Users' Guide and Glossary

AHRQ Common Formats for Event Reporting – Diagnostic Safety Version 1.0

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1. Overview of the AHRQ Common Formats

1.1 General Overview

The Agency for Healthcare Research and Quality (AHRQ) Common Formats are sets of standardized definitions and formats that make it possible to collect, aggregate, and analyze uniformly structured information about patient safety for local, regional, and national learning. They have been developed for voluntary use by healthcare providers that choose to work with patient safety organizations (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. In addition to benefiting from the Federal protections and PSO services, providers who use the Common Formats in their work with a PSO under the Patient Safety Act may contribute data to the national learning system for patient safety improvement, the Network of Patient Safety Databases (NPSD). The NPSD may only accept data that have been non-identified as to patients, providers, reporters and related entities and individuals in a manner consistent with section 3.212 of the Patient Safety and Quality Improvement Rule (42 CFR § 3.212).

AHRQ has developed Common Formats for Event Reporting (CFER) for several healthcare settings and event types. Generally, the CFER apply to patient safety concerns, which may include incidents and near misses (collectively referred to as patient safety events) and unsafe conditions:

- **Incidents** – patient safety events that reached the patient, whether or not the patient was harmed
- **Near misses (or close calls)** – patient safety events that did not reach the patient
- **Unsafe conditions** – any circumstance that increases the probability of a patient safety event

AHRQ has also developed Common Formats for Surveillance (CF-S) and continues to work on developing new Common Formats. The current versions of all of the Common Formats can be found at the PSO Privacy Protection Center (PSOPPC) website.

1.2 The Development Process

AHRQ refines existing Common Formats and considers new types for development on an ongoing basis. The first step after development of a new or updated Common Formats is review by the Federal Patient Safety Workgroup (PSWG) to assure consistency with definitions and formats used by other Federal agencies. The PSWG includes representatives from several agencies within the Department of Health and Human Services (HHS) and from patient safety programs in the Department of Defense and Department of Veterans Affairs. After addressing recommendations made by the PSWG, AHRQ seeks input from the public. 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 Forum (NQF) Common Formats for 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 the NQF Common Formats Expert Panel to review comments submitted by the public. These meetings are announced on the same NQF website and are open to the public. The NQF Expert Panel reviews the comments and makes recommendations to AHRQ.

AHRQ then finalizes the Common Formats and releases it through the PSOPPC website. Final Common Formats are released with a complete set of technical specifications that provide direction to software developers for electronic implementation.

The final Common Formats versions are also posted on the NQF website, where public comment can be submitted on an ongoing basis. The comments are periodically reviewed and considered for future updates.

When appropriate, AHRQ may implement minor updates to existing versions of the Common Formats to further clarify or bolster the information specified for reporting.

1.3 Overview of CFER Contents

All AHRQ CFER include technical specifications that facilitate local implementation and electronic transfer of data to the PSOPPC, which ensures the data are non-identifiable before transmission to the NPSD. The technical specifications are available for download on the PSOPPC website. They promote standardization by ensuring that data collected by providers, PSOs, and other entities are clinically and electronically comparable. The technical specifications provide direction to software developers, so the AHRQ CFER can be implemented electronically, and direction to PSOs, so the data reported using these CFER can be submitted electronically to the PSOPPC for non-identification and transmission to the NPSD.

The technical specifications consist of the following:

- **Data Dictionary** – The Data Dictionary defines the data elements and their attributes (data element name, data element ID, answer values, answer codes, Health Level Seven International [HL7] data type, guide for use, etc.).
- **Implementation Guide** – The Implementation Guide provides the Clinical Document Architecture Extensible Markup Language (CDA XML) file specifications to transmit AHRQ Common Formats Patient Safety Reports to the PSOPPC.
- **Resources Workbook** – The Resources Workbook provides information about the data elements and their associated answer values (where applicable) that will assist with the development of a CDA XML file. It also contains the validation rules that will be applied to the data elements and the associated answer values submitted to the PSOPPC and the CDC Location Codes that are acceptable for PSOPPC submissions.
- **Common Formats Flow Charts** – The Common Formats Flow Charts provide the data elements and associated answer values (where applicable) recommended to be captured based on the report type and event category associated with the AHRQ Common Formats Patient Safety Report. The various paths of the data elements identify the valid data elements to be included within a AHRQ Common Formats Patient Safety Report.
- **Common Formats CDA XML File Samples** – The Common Formats CDA XML File Samples provide sample patient safety concerns scenarios and the associated CDA XML file output. The sample CDA XML file contains all data elements necessary for a complete report and conforms to the AHRQ Common Formats Technical Specifications.

1.4 Additional Considerations Applicable to All CFER

Privacy, Security, Confidentiality, and Privilege Considerations

Use of the AHRQ CFER, alone, does not provide any privilege or confidentiality protections.

Providers working with federally listed PSOs under the Patient Safety Act using the CFER to create confidential and privileged patient safety work product must meet all applicable requirements in the Patient Safety Rule and the HIPAA Privacy and Security Rules.

Privilege and/or confidentiality protections may or may not be available to providers not working with a federally listed PSO. Different Federal, State, and local laws create confidentiality and privilege protections, and each has its own specific requirements. Before beginning any patient safety and quality improvement activity, consult with the appropriate point of contact in the organization to ensure implementation is designed consistent with applicable requirements pertaining to patient privacy, security, confidentiality, and/or privilege. For more information, see the AHRQ Fact Sheet: *Privacy, Security, Confidentiality, and Privilege Considerations for Patient Safety and Quality Improvement Activities*.

