

Perspective on Disclosure of Unanticipated Outcome Information



**American Society for
Healthcare Risk Management
of the American Hospital Association**

ASHRM Perspective on Disclosure of Unanticipated Outcome Information

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Executive Summary

ASHRM believes that patients are entitled to information about the outcomes of diagnostic tests, medical treatment, and surgical intervention. This perspective is the same whether the results are expected or unanticipated outcomes.

ASHRM recognizes that there are many considerations to contemplate in framing a policy for disclosure of outcome information, and particularly, results that involve negative or adverse events. Specific legal, regulatory, institutional, and cultural considerations must be taken into consideration.

In anticipation of the JCAHO Patient Safety Standards taking effect in July, 2001, ASHRM has developed this perspective paper on the disclosure of information involving unanticipated outcomes of diagnostic tests, medical treatments, and surgical interventions. Emphasized is the importance of effective communications with patients and family members and the need to discuss potential outcomes in the consent process.

The paper examines:

- the ethical and legal context for withholding information from a patient
- use of bioethics consultations
- liability issues
- management of multiple investigations stemming from an unanticipated outcome, and corporate compliance considerations
- the rights and responsibilities of healthcare professionals in disclosing unanticipated outcomes
- the use of designees to disseminate unanticipated outcome information
- the importance continuing communication with patients and family members
- documentation practices
- operationalizing a policy on disclosure of unanticipated outcomes

Examples are provided in this perspectives paper along with current practices utilized in the field to manage communication with patients and families regarding unanticipated outcomes.

ASHRM recognizes that each healthcare organization must develop its own policy on management of unanticipated outcomes. Disclosure of such information to patients and families must reflect the requirements of applicable law. Specific legal advice must be obtained in framing an institutional policy on the subject. It is hoped that this risk management perspectives paper will facilitate development of a practical policy among healthcare organizations throughout the country.

Definitions

The following terms are defined for purposes of this document.

Adverse Event – a negative or bad result stemming from a diagnostic test, medical treatment or surgical intervention.

Disclosure – communication of information regarding the results of a diagnostic test, medical treatment or surgical intervention.

Unanticipated Outcome - a result that differs significantly from what was anticipated to be the result of a treatment or procedure.

ASHRM Perspective on Disclosure of Unanticipated Outcome Information

Introduction

An integral part of the diagnostic or treatment process is to provide the patient with outcome or results information. When patients are unable to receive this information, a legally authorized representative may be the recipient of the news. The details may be shared with a surrogate decision-maker, the parents of minor children, or with the permission of the patient, a spouse, a sibling, or a significant other. When feasible to do so, information is then presented to the patient so that knowledgeable decisions may be made regarding future treatment.

Sometimes diagnostic tests or treatment result in unplanned or unwelcome outcomes. That these outcomes occur is not necessarily the result of substandard practice, error, or medical malpractice. Unwelcome outcomes may occur even when treatment is impeccable. Healthcare professionals know that sometimes “things” happen that no one ever considered a remote possibility. While some patients and families may take the attitude that “this was meant to be,” others may be far less generous. In a healthcare climate beset by highly publicized concerns about staffing shortages, medical error, and dissatisfaction, patients may equate an “unanticipated outcome” with medical negligence.

Concerned that the “bad news” might provoke a lawsuit, some observers believe that it is imprudent to discuss the details of “unanticipated outcomes” with patients and their families. They believe that furnishing such information is tantamount to an admission of fault or liability and that it will unleash a watershed of litigation.

Others take quite the opposite position. Believing that disclosing the “bad news” will actually strengthen the provider-patient relationship, they insist that the information be shared as soon as possible after the test or treatment. Proponents of this approach may or may not recognize the distinction between disclosure of unanticipated outcome information and an admission of liability. The critical issue is to disclose the results.

In between these competing perspectives is a third approach. It recognizes the importance of maintaining good communication with patients and providing information to foster good decision-making. However, it does differentiate between disclosure of “unanticipated outcomes” and an admission of liability. It also understands that disclosure of “unanticipated outcomes” is not as straightforward as it might appear. Indeed, a number of important factors are contemplated in this approach to enable the exercise of professional judgment for the well being of the patient and fiduciary responsibilities of the healthcare organization.

The issues surrounding disclosure of unanticipated outcomes have been crystallized by new accreditation requirements for hospitals. On July 1, 2001, the JCAHO Patient Safety Standards take effect. Although there are a number of important components in the JCAHO initiative, one in particular has drawn considerable attention. This standard [RI.1.2.2] states that”

“Patients, and when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes.”

The accompanying intent provision [RI.1.2.2] indicates that:

“The responsible licensed independent practitioner or his or her designee clearly explain the outcome of any treatments or procedures to the patient, and when appropriate the family, whenever those outcomes differ significantly from the anticipated outcomes.”

While JCAHO has acknowledged that the Patient Safety Standards are a work in progress, and some refinements are expected as experience is gained with the new criteria, the fact remains that the Patient Safety

requirements will be implemented as written on July 1, 2001. Current thinking on the part of JCAHO suggests that unanticipated outcomes will involve the same types of issues that constitute reviewable sentinel events. This limited definition, however, of “unanticipated outcomes” is *only* a guideline for surveyors in assessing compliance with “RI.1.2.2.” It is not intended as a definition for hospitals in implementing their own policy. JCAHO encourages hospitals to make it their practice to inform patients about all outcomes of care. During the initial phase of the survey, leadership will be asked what is the institutional policy for communicating unanticipated outcome information to patients and family members. JCAHO has suggested that there need not be any policy in writing. However, the leadership should be able to articulate the organization’s policy regarding who must inform the patient or family and under what circumstances they should be told about an unanticipated outcome. Leadership might be asked, “What would you do if the unanticipated outcome involved a reviewable sentinel event?” It is not expected that the surveyor will ask for specific information or attempt to validate that the policy has been implemented by discussing it with patients. Rather, as the survey progresses, staff will be queried on their knowledge of institutional policy on unanticipated outcomes and how these events are to be addressed. To determine that the process is working, the surveyors will compare the consistency of feedback from staff with the information provided by leadership. It is clear, however, that the JCAHO does not intend that the unanticipated outcome standard include an admission of liability. Scoring will not include how much to discuss with patients about such outcomes, nor will it include a request to furnish a list of sentinel events in an effort to “match” these occurrences with unexpected outcomes. The standard is directed at a process or communication framework for discussing unanticipated outcomes with patients.

