

Fernald DH, Pace WD, Harris DM, West DR, Main DS, Westfall JM. Event reporting to a primary care patient safety reporting system: a report from the ASIPS Collaborative. *Ann Fam Med*. 2004;2:327-332.

<http://www.annfammed.org/cgi/content/full/2/4/327/DC1>

Appendix 2. Supplemental Discussion of Harm Definitions

To assess harm, we draw from 15 codes and subcodes from axis 2 of the taxonomy (Appendix 2, Table 1). Our taxonomy allows coding of nonclinical harm, clinical harm by degree and duration, and absence of or inability to determine harm. For this analysis, all cases were sorted into 5 categories related to harm:

1. *No known harm* includes final reports for which we are unable to determine harm or no harm (usually because of insufficient information) and clearly for which no harm occurred (patient outcome not affected by event and progressed as expected; such as a delayed laboratory result is normal and no treatment needed anyway).
2. *Unstable* includes reports for which it was too early to determine harm (such as patient with atrial fibrillation and a missed low prothrombin time–international normalized ratio reported before correcting the problem).
3. *Nonclinical harm* includes reports where patients had some discomfort or inconvenience as a result of the event. Examples include patient fear stemming from incorrect information, or a patient undergoing a repeated uncomfortable procedure because of an error. This dimension was coded only if there was specific mention of either situation within a report. We hypothesize that these codes would likely be used to a greater extent from the patient's perspective.
4. *Increased future risk of clinical harm* includes future risk to the patient or future risk to others. Examples include a missed diagnosis of diabetes for several years or an Rh-negative woman who is sensitized as a result of a failure to check a blood type during a spontaneous miscarriage.
5. *Clinical harm* includes all cases for which we established some degree and duration of harm to the patient, including death. Degree of harm includes gradations of minimal, moderate, severe, and death. Minimal harm is defined as a change in some physiological function that did not require medical attention, and the patient was expected to recover fully at the time of the report. Moderate harm is defined as decreased function of an organ system that is measurable clinically, but may not have been noticeable to the patient unless the organ system was stressed. Medical intervention, but not hospitalization, might have been required. Severe harm is defined as a major change in some organ function that required hospitalization. Duration of harm can be coded as unknown, temporary, or permanent. Thus there are 10 possible combinations of codes between these 2 dimensions.

These 5 categories of harm were applied in a hierarchical manner in the following order: (1) clinical harm, (2) increased future risk, (3) nonclinical harm, (4) unstable, and (5) no known harm. Even though a report could contain multiple harm categories, for analysis all reports were classified into only 1 category reflecting the greatest degree of immediate harm.

Appendix 2, Table 1. Combined Harm Categories

Taxonomy Code	Description	Combined Harm Category
2.1.1.1:	Insufficient information	No known harm
2.1.1.3:	No change in patient	
2.1.1.2:	Too early to tell	Unstable
2.1.1.4.5-6:	Patient inconvenience or discomfort	Nonclinical harm
2.1.1.4.3.1-2:	Increased risk of future harm to patient or others	Increased future risk
2.1.1.4.2.1.1-3:	Harm: temporary, permanent, unknown duration.	Clinical harm
2.1.1.4.2.2.1-4; 2.1.1.4.4:	Harm: minimal, moderate, severe; death	