead of for a few units. Approval of particular units or isolated programmes has been supported by some groups by those in charge of the programme for prevention and control of hospital infections or isolated accreditation of hospital laboratories. A hospital may have a good programme in place to control infections or a good clinical laboratory but this does not always ensure that other services are in a position to be accredited even using minimum standards.

Risk of assigning points or giving a precise value or numerical score to findings. This approach results in problems because in some cases, the sum total of points may mask areas with deficiencies. Instead of giving a score, the surveyors by consensus should agree at the end of the accreditation visit whether the hospital is or is not accredited or if some time is required to correct deficiencies (partial accreditation).

Confusing licensing with accreditation. Some countries have not yet instituted a national hospital licensing system or a system for initial health permits for construction or renovation which are generally issued by municipal authorities and which almost always deal only with observable structural features (licensing). When a country tries to use accreditation as a tool for licensing, the degree of complexity created renders accreditation impractical.

Ensuring sustainability of a national accreditation programme. Although, accreditation may be voluntary on the part of hospitals, these institutions must have some incentive for accepting the accreditation process. In the United States for example, the vast majority of hospitals survive as a result of patients covered by Medicare or social security for the elderly. For a hospital to be contracted under Medicare, it must have prior accreditation from the National Accreditation Commission. Similar incentives for sustainability of this process will be required in countries of the Eastern Mediterranean region.

Misperception of the role of surveyors. The accreditation process must always be viewed as an auxiliary and permanent educational activity for hospital staff, never as a bureaucratic inspection or critical audit in search of victims. The basic role of surveyors should always be seen as that of specialized consultants helping the hospital to overcome its managerial or technical difficulties. Assessment teams generally include a physician recognized for his/her skills, a nurse with far-reaching experience in hospitals and an administrator with a solid background in hospitals. In many countries, most of the hospital administrators are physicians but in the surveyor team they are only administrators, leaving the clinical side to be observed by the physician on the team.

Example of the impact of accreditation at King Abdulaziz University hospital: A research regarding the impact of accreditation was conducted at King Abdulaziz University Hospital (KAUH) in Jeddah, Saudi Arabia.

A brief description of the hospital is that it is a tertiary hospital with 847 bed capacity. It is managed collaboratively by both academic and hospital staff fulfilling its mission of providing quality patient care services and promoting education and research. The current hospital database is 281 administrative positions, 1,255 technical positions including nursing (883 in-post), 629 doctors positions of which 234 are hospital positions and 395 are academic.

The impact of accreditation research collected the following indicators from year 2006-2009:

Mortality:

- Comparison of the total numbers of deaths
- Comparison of the rates of mortality per 100 admissions
- Comparison of the mortality rates per 100 discharges
- Comparison of the rates of mortality per 1000 hospital days
- Comparison of the total numbers of perioperative deaths
- Comparison of the rates of perioperative mortality per 1000 surgeries
- Comparison of the rates of perioperative mortality per 1000 total deaths
- Comparison of the rates of perioperative mortality per 100 cancelled operations
- Comparison of the total numbers of deaths in the Neonatal Intensive Care Unit (NICU)
- Comparison of the rates of neonatal mortality per 100 NICU admissions
- Comparison of the rates of maternal mortality per 100,000 deliveries
- Comparison of the rates of ER mortality per 1000 visits
- Comparison of the newborn mortality rates per 100 deliveries in Labor and Delivery Unit (L and D)
- Comparison of the total numbers of deaths within 48 h of admission in the intensive care units
- Comparison of the percentages of deaths within 48 h per 100 admissions in the intensive care units

Health care associated infections:

- Comparison of the average of the surveyed health care associated infections per month
- Comparison of the average of the health care associated infections per month in the general units
- Comparison of the average of the health care associated infections per month in the Intensive Care Units
- Comparison of the rates of health care associated infections per 1000 discharges
- Comparison of the rates of health care associated infections per 1000 hospital patient days