JCAHO is not the only group to have taken a stance on the issue. Other organizations have spurred on development of an acceptable perspective on disclosure of unanticipated outcomes. Most recently, the National Patient Safety Foundation (NPSF) published a Statement of Principles entitled, “Talking to Patients About Health Care Injury.”

In this perspectives paper, ASHRM presents an in-depth perspective on disclosure of unanticipated outcome information. ASHRM recognizes that each healthcare organization must develop its own perspective on the issue. To this end, this document examines a number of factors to consider in developing a policy and procedure on the topic. In doing so, it is hoped that the concluding illustrative practices will help healthcare organizations prepare an operational policy that provides a framework for managing disclosure of unanticipated outcome information.

What is an “Unanticipated Outcome?”

The Joint Commission intent provision provides some insight into what constitutes an unanticipated outcome. It is a result that “differs significantly” from what was anticipated to be the result of a treatment or procedure. In theory, the JCAHO statement does not restrict the discussion to negative or bad outcomes. However, the placement of this patient safety standard and intent in the context of the patient safety provisions has left many with the belief that only “negative” unanticipated outcomes merit disclosure. Additionally, it appears that the intent is to link the requirement for disclosure of unanticipated outcomes to those results that constitute a reviewable sentinel event.

Some healthcare organizations may set their policy on the topic to match that of the JCAHO. Others may take a more expansive view. Thus it is quite possible that “positive” unanticipated outcomes might occur as a result of tests or treatment. For example, a pregnant woman who underwent ultrasound was told she was carrying twins. During delivery it is learned that she was carrying triplets. All three are delivered quite healthy. This “unanticipated” outcome is positive, not negative. Another illustration involves surgery. A patient is informed that surgery will necessitate an extensive resection of his bowel and will definitely involve a temporary colostomy. Upon examination of the affected area, the surgeon determines that the patient’s condition is not as bad as thought pre-operatively. Although a resection is done for the patient, it is far less extensive and no colostomy is performed. The outcome is unanticipated, but positive in terms of the impact on

the patient's body, lifestyle, recuperation, and long-term prognosis.

The point is that not all unanticipated outcomes are negative in nature. Some can involve pleasant though unexpected results. ASHRM believes that patients are entitled to information on both types of outcomes and that the disclosure of this information is part of the communication process that forms the context for the caregiver-patient relationship.

When the Focus Turns to Unanticipated Negative or Bad Outcomes

Some believe that when a bad unanticipated outcome occurs, the JCAHO patient safety standard requires healthcare professionals to make an admission of liability or error. Clearly this is not stated in the JCAHO standard or accompanying intent. An outcome may be negative and unanticipated, but not the result of an error or negligence.

For example, a patient may suffer an unanticipated reaction to a medication administered intra-operatively. The result is anaphylactic shock and death. Nothing in the patient's history indicated that such an outcome might occur. The adverse reaction was not linked to a medication error involving the medication used, the route of administration, or the medication dose. The death – negative outcome – could not have been prevented. Under the JCAHO standard and intent, the patient, or in this case, the family, are entitled to know the outcome of the surgery. The bad outcome could not have been anticipated. However, the disclosure regarding the outcome does not require an admission of liability or error.

System and human failure may culminate in unanticipated bad outcomes. The failure to double-check patient identification bracelets may result in a patient receiving the wrong medication. The failure to properly orient an x-ray on a viewing screen may result in the surgeon operating on the wrong side of the body. The transposition of a medication dose order on a Personal Data Assistant may culminate in the pharmacy dispensing the wrong amount of an intravenous medication.

These illustrations reflect negative, unanticipated outcomes. It takes time and careful analysis to determine what went wrong, if these events involved human failures, system failures, or a combination thereof. In the interim, patients and their families want answers, *now*. Giving misinformation when all the facts are not known is wrong. It is a disservice to the patient, the patient's family, and the provider. Leaving patients with the wrong impression and then having to correct it may cast doubt about the reliability of the information provided and the credibility of those furnishing it. It could damage the caregiver-patient relationship making further communication more difficult. However, withholding information that the patient “needs to know now” is equally wrong. It leaves the patient and family to speculate, raising questions about the truthfulness and the reliability of the caregiver-patient relationship. In the middle lies the answer: a clear, understandable explanation of the outcome, free of conjecture or innuendo. The details of “how” and “why” the negative outcome might have occurred may necessarily be reserved for a later time until all the facts are known and the response to this information is addressed. An illustration helps to explain this point.

Case Illustration of Pre-empting Potential Negative Media Attention.

A 22 year-old man underwent elective rhinoplasty with general anesthesia. Midway through the surgery, the alarm systems sound indicating anoxia. So absorbed in the surgery, the surgical team had not noticed that the anesthesia provider had left the operating room. The surgical team responded to the emergency, successfully reviving the patient. The family was alerted that there had been a problem intra-operatively with anesthesia and that it was possible that the patient could sustain some short-term and long term side effects. However, since it was too soon to tell the outcome, they were told the care team would give them regular updates on the patient's progress. Arrangements were also made for the family to see the patient and to provide them with whatever immediate help

they needed in terms of contacting family, clergy, etc. An investigation was started into the event. The privileges of the anesthesia provider were temporarily suspended pending the outcome of the investigation. Proactively, the CEO of the facility called a news conference to tell the community that a patient undergoing an elective procedure had experienced an adverse event during surgery. It was believed to be linked to anesthesia. The anesthesia provider would not be carrying out regular duties pending the outcome of a two-pronged inquiry. One was an internal review and the other was a “blue ribbon” panel investigation to look at the systems involved in the event.

