MONOGRAPH

PREPARED BY THE MONOGRAPHS TASK FORCE OF THE AMERICAN SOCIETY FOR HEALTHCARE RISK MANAGEMENT

Disclosure
of unanticipated events:

the next step in
better communication
with patients

first of three parts

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TABLE OF CONTENTS

FOREWORD

Because the practice of disclosure of unanticipated medical outcomes is an evolving process in health care, ASHRM is offering this three-part monograph series on communication and disclosure.

A continuum of implementation and acceptance within health care organizations exists since the July 2001 definition of Patient Safety Standards by the Joint Commission on Accreditation of Health Care Organizations (JCAHO). This series will provide a "state of play" of the role of disclosure in health care. Models and descriptions are not intended to be prescriptive. Rather, they should serve to update readers on ways that disclosure is being used in health care and prompt them to consider strategies that could be helpful in their own organization.

This paper is not a description of the legal considerations a risk manager must bear in mind when implementing a disclosure practice. While some research has been done on the impact of disclosure on litigation, evidence regarding the ultimate impact is inconclusive. As such, risk management must not ignore the legal dimensions of developing and implementing communication processes. (*Legal considerations of disclosure were addressed in the ASHRM whitepaper titled "Perspective on Disclosure of Unanticipated Outcome Information" released in July 2001. To read the paper, visit www.ashrm.org.*)

In its entirety, this three-part series will provide the current perspectives of those working on the front lines of disclosure development and deployment.

The first paper addresses:

- The initial impact of Patient Safety Standards established by JCAHO
- Psychological and legal barriers to disclosure and open communication
- Models used by organizations to support and influence communication
- Experiences in disclosure since implementation of the Standards, including analyses of how communication worked well – or didn't – in some disclosure efforts.

The second paper, **"Disclosure policies: analysis of the influence of disclosure on litigation,"** will cover disclosure policies. It will provide models, discussions of strengths and suggestions for building an effective policy. It also will present the findings on the effect of disclosure on litigation and claims, and will discuss ways to define "harm" in policies that address the need for clinician/physician protection while allowing for specific patient needs. Finally, it will consider the implications of disclosure in different care settings: acute, long term and pediatric. (*To be released mid-2003.*)

The third paper, **"Effective disclosure: what works now, what can work better,"** will focus on techniques to improve effective disclosure and how they can be applied. In addition, this monograph will analyze disclosure situations, providing discussion on the issues to consider and the techniques to enhance the potential for effective communication with patients and families. (*To be released late 2003.*)

INTRODUCTION

In facing the issue of disclosure, health care providers need to understand and evaluate the history of disclosure in medicine as well as specific issues in the organization if they are to develop infrastructures to support open communication with patients and families.

When caregivers learn that an unexpected outcome arises, a risk management issue occurs. What ought to be told, and to whom? This issue must be faced whether these differences are positive or negative. Patients must know of any variance in their care to make decisions for future care or action, including seeking legitimate compensation for actual losses.

Patient Safety Standards and disclosure

The release of the Joint Commission Patient Safety Standards in July 2001 resulted in a great deal of activity and discussion on the topic of disclosure. Essentially, in RI.1.2.2, the Joint Commission mandates that patients are entitled to be informed of unanticipated outcomes of care. Major concerns expressed at the time included the definition and application of the term "unanticipated outcome," what specifically should be disclosed, who should be involved in a disclosure discussion and what protections, if any, would there be for organizations or individuals who comply with the Standards.

Many organizations have written disclosure policies in an effort to comply with the Standards. Their policies often set the basis for disclosure at "when the patient is substantially harmed." But what constitutes substantial harm? Some organizations define harm as "the need for additional treatment or hospitalization" while others define harm as the subjective perception by the patient or family that harm might have occurred.

Much of the debate about disclosure has focused on determining the conditions and severity of the unanticipated outcome that triggers the disclosure discussion.