2. AHRQ Common Formats for Event Reporting – Diagnostic Safety

The AHRQ Common Formats for Event Reporting – Diagnostic Safety (CFER-DS) provide a standardized vocabulary and a set of structured data elements, some with contextual unstructured text, that can be used to report and analyze diagnostic safety events for the purpose of learning and improvement. Using the CFER-DS can advance efforts to improve the diagnostic process and better support diagnostic teams.

2.1 Using the CFER-DS

The CFER-DS can be used as part of diagnostic safety and quality improvement activities in any healthcare setting. It can yield data for aggregate analysis but is also potentially useful to structure analysis of individual cases. It can form the basis for patient safety and quality improvement activities undertaken by individual clinicians and clinicians in training, service lines and clinical departments in hospitals, medical practices and other ambulatory care settings, and across different healthcare facilities and health systems.

The CFER-DS is not designed to be used intact for frontline incident reporting and is not intended to replace any current safety reporting system. It 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.

The CFER-DS includes:

1. The CFER-DS Form, which contains the complete set of data elements and corresponding answer values that can be used to describe a single Diagnostic Safety Event in a question-and-answer format.
2. The CFER-DS Event Description, which contains the complete set of data elements and substantive corresponding answer values in outline format. Note that the question numbers in the Form do not correspond to the item numbers used in the Event Description.

The sample "Preliminary Report about a Diagnostic Safety Event" is not part of the CFER-DS. As discussed in the next section, it is provided as a convenience for optional use or adaptation.

2.2 Identifying Diagnostic Safety Events

Diagnostic safety events and related information come to light in multiple ways within healthcare settings. Potential sources include:

- Patients, who reveal diagnostic safety events in their communications with clinicians, through event reporting systems specifically designed for patient use, experience of care surveys, complaints, and claims and litigation
- Quality and patient safety improvement activities, including but not limited to "trigger" methodologies[1]
- Risk management and medical peer review processes
- Incident reporting systems

Diagnostic safety events are often recognized by busy frontline clinicians and colleagues at the point of care. Enhancements to traditional incident reporting systems[2] and alternative approaches[3] consistent with patient safety principles have been successful in encouraging the identification and reporting of diagnostic safety events and engagement in related improvement activities. The optional "Preliminary Report about a Diagnostic Safety Event" included as a supporting resource to the CFER-DS could be adapted and integrated with existing internal event reporting and analysis workflows. This may facilitate capture of brief information by Clinicians at the time a Diagnostic Safety Event is recognized for later collection of the full set of CFER-DS data elements.

2.3 Understanding the CFER-DS Concepts and Definitions

AHRQ developed and defined the terms and concepts described in this Users' Guide to simplify

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[1] See, e.g., Murphy DR, Meyer AN, Sittig DF, Meeks DW, Thomas EJ, Singh H. Application of electronic trigger tools to identify targets for improving diagnostic safety. BMJ Qual Saf. 2019 Feb;28(2):151-159. doi: 10.1136/bmjqs-2018-008086. Epub 2018 Oct 5. PMID: 30291180; PMCID: PMC6365920.

[2] See, e.g., Gleason KT, Peterson S, Kasda E, Rusz D, Adler-Kirkley A, Wang Z, Newman-Toker DE. Capturing diagnostic errors in incident reporting systems: value of a specific "DX Tile" for diagnosis-related concerns. Diagnosis (Berl). 2018 Nov 27;5(4):249-251. doi: 10.1515/dx-2018-0049. PMID: 30205640.

[3] See, e.g., Okafor NG, Doshi PB, Miller SK, McCarthy JJ, Hoot NR, Darger BF, Benitez RC, Chathampally YG. Voluntary Medical Incident Reporting Tool to Improve Physician Reporting of Medical Errors in an Emergency Department. West J Emerg Med. 2015 Dec;16(7):1073-8. doi: 10.5811/westjem.2015.8.27390. Epub 2015 Dec 8. PMID: 26759657; PMCID: PMC4703179; and Marshall TL, Ipsaro AJ, Le M, Sump C, Darrell H, Mapes KG, Bick J, Ferris SA, Bolser BS, Simmons JM, Hagedorn PA, Brady PW. Increasing Physician Reporting of Diagnostic Learning Opportunities. Pediatrics. 2021 Jan;147(1):e20192400. doi: 10.1542/peds.2019-2400. Epub 2020 Dec 2. PMID: 33268395.

and standardize how users envision and frame the 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. Users will save time by becoming familiar with these terms, concepts, and definitions before attempting to implement the CFER-DS.

The Committee on Diagnostic Error in Health Care of the Institute of Medicine, now the National Academy of Medicine (NAM), defined diagnostic error as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient."[4] Singh and colleagues proposed the concept of "missed opportunities" in diagnosis.[5] AHRQ adapted and applied concepts from both in defining events that can be reported using the CFER-DS, as follows:

> **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)

As the conceptual model of the diagnostic process developed by the NAM illustrates, diagnosis of a health problem is a complex, evolving, cyclical and often iterative process.[6] Patients may engage with Treating Clinicians, other Clinicians, and other healthcare personnel in different and possibly unconnected healthcare settings for diagnosis of the same health problem over what may be long periods of time, which further complicates the analysis. As a result, it can be challenging for any one healthcare setting to capture data that paints a complete picture of a Diagnostic Safety Event.