The CEO told the news conference that he would not reveal any identifying information about the patient or his family and that he would not answer any questions until the investigation had been completed. At that time, he promised to call a news conference to discuss findings and what the facility planned to do about the results. As he left the podium, a reporter called out, “Are you not afraid that your facility will be sued?” Breaking his promise not to answer any questions, the CEO replied, “Whether we get sued or not is not the concern here. The primary concern is the patient’s well-being and the confidence of the community in this healthcare facility.” Six months later, a follow-up news conference was sparsely attended by the media. The CEO announced that a number of systems changes had been made and the anesthesia provider who had been involved in the event had participated in some specialized training and was now back to work. The patient had returned to work having undergone rehabilitation. In the end there was no lawsuit.

This case study demonstrates what turned out to be an effective method for disclosing negative, unanticipated outcome information to the patient’s family. Beyond that, it was an effective method for pre-empting adverse publicity that attends “leaked” information when a healthcare facility experiences an adverse outcome.

Communication and interpersonal support were provided to the family and patient. Information was shared with them when the facility understood what had happened. The public statement maintained community confidence in the facility that it could “take ownership” of an adverse event and address it.

Would this approach work in every situation? Clearly, there is no “right” way to deal with disclosure of negative unanticipated outcomes. Specific legislative, regulatory, and institutional cultural dynamics must be considered as healthcare organizations develop a successful approach to disclosure of such information. In addition, as seen in the following section, there are many practical issues that should be anticipated in a policy or procedure so that appropriate mechanisms are used to share information about negative, unanticipated outcomes.

The Practical Issues -Patient-Oriented Concerns *Ethical and Legal Issues in Withholding Information*

– There are very real situations in which more harm can be done than prevented with the disclosure of unanticipated outcome information. Sometimes the outcome information can put a patient at risk of harm either due to psychological trauma or exposure to physical harm. In such situations professional judgment is in order, guided by a practical policy and procedure. The reasons for withholding the information should be documented. When the prospect of psychological trauma is the concern, it may be appropriate to have a mental health caregiver conduct an assessment. Such an individual should not be associated with the regular care of the patient or a member of the attending caregiver’s practice. The information that is revealed to the patient should also be documented. If at a later time the patient is able to participate in a discussion with the caregiver, disclosure may proceed regarding the unanticipated outcome. The fact that this has occurred should be documented, along with the time, date, and names of those present during the discussion.

Case Illustration of Managing an Ethical Issue in Disclosure

A 90 year-old patient was admitted for observation following a fall in which she lost consciousness. In the Emergency Department, the woman's daughter told the staff that her mother had "missed some steps" and tumbled down an outside stairway. She claimed that the falls were occurring with increasing frequency. She also presented the ED with documentation indicating she was the legal guardian and healthcare proxy for the patient. Following admission, diagnostic tests were run, including a series of x-rays. The work-up revealed that the ED staff doctor had "missed" some broken bones in the patient's right foot, three bruised ribs, and a ruptured tendon in the right forearm. The diagnostic picture also revealed a pattern of physical abuse, complete with old "twist fractures." The results constituted an "unanticipated outcome" of the diagnostic tests. However, since there was a strong suspicion that the daughter might be implicated in the abuse situation, the attending physician did not think it was correct to disclose the clinical results. Indeed, having discussed the issue with the Director of Social Services, he worried that disclosure of the unanticipated outcome might lead to further physical abuse. Moreover, since this was a case requiring a mandatory report to the state welfare agency and local police, the officer assigned to the case suggested that revealing the findings to the daughter might cause her to leave the jurisdiction. The doctor was requested to refrain from disclosing the outcome information "at this time." The doctor dictated and signed a note explaining the circumstances of the case and the reason for withholding information from the guardian.

Patient Grievance under the Conditions of Participation for Hospitals – A patient grievance may be generated as the result of "premature" discharge, quality of care concerns, or disputes regarding financial responsibility. Under the Conditions of Participation for Hospitals, the patient can file a grievance. In return, the

patient is entitled to receive the results of the grievance process. Sometimes, a grievance may stem from tests or treatment involving an unanticipated outcome. Separating out the different facets of the issue involves careful evaluation, review of documentation, and interviewing pertinent individuals. The discussion of the unanticipated outcome may take place far sooner than revelations about the results of a patient grievance process. Indeed, the latter may reveal information that changes earlier perceptions about the unanticipated outcome. To avoid the prospect of contradictory information, it is important to provide "unanticipated outcome" information with a caveat that as information becomes available from the grievance process, it may help to shed light on the unexpected result. [For discussion of similar issues relating to external investigations, see "*Managing Multiple Reviews and Investigations Stemming From an Unanticipated Outcome*," *infra*]

The Practical Issues — Professional Oriented Concerns

Admission of Liability – An unanticipated outcome may not be the product of medical error, misfeasance, or negligence. Nonetheless, the discussion of an "unanticipated outcome" may lead the patient or family to infer that it is the result of malpractice. It is difficult if not impossible to avoid such inferences from being drawn in such cases. However, caregivers can discuss unanticipated outcomes without making an admission of liability. Providing an explanation of what resulted from a test or treatment does not need to get into expressions of fault or blame. Indeed, until all the facts are known about what occurred, what systems were implicated, etc., it may be inadvisable to do more than furnish an explanation regarding the unanticipated outcome.

