I. DEFINITIONS

Many terms have been used to refer to bad outcomes of care, often causing confusion. For example, in its disclosure policy, JCAHO calls for informing patients of "unanticipated outcomes," in an attempt to distinguish complications of treatment from complications of disease. Yet, this has led to debates over whether the fact that certain complications of treatment, such as postoperative infections, are well known to occasionally occur means that they are "anticipated" and therefore do not require disclosure.

Another source of confusion is the use of terms for injury and error interchangeably. To avoid confusion, we use the following definitions from the American Society of Healthcare Risk Management (ASHRM)[4] in this document:

Adverse Event: An injury that was caused by medical management rather than the patient's underlying disease; also sometimes called "harm", "injury", or "complication".

- An adverse event may or may not result from an error. See further classification of preventable and unpreventable adverse events below.
- "Medical management" refers to all aspects of health care, not just the actions or decisions of physicians or nurses.

Medical Error: The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Medical errors include serious errors, minor errors, and near misses. (Note: A medical error may or may not cause harm. A medical error that does not cause harm does not result in an adverse event.)

In addition, we define the following:

Serious Error: An error that has the potential to cause permanent injury or transient but potentially life-threatening harm.

Minor Error: An error that does not cause harm or have the potential to do so.

Near Miss: An error that could have caused harm but did not reach the patient because it was intercepted.

Preventable adverse event: An injury (or complication) that results from an error or systems failure. Even if one agrees that individual errors are often the end result of systems failures, they are still perceived by patients and caregivers as very personal events. It is useful to distinguish three categories:

- Type 1: Error by the attending physician.
  Example: technical error during performance of a procedure
- Type 2: Error by anyone else in the healthcare team
  Examples: a nurse gives wrong medication to patient; a resident makes a technical or decision error; a radiologist misses a lesion.
- Type 3: Systems failure with no individual error.
  Examples: IV pump failure that causes drug overdose; Failure of system to communicate abnormal lab results to ordering physician.

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 state of scientific knowledge. There are two major categories:

- Type 1: Common, well-known hazards of high-risk therapy. Patients understand the risks and accept them in order to receive the benefit of the treatment.
  Example: complications of chemotherapy
- Type 2: Rare but known risks of ordinary treatments. The patient may or may not have been informed of the risk in advance.
  Example: side-effects of medications; certain wound infections

Incident: An adverse event or serious error. Also sometimes referred to as an *event.*

Disclosure: Providing information to a patient and/or family about an incident. Because this term suggests revealing of privileged information and implies an element of choice, in this document we use instead the term *communication*, by which we wish to convey a sense of openness and reciprocity.

Reporting: Providing information to an appropriate authority, internal or external, regarding adverse events or errors. (See section on Reporting for more details on what events are to be reported.)