- Comparison of the average of the clean surgical site infections per month
- Comparison of the rates of clean surgical site infections per 1000 operations
- Comparison of the rates of postpartum health care associated infections per 1000 patient days
- Comparison of the neonatal health care associated infection rates per 1000 patient days
- Comparison of the rates of blood stream health care associated infections per 1000 patient days
- Comparison of the rates of health care associated central line blood stream infections per 1000 device days in Medical Intensive Care Unit (MICU)
- Comparison of the health care associated central line blood stream infection rates per 1000 device days in Pediatric Intensive Care Unit (PICU)
- Comparison of the rates of health care associated central line blood stream infections per 1000 device days in Surgical Intensive Care Unit (SICU)
- Comparison of health care associated central line blood stream infection rates per 1000 device days in Neonatal Intensive Care Unit (NICU)
- Comparison of the urinary tract health care associated infection rates per 1000 patient days
- Comparison of health care associated Foley catheter urinary tract infection rates per 1000 device days in Medical Intensive Care Unit (MICU)
- Comparison of the health care associated Foley catheter urinary tract infection rates per 1000 device days in Pediatric Intensive Care Unit (PICU)
- Comparison of the health care associated Foley catheter urinary tract infection rates per 1000 device days in Surgical Intensive Care Unit (SICU)
- Comparison of the health care associated Foley catheter urinary tract infection rates per 1000 device days in Neonatal Intensive Care Unit (NICU)
- Comparison of the respiratory tract health care associated infection rates per 1000 patient days
- Comparison of the incidence rates of health care ventilator associated pneumonia infections per 1000 device days in Medical Intensive Care Unit (MICU)
- Comparison of the incidence rates of health care ventilator associated pneumonia infections per 1000 device days in Pediatric Intensive Care Unit (PICU)
- Comparison of the incidence rate of health care ventilator associated pneumonia infections per 1000 device days in Surgical Intensive Care Unit (SICU)
- Comparison of the incidence rate of health care ventilator associated pneumonia infection per 1000 device days in Neonatal Intensive Care Unit (NICU)
- Comparison of incidence rates of upper respiratory tract infections per 100 Nursing database
- Comparison of the rates of skin and soft tissue health care associated infections per 1000 patient days

Medications:

- Comparison of the total numbers of adverse drug reactions reported
- Comparison of the total numbers of adverse drug reactions resulting in temporary or permanent patient injury
- Comparison of the total numbers of medication errors
- Comparison of the rates of medication errors per 100 admissions
- Comparison of the rates of medication errors per 100 hospital beds

Blood:

- Comparison of the total numbers of blood transfusion reactions
- Comparison of the rates of blood transfusion reactions per 100 transfusions

Surgery/invasive procedures:

- Comparison of total numbers of unplanned returns to surgery within 48 h
- Comparison of the rates of unplanned returns to surgery per 100 operations
- Comparison of the total numbers of cesarean sections
- Comparison of the total numbers of emergency cesarean section
- Comparison of the averages of repeated cesarean sections
- Comparison of the rates of cesarean sections per 100 deliveries
- Comparison of the rates of emergency cesarean sections per 100 cesarean sections

Codes:

- Comparison of the total numbers of cardiopulmonary resuscitations
- Comparison of the total numbers of patients who survived the first cardiopulmonary resuscitation
- Comparison of the survival rates of patients after first cardiopulmonary resuscitation per 100 coded patients
- Comparison of the rates of successful cardiopulmonary resuscitations per 100 coded patients in the Emergency Department
- Comparison of the rates of successful cardiopulmonary resuscitations per 100 coded patients in the Medical Intensive Care Unit (MICU)
- Comparison of the rates of successful cardiopulmonary resuscitations per 100 coded patients in the pediatric units
- Comparison of the rates of successful codes per 100 coded patients in the Medical/Surgical units
- Comparison of the rates of successful codes per 100 coded patients in the Obstetric Unit

Adverse event:

- Patient risk indicator
- Comparison of the total numbers of patients/visitors' falls
- Comparison of the rates of patients/visitors' falls per 1000 hospital days
- Comparison of the total numbers of pressure ulcers developed in the hospital
- Comparison of the rates of pressure ulcers developed per 1000 admissions
- Comparison of the total numbers of readmitted patients within 48 h following discharge
- Comparison of the rates of readmitted patients per 100 discharges
- Comparison of the total numbers of reported sentinel events