Jeopardizing the Rights of the Healthcare Professional – Those who believe that disclosure of unanticipated outcome information is tantamount to an admission of liability see the explanation as jeopardizing the rights of the healthcare professional. They are concerned that the information provided by the caregiver

will be used adversely against the caregiver in peer review and corrective action proceedings under the medical staff bylaws and as the basis for reporting to licensure bodies. They are equally concerned that documenting in the medical record that a discussion occurred with the patient or family regarding the unanticipated outcome might be construed as an abrogation of evidentiary protection. Such concerns can be addressed in a number of ways. For example, peer review and corrective action policies and procedures can explicitly state that discussion of unanticipated outcomes with patients and family members is not considered an admission of liability unless the caregiver acknowledges such culpability. Similarly, documenting that the discussion took place need not jeopardize the rights of a caregiver if put in context as part of the communication process with the patient. The key point is to differentiate information about the treatment process from admissions of liability.

Corrective Action- Some observers believe that disclosure of unanticipated outcome information may be used adversely against a caregiver in the credentialing process. If, for example, a caregiver accumulates six unanticipated outcomes in one year, this might trigger an in-depth peer review and lead to corrective action. The fact that a performance profile reveals such unexpected results *may* trigger an in-depth peer review. Much depends upon the criteria used for this purpose. However, such peer review proceedings would be independent of the disclosure of unanticipated outcomes. In other words, the disclosure of treatment outcomes to a patient or family member would not be the mechanism that provokes the in-depth review.

Union Grievance – Caregivers are joining unions at an increasing rate. Collective agreements delineate certain rights for caregivers who are union members. Since this a fairly new endeavor for the healthcare field, many operational issues may not be contemplated in the collective agreement. Once encountered, these issues may result in disputes and possibly, a union grievance. Disclosure of unanticipated outcomes *may* come within this category. This is especially the case if a caregiver believes that it is not his or her responsibility to disclose

this information to a patient or family member. As a union member, the caregiver may look to the collective agreement as a mechanism to reinforce his or her refusal to disclose unanticipated outcome information, particularly when the caregiver believes it is the duty of another individual to share the details with the patient or family. Such an impasse could result in a formal grievance. This could be a complicating factor, especially with ongoing reviews, root cause analysis, and internal investigations of the events leading up to the unanticipated outcome. Knowing that this is a potential difficulty, a prudent approach would be to anticipate this issue in collective agreements.

Use of “Designees” to Discuss the Unanticipated Outcome – The discussion of treatment outcomes, whether anticipated or unexpected, rests with the caregiver. This responsibility stems from the caregiver-patient relationship, reinforced by the principle of informed choice-making by the patient. When an unanticipated outcome does occur, the caregiver may be traumatized by the result or feel uncomfortable discussing the situation with the patient or family. In such cases, some observers believe that a “designee” should step to the plate and inform the patient or family. While this sounds quite reasonable on the surface, it is fraught with serious concerns. For example, “who” will be the designee? Will it be a nurse or social worker standing in for a physician? Who will make the designee selection? Will it be the caregiver? The Director of Patient Services? The Medical Director? What criteria will be used to make the selection? What training will be provided to the designee to qualify him or her to serve in this capacity? How will the designee respond to care-related questions when he or she is not conversant with the patient history, the pre-treatment dialogue between the caregiver and patient, and particular needs of the individual? How will the healthcare organization safeguard the rights of the caregiver where the potential exists for the designee to make assertions or import innuendo that “blames” the caregiver for the outcome? How will the healthcare organization explain to the patient or family why the caregiver did not discuss the unanticipated outcome with them?

These questions should be addressed in developing an operational policy on disclosure of unanticipated outcomes. To the extent practical, the caregiver should be encouraged to discuss unanticipated outcomes with the patient and family. When there are situations in which it is impractical to do so, the use of a designee may be in order. However, the qualifications, training, and scope of responsibility of the designee should be well delineated. In this way, effective communication may occur with the patient or family without jeopardizing the rights of the healthcare professional or the caregiver-patient relationship.

The Practical Issues — Institutional Concerns

Managing Multiple Reviews and Investigations Stemming From an Unanticipated Outcome –

Healthcare organizations must respond to a number of reviews and queries that involve unanticipated outcomes. Some of these procedures are internally driven whereas others may come about as a result of a formal inquiry from an outside state or federal regulatory body. Thus, a healthcare organization may embark upon a patient grievance process and a root cause analysis that comes about from an unexpected test or treatment outcome. A similar scenario may involve an evaluation of whether the outcome requires a report under the Safe Medical Devices Act. On other occasions, the unanticipated outcome may trigger both internal review *and* external inquiries, such as a patient grievance, a PRO query, or an EMTALA investigation.

Some observers worry that the response given to an external body may be contradictory to the explanation given to the patient regarding the unanticipated outcome. That the two explanations differ may be a result of the questions posed by the outside authority or the consequence of more in-depth information being collected *after* the disclosure has been made regarding the unanticipated outcome.

To avoid the appearance of contradictory information, a prudent approach is to encourage caregivers to put the explanation in a context that allows for further elaboration as details become available. At the same time, the explanation can be couched in a way that anticipates the

perception of contradictory information being given to a regulatory body. For example, in response to a patient grievance, the healthcare entity may state, “The determinations provided here may be different than the information provided by a caregiver regarding the unanticipated result of your test or treatment. The opportunity to perform a detailed analysis led to a better understanding of what transpired and a more in-depth explanation which may differ from the earlier discussion of the test or treatment outcome.” Taking this approach can dispel the prospect of patients coming away with “mixed signals” and uncertainty as to whose explanation is credible.

Corporate Compliance Investigation – An unanticipated outcome may occur in the context of an ongoing corporate compliance investigation. It is not inconceivable that pending the completion of the compliance inquiry, it may be imprudent to discuss specific details of the unanticipated outcome with the patient or a family member. At the same time, the patient or family member needs information to understand what occurred in the test or treatment.

A balanced perspective is to develop a thoughtful explanation of the unanticipated outcome that does not jeopardize any ongoing corporate compliance investigation. If, at a later time, it is determined that additional information can or should be provided to the patient, it should be accomplished as soon as possible. Such an approach respects the rights of the patient and the integrity of the healthcare organization.