Although organizations may accept "harm" as the *de facto* guideline for when disclosure "must" occur, it remains a reactive measure based upon compliance with external standards rather than a reflection of understanding of the spirit of open, honest communication. Harm may occur to patients in the absence of error. Pain (anticipated or not), reaction to medication or intervention, or a poor outcome can occur when all standards of care are met. Likewise, errors may not result in harm if they have insufficiently serious outcomes, or they may never reach the patient. Although judgment must be used about the extent to which patients and families should be advised of potential or clinically insignificant events, discussion about disclosure is incomplete at best – and misguided at worst – if the focus is on when the patient must be told of an outcome in order to comply with standards. The more important question is: How do we build a system that supports honest communication between patients and practitioners so that discussion of error and harm are part of the process, and not separate concerns?

In an ideal collaborative relationship, health care providers would be expected to communicate with patients about near misses because patients could help block similar occurrences in the future. Errors that cause no harm to the patient or harm that might be caused by side effects or bad reactions to medications would be communicated, as well. In a culture of fear, these discussions are perceived as threatening – with the potential for punitive action prompting inaction and silence. In a culture of preventing harm and sharing responsibility, however, discussion of unanticipated events in well-intended and appropriate care is part of the ongoing dialogue. The public discussion of disclosure is moving toward that collaborative spirit.

Because the focus has been on compliance with the Standards, debate continues about whether it is essential that the attending physician or a physician from the team participate in the disclosure discussion. Is it better to call on a physician who is an unwilling or unskilled communicator, or should a hospital representative with stronger communication skills take responsibility for the disclosure? (In a compliance model, the presence of a "licensed independent practitioner" is required.) In fact, patients and families often feel the closest alliance with their physician. Furthermore, their physician is in the best position to advise the most appropriate next steps. Other staff cannot handle this adequately. Furthermore, in most cases, the physician will feel tremendous responsibility, both personally and professionally, and may want to be involved.

Experience is proving that the presence of an attending physician, whether or not that person is the one who leads the communication, is paramount to the success of the encounter from the patient's perspective.

Concerns over discoverability

Although there is growing agreement that the admission of an unanticipated outcome or even an error is simply a factual statement, insurers justifiably enjoin their insureds not to assume liability for the company or promise compensation on behalf of the company. The admission of liability comes at the point at which the insured makes statements about the acceptance of culpability or negligence and assumes financial responsibility. In a hard economic market where increasing numbers of organizations are self-insured, the use of disclosure and ultimate admission of error is being used to leverage early resolution of claims.

Health care organizations have questioned the value of sharing the findings of root cause analyses or process changes made subsequent to an error to a patient or family in a disclosure conversation. Although some individuals believe this information should be protected, others take the stand that process changes would be discovered during any litigation process and should be revealed. How these activities are conducted will depend on individual states' protections for peer review as well as whether the root cause analysis process is considered a peer review activity. (For example, the state of New York requires that patients be told the results of investigations that often include root cause analyses.)

The disclosure of investigation outcomes should be factual and broad. Most patients do not need nor want details of the process improvement. As Vincent, et al found in 1994, patients stated that they desired to know that the health care organization responded to the event by making changes so that the same event would not happen again(1). Possible approaches include saying: "In our investigation we learned we have an area in our pharmacy process that could be improved in order to prevent this type of error from happening again. We have instituted some of those changes already." Where the root cause may identify an employee performance factor, an approach may be to say: "In our investigation, we learned that additional counseling/training would benefit our employees. We are taking steps to ensure that our employees are receiving the help they need."

In June 2001, ASHRM held a national videoconference featuring a panel discussion about disclosure from the perspectives of a risk manager, an insurer and a plaintiff's attorney. Appraising the benefits of disclosure, the plaintiff's attorney made a profound statement: Most often, patients find an attorney because they feel there is information that the hospital or clinician has denied them. The feeling of betrayal and distrust is exacerbated when a review of the record or deposition reveals that information had not been disclosed. This sense of betrayal often contributes to the anger that fuels litigation and the desire for punitive action.

BARRIERS TO DISCLOSURE

Barriers to disclosure and open communication fall into two primary categories: psychological and legal. The combined psychological and legal aspects of the barriers are clearly demonstrated in the absence of a culture of safety and through the absence of a patient-centered philosophy of care. In order for a true culture of safety to exist, patients, staff and physicians/clinicians must feel free to express concerns about potential harm and have no fear of discussing error. Similarly, patient-centered care requires that communication and attention be focused on the medical and psychological needs of the patients rather than the protection of the organization.