OVR reporting as quality indicator:

- Comparison of the total numbers of occurrence variance reports
- Comparison of the total numbers of needle stick injuries
- Comparison of the rates of needle stick injuries per 100 beds per year

Quality culture indicator:

- Comparison of the total numbers of incidents related to non adherence to the policies and procedures
- Comparison of the rates of incidents related to non adherence to the policies and procedures per 100 nursing staff
- Comparison of the total numbers of patients who discharged against medical advice or absconded
- Comparison of the rates of patients who discharged against medical advice or absconded per 1000 ER visits
- Comparison of the rates of patients who discharged against medical advice or absconded per 1000 admissions
- Comparison of the total numbers of doctors, technicians or staff showing aggressive behavior towards patients and colleagues
- Comparison of the total numbers of doctors or technicians not responding to pages, patients' needs or staff negligence
- Comparison of the total numbers of patients or relatives showing aggressive behavior towards hospital staff or smoking. Overall total of indicators were 81

Using SPSS, the following tests were performed:

Kolmogorov-Smirnov Test-determine if normal distribution or not

- ANOVA-normal distribution
- Non Parametric Tests-non normal distribution
- Friedman test global plus Wilcoxon and Bonferroni Correction

Aside from the indicators collected, two (2) surveys were conducted among nursing staff-Perceived Impact of Accreditation on Patient Safety and Nursing Patient Safety Culture survey.

Statistical findings showed that 28 out of 81 indicators significantly improved that is 34.57%. Indicators that improved were:

Mortality (5/15 = 33%):

- Total numbers of perioperative deaths
- Rates of perioperative mortality per 1000 surgeries
- Rates of perioperative mortality per 1000 total deaths
- Rates of neonatal mortality per 100 NICU admissions
- Rates of perioperative mortality per 100 cancelled operations

Healthcare Associated Infections (16/26 = 62%):

- Average of the surveyed overall HAI
- Average of the surveyed HAI in general units
- Average of the surveyed HAI in ICUs
- Rates of HAI per 1000 discharges
- Rates of HAI per 1000 hospital patient days
- Average of clean surgical site infections
- Rates of clean surgical site infections per 1000 operations
- Rates of neonatal HAI per 1000 patient days
- Rates of blood stream HAI per 1000 patient days
- Rates of healthcare associated central line BSI per 1000 device days in MICU
- Rates of healthcare associated central line BSI per 1000 device days in NICU
- Rates of urinary tract HAI per 1000 patient days
- Rates of healthcare associated Foley catheter UTI per 1000 device days in MICU
- Rates of healthcare associated Foley catheter UTI per 1000 device days in PICU
- Incidence rates of healthcare ventilator associated pneumonia infections per 1000 device days in MICU
- Rates of skin and soft tissue HAIs per 1000 patient days

Transfusion reactions (1/2 = 50%):

 The total numbers of blood transfusion reactions have decreased from year 2006-2009

Surgery/Invasive procedures (2/7 = 29%):

 Total numbers of unplanned returns to surgery within 48 h Rates of unplanned returns to surgery per 100 operations

Codes (2/8 = 25%):

- Total numbers of patients who survived after the 1st CPR
- Rates of survival after 1st CPR per 100 coded patients

Adverse events (2/18 = 11%):

- Rates of pressure ulcers developed per 1000 admissions
- Total numbers of OVRs
- Survey results showed perception of nursing staffs are correlated with statistical findings. The overall average of relative improvement percent is 34.43%

CONCLUSION

In the impact of accreditation research at King Abdulaziz University Hospital, assuming that no alteration of variables occurred such as operational plan, staff qualification and manpower ratio and that the only change implemented was the accreditation process with its related requirements, it is therefore concluded that the accreditation process at King Abdul-Aziz University Hospital with the strong support of the Hospital Administration has significantly improved (28/81 = 34.57%) the quality of patient care and patient safety indicators reviewed in the research and perception of nursing staffs is correlated with the statistical findings.

Overall, it is recommended that accreditation in both emerging and industrialized countries be provided especially if there is a strong commitment from the leadership and that process is voluntary rather than obligatory. More in-depth studies regarding accreditation should be made to establish its conclusive results.

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