> **Clinician:** A healthcare professional whose scope of practice includes medical diagnosis.
>
> **Treating Clinician:** A healthcare professional whose scope of practice includes medical diagnosis and who had a direct treatment relationship with the patient during a Diagnostic Episode, even if only briefly or as a member of a team with other Treating Clinicians. For example, a Clinician who ordered a diagnostic test for the patient (such as a primary care provider, attending physician, hospitalist team) is a Treating Clinician for purposes of the CFER-DS. The Clinician who determined and reported the results of the diagnostic test (such as a pathologist or radiologist) is a Clinician with an indirect treatment relationship with the patient and is not a Treating Clinician for purposes of the CFER-DS.

The CFER-DS is completed after a Diagnostic Safety Event has been recognized. For purposes of

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[4] Committee on Diagnostic Error in Health Care; Erin P. Balogh, Bryan T. Miller, and John R. Ball, Eds.; Board on Health Care Services, Institute of Medicine, The National Academies of Sciences, Engineering, and Medicine. Improving diagnosis in health care. Washington, DC: The National Academies Press, 2015, p. 85.
[5] Singh H. Editorial: Helping health care organizations to define diagnostic errors as missed opportunities in diagnosis. Jt Comm J Qual Patient Saf. 2014 Mar;40(3):99-101. doi: 10.1016/s1553-7250(14)40012-6. PMID: 24730204.
[6] Committee on Diagnostic Error in Health Care; Erin P. Balogh, Bryan T. Miller, and John R. Ball, Eds.; Board on Health Care Services, Institute of Medicine, The National Academies of Sciences, Engineering, and Medicine. Improving diagnosis in health care. Washington, DC: The National Academies Press, 2015, FIGURE 2-1 The committee's conceptualization of the diagnostic process, p. 32.

completing the CFER-DS, users are asked to begin by considering how much information is available to them about the entire Event Trajectory.

The **Event Trajectory**:

- Began the first time the patient received care from a Treating Clinician in any setting or location that could identify or lead to identification of the diagnosis or health problem that is the subject of the Diagnostic Safety Event; and
- Ended when the accurate (final) diagnosis was pursued or identified in a subsequent Diagnostic Episode in the Event Trajectory for the Diagnostic Safety Event.

Diagnostic Episode: A Diagnostic Episode is a distinct point in time or period of time during the Event Trajectory of the Diagnostic Safety Event when some explanation for the patient's health problem had been established by one or more Treating Clinicians. The explanation of the health problem might have been a definitive diagnosis or diagnoses; a differential, working diagnosis or set of working diagnoses; acknowledgment that a diagnosis was uncertain; or there may have been no clear documentation regarding a diagnosis. The term is neutral as to the accuracy of the explanation; it may have been accurate or inaccurate, reasonable, or unreasonable, depending on the circumstances at the time. It is also neutral as to the nature, extent and quality of the diagnostic assessment underlying the explanation of the health problem that was established during the particular Diagnostic Episode.

Diagnostic Episodes can happen in various ways in different settings, so the definition is flexible and can be applied by the user of the CFER-DS to fit any situation; examples are provided in Section 2.6 of this Users' Guide.

For purposes of the CFER-DS, there will always be at least two Diagnostic Episodes in the Event Trajectory for every Diagnostic Safety Event – the one that began the Event Trajectory and the one that ended it. At least one of the Diagnostic Episodes in the Event Trajectory will be a Diagnostic Episode with Missed Opportunities.

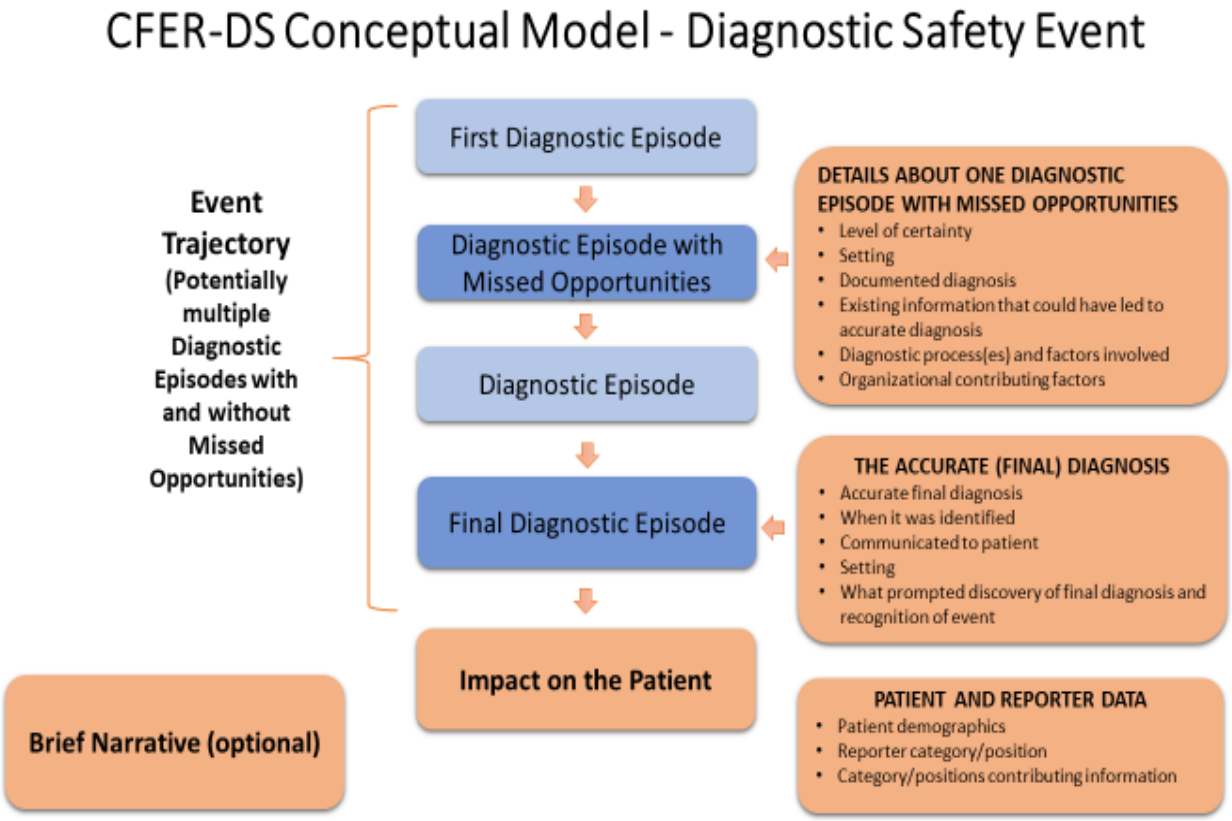
Diagnostic Episode with Missed Opportunities: Based on the information that existed at the time of the Diagnostic Episode, something different could have been done to pursue or make and communicate the accurate (final) diagnosis earlier. Missed Opportunities usually arise from an interplay of factors related to the patient, Clinicians, care team, local circumstances and/or the surrounding healthcare system and may occur due to factors outside the immediate control of Clinicians.