In moving the system away from blame and toward collaborative relationships, it's vital to understand that these changes are complex. The evolution starts within the organization and moves to the community through regular and ongoing reinforcement through action. Nonetheless, the psychological and legal barriers are real and must be addressed first.

Psychological barriers

Psychological barriers to disclosure are no different from barriers to any other difficult communication that involves bad news. While it is easy to agree that patients ought to be able to direct their care and make decisions about future care, it is fair to say that physicians and clinicians feel the weight of deciding when, if and how to tell patients about poor prognoses, unanticipated outcomes and medical error. Psychological barriers may include:

- **Fear of retribution from the recipient of the news.** "Will the recipient try to punish or harm me legally or physically?"
- **Fear of retribution from colleagues or peers.** "Will I be ostracized or otherwise criticized for my involvement in the unanticipated event, or for my action as part of the disclosure discussion?"
- **Fear of conducting the conversation poorly.** "What if I upset the patient or family if I don't convey the information effectively? Will the hospital be angry with me for communicating ineffectively?"
- **Fear of having to handle the recipient's as well as their own emotions.** "What if the patient or family member cries, becomes angry or threatens me?"
- **Belief that the disclosure is unnecessary.** "If we didn't tell the family, they would never know this had happened."
- **Belief that disclosure is primarily a factual conversation and not a complex interpersonal conversation**. "If I just state the facts, haven't I disclosed adequately?"
- **Belief that the outcome is not related to action on the part of the discloser.** "If I were not directly involved in the event leading to the outcome, why should I be involved in disclosing the outcome?"
- **Belief that the outcome would potentially have occurred without the error or intervention. "**What difference would it make? The patient might have had the outcome anyway. He/She was very old and/or sick."

Legal barriers

Legal barriers to disclosure are both real and perceived, entrenched in years of punitive attitudes and cultures of blame. These barriers may include beliefs that:

- **There is no legal protection for information provided during the disclosure of a medical error.**
- **There is no legal protection for information in the medical record.** Potential discovery can be mitigated by following procedures under state laws that permit limited protections for work related to peer review or quality improvement.(2)
- **There is no sharp line that determines when a disclosure is not necessary.** Is disclosure "necessary" for an error that does not reach the patient or for an error that results in no additional treatment?
- **There is no "benefit" for disclosure during the claims/litigation process, other than jury perception of an effort to be honest and forthcoming by the system.** *(This will be discussed in greater detail in the second monograph in this series.)*

MODELS FOR MANAGING THE PROCESS

The movement toward a culture of safety and partnership with patients is a process that every organization, practice group and community will assume at differing rates and with differing challenges and concerns.

Compliance with the Joint Commission Patient Safety Standards is the beginning step. The challenge is to recognize that the process of developing open communication with patients is dynamic. Static policies, processes or approaches to communication with patients and families reflect a culture that is failing to mature in its approach toward partnering with patients. Ongoing improvement of communication skills among practitioners and staff should be a part of every approach to disclosure management. Furthermore, as the culture of patient safety grows within an organization, policies and procedures should begin to reflect a broader approach to open communication with patients; the models for supporting open communication with patients might evolve, too.

Given the needs of organizations based upon their size, their current place on the continuum toward a culture of safety and the needs of the medical staff, organizations have found different models for supporting the activity:

One-Person Model

- **Description:** The organization designates one person, frequently the risk manager, as the anchor for all disclosure communication. This model places tremendous accountability for coaching clinicians and others for disclosure discussions, or participating in disclosure discussions, on one person.
- **Benefit:** The organization can assure itself that the designated person can be trained to have the communication skills for effective disclosure.
- **Drawback:** There is no room for shared responsibility or imbuing the entire organization with the disclosure philosophy and skills so that honest communication becomes part of the fabric of daily interaction with patients.
- **Best organization fit**: In a small organization, the single point person method might be the most efficient way to ensure consistency and quality of communication.

Team Model

- **Description:** This approach requires intense training of a select group of individuals in the effective disclosure skills and the communication policies of the organization. Usually team members are chosen from among the organization's identified effective

communicators. They are likely to be from a variety of services and known for their interpersonal skills. Subsequent to training, team members are assigned to coach physicians/clinicians or staff and accompany them in disclosure discussions.

