

## Sample Disclosure Policy

Southwestern Vermont Health Care in partnership with Dale Ann Micalizzi

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This disclosure policy is the result of lengthy 2-year collaboration between patients and family members (who had experienced adverse medical events at several facilities—myself included), non-affiliated facilitator and consultants, quality improvement advisors, patient safety officers, medical directors, risk managers, insurance carriers, nurses, physicians, CEO, pharmacists, technicians, compliance, and legal staff.

The courage and passion that the families articulated throughout the process made a significant contribution to finalizing this document. The leadership, will, and professionalism of the involved staff were phenomenal. The emotions displayed were authentic.

This is a **sample disclosure document** that is meant to assist facilities with replacing antiquated policies and moving towards a compassionate and fair discussion following adverse medical events. Our hope is for complete transparency and learning from events instead of silencing them.

### Other suggestions:

- Promise to disclose statement added to your informed consent/choice documents or disclosure policies and shared with patients and families. It would be signed by supervising physicians agreeing to an honest discussion with their patient and/or family prior to and following an adverse medical event.
- Add patients and families to your RCA discussions, Boards, Quality Team, Grief support services, health education dept., infrastructure team, Advisory Councils, etc.
- Introduce in house Trauma Support Teams for patients and staff

consisting of clergy, social work, psychologists, former patients, physicians, nurses, students, pharmacists, etc.

I offer many thanks to all who assisted with the development of this document and for allowing me to share it with a forward thinking community.

### **PURPOSE:**

To provide guidelines for how to:

- Respond to failures in care processes and other complications of treatment that result in actual or perceived patient injury.
- Determine what adverse events warrant disclosure.
- Decide when disclosure of adverse events should occur; communicate with the patient about an adverse event.
- Provide emotional support to patients, families, and caregivers when adverse events occur.

### **DEFINITIONS:**

Adverse Event: An injury caused by medical management rather than the patient's underlying disease; also referred to as "harm", "injury," or "complication". It is an undesirable outcome that the patient experiences as the result of error, mistake, incident, accident, or deviation from standard of care that requires a documented change in clinical care.

Preventable Adverse Event: An injury (or complication) that results from an error or systems failure in the medical management of a patient.

Examples: technical error during performance of a procedure, giving the patient a wrong medication, an error in decision-making, iv pump

failure that causes a drug overdose, or failure of the system to communicate abnormal lab results to a physician who can act on the information.

**Unpreventable adverse event:** An injury (or complication) that was not due to an error or systems failure and is not always preventable at the current stage of scientific knowledge.

Example: surgical complication that is expected or characteristic of a certain percentage of patients undergoing a procedure, such as a post-T&A bleed.

**Disclosure:** Providing information to a patient and/or family about an incident. There are two types of disclosure: clinical and administrative. Clinical disclosure is communication that occurs between clinicians and the patient/family; administrative disclosure is communication that occurs between hospital administration, physician(s), and the patient/family.

**Medical Error:** The failure of a planned action to be completed as intended or the use of a wrong plan to achieve a goal. Medical errors may or may not cause harm. A medical error that does not cause harm is not considered an adverse event.

**Serious Adverse Event:** An adverse event of sufficient severity as to require immediate notification to the Quality/Safety Department.

Examples include, but are not limited to:

- *Unanticipated death or major permanent loss of function not related to the natural course of a patient's illness or underlying condition.*
- *Intra or post-operative death*
- *Injuries sustained in a fall in the healthcare setting*
- *Death from a hospital-acquired infection*
- *Suicide of a patient receiving care, treatment, or services in the in-patient setting or within 72 hours of discharge*

- *Unanticipated death of a full-term infant*
- *Neonatal transfer to tertiary care for injuries sustained at birth*
- *Adult transfer to tertiary care from the in-patient setting*

#### **POLICY:**

Hospital shall utilize a standardized process to identify, analyze, and respond to adverse events in which either patient harm or the potential for patient harm is identified. This policy addresses:

- *Timely and appropriate reporting of an adverse event as soon as it is identified.*
- *Rapid and open disclosure to patients and families who experience serious incidents.*
- *Ongoing communication with the patient and family.*
- *Emotional support to patients, families, clinicians, and others affected by such incidents.*

#### **PROCEDURE:**

##### **Timely and Appropriate Reporting Of an Adverse Event**

It is the responsibility of hospital staff and physicians to identify and respond to adverse patient events (as defined above) occurring within the organization or associated with services the organization provides.

