

## **AHRQ Common Formats Supplemental Details**

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other healthcare providers may assemble information regarding patient safety events and quality of care. 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, 42 CFR 3.102(b)(1)(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 health care providers.

### Scope of the Common Formats

The term Common Formats refers to the common definitions and reporting formats, specified by AHRQ, that allow healthcare providers to collect and submit standardized information regarding patient safety events. 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.

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; rather the formats are intended to enhance the ability of healthcare providers to report information that is standardized both clinically and electronically.

### Common Formats Development

In anticipation of the need for Common Formats, AHRQ began their 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).

Since February 2005, AHRQ has convened the Patient Safety Work Group (PSWG) to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS—CDC, Centers for Medicare and Medicaid Services, FDA, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration—as well as the DoD and VA. The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues. To the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, framework, and definitions for patient safety.

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### Common Formats Releases & Next Steps

In August 2008, AHRQ and the PSWG developed, piloted, drafted, and released Version 0.1 Beta of the Common Formats for acute care hospitals. To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the National Quality Forum (NQF), a non-profit organization focused on health care quality, to solicit comments and advice to guide the further refinement of the Common Formats. The NQF then convenes an expert panel to review the comments received and provide feedback. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, revises and refines the Common Formats.

The review process was repeated to further refine the Common Formats and to incorporate any public comments on Version 1.0 prior to finalization of the technical specifications for electronic implementation. These modified formats for acute care hospitals were made available as Version 1.1 in March 2010.

In conjunction with the Food and Drug Administration (FDA), the Office of the National Coordinator for Health Information Technology (ONC), and the full PSWG, AHRQ revised the device event-specific Common Format (available in Version 1.1) to include patient safety events related to Health Information Technology (HIT). This Common Format, *Device or Medical/Surgical Supply including HIT Device (Version 1.1a)*, was released in October 2010.

AHRQ and the PSWG released Common Formats for skilled nursing facilities in March 2011, and in November 2011, an additional module (Beta Version) for venous thromboembolism (VTE) was incorporated that includes both deep vein thrombosis (DVT) and pulmonary embolism (PE). In April 2012, AHRQ and the PSWG developed *Common Formats—Hospital Version 1.2*, which featured new content to incorporate the event-specific formats VTE and Device/HIT. In July 2012, *Common Format—Readmissions Version 0.1 Beta* was released to allow hospitals to aggregate data and analyze readmission attributes.

In January 2014, AHRQ released *Common Formats for Surveillance—Hospital* for public review and comment. These formats will facilitate improved detection of events and calculation of adverse event rates in populations reviewed. The *Common Formats for Surveillance – Hospital* - includes modules entitled Generic Adverse Event Information, Blood or Blood Product, Delivery-Maternal, Delivery-Neonatal, Device or Medical/Surgical Supply Including Health Information Technology (HIT), Fall, Medications, Pressure Ulcer, Readmissions, Surgery or Anesthesia, Venous Thromboembolism, and Other Outcomes of Interest.

Currently, the Common Formats are limited to patient safety reporting in two settings of care—acute care hospitals and skilled nursing facilities. Future versions of the Common Formats will be developed for ambulatory settings, such as ambulatory surgery centers and physician and practitioner offices.