Mandatory Reporting Determinations - There are situations in which the explanation provided to a patient or family member may be inconsistent with information disseminated to a governmental body or agency under a mandatory reporting obligation. This is particularly so in cases involving physical abuse or neglect. The safety or well-being of the patient may necessitate a different explanation. The same response may be the result of requests by law enforcement authorities who fear that a complete explanation now could harm on-going criminal investigation or cause a suspect to flee.

Safeguarding the patient is of paramount importance. If providing for the welfare and safety of the patient necessitates a different explanation than that made under mandatory reporting, provision can be made a subsequent dialogue to provide additional details to the patient when it is prudent to do so.

Media Inquiries – Patients are entitled to confidential treatment. Respecting the confidentiality of the patient may frustrate the media that desires details about unanticipated test or treatment outcome. The media believe that the public has a “right to know” as consumers of healthcare services in hospitals. Declining to share information may lead to the perception that the healthcare provider or facility is trying to hide “something.”

Avoiding the negative perception, healthcare organizations can set some ground rules with the media on what will be shared about unanticipated outcomes. Statements declining to provide information should include a consistent message: “The hospital protects the confidentiality of patient care. It is not at liberty to disclose the results of specific tests or treatment. If the patient decides to do so, that is the prerogative of the individual. However, it is not the result of the healthcare facility trying to hide information from the public.”

Strategies for Addressing Disclosure of Adverse Outcomes

While recognizing that there are a number of challenges to disclosure of unanticipated outcome information, ASHRM believes there are practical strategies to surmount these hurdles. These include emphasis on communication, innovations in the consent process, supportive programs for patients, families and caregivers, as well as the use of bioethics consultations. Examples of current systematic approaches are summarized here with some strategies appended to this paper.

Communication – A fundamental component of the caregiver-patient relationship is communication. The give and take of information, the ability to pose questions and provides answers, and the opportunity to learn

about patient expectations all stem from the communication. It is part of the interaction that forges the relationship between caregiver and patient.

Having established a communications bond prior to treatment is important, particularly if the test or treatment results in an unanticipated outcome. Although the situation may be sad or tense, the fact remains that there is a framework for discussion and a relationship established beforehand. The fact that a relationship grounded on solid communication exists is an important consideration in discussing unanticipated outcomes. While a patient may be angry, sad, frightened, or emotionally distraught, there is nonetheless a rapport that enables the caregiver to talk with and explain the situation. Such a dialogue can be reassuring, diffusing the possibility of misunderstanding or distrust.

It is quite a different situation when circumstances prevent the establishment of a dialogue or a caregiver-patient relationship. Contrast what it is like for an Emergency Department physician who does not know the patient or family as compared to the surgeon who embarks upon an elective procedure. The former does not have the opportunity to establish a relationship in a relaxed manner, something that is available to a colleague providing elective surgical services.

Communication is an important patient safety tool. However, like any tool, it needs to be used effectively. It cannot be taken for granted. Thus, special types of communication may be needed in certain circumstances. For example, patients and families with limited English proficiency, individuals with a dramatically different cultural framework for healthcare services, patients with language, auditory or visual challenges, and those with diminished or cognitive impairment come within this category. It may require the use of qualified interpreters or social service workers who are culturally attuned to the patient’s needs. Taking these extra steps may make the difference between a patient receiving medication that is “safe” as compared to one with a demonstrated history of allergic reaction. Indeed, even with patients who “seem” to understand, it is useful to ask questions designed to illicit answers that affirm an appreciation of the information provided by the caregiver.

ASHRM believes that communication is an important component of the provider-patient relationship. As such, it is an integral tool for fostering patient safety. It is an important tool in the dialogue that occurs after an unanticipated outcome. To this end, it is seen as a key ingredient that merits careful consideration in terms of ongoing education and training for healthcare professionals.

Consent - What might be characterized as an “unanticipated outcome” may actually be a known remote risk that could have been discussed in the consent process. In other instances, the exchange of information that takes place during the consent process may actually reveal important details that lead a caregiver to change the care plan. In such circumstances, consent is a true patient safety tool since it avoids risk-prone treatment.

The value of the consent process as a patient safety tool is not well understood. Consent is a *communications process*; it is not a form. It is the opportunity for the caregiver to provide the patient with information with which to make a decision regarding diagnostic tests, medical treatment, or surgical intervention. The information is patient-specific, based upon salient medical history information and an understanding of the patient’s desire outcomes of the test or treatment.

Although the laws of 50 states differ to some extent, the basic consent elements share a common core:

- An explanation of the indications for the test or treatment
- An explanation of the proposed test or treatment
- The probable benefits and the probable risks associated with the proposed test or treatment
- A description of alternatives and the probable benefits and probable risks associated with these options
- An explanation of the consequences of declining the proposed test or treatment or any of the stated options

Beyond these common core elements, there are other well-accepted tenets. For example, the patient is entitled to ask questions and to receive understandable answers. No degree of undue influence or coercion should be exerted to secure a treatment authorization. In addition, the patient needs sufficient time to weigh the information provided before making a decision.

Certain types of remote risks also merit disclosure. These involve outcomes involving death, permanent disability, or disfigurement. Although it is important to put this information in context so that patients can understand it, the fact remains that patients are entitled to have this data in making a treatment decision.

When patients are unable to participate in the consent process, and there is a legally authorized representative empowered to make such decisions, it is important to obtain the authorization from such an individual. In doing so, the surrogate decision-maker is entitled to the same degree of information in order to make an effective choice for the patient.

There are a number of exceptions regarding consent to treatment recognized in the law. These involve emergency treatment cases, situations in which it is impractical to go through the complete consent process, mandatory treatment cases, and circumstances in which it is not therapeutically indicated to provide information to patients. In each exceptional case, there are specific criteria that must be met to comply with the principles of consent.