Upon discovery of a "serious" adverse event, the staff member or physician must immediately report the event to the Quality/Safety Department with a phone call to the Patient Advocate.

In the event that the Patient Advocate is unavailable, the Patient Safety Department should be called via overhead page.

The Patient Advocate or another member of the Patient Safety/Quality Department shall notify members of sentinel event review subcommittee as outlined in the organization's policy on Sentinel Events (See "Sentinel Events-JCAHO") to determine whether or not the event is reportable to the Joint Commission.

Upon discovery of all other adverse events, the staff member or physician should notify the Patient Advocate, any member of the Patient Safety Department, or report on-line via the Intranet.

Upon notification, the Patient Safety Department will work with the Chief Medical Officer and Medical Director for Quality as needed to determine the severity of the event and steps for appropriate response both to staff and to the patient and family involved.

The Quality/Peer Review process will be initiated immediately to conduct a full and thorough investigation of the adverse outcome.

The Patient Safety Department shall maintain documentation of all activities related to follow-up of an adverse event. This documentation is considered peer protected.

#### **Adverse Events that Warrant Disclosure**

Patients and/or their representatives must be informed of the probable or definite occurrence of any adverse event that has resulted in, or is expected to result in, harm to the patient, including the following:

Adverse events that have had or are expected to have a clinical effect on the patient that is perceptible to either the patient or the health care team.

Adverse events that necessitate a change in the patient's care.

Examples: a medication error that requires close observation, extra blood tests, extra hospital days, or follow-up visits that otherwise would not be required; or a surgical procedure that necessitates further (corrective) surgery.

Adverse events with a known risk of serious future health consequences, even if the likelihood of that risk is very small.

Adverse events that require providing a treatment or procedure without the patient's consent.

Example: an adverse event that occurs while a patient is under

anesthesia, necessitating a deviation from the procedure the patient expected.

Disclosure of other adverse events is optional and at the discretion of the providers involved. Cases need to be considered individually and in relation to specific circumstances. Note: Although the disclosure to the patient is optional, reporting the occurrence of these events is required.

Disclosure of near misses and "close calls" to patients is also discretionary. Note: Although the disclosure to the patient is optional, reporting the occurrence of these events is required.

#### **WHEN COMMUNICATION OF AN ADVERSE EVENT SHOULD OCCUR**

Optimal timing of communication about adverse events varies with the specific circumstances of the case.

*Clinical Disclosure:* If a patient needs immediate treatment to minimize injuries resulting from an adverse event, clinical disclosure must occur within 24 hours of a practitioner's discovery of the adverse event.

*Administrative (Institutional) Disclosure (see #2 below):* Administrative disclosure of adverse events, when necessary, needs to take place as soon as is possible after discovery of an event. Administrative disclosure is generally warranted when there is a serious (sentinel) or emotionally charged adverse event, or when there is an expressed expectation on the part of the patient or family that the "hospital" respond.

If immediate corrective action is not required, disclosure may be delayed long enough to give clinicians and administration time to collect preliminary information and plan how to disclose the information.

Administrative disclosure is generally conducted by an administrative leader of the hospital, including, but not limited to, the CEO, CMO, President of the Medical Staff and Medical Director for Quality.

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## **HOW ADVERSE EVENTS SHOULD BE COMMUNICATED**

### **Clinical Disclosure**

Disclosure of an adverse event should occur in an appropriate setting and be done face-to-face. The location must be a quiet, private place and adequate time needs to be set aside, with no interruptions.

