## Seriousness

**DDI minimum information models definitions**

<https://docs.google.com/spreadsheets/d/1dhUp496riwZ0AHqRP7I85oEvuP2jjEI0rcw1Fcm2zI8/edit#gid=0>

### Proposed User-Centered Definition (Qualtrics)

**Seriousness:**

The degree to which a drug-drug interaction clinical consequence may result in harm and that will determine the type and speed of clinician intervention.

**Severity:**

The intensity of a drug-drug interaction clinical consequence.

**For example:**

* **Seriousness**: An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to FDA when the patient outcome is:
  + Death
  + Life-threatening
  + Hospitalization (initial or prolonged)
  + Disability or Permanent Damage
  + Congenital Anomaly/Birth Defect
  + Required Intervention to Prevent Permanent Impairment or Damage (Devices)
  + Other Serious (Important Medical Events)
    - **Source**: U.S. Food and Drug Administration. “What is a Serious Adverse Event?” <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm> (accessed August 19, 2016)
* **Severity**: “*Severity* is a more ambiguous term and describes the intensity of an adverse reaction in an individual. For example, a headache may be severe but not serious.”
  + **Source:** Tilson H, Hines LE, McEvoy G, et al. Recommendations for selecting drug-drug interactions for clinical decision support. *Am J Health Syst Pharm*. 2016;73(8):576-85. Link: <http://www.ashp.org/DocLibrary/Bookstore/AHFS-CDI-Landing-Page.pdf>

**Background Information:**

* **AHRQ DDI Work Group**
  + **Seriousness**: “We recommend use of the term *seriousness*, rather than *severity*, to describe the extent to which a DDI can or does cause harm”
    - **Source**: Scheife RT, Hines LE, Boyce RD, et al. Consensus Recommendations for Systematic Evaluation of Drug-Drug Interaction Evidence for Clinical Decision Support. Drug safety. 2015;38(2):197-206.
* **DIDEO:**
  + **Severe adverse event**: serious adverse event is an adverse event that requires in-patient hospitalization, or prolongation of existing hospitalization, or that causes congenital malformation, or that results in persistent or significant disability or incapacity, or that is life threatening or results in death.
* **DINTO**:
  + Severity – (it can take three values: {“major” , “minor” , “moderate”}): “Used of the degree of something undesirable e.g. pain or weather; also, strictness (NCIT). The potential severity of the interaction is particularly important in assessing the risk vs benefit of therapeutic alternatives. With appropriate dosage adjustments or modifications of the administration schedule, the negative effects of most interactions can be avoided. There are three degrees of severity: major, moderate and minor (Tatro).

**Suggested User-Centered Definition (Google Sheets)**

* **Seriousness** 
  + Unfavorable clinical consequences can have different severity levels: moderate, severe (life-threatening), death. Moderate consequences need instant clinical attention. Severe consequences can be defined as harms and need instant clinical actions. "
    - Even for a user centered definition, this needs a little more flesh to the bone.
    - Not “severity” because that describes intensity
    - A single word
    - research needed to determine what words or phrases would be most appropriate"
    - Including definitions and explanation of medical logic
    - No more than 3 categories – interruptive, clinical notification, “clinically inconsequential”
      * Why is 3 the max?
      * We should not touch on what type of CDS alert a DDI should produce (e.g., hard stop, interruption, etc) as different consumers will disagree on how the CDS should behave (i.e., one organization may think a DDI should be a hard stop, the other organization uses no hard stops ever). Rather, we should calculate a score and let consumers implement CDS how they see fit based on the score.
    - Driven by seriousness and frequency of the clinical outcome
  + Should be a result of something like: severity of clinical consequences + freq of harm + modifying factors + evidence type
  + Maybe all of these should be weighted and run through a “seriousness algorithm”. Then a final “seriousness score” can be calculated.
  + "I think that, as it was said in the first Content sub-group meeting, different groups have created different scores for DDI severity (or seriousness), with the problem that there are important differences among them, because they use different criteria. However, maybe creating a new score system might not be better than the existing ones, but only different. Instead, I would focus on a more detailed description of the different factors that determine DDI seriousness, where these can be obtained from the different information sources, and how they can be integrated in the evidence framework.
    - Also, if we are going to include individual factors (such as age, co-morbidities, pharmacogenomics, etc) that means that we should assume that seriousness of a DDI may be different for a patient (or group of patients).
    - A DDI might be rated as “major” for a 85 years old patient with a previous episode of myocardial infarction, while it could be “severe” or “minor” for a 25 years old patient without previous history of CV disease.
    - "In DINTO we adopted the definition in Tatro´s “Drug Interactions Facts” and represented the concepts “relevance”, “severity” as data properties.
  + Relevance – (it can take two values: “clinical relevance” , “non-clinical relevance”) “The real importance that the DDI has in the clinical practice” (This definition must be improved)
  + Severity – (it can take three values: {“major” , “minor” , “moderate”}): “Used of the degree of something undesirable e.g. pain or weather; also, strictness (NCIT). The potential severity of the interaction is particularly important in assessing the risk vs benefit of therapeutic alternatives. With appropriate dosage adjustments or modifications of the administration schedule, the negative effects of most interactions can be avoided. There are three degrees of severity: major, moderate and minor (Tatro).