In the elective setting, the core criteria must be met. The person accountable for securing the authorization is the caregiver who is to perform the test or treatment. While a caregiver may delegate elements of the consent process, the ultimate responsibility for the authorization resides with the accountable caregiver.

With rare exception, the consent form is looked upon as the document reflecting the consent process. The fact that it provides a list of known possible or known remote risks does not replace the dialogue between the caregiver and the patient. The same can be said of

ancillary tools that are used to “inform” the patient such as videotapes, interactive computer programs, information sheets, booklets, and brochures. It is the communications process, the give and take of information that is central to an effective consent.

The consent process is between caregiver and patient. However, in a very practical way, having the input of a close relative or someone familiar with family history may lead to a much richer base of information from which care plans can be made for a safe, quality outcome. With the permission of the patient, another individual can be included in the discussion. If this person has a knowledge of family medical history or a deep understanding of the patient’s own history, the result may be important data that “fills in” the gaps that are important to recommending a specific type of test or treatment. Most importantly, the added information enables the caregiver to discuss patient-specific risks that can be anticipated or those that are remote. Having that information “up front” enables the patient to make a knowledgeable treatment decision.

When a patient is informed in advance about risk potential, the fact that it has come to fruition no longer renders the outcome unexpected. Patients are entitled to an explanation of the outcome of a diagnostic test, medical treatment or surgical intervention. However, there is a major difference for all concerned discussing what is categorized as an “unanticipated” risk as compared to what was known as a potential outcome. Having the framework of the pre-diagnostic or treatment consent dialogue, and the benefit of a good communication, the caregiver can better discuss the results of less than desired diagnostic or treatment outcomes.

Empathetic Support for Patients and Families – Another tool is providing the patient and family with empathetic support, including the caregiver being a good listener, and providing expressions of concern. This does *not* mean an admission of liability. Indeed, depending upon the circumstances of the unanticipated outcome, it may be necessary to tell the patient or family that the cause or causes of the result may not be known

for some time. If this is the case, some have suggested that the caregiver discuss what the outcome means in terms of additional tests or treatment. As details are learned about the unanticipated outcome, this information would be provided to the patient or family. The fact that this process has been used is documented so that there is a record to substantiate communication with the patient and family and to provide for presentation of consistent information during subsequent discussions.

While it is recognized that the caregiver is responsible for patient communications, it is also important to utilize the services of other individuals in addressing unanticipated outcomes. This is particularly important for providing empathetic support services that take into consideration specific religious, cultural, linguistic or other needs of the patient and family. To this end, ancillary support may come from clergy, social services, or other staff with whom the patient and family have a special rapport. Critical to effective, empathetic support is providing the patient or family with ways in which to address their immediate needs (e.g., housing, long distance telephone call services, contacting relatives, etc). However, these steps do not signify an admission of liability or of error on the part of the caregiver or the healthcare organization. Instead, it is a genuine effort to provide needed support to the patient and family. Those who are enlisted to assist the caregiver must understand their role and responsibility. Thus they should refrain from offering an opinion or speculating about the unanticipated outcome or attempting to answer any questions about it. To make certain that accurate, consistent explanations come from the same source, such queries should be directed back to the caregiver.

Empathetic Support for Caregivers – Healthcare professionals involved in an unanticipated outcome require understanding and support. It is very disturbing to dedicated caregivers to see patients experience negative outcomes.

There are a variety of mechanisms that can be used to assist these caregivers. These include EAP (employee assistance program or professional) hotlines, counseling, and time. Much depends upon the relationship of the healthcare organization to such professionals. Employee handbooks, employment practice guidelines, rules and regulations of the medical staff, and collective agreements may provide direction on the alternatives available.

That assistance and support is available does not negate the need, in appropriate circumstances, for corrective action or discipline. Such steps are taken when considered necessary by the leadership of the healthcare organization.

Availability of Bioethics Consultation – As noted earlier [See subsection entitled, "Ethical and Legal Issues in Withholding Information," supra], there are situations in which there may be legal, regulatory, or psychological factors that mitigate toward withholding some or all information about the unanticipated outcome. This decision may involve the patient, the family, or an authorized legal representative. Withholding information has both legal and ethical connotations. Having the input of a neutral, objective resource can be helpful in determining the "right" course of action. Thus it has been suggested that one approach is to include bioethics consultations in an unanticipated outcome policy. This may be done by an individual bioethics consultant or by a bioethics committee. When such a resource is used, it is understood that it must be done in concert with applicable policy of the healthcare organization. The fact that this has been done should be documented to demonstrate the framework for deciding what to do in such cases.

Documentation Practices – An important concern is "how" to record the disclosure of unanticipated outcome information. Some are concerned that a detailed note might be construed or misinterpreted as an admission of liability. Others believe that the absence of such a note may cast doubt that such a conversation took place, especially if the patient and/or family are adamant that they were not "informed" of the results of a test or

treatment. Specific legal advice is needed to develop an approach consistent with applicable law. However, from a risk management perspective it is believed that the following should be considered:

- a. Documentation of the time, date, and place of the discussion.
- b. Recordation of the name and relationships of those present.
- c. Documentation that there was a discussion of the unanticipated outcome.
- d. Documentation in appropriate cases that as further information becomes available, this information will be shared with the patient, family, or legally authorized representative.
- e. Documentation of an offer to be of assistance and the response to it.
- f. Documentation of any questions posed by the patient, family, or legally authorized representative, and that answers were provided by the caregiver.
- g. In specific cases in which a decision is made to withhold some or all information, appropriate documentation is made of the reason(s) for this decision. It is acknowledged that in some cases the documentation may be separate from the medical record to protect the safety or welfare of the patient or to prevent interference in law enforcement investigations.
- h. Consultations with those providing psychiatric or ethics evaluations should be recorded in accordance with institutional policy.
- i. Any follow-up discussions should be documented, including time, date, place, and the names and relationships of those present.