In general, clinical disclosure should be done by one or more members of the clinical team along with the Patient Advocate, Medical Director for Quality or other member of the Patient Safety Department.

The role of the administrative representative is to take notes and listen to what is said by both the clinician and the patient or family.

The patient's treating/attending practitioner, or the practitioner who has an established relationship with the patient/family, is responsible for determining who shall communicate the information.

Clinicians may access a peer from the medical staff to coach him or her in techniques for effective and honest apology by contacting the Patient Advocate or other member of the Patient Safety Department.

Initial explanations should focus on what happened and how it will affect the patient, including immediate effects and the prognosis, using the following guidelines:

- Tell the patient and family what happened. Provide preliminary factual information to the extent it is known.
- Apologize. Expressing regret for what happened and concern for the patient's welfare.
- Take responsibility. Whether or not the incident resulted from a specific act, the attending physician should make a statement of responsibility to the patient and/or family. In doing so, the physician and hospital leaders accept responsibility for future action, trying to find out the causes of the event, informing and updating the patient and family, and monitoring and managing any complications of the adverse event.

They also communicate the hospital's responsibility to do whatever possible to improve systems to prevent similar events from happening to other patients in the future.

(See "Guidelines for Physician Communication Following an Adverse Outcome" and the JAMA commentary on "Apology in Medical Practice: An Emerging Clinical Skill" by A. Lazare, M.D.)

The Patient Advocate, social workers or other staff may be present to help the patient or representative cope with the news and to offer support if needed.

Clinicians are to document the unexpected medical/treatment/care outcome in the medical record objectively and factually where appropriate. (See "Full Disclosure Documentation Guidelines")

The attending practitioner or Patient Advocate shall maintain contact with the patient and/or identified family members to keep the lines of communication open, unless the patient requests otherwise or another contact has been designated.

The attending practitioner shall provide further information, as appropriate, about the adverse outcome to the patient/family at a later date when the results of a full and thorough investigation are known, taking care to disclose only factual information and not information that is purely protected such as peer review deliberations and outcomes.

The patient and family should be provided with appropriate business cards and phone numbers to facilitate easy access to the physicians and/or principals involved in the prior communication around the event.

The attending practitioner shall document all contact with the patient/family in the medical record as long as the patient remains in the hospital.

Once the patient is discharged, documentation of disclosure and follow-up with the patient/family shall be maintained by the Patient Safety Department and is peer review protected

### **Administrative Disclosure**

At times, given the nature, severity of injury and likelihood and degree of risk for legal liability, there may be a need for administrative communication about adverse events either instead of, or in addition to, clinical disclosure.

In all cases of administrative disclosure, the CMO or Medical Director for Quality must notify the attending physician(s) and Risk Manager immediately upon the decision that such communication with the patient and/or family will occur.

The leader responsible for disclosing the case to the patient must offer the attending physician(s) involved in the adverse event the opportunity to participate in the patient/family meeting.

The Risk Manager or other Hospital personnel deemed appropriate may be included in this conference at the discretion of hospital leadership in consultation with the attending provider(s).

Administrative communication about adverse events should not take place until both the attending physician and hospital leaders have conferred with their respective legal representatives and/or insurers to address what is to be communicated, by whom and how.

Communication with the patient and/or family regarding the meeting will be arranged by the CMO or his/her designee.

Any request by a patient or personal representative to bring an attorney must be honored, but may influence whether providers will participate.

The Risk Manager or organizational leaders will determine who and how they will engage in ongoing communication with the patient or personal representative to keep them apprised, as appropriate, of information that emerges from the investigation of the facts of the case.

The Risk Manager, in order to mitigate financial impact of unexpected outcomes to a patient, will confer with the Vice President of Operations and legal counsel to determine the appropriateness of assessing

financial contributions from the Hospital Patient Assistance Fund.