- **Benefits:** The organization can be assured that effective communicators are involved in every disclosure discussion. In addition, the physician/clinician is coached and accompanied by a colleague with identified skills in effective communication. Finally, the team shares responsibility for participation and coaching of disclosure communication so the best "fit" for any situation can be selected to participate in that discussion.
- **Drawback:** Health care staff may be diverted from daily responsibilities to participate in a disclosure discussion. Depending upon the nature and volume of the work, that diversion could be a burden.
- **Best organization fit:** In a small- to medium-sized organization, this model could easily be an effective way to teach honest communication through role model behavior.

Train the Trainer Model

- **Description:** The organization invests in the comprehensive training of a large group of physicians and other staff. The trained individuals train, and are rewarded for training, a number of people each year. The philosophy is that these trainers are doubly valuable to the organization. First, they are selected for their amenability to interpersonal skills training and they become highly trained. Next, those individuals provide a service to the organization by training other staff. As they train, they become more comfortable in the concepts of disclosure. In addition, they become mentors and role models.
- **Benefits:** This model uses individuals throughout the organization, including physicians and clinicians, to spread the skills and the philosophy of open communication. In addition, it provides an economical way to ensure that all staff and employees are introduced to the concepts of honest communication with patients.
- **Drawbacks:** Quality control and distribution of responsibility are the main drawbacks. This model must include a single individual who is ultimately responsible to ensure that the trainers are training at the level expected and that training opportunities are scheduled throughout the organization.
- **Best organization fit**: Large- to medium-sized organizations with several campuses might find this method the most efficient and effective for providing consistent education. In addition, this method can generate physician/clinician buy-in if respected members of the medical staff are trainers.

Just-in-Time Coaching Model

- **Description:** In this model, the individual practitioner at the site of the event discloses what is known at the time. The discloser may be a nurse, attending physician or other practitioner with whom the patient has a relationship depending upon the significance of the event and seriousness of the outcome. There generally is an in-house coach, frequently the risk manager, with whom practitioners can discuss the disclosure prior to the discussion.
- **Benefits:** This model is direct and easy. It places the responsibility for effective communication skills at the point of care. It is the ultimate in mature patient/family partnering.

- **Drawbacks:** This model is dependent upon the skill of the individuals at the point of care. Where communication skills are effective, this is an ideal model. Where there is the potential to lay blame or fail to support the organization's improvement efforts, or where communication skills are insufficiently empathetic, this model can result in less effective patient/family partnering.
- **Best organization fit:** Any organization that is mature in its patient safety culture could use this approach. By the time the organization has passed through the various stages of cultural maturation, the staff and physicians/clinicians will know their own strengths and shortcomings and when and how to seek coaching.

EXPERIENCES WITH DISCLOSURE

Since release of the Standards, many stories have emerged that tell of successful communication and satisfactory results. Other experiences have been less successful.

The Standards do not define "success." Nonetheless, they require organizations to ensure that patients and families are informed about the outcomes of care. By doing this they are, in essence, supporting the rights of patients to be involved in their care. Some health care providers, however, have created internal standards for "successful" disclosure that are not based upon the intent of the JCAHO Standards, but upon their own hopes and desires. They link a lack of compensation requests or retribution to "success." Definitions of a successful disclosure conversation may include:

- The patient and family do not sue
- The patient and family understand that mistakes happen and do not get angry
- The patient and family don't go to the press
- In the event of coverage, the press praises the caregivers' action and honesty.

This measurement for success is based upon self-serving outcomes. It fails to recognize the true purpose of disclosure: the open communication about all aspects of care with patients and families. A successful disclosure process could best be described as one that enables the patient and family to understand what happened and the ramifications of the event as well as have sufficient information to make future decisions. Future actions might include seeking compensation. When caregivers humanize the situation, there is a greater likelihood that the demand for compensation is to cover financial damages rather than to be punitive. Indeed, there is no guaranteed reaction. Given that, the true success of disclosure can only be measured in the efficacy of communicating facts and sharing regret for the patient's/family's trauma.

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In the spirit of improving patient safety and creating a "learning organization," it would help to think of all disclosure communications as opportunities for improving communication with patients at all points of the health care continuum. If health care providers can get to the place where they begin their relationships with patients talking about the potential for error and the need for communication and partnership, the stage can be set for more effective interaction should the need for the disclosure of an unanticipated event arise.

