Educational Brief

Common Formats for Event Reporting – Diagnostic Safety Version 1.0 Issue 50: June 2022

Introduction

The Agency for Healthcare Research and Quality (AHRQ) has released the Common Formats for Event Reporting – Diagnostic Safety Version 1.0 (CFER-DS V1.0). Available supporting documents include the Event Description, Form, and Users' Guide and Glossary. The Patient Safety Organization Privacy Protection Center (PSOPPC) plans to release additional supporting materials and begin accepting data on diagnostic safety events from federally listed Patient Safety Organizations (PSOs) using CFER-DS V1.0 in Fall 2022.

Common Formats for Event Reporting (CFER)

AHRQ leads the development of CFER to enable the collection, aggregation, and analysis of uniformly structured information about patient safety. They have been developed for voluntary use by healthcare providers that choose to work with PSOs under the Federal Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and are also available in the public domain to encourage their widespread adoption. An entity does not need to be listed as a PSO or working with one to use the Common Formats. However, while anyone may use the Common Formats, only information created as patient safety work product by providers and federally listed PSOs working under the Patient Safety Act can be covered by its privilege and confidentiality protections and submitted to the national Network of Patient Safety Databases (NPSD). The directory of federally listed PSOs is available at Listed PSOs | PSO (ahrq.gov).

AHRQ's other CFER focus on specific healthcare settings: hospitals, community pharmacies, and nursing homes.

The CFER-DS V1.0 is designed for use in any healthcare setting.

CFER-DS V1.0

Overview

CFER-DS V1.0 identifies the basic set of meaningful data elements about diagnostic safety events that can be used, aggregated, and analyzed for learning and improvement. Using this common frame of reference and standardized data elements makes shared learning possible at local, regional, and national levels. Users decide if and how to integrate collection of specific CFER data elements into their incident reporting systems and other existing work processes.

CFER-DS Definition of Diagnostic Safety Event

AHRQ defined the term "Diagnostic Safety Event" and other concepts to simplify and standardize how users envision and frame the diagnostic safety events they plan to describe using the CFER-DS. All terms defined for use in the CFER-DS appear with Capitalized First Letters in the CFER-DS Form and Event Description. The definitions, examples and other helpful information can be found in the CFER-DS Users' Guide and Glossary. Users will save time by becoming familiar with these terms, concepts, and definitions before attempting to implement the CFER-DS.

Table 1: Definition of Diagnostic Safety Event

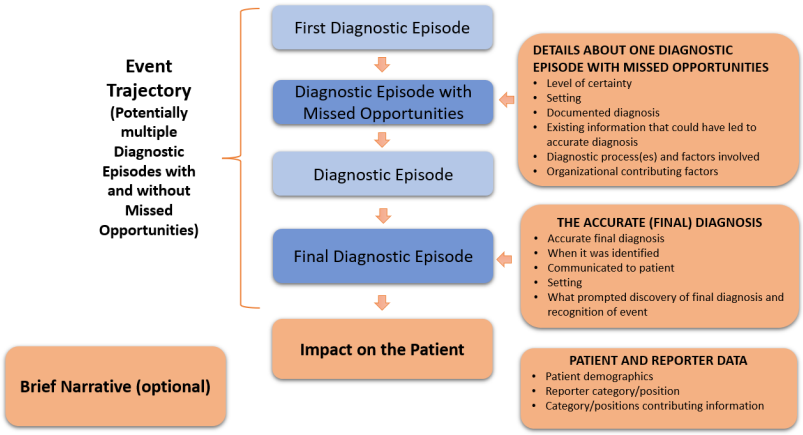
Diagnostic Safety Event	One or both of the following occurred, whether or not the patient was harmed: DELAYED, WRONG OR MISSED DIAGNOSIS: There were one or more missed opportunities to pursue or identify an accurate and timely diagnosis (or other explanation) of the patient's health problem(s) based on the information that existed at the time. DIAGNOSIS NOT COMMUNICATED TO PATIENT: An accurate diagnosis (or other explanation) of the patient's health problem(s) was available, but it was not communicated to the patient (includes patient's representative or family as applicable)

This educational brief was prepared under Contract No. 75Q80121C00004 for the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

Conceptual Model of CFER-DS Contents

Conceptually, the CFER-DS data elements are organized into five main sections that together describe a single Diagnostic Safety Event. In terms of implementation, however, data collection should be organized in any way that minimizes burden and fits as seamlessly as possible with existing work processes and systems.

Figure 1: CFER-DS Conceptual Model – Diagnostic Safety Event



Coming Fall 2022: Ways to Submit CFER-DS V1.0 Data for the NPSD

The concepts in the CFER Event Description are converted to data elements and answer values for all of the submission methods described below. The technical specifications for CFER-DS V1.0, to be released later this year, will indicate which data elements should be completed for a given diagnostic safety event. All data intended for transmission to the NPSD must adhere to the instructions and logic provided in the technical specifications in order for them to be accepted by the PSOPPC.

Single Report Data Submission (SRDS)

SRDS displays the data elements and answer values for each CFER in a simple question and answer format. This tool enables PSOs to submit data from a single CFER event report directly into a secure section of the PSOPPC website for processing and transmission to the NPSD. In order to access SRDS, PSOs must have a valid Data Use Agreement with the PSOPPC and a Level 3 user account on the PSOPPC website. Information and additional resources on the SRDS tool are available on the PSOPPC website.

CDA XML Report Submission

Clinical Document Architecture Extensible Markup Language (CDA XML) accepts patient safety data in XML formats that conform to the Health Level Seven (HL7) Clinical Document Architecture, Release 2.0 (CDA R2) standards. CDA XML is recommended for large volume data submissions to the PSOPPC. For CFER-DS V1.0, AHRQ is developing documents that will provide the information and guidance necessary for PSOs to generate a CDA XML report.

Alternate Data Submission

The Alternate Data Submission file format enables PSOs and vendors to submit patient safety data in basic XML or DSV format. Alternative data submission is also recommended for large volume data submissions to the PSOPPC.

The documents listed below will provide detailed technical specifications for CFER-DS V1.0:

- Data Dictionary – Describes the metadata associated with each CFER-DS V1.0 data element and answer value and provides general reporting guidance.
- Flow Chart – Outlines the appropriate logic for reporting diagnostic safety events using CFER-DS V1.0.
- Resources Workbook – Provides information on all CFER-DS V1.0 data elements and answer values, and specifies requirements for the successful submission of event reports.
- CDA XML Sample – Provides an example of the required CDA XML file format using a fictitious event scenario.

Technical Assistance

PSOs may contact the PSOPPC Help Desk for technical assistance via email at support@psoppc.org, via phone at (866) 571-7712, Mon-Fri, 9am – 5:30pm, ET, or on the Contact Us page on the PSOPPC website.

This educational brief was prepared under Contract No. 75Q80121C00004 for the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.