SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

July 1, 2021
National Quality Forum Expert Panel on Common Formats
Washington, DC (via email)

Dear David Classen and Matt Grissinger,

The Society to Improve Diagnosis in Medicine (SIDM) commends AHRQ on the release of the Common Format for Event Reporting – Diagnostic Safety (CFER-DS) Version 0.1. Despite the complexity, uncertainty, and variability associated with diagnosis, the proposed CFER-DS represents a starting point for a broader discussion around the need for consistent approaches to diagnostic safety event reporting and the necessity to give voice to all relevant stakeholders' perspectives on approaches. The SIDM-led and convened *Coalition to Improve Diagnosis* includes a diverse set of members representing a collaboration of more than 60 leading healthcare organizations composed of patient and family groups, physician and nursing societies, hospitals and healthcare systems, hospital associations, quality and safety organizations, and federal partners. SIDM solicited feedback on the CFER-DS from Coalition members as well as non-Coalition member patient and family groups through stakeholder interviews, meetings, and e-mail exchanges. Their insights shaped the comments and observations that follow.

While the comments attached represent SIDM's formal comments to the proposed CFER-DS v0.1, Coalition members were given an opportunity to preview our submission and to indicate whether they agreed with our comments and would like to be identified as agreeing with our comments. Nineteen organizations documented their agreement to be identified in our letter and are named below.

Thank you for the opportunity to provide you with these comments.

Sincerely,

Paul L. Epner
CEO

ABIM Foundation	Arthritis Foundation	Michigan Health & Hospital Association	PRIDE Project	Washington Patient Safety Coalition
Advocate Aurora Health	Cleveland Clinic	Northwell Health	Sepsis Alliance	Washington State Hospital Association
Alliance for Academic Internal Medicine	Consumers Advancing Patient Safety	Ovarian Cancer Research Alliance	Society of Bedside Medicine	WomenHeart: The National Coalition for Women with Heart Disease
American Board of Medical Specialties	FH Foundation	Patient Safety Authority	The Leapfrog Group	

Overall

The CFER-DS is a comprehensive and structured approach to analyzing diagnostic safety events that can yield standardized data for improving diagnostic safety. A fundamental component of safe diagnosis are contributions from all members of the team including engaged and activated patient and family members. Currently patients and family members are not listed as potential contributors to the CFER-DS, despite being key "witnesses" to the diagnostic process with a longitudinal view across every single clinical encounter that no other healthcare stakeholder has. The patient perspective and "team" aspects of diagnosis are not well represented in the proposed CFER-DS.

Specifically, we recommend that the patient or family member be asked to review the content of a CFER-DS and have an opportunity to work with their health system to reach a consensus on the facts of the matter. Since this might not be practical in all cases, at a minimum we believe that a yes/no question should be added to the form that indicates whether the form was reviewed by the patient/family involved and whether they were given an opportunity to collaborate on its contents.

Disparities in diagnostic outcomes are a recognized issue and it would be beneficial if addressed in the CFER-DS. While still challenging to characterize and quantify, relevant demographics should be captured that could help uncover biases based on race, sex, age, or another socio-demographic factor and the form should explicitly ask for such information.

We have some concerns that the terms and definitions are incomplete or inappropriate. We have made some specific comments in those sections below but believe overall that the CFER-DS should not exacerbate language imprecision with new definitions, e.g., diagnostic error, or anachronistic concepts, e.g., a setting as a key determinant of the start of the trajectory.

CFER-DS Guide

Background and Purpose

- The phrase "better support clinicians" in the diagnostic process discounts patient's contributions to the diagnostic process and the team approach to diagnosis. Consider "better support the diagnostic team" in the diagnostic process.

Identifying Diagnostic Safety Events

- The optional CFER-DS "Preliminary Report about a Diagnostic Safety Event for Front Line Clinician Use" can be confused to suggest that there is an additional form. Since there is not an additional form, this statement should be deleted.