There are often more than two Diagnostic Episodes in an Event Trajectory, and they may have taken place in different healthcare settings and locations. There will always be at least one Diagnostic Episode with Missed Opportunities before the (accurate) final diagnosis is identified and the Event Trajectory ends. There might be more than one, but not necessarily.

Users of the CFER-DS will typically be collecting the CFER-DS data elements sometime after the last Diagnostic Episode in the Event Trajectory, when identification or pursuit of the accurate (final) diagnosis may have prompted discovery of the Diagnostic Safety Event. CFER-DS users will have information about at least one previous Diagnostic Episode with Missed Opportunities, enough to recognize that there has been a Diagnostic Safety Event. However, users may not have information about all of the Diagnostic Episodes in the Event Trajectory. Users should complete the CFER-DS based on the information available to them.

2.4 Overview of the CFER-DS Form

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.



CFER-DS Form Sections	Overview of Data Elements in this Section
Form Section 1.0: The Accurate (Final) Diagnosis (seven primary data elements)	Data describing the accurate (final) diagnosis and some general information about previous Diagnostic Episodes in the Event Trajectory.
Form Section 2.0: Details about One Diagnostic Episode with Missed Opportunities (eight primary data elements, options for multiple subsidiary data elements)	Data describing **ONE** Diagnostic Episode with Missed Opportunities. **NOTE: If more than one Diagnostic Episode with Missed Opportunities occurred during the Event Trajectory, users may:** • Collect the section 2.0 data elements only once, describing the one Diagnostic Opportunity with Missed Opportunities the user considers to be the one most important for learning: **OR** • Collect a separate, additional set of the section 2.0 data elements for each Diagnostic Episode with Missed Opportunities the user wishes to include in the event report.
3.0 Impact of the Diagnostic Safety Event on the Patient (three data elements)	Data describing how the diagnostic safety event – not the underlying disease itself – affected the patient.
4.0 Patient and Reporter Data (nine data elements)	Data describing patient demographics and the position type of the staff that contributed information used in completing the CFER-DS report.
5.0 Brief Narrative	An optional narrative about the event.

2.5 Preparing to Implement the CFER-DS

Understanding the CFER-DS-specific terms, concepts, and definitions in this Guide prior to implementation is essential. Information used to address the various data elements in the CFER-DS should be based on factual information obtained from appropriate sources. Clinical judgment by a healthcare professional whose scope of practice includes medical diagnosis will generally be needed when considering certain data elements in Form sections 2.0 and 3.0. As with any event type, involving individuals with safety science perspectives and expertise can improve data collection and analysis of Diagnostic Safety Events.

As noted by the NAM Committee[7], diagnosis is a collaborative process involving multiple health care professionals interacting with the patient and the patient's family. The patient may be the best source of certain information regarding a Diagnostic Safety Event and is often the only participant present for every Diagnostic Episode throughout the Event Trajectory.

The NAM Committee also noted that learning may be enhanced by taking advantage of

[7] Committee on Diagnostic Error in Health Care; Erin P. Balogh, Bryan T. Miller, and John R. Ball, Eds.; Board on Health Care Services, Institute of Medicine, The National Academies of Sciences, Engineering, and Medicine. Improving diagnosis in health care. Washington, DC: The National Academies Press, 2015, p. 176.

opportunities to include patients and families in efforts to improve the diagnostic process. Healthcare professionals and organizations considering patient and family involvement in patient safety improvement work using the CFER must assess and respect the needs and preferences of patients and families as well as applicable legal requirements pertaining to privacy, confidentiality, and privilege protections for such work. Psychological safety within the context of the particular organization's safety culture is also a consideration in determining the right approach to achieving the ultimate goal: thorough data collection and candid analysis that will result in learning and diagnostic safety improvement for all patients.

The numbered subsections below explain how to apply the concepts and definitions in Section 2.3 above to a Diagnostic Safety Event.

1. Determine whether the event meets the CFER-DS definition of a Diagnostic Safety Event.

If it does not, stop here. A different CFER that more appropriately describes the event type may be available.

