FHIR Implementation Guide for Transfusion and Vaccination Adverse Event Reporting

Committee Approval Date:

November 3, 2020

Publishing Lead:

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Contributing or Reviewing Work Groups:

Biomedical Research & Regulation
Patient Care
Public Health
Orders & Observations

FHIR Development Project Insight ID:

1644

Scope of coverage:

The scope of the guide is to allow EHRs to create Adverse Event reporting messages as required by FDA’s Individual Case Safety Report (ICSR) specification but using FHIR resources instead of the existing V3 specification.

We are creating profiles on the following resources:
AdverseEvent (for adverse reactions to biologic products)
Procedure (for transfusion events)
Immunization (for vaccine product exposures)
BiologicallyDerivedProduct (for representing blood products involved in transfusion)
Condition/Observation (for representing inputs into the AE detection algorithms)

Since ICSR is currently a document contained in a message, there will be profiles on MessageHeader and Composition to allow for the transformation into a current ICSR submission.
Content location:

https://github.com/HL7/icsr-ae-reporting

Proposed IG realm and code:

us/icsr-ae-reporting

Maintenance Plan:

The BR&R Workgroup will be the owners of this content. As well, the HL7 Vulcan Accelerator will also be looking at our content and expanding on it and then maintaining it.

Short Description:

This Implementation Guide provides a set of profiles and algorithms around the detection, validation, and reporting, as well as the eventual recording and persisting of Adverse Events associated with blood transfusions and vaccinations. EHRs and Provider Networks can use this guide to understand the data elements needed to facilitate the electronic reporting of these adverse events as well as ways of mining their data to detect adverse events.

Long Description:

This Implementation Guide gives guidance on the data elements needed for detection, validation, and reporting, as well as the eventual recording and persisting of Adverse Events associated with blood transfusions and vaccinations. EHRs and Provider Networks who use this guide will be able to capture the granular details of exposure to the suspect biologic/drug along with the documentation of the adverse event associated with that biologic/drug. Instead of manually creating the adverse event reports, this will provide FHIR systems the ability to generate electronic submission of adverse event reports. Although the FDA uses the ICH standard for adverse event reporting, which does not use FHIR, the FHIR elements can all be translated into the appropriate transmission format.

Along with the set of profiles, this IG also documents the algorithms used to detect adverse events in clinical data. These algorithms can be implemented by systems so that adverse events can be automatically identified. The algorithm value sets define the code systems and codes relevant to a given AE. For example, the febrile seizure value set includes 3 ICD-10-CM and 14 SNOMED codes. The algorithm logic will be defined in the IG to combine exposure and outcome (as well as rule-out) logical components using CQL.

This IG was initially created for automating the surveillance and reporting of biologic AEs. However, it may be valuable for other related use cases and domains such as drug adverse event reporting to FAERS or reporting of other public health-related events.

Involved parties:

FDA
IBM (leader of the FDA CBER Biologic Effectiveness and Safety initiative team)

Expected implementations:

IBM
MedStar
OneFlorida
Content sources:
ICH ICSR E2B(R2), ICH ICSR E2B(R3), FDA FAERS, FDA VAERS

Example Scenarios:
1) Mine existing EHR data using the Phenotyping algorithms to detect Adverse Events due to vaccinations or transfusions and create Adverse Event FHIR instances and associated data
2) Create a valid ICSR submission using FHIR resources that could be converted into existing XML submission formats

IG Relationships:
N/A

Timelines:
STU Ballot - September 2021
Normative Ballot - September 2022

FMG Notes