Understanding the CFER-DS Concepts and Definitions

- In the first paragraph it is stated, "All terms defined for use in the CFER-DS are capitalized." The terms "Diagnostic Safety Event," "Clinician," "Event Trajectory," "Diagnostic Episode," and "Diagnostic Episode with Missed Opportunities" are bolded, not capitalized, but are included the CFER-DS.

- Suggest editing the definition of Diagnostic Safety Event by amending “whether or not the patient was harmed” to “that could have or did result in patient harm.” The rephrasing better suggests the risk for harm.
- Defining Diagnostic Safety Events using the criteria "missed opportunities" is appropriate however, “Delayed, wrong or missed” should not be used as replacement of the National Academy of Medicine criteria of timely and accurate. The criteria "missed opportunities" makes the definition more operational versus theoretical, whereas “missed diagnosis” is theoretical since one cannot know that it is missed until it is identified and at that point it is delayed. There is no value added by reverting to older, more theoretical phrasing.
- The definition of “clinician” in this section, while accurate, seems to interject that it is only clinicians that contribute to the diagnostic process which conflicts with the notion of the team approach to diagnosis. Suggest adding a new definition for diagnostic team which could include patient and family.
- The event trajectory begins the “first time the patient presented (to any healthcare setting or location)” however “healthcare setting or location” may be confused not to include a patient’s home for a telehealth “visit” or home health care. It might also exclude non-skilled nursing homes or even EMS visits without transport. Recommend changing to the “first time the patient presents to a healthcare professional for purposes of evaluation regardless of the physical setting.”
- It would be beneficial to provide an example of a case where an incidental finding was made but not followed up since the patient presents to the healthcare provider for one health problem, but the subject of the Diagnostic Safety Event or Diagnostic Episode with Missed Opportunities was the incidental finding.
- Diagnostic episode is defined as a point in time “when some explanation had been established for the health problem,” but for purposes of safety event reporting, it should also include a specific time when a missed opportunity is recognized, e.g., missing test result.
- It might be helpful to “bookend” the possible times for the diagnostic trajectory or the diagnostic episode in the definition. While the form itself includes items like telemedicine, EMS (although limited to transport when 30% of EMS visits do not include transport), and autopsy, these options are late in the form completion process and the examples could be useful in the definitions to help frame the thinking needed to complete the form.
- The event trajectory ends when the accurate (final) diagnosis was pursued or identified, however for some patients’ conditions there is no accurate or final diagnosis and therefore would not have a complete event trajectory. For these patients there still can be diagnostic episodes with missed opportunities and should be considered Diagnostic Safety Events. We should also recognize that a final diagnosis can be superseded by a new final diagnosis. In addition, there are times when the clinician moves into treatment presumptively and if it works, they stop diagnostic activities. We suggest reframing that the event trajectory ends when the clinician stops searching for an explanation or, for purposes of initiating a safety event report, when a missed

opportunity is recognized regardless of the attainment of a final diagnosis, e.g., patient misidentification for test result.

Applying the CFER-DS Concepts and Definitions: Clinical Examples

- In Example 1's first diagnostic episode, recommend adding under the column "Was this a Diagnostic Episode with Missed Opportunities?" the following to ensure there is no question that there was no missed opportunity: No – "red flags" were addressed and ruled out, patient given instructions on when to reengage with the health system if the problem did not resolve.
- A more illustrative example might be to use the EMS as the first point of health contact.

CFER-DS Form

1.0 The Accurate Final Diagnosis

- 1.3 Accurate final diagnosis communicated to the patient – there should be some definition of what constitutes communication to the patient included here and in the Guide.
- 1.5 Time to accurate final diagnosis – the specifications for different time increments make sense when comparing situations of "failure to rescue" and diagnosis of rare conditions where minutes and years, respectively, are relevant. However, this kind of differentiation leads to added length and potentially diminishes usability. Suggest using "Approximate length of time from first Diagnostic Episode in Event Trajectory to accurate (final) diagnosis" from the Event Description.
- 1.6 Approximate number of diagnostic episodes – given the subjectivity associated with defining a diagnostic episode, aggregating the number of diagnostic episodes may have limited value.