If the event does meet the definition of a Diagnostic Safety Event, it will be helpful to begin by thinking through the following:

a. Identify the beginning and end points of the Event Trajectory, to the extent known.
b. Determine how many of the Diagnostic Episodes that took place during the Event Trajectory are known.

Diagnostic Episodes can happen in various ways in different settings, so the definition is flexible and can be applied to fit the situation. A Diagnostic Episode can be a single office or virtual encounter with a Treating Clinician, but in settings that involve multiple individual encounters with various members of the care team, it might be more useful to think of a Diagnostic Episode as one (or more) points in time or periods of time during the Event Trajectory. For example:

- An emergency room (ER) visit could be a single Diagnostic Episode, or it might involve more than one. For example, there might be two different Diagnostic Episodes during the same ER visit if a different care team came on duty at change of shift and reached a new and different conclusion about the diagnosis.
- An entire inpatient stay where the diagnosis remained the same from admission through discharge could be one single Diagnostic Episode. However, during an inpatient admission for an evolving critical illness, there might be several different Diagnostic Episodes as the care teams reached different explanations for the health problem at different points in time over the course of the hospitalization.

2. Determine which Diagnostic Episode(s) during the Event Trajectory were Diagnostic Episode(s) with Missed Opportunities.

When reviewing a particular Diagnostic Episode to determine whether it meets the CFER-DS definition of a Diagnostic Episode with Missed Opportunities, focus only on what was knowable at the time. Resist biases that can affect the quality of the event analysis,[8] such as hindsight bias,

[8] Henriksen K, Kaplan H. Hindsight bias, outcome knowledge and adaptive learning. Qual Saf Health Care. 2003 Dec;12 Suppl 2(Suppl 2):ii46-50. doi: 10.1136/qhc.12.suppl_2.ii46. PMID: 14645895; PMCID: PMC1765779.

which causes those reviewing events after the fact to erroneously judge the outcome as more foreseeable and therefore more preventable than they would have appreciated in real time. With outcome bias, the more severe the outcome for the patient, the more likely it is that the decisions leading up to this outcome will later be incorrectly perceived by others as having involved Missed Opportunities.

For purposes of the CFER-DS, there will always be at least one Diagnostic Episode with Missed Opportunities before the (accurate) final diagnosis is identified and the Event Trajectory ends. All of the Diagnostic Episodes in the Event Trajectory might have been Diagnostic Episodes with Missed Opportunities, but not necessarily.

3. If there was more than one Diagnostic Episode with Missed Opportunities during the Event Trajectory, decide which one (or ones) you wish to include.

If more than one Diagnostic Episode with Missed Opportunities occurred during the Event Trajectory, you may:

- Collect the Form section 2.0 data elements only once, describing the one Diagnostic Opportunity with Missed Opportunities you consider most important for learning: **OR**
- Collect a separate, additional set of the Form section 2.0 data elements for each Diagnostic Episode with Missed Opportunities you wish to include in this event report.

If all care related to the Diagnostic Safety Event took place within the CFER-DS user's setting or system, the user will most likely have access to information about every Diagnostic Episode that took place during the entire Event Trajectory. If some of the Diagnostic Episodes took place in different healthcare settings or locations, users may have information about some or all of them based on history provided by the patient/family/other healthcare providers. Some users will not have any information about the patient's initial presentation or other Diagnostic Episodes that occurred prior to the one they recognized as having been a Diagnostic Episode with Missed Opportunities. Complete data collection for a CFER-DS event report to the best of your knowledge based on the information available to you.

The next section applies the CFER-DS concepts and definitions to hypothetical clinical examples.

2.6 Applying the CFER-DS Concepts and Definitions: Clinical Examples

Example 1: Hypothetical Diagnostic Safety Event involving delayed diagnosis of a spinal epidural abscess.

1st Diagnostic Episode in Event Trajectory

A 62-year-old man called his primary care provider's (PCP) office for an appointment after a week of experiencing unrelenting back pain. The scheduler told him there were no available appointments; the best she could do would be to squeeze him into the schedule the following week. The patient accepted this and arrived on time for his appointment on August 5, 2019. He was finally called into an exam room to be seen by the PCP after a 30-minute wait. He reported a now two-week history of persistent, dull, low back pain that did not radiate elsewhere. The patient's past medical history was notable for poorly controlled type II diabetes mellitus; his next routine

diabetic follow-up visit was scheduled for August 30, 2019. The patient denied unintentional weight loss, fever, or night sweats, history of recent infections, history of injection drug use, and history of recent epidural or spinal procedures. Vital signs were normal. There was mild bilateral paraspinal tenderness on palpation in the lumbar region, no signs of scoliosis or hyperkyphosis. As the patient's gait had appeared normal as he entered the exam room and the PCP's schedule was overbooked, examination of the patient's lower extremities was deferred to the upcoming routine appointment. Laboratory studies and imaging were not ordered. The patient was diagnosed with subacute low back pain (ICD-10-CM Diagnosis Code M54.5) and was prescribed 600 mg ibuprofen po q 8 hours as needed. The patient was also advised to apply heat to his lower back, avoid overexertion, keep his upcoming appointment, and to call the office if the pain increased or any other symptoms developed.

