AHRQ Common Formats Supplemental Details – June 2021

The Agency for Healthcare Research and Quality (AHRQ) coordinates the development of common definitions and reporting formats (Common Formats) for reporting and analysis of health care quality and patient safety data. This activity is authorized by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act).

The Patient Safety Act and Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) establish a framework by which health care providers may voluntarily report information to Patient Safety Organizations (PSOs) on a privileged and confidential basis for the aggregation and analysis of patient safety events. The Patient Safety Act (at 42 U.S.C. 299b-24(b)(1)(F)) requires PSOs to collect information from providers in a standardized manner that permits valid comparisons of similar cases among similar providers, to the extent practical and appropriate. As explained in the Patient Safety Rule (at 42 CFR 3.102(b)(2)(iii)(A)(1)), one option for a PSO to satisfy this requirement is by certifying that it is using the Secretary's published guidance for Common Formats and definitions in its collection of information from providers. PSOs may also contribute data in the Common Formats to the Network of Patient Safety Databases, an interactive, evidence-based management resource for providers, PSOs, and other entities. The Common Formats allow "apples to apples" comparisons that support aggregation of data across organizations and accelerated learning among those who use them.

Information on the AHRQ Common Formats is available on the AHRQ PSO website at www.pso.ahrq.gov as well as the PSO Privacy Protection Center website at https://www.psoppc.org/.

Scope of the Common Formats

The scope of Common Formats applies to all patient safety concerns including: incidents – patient safety events that reached the patient, whether or not there was harm; near misses or close calls – patient safety events that did not reach the patient; and unsafe conditions – circumstances that increase the probability of a patient safety event.

AHRQ Common Formats include:

- Event Descriptions
- Forms and sample reports (only available for some Common Formats and versions)
- A Users Guide
- CDA XML File Samples
- A Data Dictionary which defines the data elements
- A Clinical Document Architecture Implementation Guide, which shows how to enable electronic transmission of the Common Formats data
- The Validation Rules and Errors Guide; Common Format Flow Charts; and specifications for processing, linking and reporting on events
- A Metadata registry with data element attributes and technical specifications for use by developers.

The formats include data elements that are structured and narrative:

> *Structured data* elements permit sorting of patient safety incidents and near misses for event analysis, as well as for pattern and trending analysis at all levels of the healthcare system. Structured data encompasses important descriptors, known risk factors, and the use of established risk reduction

methods to permit efficient analysis of incidents and patterns of patient safety events. Structured data can be aggregated within and across provider organizations, as well as for national reports.

Narrative data elements cannot be aggregated but provide the necessary details about an individual event or condition needed to better understand patient safety concerns at the local level. The narrative information may also assist with how the provider and/or PSO can act to reduce risk to patients.

The Common Formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/recording system. They are intended to facilitate the collection and organization of a basic set of meaningful data about patient safety concerns that can be used, aggregated and analyzed for learning and improvement. Having a common frame of reference and standardized data elements is what makes shared learning possible at local, regional and national levels. Users decide if and how to integrate collection of specific data elements into their incident reporting systems and other existing work processes.

AHRQ Common Formats Development

In anticipation of the need for Common Formats, AHRQ began its development by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provides an evidence base that informed construction of the Common Formats. The inventory includes many systems from the private sector, including academic settings, hospital systems, and international reporting systems (e.g., from the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems are included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Beginning in February 2005, AHRQ convened the Federal Patient Safety Work Group (PSWG) as needed to assist AHRQ with assuring consistency with definitions and formats used by other Federal agencies. The PSWG includes offices and agencies within HHS - Office of the Assistant Secretary for Health (OASH), CDC, Centers for Medicare and Medicaid Services, FDA, Health Resources and Services Administration, Indian Health Service, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration - as well as the DoD and VA.

To solicit comments from the public in the development of the Common Formats, a Notice of Availability to comment on the draft Common Formats is published in the Federal Register, and the draft is posted on the National Quality Form (NQF) Patient Safety Data website. The NQF website contains a tool that any member of the public can use to submit comments. After the initial comment period, the NQF convenes a meeting of an expert panel to review the public comments received and provide feedback. These meetings are announced on the same NQF website and are open to the public. Based upon the expert panel's feedback, AHRQ revises and refines the Common Formats.

AHRQ Common Formats Releases

Currently, AHRQ has active for reporting Common Formats for three settings of care - hospitals, community pharmacies and nursing homes.

Common Formats for Hospitals

There are currently two types of Hospital Common Formats: Hospital Common Formats for Event Reporting and Hospital Common Formats for Surveillance. After completing a review of the existing patient safety

reporting systems from a variety of health care organizations, AHRQ developed, piloted, drafted, and released Version 0.1 Beta of the Common Formats for Event Reporting – Hospital (CFER-H) in August 2008.

AHRQ further collaborated with NQF to solicit feedback on Version 0.1 Beta from private sector organizations and individuals. Based on the NQF's feedback, AHRQ in conjunction with PSWG further revised the CFER-H and released Version 1.0 in September 2009.

