Institute for Healthcare Improvement | Lucian Leape Institute

Patient Safety: Important Definitions

Moving Measurement into Action: Designing Global Principles for Measuring Patient Safety | Pre-Seminar Briefing Document

Please note: The definitions in this document are meant to be utilized as standard working definitions for the purpose of this seminar. We acknowledge the many nuances in defining patient safety measurement and hope this document will serve as a useful tool for consistency in language and understanding across participants and conversations.

Adverse Event: Any injury caused by medical care.

Examples include pneumothorax from central venous catheter placement, anaphylaxis to penicillin, and postoperative wound infection. Identifying something as an adverse event does not imply "error," "negligence," or poor quality care, it simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process. Preventable adverse events are the subset that are caused by error.

Error: Failure to carry out a planned action as intended or application of an incorrect plan.*

An error may be considered an act of commission (doing something wrong) or as an act of omission (failing to do the right thing) that may lead to an undesirable outcome or significant potential for such an outcome.

For example, ordering a medication for a patient with a documented allergy to that medication would be an act of commission. Failing to prescribe a proven medication with major benefits for an eligible patient (e.g., low-dose unfractionated heparin as venous thromboembolism prophylaxis for a patient after hip replacement surgery) would represent an error of omission.

Harm: Physical or psychological injury (including increased anxiety), inconvenience (such as prolonged treatment), disrespect, monetary loss, and/or social impact, etc. suffered by a person.

> **Health Care Associated Harm (Patient Harm)**: Harm arising from or associated with plans or actions taken during the provision of health care rather than an underlying disease or injury.
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> **Harm Incident**: An incident that resulted in harm to a patient.

Patient: A person receiving medical care, which includes treatment, intervention, procedure, and diagnostic tests as well at the continued monitoring of health, and signs as well as symptoms of disease over time. The term patient also encompasses the person's family, carer(s), or other surrogates who would be involved in, and affected by the efforts of the patient's care.*

Patient Safety: The reduction of risk of unnecessary harm associated with health care to an acceptable minimum.*†

Patient Safety Culture: A pattern of individual and organizational behavior, based upon shared beliefs and values that continuously seeks to minimize patient harm, which may result from the process or delivery of care.*

Patient Safety Event: Something that happens to or involves a patient; encompasses patient safety incidents and near misses.

> **Patient Safety Incident**: An event or circumstance that could have resulted (no harm incident), or did result (harm incident), in unnecessary harm to a patient. For example: if a nurse gives a patient an incorrect medication to take and the patient recognizes it as such and refuses to take it, an incident has occurred.
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> **Near Miss**: An event that did not reach a patient. For example: discovery of a dispensing error by a nurse as part of the process of administering the medication to a patient (which if not discovered would have become an incident); discovery of a mislabeled specimen in a laboratory (which if not discovered might subsequently have resulted in an incident). The terms "potential adverse event" and "close call" are also used to describe a near miss.
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> **Serious Safety Event (SSE)**: A variation from expected practice followed by death, severe permanent harm, moderate permanent harm, or significant temporary harm.
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> **Serious Safety Event Rate (SSER)**: The number of serious safety events that occur in a given period of time, divided by the number of patient days in that time.

Patient Safety Measurement: The collection and analysis of information for the purpose of the understanding and prevention of health care associated errors and adverse effects to patients. Safety measurement may be used for a variety of purposes: to evaluate the effectiveness of safety interventions, identify new or emerging safety threats, compare safety across hospitals and clinics, or to determine whether patient safety is improving over time.

> **Proactive Measurement**: The review of data that anticipates risks and hazards, with the intention of mitigating risk and preventing the occurrence of an adverse event.
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> **Reactive Measurement**: The review of data in response to an error or adverse event, with the intention of mitigating or preventing recurrence.

Performance Measurement: The use of statistical evidence to determine progress toward specific defined organizational objectives. In general, performance measurement seeks to monitor, evaluate, and communicate the extend to which various aspects of the health system meet their key objectives.†

Safety I: A state where as few things as possible go wrong. A Safety-I approach presumes that things go wrong because of identifiable failures or malfunctions of specific components: technology, procedures, the human workers and the organizations in which they are embedded. The purpose of accident investigation in Safety-I is to identify the causes and contributory factors of adverse outcomes, while risk assessment aims to determine their likelihood.

Safety II: The system's ability to succeed under varying conditions. A Safety-II approach assumes that everyday performance variability provides the adaptations that are needed to respond to varying conditions, and hence is the reason why things go right. In Safety-II the purpose of investigations changes to become an understanding of how things usually go right, since that is the basis for explaining how things occasionally go wrong.

Structure-Process-Outcome Triad: A classification system for measurement used to assess and compare the quality of health care organizations, also known as the Donabedian model.

Structure refers to the setting in which care occurs and the capacity of that setting to produce quality. Processes encompass all that is done to patients in terms of diagnosis, treatment, monitoring, and counseling. Outcome measures reflect the impact of the health care service or intervention on the health status of patients and/or populations.

Safety Monitoring: The continuous tracking and assessment of process and outcome measures to obtain a real-time understanding of an organization's past and present safety and harm incidents and risks for future incidents of harm, as well as ensure maintenance of best practice operations.

Triggers: Signals for detecting likely adverse events. Triggers alert providers involved in patient safety activities to probable adverse events so they can review the medical record to determine if an actual or potential adverse event has occurred.

For example, if a hospitalized patient received naloxone (a drug used to reverse the effects of narcotics), the patient probably received an excessive dose of morphine or some other opiate. In the emergency department, the use of naloxone would more likely represent treatment of a self-inflicted opiate overdose, so the trigger would have little value in that setting. But, among patients already admitted to hospital, a pharmacy could use the administration of naloxone as a "trigger" to investigate possible adverse drug events.

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* Definition used by Organisation for Economic Co-operation and Development (OECD)

† Definition used by World Health Organization (WHO)

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