2nd Diagnostic Episode in Event Trajectory

The patient's low back pain was tolerable but increasing. He also had some mild nasal congestion, felt a bit feverish, and noticed that his left leg was starting to feel clumsy, so he went to the Emergency Department (ED) at the local hospital on August 11, 2019. He was assessed by a first-year resident who was finishing up a 24-hour shift. Vital signs were notable for the patient being febrile with a temperature of 100.7ºF but there were no signs of respiratory infection other than mild nasal congestion. On lumbar exam, the ED resident noted moderate tenderness when palpating in the region of the L5 vertebral body. On neurological exam, the ED resident identified mild sensory impairment in the left foot, which he attributed to peripheral neuropathy due to diabetes. The ED resident ordered a CBC, chemistry panel, and HbA1c. The patient's WBC was 11.73 K/µl; he had a normal chemistry panel, and a HbA1c of 10.1. The ED resident diagnosed the patient with subacute low back pain (ICD-10-CM Diagnosis Code M54.5) and acute nasopharyngitis (ICD-10-CM Diagnosis Code J00). He was prescribed 650 mg acetaminophen q 6 hours as needed for his back pain and cold and instructed to keep the upcoming appointment to follow up with his PCP. He was also instructed to call the PCP sooner if his fever did not resolve or his symptoms worsened in the interim.

At the time the ED resident was assessing the patient, the only attending physician on duty was busy with a critically ill patient. Given that the ED resident felt the diagnosis and management of the patient was straightforward, he discharged the patient and planned to present the case to the attending when they were both free.

3rd Diagnostic Episode in the Event Trajectory

Two days after being discharged from the ED, the patient's low back pain increased in severity, and he was noticing some numbness and possible weakness in his left lower extremity. He returned to the ED and the ED team decided he should be admitted immediately.

4th Diagnostic Episode in the Event Trajectory

The hospitalist on call admitted the patient to a med-surg unit and requested a neurology consult. She ordered an MRI with contrast, which revealed a liquid abscess surrounded by inflammatory tissue in the area of the L5 vertebral body. The neurologist confirmed the diagnosis of a spinal epidural abscess at L5 (ICD-10-CM Diagnosis code G06.1), communicated the diagnosis to the patient, and referred the patient to neurosurgery. The patient was started on IV antibiotics (15 mg/kg IV Vancomycin q 8 hours plus 2 g IV Ceftriaxone q 12 hours) and underwent spinal surgery the next morning to decompress and drain the abscess. The patient's low back pain and lower

extremity numbness and weakness began to subside post operatively and was gone completely after several weeks.

Patient demographics: White, not Hispanic or Latino. Sex assigned at birth: male. Sexual orientation: unknown Gender identity: unknown

The hospital Patient Safety Manager completed the CFER-DS. Information about the two Diagnostic Episodes with Missed Opportunities was obtained from the medical record, the hospitalist who admitted the patient, and the ED resident who saw the patient during his first ED visit.

Event Trajectory	Diagnostic Episodes	Was this a Diagnostic Episode with Missed Opportunities?
BEGINS	1st Diagnostic Episode: Visit with the primary care provider	Uncertain whether this meets the definition of Diagnostic Episode with Missed Opportunities – there is not enough information to determine whether information that could have led to pursuit of the accurate (final) diagnosis existed at the time.
	2nd Diagnostic Episode: First ED visit	Meets definition of Diagnostic Episode with Missed Opportunities – information that could have led to pursuit of accurate (final) diagnosis existed at the time but was not identified or pursued.
	3rd Diagnostic Episode: Second ED visit	Diagnostic Episode, no Missed Opportunities – information that could lead to accurate (final) diagnosis was identified and pursued.
ENDS	4th Diagnostic Episode: Hospital admission, evaluated by a hospitalist and consulting neurologist	Diagnostic Episode, no Missed Opportunities – information that could lead to accurate (final) diagnosis was identified, pursued, and patient received definitive diagnosis and treatment.

There were three Diagnostic Episodes in this Event Trajectory before the accurate (final) diagnosis was identified; at least one was a Diagnostic Episode with Missed Opportunities. CFER-DS users should collect the CFER-DS section 2.0 data elements once, describing the Diagnostic Episode with Missed Opportunities. CFER-DS users could also choose to collect the CFER-DS section 2.0 data elements to describe the first Diagnostic Episode in this Event Trajectory as one with Missed Opportunities. While there is not enough information to be certain that the first Diagnostic Episode in this example involved Missed Opportunities, it could be included as such if the CFER-DS user appropriately acknowledges the level of uncertainty as noted in Question 2.1 on the CFER-DS Form.

Example 2: Hypothetical Diagnostic Safety Event involving delayed diagnosis of lung cancer

1st Diagnostic Episode in Event Trajectory

A 42-year-old woman presented to the emergency department (ED) on February 17, 2018, after a minor, low-speed motor vehicle accident. She was wearing a seat belt with a chest restraint, but briefly hit the steering wheel upon impact. The patient did not think she was injured but was very upset about the accident and complained of discomfort in the upper chest and back, palpitations, and nausea. The patient reported no significant past medical history, no tobacco or other substance use, and exercised regularly. Blood pressure was 156/80; no bruising or tenderness were noted on physical examination of the chest; and an electrocardiogram, troponin, and comprehensive metabolic panel were normal. The ED clinician ordered a CT of the chest. The report issued by the radiology resident on duty noted no injuries or abnormalities. A final read of the CT scan would not be performed until the following morning, so the ED clinician also reviewed the images. The patient was feeling much better at this point. The ED clinician reassured the patient that there was no sign of injury or heart problems but forgot to mention that there would be a later, final read of the CT. The patient was instructed to return to the ED if symptoms recurred or if new concerning symptoms developed and to follow up with her primary care physician (PCP) within a week. The ED clinician who saw the patient would be leaving for vacation the next day. ED clerical staff generally tried to help with following up on test results that arrived after patients were discharged from the ED, but they were understaffed and there was no formal system in place for this.