Training – The accountable caregiver may find it difficult to discuss an unanticipated outcome. In-service training is a useful vehicle for disseminating practical training in this regard. This would include information about the unanticipated outcome policy of the institution, individual responsibilities, and documentation requirements.

Consideration might be given to use of training videos that depict the "right" way and the incorrect way to handle such matters. Training may also include videotaping caregivers as they role play unanticipated outcome discussions and thereafter providing them with

one-on-one communications techniques. Training may also include information on acceptable documentation practices. The fact that staff has received this training might be documented so that they can be notified of updated in-service programs.

Training might be a consideration for orientation programs for supplemental staff. Those engaged in residency programs, doing practicums, etc., might well be considered candidates for such training.

It is recognized that even with the benefit of in-service training, some will still find it difficult to discuss unanticipated outcomes. Nonetheless, the insights gained through the in-service programs may help to make it a more useful and productive discussion for all concerned than might be the case without the benefit of such training.

Responsibility for Disclosure of Unanticipated Outcome Information – As noted earlier, [See, *Use of “Designees” to Discuss the Unanticipated Outcome*, supra] some individuals may be more comfortable letting a designee discuss unanticipated outcome information with a patient, family, or legally authorized representative. This may be due to discomfort in discussing such matters, emotional trauma from involvement in the event, fear of liability, or difficulty with interpersonal communications. While a designee may be more adept at interpersonal communications he or she may not have the background necessary to talk about the outcome. Moreover, the “silence” of the caregiver involved in the unanticipated outcome might lead someone to draw the inference that “they” did something wrong and want to hide it.

Healthcare organizations must decide how to address the issue of who should be the spokesperson. Care should be taken not to interfere in the caregiver-patient relationship by substituting someone as the spokesperson. The responsibility for doing so rests with the caregiver.

Healthcare organizations have a number of alternatives to consider on the issue of the “responsible party.” For example, in the case of the medical staff, it may be made a requirement under the bylaws or the rules and regulations of the caregiver staff that the caregiver is responsible for discussing unanticipated outcomes with the patient, family or legally authorized representative. It could be made clear that administration can make available ancillary services to assist the caregiver in discharging this responsibility. If the caregiver is an employee, the issue may be addressed through employment contracts or the employee handbook. If the responsible person is a contracted individual from a supplemental staffing agency, it is an issue to be addressed in the written agreement with the vendor. With respect to unionized personnel, it is a topic for consideration in collective agreements. In each instance – medical staff, employee, union member, contracted personnel – the use of a designee spokesperson should be addressed so that there is no ambiguity on the topic during the aftermath of an unanticipated outcome.

The Question of an Unanticipated Outcome Policy and Procedure – A framework for discussing unanticipated outcomes is premised on strong communication processes, both before and after the test or treatment that gives rise to the triggering event. Communication is part of a patient safety perspective for a healthcare organization, the consent process, and a mechanism for supporting subsequent tests or treatment. Thus, some question the need for a stand-alone policy and procedure for “unanticipated events.” In fact, it may be part of a number of existing policies and procedures in a healthcare organization.

ASHRM believes that each organization must determine how it wants to handle the matter. For some, a stand alone policy and procedure is the best approach. For others, addressing the issue may mean enhancing existing internal processes. However, it is handled, it is believed that there are certain basic elements to consider for inclusion in either a new policy or procedure or existing internal processes. These considerations include the following:

- 1. Institutional policy or position statement on disclosure of unanticipated outcomes
- 2. Definition of an unanticipated outcome policy and procedure
- 3. Training
- 4. Responsibility for informing the patient
- 5. Responsibility for informing the family or legally authorized representative
- 6. Disclosure of unanticipated outcome information
 - a. What it does not require: it does not require admission of liability
 - b. What it does require: explanation of outcome or results, recommended next steps, offer of assistance (accommodations, contacting family, etc.)
- 7. Management of exceptional cases
 - a. Suspected or known abuse and neglect
 - b. Police or compliance investigations
 - c. Psychological and emotional concerns for the patient
 - d. Use of psychiatric or psychological consultations
 - e. Use of ethics consultations
- 8. Use of ancillary services
 - a. Clergy
 - b. Culturally conversant personnel
 - c. Social services
 - d. Interpreters
- 9. Additional discussions with patient, family or legally authorized representative regarding findings linked to unanticipated outcome
 - a. Continued communication
 - b. Discussion of patient grievance findings
 - c. Operational aspects of continued communication: in-person, telephone, or in writing

- 10. Documentation requirements
- 11. Assistance for the healthcare professional responsible for discussing unanticipated outcomes
- 12. Coordination with ongoing administrative issues
 - a. Adverse event reporting and triage for management
 - b. Patient grievance
 - c. Sentinel Event – root cause analysis
 - d. Federal or state agency inquiry
 - e. Litigation
 - f. Corrective action directed toward individual healthcare provider

Beyond these elements of policy and procedure for addressing unanticipated outcomes, ASHRM believes that there is ample room for improving communication and consent practices. Greater emphasis on discussing anticipated benefits and risks prior to diagnostic tests or treatment might avert many of the issues that must be managed as unanticipated outcomes.

Examples of Unanticipated Outcome Policy and Procedures

ASHRM membership responded to a request for suggestions and examples of unanticipated outcome policy and procedures. These are provided as illustrations of current thinking and practice on the subject of unanticipated outcome. Healthcare organizations might use these illustrations in framing their own policy on the subject. In doing so, they are encouraged to seek specific legal advice to make certain that the policy is consistent with applicable law in the jurisdiction. The following information is shared with permission.