Administrative communication about adverse events must include:

- *An apology for the fact that the care of the patient did not go as well as intended*
- *A complete explanation of the facts as they are known*

### **Responsibility for follow-up of the event:**

(See "Guidelines for Physician Communication Following an Adverse Outcome" and the JAMA commentary on "Apology in Medical Practice: An Emerging Clinical Skill" by A. Lazare, M.D.)

- The patient and family should be provided with appropriate business cards and phone numbers to facilitate easy access to the physicians and/or principals involved in the prior communication around the event.
- The administrative leader responsible for communicating with patients/families about an adverse event shall verbally report on results of the meeting(s) to involved providers.
- Documentation of administrative disclosure and follow-up with the patient/family shall be maintained in a peer review protected file in the Patient Safety Department.

### ***FOLLOW-UP COMMUNICATION WITH AND CARE OF THE PATIENT/FAMILY***

One or more subsequent discussions are always indicated following a serious event.

The primary purpose of follow-up communication is to provide fuller description of the events that occurred and the nature of systems changes that have been identified to address them.

Communication about final results of investigations and remedial actions should occur as soon as they are available.

If delay is encountered, the patient or family should be frequently apprised of the situation, with apology for delay.

The attending physician or team members may conduct these follow-up meetings as appropriate.

In especially serious or highly charged cases, senior administrators, including the CMO or CEO, should be involved. Senior administrative involvement is especially indicated if faith in the attending provider has been compromised and he/she has not been fully successful in communicating with the patient.

#### **FINANCIAL SUPPORT OF PATIENTS FOLLOWING AN ADVERSE EVENT**

Patients may expect hospital and physician fees to be waived when there is a complication. This is especially likely to be so if the injury is perceived to be caused by an error or other failure in the treatment process.

Decisions about waiving fees or reimbursement for expenses incurred as a result of a preventable injury will be made by the Director of Risk Management in consultation with senior management.

#### **PATIENT/FAMILY DISCUSSIONS ABOUT "LIABILITY" OR DESIRE FOR "SETTLEMENT"**

Should the patient and/or family indicate a desire to seek legal action or express the need for financial settlement, clinicians, and administrative representatives should listen without entering into any discussions about liability and/or settlement.

Discussions of this nature should not take place until a provider and/or the hospital has first consulted with their respective insurers and/or attorney.

#### **SUPPORT OF CAREGIVERS**

Like patients and families, caregivers are equally likely to be affected, both emotionally and functionally, following an adverse event. A comprehensive institutional support system is needed to assist caregivers in preparing for and quickly responding to an adverse event.

The Chief Medical Officer will notify Medical Staff Department Chairs when a provider or providers have been involved in an adverse patient event for follow up with the provider(s) to determine what level of support is needed.

A representative from the Patient Safety Department will notify department managers of staff involved in an adverse patient event for follow up with caregivers.

Support may include, but not be limited to:

- *Appropriate adjustment of responsibilities and time off if needed so that healing can occur.*
- *Peers or others with whom the provider or caregiver can debrief the adverse event.*
- *Instruction in documenting the event in the medical record.*
- *Trained peer medical staff coaches to provide caregivers with support in communicating with the patient and family.*
- *Access to legal support to staff and caregivers involved in adverse events provided through the Risk Manager.*

#### **COMMUNICATING WITH THE PRESS**

In the event of a "high profile" adverse patient event that carries a strong likelihood of media attention, it is important that the hospital use methods of communication that demonstrate transparency and restore community confidence that systems are in place to minimize the likelihood of future accidents.

The CEO, Chief Medical Officer, and/or Chief Nursing Officer will determine the need for communicating with the press in consultation with the Public Relations Department.

The Public Relations Department will coordinate the hospital's public response in tandem with members of the executive management team and the Risk Manager.

One or more members of the executive management team will be appointed to publicly disclose the event on behalf of the hospital.



The Patient Safety Department will report events externally to relevant regulatory

bodies according to hospital policy and regulatory requirements.

This Disclosure Policy was created by: Southwestern Vermont Health Care, Bennington Vermont. <http://svhealthcare.org/>

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