Examples of communicating disclosure

Analyses of disclosures that have not worked as well as anticipated often show that less effective communication choices were made by the discloser which resulted in defensiveness on the part of the patient or family.

- **The ophthalmologist.** The ophthalmologist at a large facility performed laser surgery on a 65-year-old woman. The consent process included the possibility of error, which ultimately occurred. The patient's vision did not improve as predicted. The physician disclosed the error to the patient and was surprised to learn later that she was angry and considering pursuing a claim. He called her to discuss what happened. She felt that the ophthalmologist seemed more interested in impressing upon her that it had never happened to him before – he seemed more concerned about himself than about her. Fortunately, this physician followed up and was able to apologize and remediate the situation.

- **The baby.** A medication error resulted in the death of a 5-week-old premature infant in the NICU. The physician was coached by the risk manager and seemed to know how to approach the situation. In the family meeting the physician felt cornered and threatened by an angry father. In his discomfort, he admitted liability. The organization was upset with him for handling the disclosure badly.

- **The understanding parent.** A baby in the NICU was the recipient of two medication errors in a 12-hour period. One health care clinician's opinion was that error was simply part of what happens in hospitals and should be handled matter-of-factly. A colleague, on the other hand, believed the parents would understand if the matter were approached more sensitively and accompanied by an apology. The risk manager suggested that both physicians participate in the disclosure, with the second physician leading. The discussion resulted in tears. The mother realized that the infant was very ill and that the hospital had allowed her to have more time with the child than she might have otherwise. She did not pursue litigation.

CONCLUSION

The passage into a culture where open communication with patients is the norm is still in the early learning stages. This monograph focused on where health care providers are in their current development. As health care providers move forward to an era when "disclosure" is not an issue on its own, but simply one aspect of the communication process with patients, they will move into a time where appropriate, uniquely collaborative relationships with patients will involve the spectrum of communication – from involvement in selection of outpatient alternatives to traditional treatment, through facilitated education prior to consent for treatment, and full involvement in the complex process of inpatient care. Health care cannot get there in one step. Nevertheless, it is an evolution that must be undertaken.

DISCLOSURE OF UNANTICIPATED EVENTS: HISTORICAL PERSPECTIVE

The issue of disclosure was rarely discussed before 2001, when JCAHO ventured to make requiring the disclosure of unanticipated medical outcomes an industry standard.

Historically, the research on how much information to provide to patients was done in the area of oncology. The prevailing belief system was that patients and families might be inclined to lose hope if they believed that the potential outcome would not be perfect Other rationale for not disclosing included the potential for the patient to lose trust and confidence in the physician or clinician(3).

Confounding this belief system was the prevailing form of medical education at the time that supported a distancing of physicians/clinicians emotionally from patients and their care. The medical education philosophy stated that any type of consideration of patients or their feelings would detract from the health care provider's ability to make rational, detached decisions about care(4).

What health care providers have learned

Patients and their families have interpreted much of this distancing as an attempt by health care providers to protect themselves from patients. Research has found that:

- 98 percent of patients desire to be informed of even a minor error; the greater the severity of the outcome, the more patients and families want information(5)
- While 92 percent of patients believed they should always be told about complications, only 60 percent of the physicians believed that patients should always be told(3)
- Furthermore, 81 percent of the patients believed they should be advised of the possible future adverse outcomes of the complications, while only 33 percent of the physicians believed that patients should be told about possible future adverse outcomes(3).

Health care providers' lack of engagement is seen as disparaging of a patient's perspective and not recognizing the extent of the patient's or family's trauma in the face of medical error or unanticipated outcome. Studies conducted in the 1990s show that patients want to know the truth, want the health care organization to take responsibility for its actions, and want an apology in recognition of both their trauma and health care practitioners' participation in the experience. The desire for human interaction supersedes the need for monetary compensation(1).

The literature continues to support the desire for improved communication. Patients continue to feel that the greatest problem in health care is lack of communication among the health care team, and insufficient time to communicate with their physician(6). Furthermore, complaints and allegations of malpractice continue to be linked with lack of communication as well as poor communication skills(7-8). Yet despite the ongoing research supporting the need for communication between practitioners and patients, we continue to struggle with how much, what, and when to talk with patients about outcomes and errors. A key to this may also be in the literature. Research shows that when there is an error or unexpected outcome, both patients and clinicians have needs for support and guidance that are yet unmet(9).