The Farmers Group of Insurance Companies – The Director of Risk Management Education canvassed a network of risk managers and learned about different approaches being use with regard disclosure of unanticipated outcomes. One respondent shared a “track system.” Different tracks were identified that were specific to hospital-only events (such as a laboratory error), physician events, and shared events in which both physicians and hospitals were involved in the

occurrence. When a facility or the facility and a physician are involved in an event, appropriate documentation is completed. This might include incident reports, and, in reviewable sentinel event cases, a root cause analysis. A meeting is held with the patient or family. Insurance carriers are put on notice and legal counsel is contacted. The respondent emphasized the importance of leadership adopting a policy on disclosure and the importance of education for the management team, the medical staff, and all employees. **Contact:** Annie Stoeckmann, Director of Risk Management/Education; Astoeckmann@worldnet.att.net.

Norcal – Norcal Mutual Insurance Company, a California based professional liability insurer has embarked upon a large scale education program for its physicians. They encourage an early intervention by physicians in compliance with the JCAHO policy. In doing so, they encourage an expression of sympathy, a heartfelt apology, an explanation of the circumstances surrounding the adverse outcome, a treatment plan designed to correct or mitigate any medical injury and a description of steps that will be taken to prevent a recurrence. Norcal believes that its early intervention program will help to maintain the physician-patient relationship and build trust so that the physician can continue to manage the patient's care in a supportive manner. It should also be noted that Norcal is sponsoring legislation in California and in other states that will protect physician reports of medical errors and statements made to patients about unanticipated outcomes. **Contact:** Philip Hinderberger; (415) 835-0816; phinderberger@norcalmutual.com.

St. Luke's Episcopal Hospital – This Houston-based hospital uses a "Patient Care Conference" to communicate patient status in certain cases. For example, the Conference may be used when the physician does not want to address an issue alone or when there are many consultants involved in caring for the patient. Particularly useful in discussing unanticipated outcomes, the Conference may include a number of physicians as well as representatives from respiratory care, physical therapy,

social service, pharmacy and risk management. The focus is on current status and plans for the future. The result is that everyone shares a common understanding of important information. **Contact:** Pat Crossman, Director of Risk Management; (713) 791-2063; pcrossman@sleh.com.

Valley Health System – VHS is augmenting existing policy and procedure to provide for patients and families to be informed about the outcomes of care, including unanticipated outcomes. Policy changes include a discussion of who is responsible for informing the patient and family and managing communication of adverse outcomes. **Contact:** Sue Perkins, Corporate Director, Risk Management; (540) 536-8870; sperkins@valleyhealthlink.com.

Midwest Medical Insurance Company: Written Guidance on How to Manage Adverse Outcomes for Physicians – An insurer has provided caregivers with written guidance on adverse outcomes and how to discuss mistakes with patients. This includes guidance on what the caregiver should say, how to explain this information to avoid drawing conclusions, and to be honest with patients. **Contact:** Deborah McBride, VP of Risk Management; (800) 758-9870.

University of Virginia Health System – UVA Health System has implemented an "Adverse Patient Event Management Plan." The UVA Health System Plan describes the interaction between the institution, the patient, and families subsequent to a significant adverse patient event. Notification, assessments, and ongoing management are contemplated, including the role and responsibility of leadership. **Contact:** Abraham Segres, MHA, HRM, Director of Risk Management; (804) 924-5595; as8f@virginia.edu.

VA Medical Center, Lexington, KY – The VA Medical Center in Lexington, Kentucky has developed "Adverse Event Reporting Guidelines" and other tools to address patient safety. Included in the organization's Integrated Risk Management Program patient safety initiative is a

process for informing patients and their families about injuries that result from adverse events and the options that are available to them. **Contact:** Connie Johnson, RN; (859) 381-5968; connie.johson@va.med.gov, or Steve Kraman, MD; (859) 281-4902; Steve.Kraman@va.med.gov.

HCA – The Healthcare Company, Nashville, TN – HCA has developed a white paper entitled “The Right To Know - Informing Patients if Error Occurs” to encourage each facility to openly discuss the issues surrounding informing patients of medical errors.

Through the HCA Rapid Design Team process, facilities have been encouraged to review their hospital’s existing policies and procedures in conjunction with other regulatory/accreditation requirements to define their process for informing patients if error occurs. Each hospital will define parameters for disclosure and discussion with the patient as well as defining processes to determine who should inform the patient of the error, if others should be present, and guidelines of what the correct documentation within the record should be for each individual situation. **Contact:** Jill Fainter, Vice President, Quality Standards; (615) 344-5865; jill.fainter@hcahealthcare.com.

Examples of Communication Strategies for High Risk Cases

Knowing that some procedures involve a high risk of negative outcome, some place great emphasis on communication. Two books have identified the importance of communication with respect to dispute management—litigation avoidance [Dauer, et al, *Health Care Dispute Resolutions Manual: Techniques for Avoiding Litigation*. Gaithersburg, Maryland: Aspen Publishers, 2000] and as a focal point of managing patient expectation [S.K. Baker, *Managing Patient Expectations*. San Francisco: Josey-Bass, 1998]. Although there is a robust literature on the issue of adverse event reporting and disclosure, these volumes offer useful guidance on the practical aspects of putting the process into operation.

One ASHRM member has worked with colleagues at her institution to develop a communication process for families whose relatives are undergoing risk prone cardiac procedures. Prior to elective procedures, the patient and family are introduced to a nurse specialist who serves as a channel for communication intra-operatively and post-operatively. When bad outcomes occur intra-operatively, the nurse specialist works with the family in a private room away from the surgical waiting area. Additional resources are brought in to assist. The family does meet with the surgeon. This practice has been in existence for some years. Importantly, the disclosure of negative outcomes does not necessarily relate to an adverse event.

Conclusion

This document demonstrates that there are a number of important considerations in framing policies and procedures to address unanticipated outcomes. ASHRM recognizes that it is a highly complex area that is likely to change as experience evolves in the field in managing disclosure of unanticipated outcome. As such, the perspectives discussed here are apt to change over time as will be reflected in future papers on the subject.

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