AdverseEvent FHIR Resource Proposal

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Owning Committee Name
RCRIM WG and Patient Care WG

Contributing or Reviewing Work Groups
• Patient Care, Pharmacy, CDS, PHER, EC

FHIR Resource Development Project Insight ID

Scope of coverage


To enhance patient safety, it is noted that many countries have strong needs to exchange product safety information between varieties of stakeholders in the healthcare domain. Currently many regulatory agencies collect safety reports of adverse drug reactions, adverse events, infections, contamination and other incidents from consumers, pharmaceutical companies and healthcare professionals.

The adverse event resource will address the exchange of the following types of information: 1) Individual Case Safety Report (ICSR): framework for data exchange and information sharing by providing a common messaging format for transmission of ICSRs for adverse drug reactions (ADR), adverse events (AE), product problems and consumer complaints that may occur upon the administration or use of one or more products or substances. The reports can relate to a specific subject or may be used to relay an issue or finding related to a specific substance, product or device. 2) (Not in current standard) – Individual Occurrence Report (IOR): the identification and characterization of exceptional events related to patient care, patient safety, protocol implementation, and service delivery. Examples might be falling out of bed, slipping on a wet floor, inappropriate use of restraints.

Does the concept of sentinel event need to be included? Can system triggers for alerts be addressed in the resource?

C-CDA for hospital acquired infections. NHS safety network under CDC. – possible sources of other data elements

RIM scope

1. InvestigationalEvent: Class Code INVSTG
2. Causality: ? Code based on event vs. associations
3. Report: Class Code CACT (can have multiple reports)

Common data elements for ICSR

• Identifiable patient (Note that this may be restricted by regulation and can be masked using “Privacy” or initials. However, for product problems there may or may not be an identifiable patient.)
• Identifiable reporter
• Date of Event
• Description of the event or problem
• Substance or Product name

Common data elements for IOR
• Identifiable patient (Note that this may be restricted by regulation and can be masked using "Privacy" or initials. However, for product problems there may or may not be an identifiable patient.)
• Identifiable reporter
• Date of Event
• Description of the event or problem

Resource appropriateness
An adverse event is a well-known healthcare concept that is regularly tracked and reported for clinical care, public health and research.

Expected implementations
Adverse event documentation and reporting of an adverse event is an integral part of any care setting, research setting or public health reporting entity.

Content sources
Existing ISO/HL7/CEN standards as well as examples of health care institution occurrence reporting systems. Will also review data elements in the CDC National Health Safety Network.

Example Scenarios
• 1. During the course of a clinical trial, a research subject develops an adverse reaction to a research drug. Documentation of this observation is reporting to the drug sponsor and the US Food and Drug Administration.
• 2. A patient slips and falls on spilled water in the health care institution bathroom. The patient suffers no ill effects but the nurse documents the fall in the hospital occurrence reporting system to document the fall and to alert hospital administration.

Resource Relationships
AllergyIntolerance, Condition, Procedure, Risk Assessment, Medication Statement, Immunization, Observation

Timelines
DSTU 2.1 - DRAFT

gForge Users
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