Moving from 'disclosure' to 'communication'

Not only is there movement from a historical period where it was both the prerogative and the duty of the physician or clinician to decide for patients what was in their best interest, interpersonal communication skills are now becoming essential for partnering in a new way with patients.

Old forms of communication in health care focused on a hierarchical relationship with the physician at the top of the pyramid and the patient at the bottom (receiving end) of care. Communication did not involve the patient and often did not involve many of other members of the health care team.

In a culture of safety where learning from mistakes, working together to create safe processes and involving the patient in all aspects of care is expected – a different approach to communication must be integrated into the system. Part of that new approach includes disclosure.

The next wave of activity around disclosure will involve determining how to integrate the concept of open communication into all aspects of the health care environment. This will include moving from

"disclosure policies" to "communication policies"; from concern about discoverability and liability to concern about accountability and fair compensation before the start of litigation; and from concern about whether to disclose to concern about what patients need to know in order to best partner in directing their care.

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ADDITIONAL RESOURCES

Perspective on Disclosure of Unanticipated Outcome Information. ASHRM whitepaper/monograph, www.ashrm.org, April 2001.

Communicating About Unexpected Outcomes and Errors. ASHRM/National Patient Safety Foundation audio conference (HRM 6990-0). May 2002. Cassettes: $159 for ASHRM members, $209 for non-members; call KRM Information Services, (800) 775-7654, or visit www.ashrm.org.

Disclosure of Medical Errors: Demonstrated Strategy to Enhance Communication. ASHRM video program (catalog #169520). June 2001. Tapes: $50 for ASHRM members, $60 for non-members; call (800) AHA-2626, or visit www.ahaonlinestore.com.

ASHRM Journal of Healthcare Risk Management Special Issue. "Approaches to Patient Safety, the Risk Management Perspective" (catalog #178556). Fall 2001. $25 for members/non-members; call (800) AHA-2626, or visit www.ahaonlinestore.com.

The Risk Management Handbook for Healthcare Organizations (3rd Ed.). San Francisco: Jossey-Bass, 2001. (catalog #178160). $99.95 for ASHRM members, $129.95 for non-members; call (800) AHA-2626, or visit. www.ahaonlinestore.com.

American Hospital Association Strategies for Leadership: Hospital Executives and Their Role in Patient Safety Tool (catalog #WS-166924). March 2001. $10 for AHA members, $20 for non-members; call (800) AHA-2626, or visit www.ahaonlinestore.com.

Institute for Family-Centered Care, a non-profit organization, promotes collaborative, empowering relationships between providers and consumers. 7900 Wisconsin Ave., Suite 405, Bethesda, MD 20814; (301) 652-0281; www.familycenteredcare.org.

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For details on the Team Model for disclosure responsibility, contact **Roben Nutter,** East Alabama Medical Center, 2000 Pepperell Pkwy., Opelika, AL 36801; (334) 705-1815; roben_nutter@eamc.org. For details on the Train the Trainer Model, contact **Peter Wong,** Ph.D., Good Samaritan Hospital, 375 Dixmyth Ave., Cincinnati, OH 45220-2489; (513) 872-1400.

ASHRM DISCLOSURE CHECKLIST

Once you have reviewed guidelines described here, use this checklist to conduct your own organizational self-assessment on disclosure:

- ✓ Integrate disclosure as a vital part of your organization's patient safety program.
- ✓ Share the guidelines with your risk and quality management staff, legal counsel, accreditation and compliance officers, clinical leadership and board of directors.
- ✓ Consider the applicability of these guidelines to your organizational disclosure philosophy and practices.
- ✓ Review organizational policies and procedures for suggested elements on disclosure.
- ✓ Conduct education programs for board members, medical staff and other clinicians on the themes of these guidelines and how they apply within your organizational culture.
- ✓ Implement mechanisms for coaching, emotional support and guidance for staff to feel supported by the organization and for disclosure discussions to have the best opportunity for effective handling.
- ✓ Monitor compliance with JCAHO and other related standards.