2nd Diagnostic Episode in Event Trajectory

The patient saw her PCP about 1 month later, as that was the earliest follow-up appointment that fit her busy work schedule. The PCP's office and the hospital where the patient had been seen in the ED had different electronic medical record vendors, so the PCP did not have easy access to the records of the ED visit or the radiology report. The patient provided the PCP with a copy of her after-visit summary from the ED, which noted that a chest CT had been performed and was normal. The patient reported that she felt fine overall. She had an occasional non-productive cough, which she attributed to the dry air in her new office. The chest and back discomfort had almost entirely resolved. The patient's blood pressure was 120/76; no bruising or tenderness were noted on physical examination of the chest. The PCP advised the patient that there was no need to be seen again until it was time for her next routine exam unless she had any persistent or new symptoms.

3rd Diagnostic Episode in the Event Trajectory

The patient returned to the PCP's office for a routine visit in November 2018. She reported continuing occasional chest and back discomfort. Her cough was somewhat more frequent although not bothersome. She was feeling more fatigue than usual, which she attributed to working long hours. She was pleased that she had lost 5 pounds since her last visit without really trying. On physical exam, the PCP detected decreased breath sounds in the right upper chest. She ordered a chest x-ray and CBC and scheduled the patient for a follow-up visit in 2 weeks.

The only available appointment for the chest x-ray was 3 weeks later, so the patient was unable to

keep the 2-week follow-up appointment with the PCP. The radiologist found a right upper lobe mass on the chest x-ray. He reviewed the images and report from the February 2018 CT that had been done in the emergency department for comparison. He discovered that, in the “Findings” section, the final CT report had documented "a solitary, slightly irregular noncalcified, subsolid nodule in the right upper lobe of the lung measuring approximately 1.2 cm in diameter. Recommend repeat CT in 3 months.” It was not clear if a treating clinician in the ED had ever seen the final report. ED The radiologist contacted the PCP’s office immediately to report the chest x-ray findings and comparison and explain what had happened.

4th Diagnostic Episode in the Event Trajectory

The PCP called the patient immediately upon receipt of the x-ray report and comparison to the earlier CT. She informed her of what had happened and quickly arranged for appropriate referrals. The patient was ultimately diagnosed with primary lung adenocarcinoma involving the right upper lobe.

Patient race/ethnicity: Black, not Hispanic or Latino. Sex assigned at birth: female. Sexual orientation: unknown Gender identity: unknown

The PCP completed the CFER-DS using information she learned from the patient, the radiologist who read the x-ray she ordered, and from her office medical record.

Event Trajectory	Diagnostic Episodes	Was this a Diagnostic Episode with Missed Opportunities?
BEGINS	1st Diagnostic Episode: ED visit after motor vehicle accident	Meets definition of Diagnostic Episode with Missed Opportunities – information that could have led to pursuit of accurate (final) diagnosis existed at the time but was not identified or pursued.
	2nd Diagnostic Episode: Follow-up visit with PCP	Meets definition of Diagnostic Episode with Missed Opportunities – information that could have led to pursuit of accurate (final) diagnosis existed at the time but was not identified or pursued.
	3rd Diagnostic Episode: Routine PCP visit	Diagnostic Episode, no Missed Opportunities – information that could lead to accurate (final) diagnosis was identified and pursued.
ENDS	4th Diagnostic Episode: PCP call with patient	Diagnostic Episode, no Missed Opportunities – the accurate (final) diagnosis was preliminarily identified, and patient was referred for definitive diagnosis and treatment.

As with the previous example, there were three Diagnostic Episodes before the final Diagnostic Episode that concluded with determination of the accurate (final) diagnosis. In this case, two of the three were Diagnostic Episodes with Missed Opportunities. Users could choose to collect the CFER-DS section 2.0 data only once, describing the one Diagnostic Episode with Missed Opportunities they think has the most value for learning how to prevent such an event; or users could complete it twice, describing both of the Diagnostic Episodes with Missed Opportunities that occurred during this Event Trajectory.

2.7 Questions Specific to the CFER-DS

Form item 1.3: *Once the accurate (final) diagnosis was identified, was it communicated to the patient by a Treating Clinician?*

- QUESTION: Should immediate release of test results in the electronic health record's patient portal as required by the information blocking provisions of the 21st Century Cures Act alone be considered "…communicated to the patient by a Treating Clinician" for purposes of this data element?

  ANSWER: No. The communication must have been made by a Treating Clinician, i.e., a Clinician with a direct treatment relationship with the patient to select a "Yes" answer value.

Form item 2.6 (and subsidiary data elements): *Identify the specific diagnostic process(es) in a. through h. below that involved Missed Opportunities during this Diagnostic Episode.*

- QUESTION: If the Missed Opportunity during a particular diagnostic process, such as "History," involved a situation in which the patient did not share relevant information (e.g., the patient forgot to mention it, didn't understand it was relevant, had a reason to deliberately withhold it, etc.), which answer value applies?

  ANSWER: "Communication" is the appropriate answer value.

- QUESTION: If the patient's primary language differed from that of the Clinicians and we think Missed Opportunities during some of the diagnostic processes listed in Form question 2.6 were related to a language barrier, which answer value applies?

  ANSWER: The applicable answer value is "Communication assistance" found under "Access to Care Factors".

- QUESTION: If we think a knowledge deficit or cognitive bias on the Treating Clinician's part was related to a Missed Opportunity during one of the diagnostic processes listed in Form question 2.6, which answer value applies?