The review process was repeated to refine the CFER-H and incorporate public comments on Version 1.0, prior to finalizing the technical specifications for electronic implementation. Those modified formats for acute care hospitals were made available as –CFER-H Version 1.1 in March of 2010 and included the event-specific modules of Blood or Blood Product; Device or Medical/Surgical Supply; Fall; Healthcare-associated Infection (HAI), Medication or Other Substance; Perinatal; Pressure Ulcer; and Surgery or Anesthesia. This version was retired with the release of Version 1.2.

In April 2012, AHRQ rolled out Common Formats for Event Reporting - Hospital Version 1.2, which featured the new event-specific module Venous Thromboembolism (VTE) and revised the Device or Medical/Surgical Supply module to capture patient safety concerns associated with Health Information Technology (HIT) devices. These formats include the event descriptions, sample reports, and forms for both generic and event-specific categories. The Generic Hospital Common Formats forms include the Healthcare Event Reporting Form (HERF), Patient Information Form (PIF), and Summary of Initial Report (SIR), and specify information that is to be collected pertaining to all patient safety concerns.

The event-specific categories for CFER-H Version 1.2, allow the collection of structured information for the following patient safety concerns: Blood or Blood Product; Device or Medical/Surgical Supply, including HIT; Fall; Healthcare-associated Infection (HAI); Medication or Other Substance; Perinatal; Pressure Ulcer; Surgery or Anesthesia; and VTE.

Common Formats for Event Reporting - Hospital Version 2.0 constitutes a major release of the AHRQ Common Formats. Version 2.0 incorporates new and modified content and technical specifications revised since the release of Hospital Version 1.2 in April 2012. Version 2.0 represents an overall decrease in scale from Version 1.2 to reduce reporting burden.

Version 2.0 consolidates the Healthcare Event Reporting Form (HERF), Patient Information Form (PIF), and Summary of Initial Report (SIR) into one module, called the Generic module. This version also eliminates paper forms to encourage electronic reporting of patient safety concerns, and designates a set of Core content required for event reporting, by providers to PSOs and by PSOs to the PSOPPC for national aggregation and analysis.

In February 2014, AHRQ released Common Formats for Surveillance – Hospital (CFS-H) Version - 0.1 Beta, which also includes both generic and event-specific categories. The event-specific categories for patient safety surveillance included in the Beta version are Blood or Blood Product; Delivery-Maternal; Delivery-Neonatal; Device or Medical/Surgical Supply, including HIT; Fall; Medication; Pressure Ulcer; Readmission; Surgery or Anesthesia; VTE, and Other Outcomes of Interest. –CFS-H are designed for use in retrospective review of medical records to identify whether certain patient safety events occurred. The CFS-H is designed to provide information that is complementary to that derived from event reporting systems. These formats facilitate improved detection of events and calculation of adverse event rates in populations reviewed that will facilitate collection of comparable performance data over time and across populations of patients.

In November 2019, AHRQ released Common Formats for Surveillance - Hospital Version 0.3 Beta (CFS-H V0.3 Beta), which added the Hospital Acquired Condition (HAI)-Other along with the existing HAIs. An HAI-Other event is an infection other than those HAIs identified in the specific HAI Event Descriptions (EDs).

Common Formats for Nursing Homes

AHRQ released the Common Formats - Nursing Home Version 0.1 Beta in March 2011, including event descriptions, sample reports, and forms for generic and event-specific categories. The generic categories of the Common Formats - Nursing Home include the HERF, PIF, and SIR, which pertain to all patient safety concerns. The event-specific categories for the Nursing Home Common Formats are the Device or Supply, including HIT; Fall; HAI; Pressure Ulcer; and Medication or Other Substance modules.

Based on the feedback received through public comments and consultation with various stakeholders, AHRQ released Common Formats for Event Reporting - Nursing Home Version 1.0 (CFER-NH V1.0) in August 2019. These formats allow Patient Safety Organizations (PSOs) or vendors to submit patient safety concerns to the PSOPPC and to the Network of Patient Safety Databases (NPSD).

Common Formats for Community Pharmacies

AHRQ released the Common Formats - Retail Pharmacy Version 0.1 Beta in October 2015. AHRQ worked with the NQF based on the public review and comment received, and developed and released the Common Formats - Community Pharmacy Version 1.0 in December 2016. The Community Pharmacy Version 1.0 module is designed for use in the community pharmacy environment to gain enhanced understanding about the circumstances surrounding patient safety data in the community pharmacy setting. This module is self-contained, covering everything necessary to report patient safety data in the Community Pharmacy event-specific category.

Next Steps

As part of the agency's efforts to improve diagnostic safety and quality in healthcare, AHRQ is in the process of developing Common Formats for Event Reporting - Diagnostic Safety (CFER-DS). The CFER-DS is intended to help health care providers identify and report missed opportunities in the diagnostic process in a standardized manner across healthcare settings and specialties. Widespread use of the CFER-DS will make it possible to collect, aggregate and analyze diagnostic safety-related information from healthcare providers across the country, which in turn can accelerate learning in this vital area of patient safety. The PSWG was convened in January 2021 to review a draft of the CFER-DS. CFER-DS version 0.1 was posted on the NQF website for public comment, and a notice of availability was published in the Federal Register on June 1, 2021. The public comments will be reviewed by an expert panel with the assistance of the NQF. The initial version of the CFER-DS will be released upon completion of the development and review process.