  ANSWER: Item 2.6 does not currently contain a data element specific to an individual's knowledge or cognitive bias. "Overall Diagnostic Assessment" (Form item 2.7) captures potentially related information.

  AHRQ appreciates the significance of knowledge and clinical reasoning to diagnostic safety and the challenge of how best to align them with a contemporary perspective on the

concept of human error.[9] Suggestions for data elements with reasonable validity and objectivity that would be useful for national learning about how to improve diagnostic safety are welcome at any time via the commenting tool at the National Quality Forum website, "Common Formats for Patient Safety Data."

It should be noted that an individual's actual knowledge and thought process at a point in time cannot accurately be determined by others and may be unclear to the individual, especially in retrospect. Attributions such as "knowledge deficit" are strongly susceptible to bias, and various cognitive processes and circumstances may be incorrectly perceived by others as a knowledge deficit. For example, an individual may have consciously considered the diagnosis but discounted it for reasons that seemed valid at the time; may have had knowledge of a particular diagnosis but was unable to recall it at the time; or may have experienced the phenomenon known as inattentional blindness[10].

[9] Read GJM, Shorrock S, Walker GH, Salmon PM. State of science: evolving perspectives on 'human error'. Ergonomics. 2021 Sep;64(9):1091-1114. doi: 10.1080/00140139.2021.1953615. Epub 2021 Aug 6. PMID: 34243698.

[10] See, e.g., Williams L, Carrigan A, Auffermann W, Mills M, Rich A, Elmore J, Drew T. The invisible breast cancer: Experience does not protect against inattentional blindness to clinically relevant findings in radiology. Psychon Bull Rev. 2021 Apr;28(2):503-511. doi: 10.3758/s13423-020-01826-4. Epub 2020 Nov 2. PMID: 33140228; PMCID: PMC8068567; and Jones A, Johnstone MJ. Inattentional blindness and failures to rescue the deteriorating patient in critical care, emergency and perioperative settings: Four case scenarios. Aust Crit Care. 2017 Jul;30(4):219-223. doi: 10.1016/j.aucc.2016.09.005. Epub 2016 Oct 5. PMID: 27720335.

A. Glossary

Glossary of terms used in the AHRQ Common Formats for Event Reporting – Diagnostic Safety

Word or Phrase	Definition
Clinician	A healthcare professional whose scope of practice includes medical diagnosis.
Diagnostic Episode	A Diagnostic Episode is a distinct point in time or period of time during the Event Trajectory of the Diagnostic Safety Event when some explanation for the patient's health problem had been established by one or more Treating Clinicians. The explanation of the health problem might have been a definitive diagnosis or diagnoses; a differential, working diagnosis or set of working diagnoses; acknowledgment that a diagnosis was uncertain; or there may have been no clear documentation regarding a diagnosis. The term is neutral as to the accuracy of the explanation; it may have been accurate or inaccurate, reasonable, or unreasonable, depending on the circumstances at the time. It is also neutral as to the nature, extent and quality of the diagnostic assessment underlying the explanation of the health problem that was established during the particular Diagnostic Episode.
Diagnostic Episode with Missed Opportunities	Based on the information that existed at the time of the Diagnostic Episode, something different could have been done to pursue or make and communicate the accurate (final) diagnosis earlier. Missed Opportunities usually arise from an interplay of factors related to the patient, clinicians, care team, local circumstances and/or the surrounding healthcare system and may occur due to factors outside the immediate control of clinicians.
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)
Event Trajectory	The Event Trajectory: • Began the first time the patient received care from a Treating Clinician in any setting or location that could identify or lead to identification of the health problem that is the subject of the Diagnostic Safety Event; and • Ended when the accurate (final) diagnosis was pursued or identified in a subsequent Diagnostic Episode in the Event Trajectory for the Diagnostic Safety Event.
Handover/Handoff	The process that occurs when one healthcare professional updates another on the status of one or more patients for the purpose of taking over their care.

Word or Phrase	Definition
Health Information Technology (HIT)	The application of information processing involving both computer hardware and software that deals with the storage, retrieval, sharing, and use of healthcare information, data, and knowledge for communication and decision making. (Brailer, D., & Thompson, T. (2004). Health IT strategic framework. Washington, DC: Department of Health and Human Services.) (https://www.healthit.gov/)
Treating Clinician	A healthcare professional whose scope of practice includes medical diagnosis and who had a direct treatment relationship with the patient during a Diagnostic Episode, even if only briefly or as a member of a team with other Treating Clinicians. For example, a Clinician who ordered a diagnostic test for the patient is a Treating Clinician for purposes of the CFER-DS. The Clinician who determined and reported the results of the diagnostic test is a Clinician with an indirect treatment relationship with the patient and is not a Treating Clinician for purposes of the CFER-DS.

B. Acronyms

Table 3. Acronyms used in the Users' Guide for AHRQ Common Formats for Event Reporting – Diagnostic Safety

Acronym	Expanded Phrase
AHRQ	Agency for Healthcare Research and Quality
CDA XML	Clinical Document Architecture Extensible Markup Language
CDC	Centers for Disease Control and Prevention
CFER	Common Formats for Event Reporting
HHS	U.S. Department of Health and Human Services
HL7	Health Level Seven
NAM	National Academy of Medicine
NHSN	National Healthcare Safety Network
NPSD	Network of Patient Safety Databases
NQF	National Quality Forum
PSWG	Patient Safety Work Group
PSO	Patient Safety Organization
PSOPPC	PSO Privacy Protection Center

C. CFER-DS References

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