2.0 Details about One Diagnostic Episode with Missed Opportunities

- 2.1 Certainty that there were missed opportunities – the concept of quantifying "uncertainty of diagnosis" is an area of interest in the field, but the terms used in this item characterize the certainty associated with the missed opportunity which starts to move into the spectrum of "blame" and accountability especially if "red flags" were clearly present and missed. If the underlying concept intended to be captured here is the "detectability" of missed opportunity which is adapted from FMEA risk priority number scoring (RPN = detectability x severity x occurrence) then the terminology should be clarified to reflect this concept.
- 2.3 What explanation for the health problem (if any) was documented – we appreciate what you are trying to get at here (i.e., capturing what was the wrong initial diagnosis; was there a differential diagnosis and did it include the correct final diagnosis) but language here is not as direct as it could be, and suspect end users will find it hard to fill in.
- 2.5 If a key piece of information that existed at the time – it may be simpler to ask was any information overlooked and/or given insufficient consideration in any of these check box areas. Perhaps 2 different concepts are being confused here. Overlooked

items (i.e., an abnormal lab test that was missed). The other being whether we think it is "fair" to penalize a clinician for something that may not have existed (i.e., they were afebrile when initially seen) or could be discovered (a palpable mass before it had enlarged to a point it could be more easily detected).

- 2.4 Plan for follow-up and/or further work-up – the terms "plan for follow-up and/or further work-up" are vague. One may consider unspecific instructions such as "contact your primary care physician if your symptoms persist" or follow-up on testing (did the patient get the test, were the results reviewed) as an adequate follow-up plan.
- 2.6.a. Patient access and communication – even though this is adapted from the original terms of the Diagnosis Error Evaluation and Research (DEER) Taxonomy "Access/Presentation: Failure/denied care access" it is not clear if 2.6.a. means clinician access to the patient or as some of the additional details suggest patients' lack of access to care. We know that patients' lack of access to specialty care due to system-related factors such as geography, scheduling, etc. can contribute to a delayed diagnosis. The additional detail items 2.6.1.b. and 2.6.1.c. are patient-related factors but are phrased in a way that seems to shift accountability to the patient. Personal circumstances such as not being able to take off work for a specialist appointment or unable to afford transportation or testing are broader system factors not patient factors. Suggest item 2.6.1.b. be phrased "Patient unable to access care (e.g., due to personal circumstances, transportation, financial, access to information technology, lack of coverage)" and item 2.6.1.c. "Unable to reach patient after extensive effort to contact." It is also unclear if failure to communicate test results or follow up (i.e., failure to "close the loop") would be characterized here or in sections 2.6.4, 2.6.5, or 2.6.6.
- 2.6.1 Additional details known – some patients have limited English proficiency (LEP) and this can impact communication and outcomes. The presence of LEP should be noted here or in the demographic section.
- 2.6.b History – suggest including options to reflect whether the medication list was confirmed and whether the problem list (comorbidities) were complete and accurate.

4.0 Patient and Reporter Data

- 4.5 Participated or contributed information to section 2.0 – recommend adding 4.1.4 "Patient, family member, volunteer, caregiver, or homecare assistant" from Common Formats for Event Reporting – Hospital Version 2.0a Event Description (Core).

CFER-DS Event Description

2.1.1 Accurate (final) diagnosis – diagnostic label with ICD code or explanation if no medical/psychiatric diagnosis

- ICD 10 codes include symptoms without an explanation, e.g., R50 or R50.9 (fever unspecified). This should not be allowed to count as a diagnosis.

2.1.2 Date accurate (final) diagnosis identified

- HIPAA identifiable information, so uncertain why this is needed when 2.1.5 Approximate length of time from first Diagnostic Episode in Event Trajectory to accurate (final) diagnosis is captured.

2.1.4.3 Emergency transport

- Emergency transport implies that transport happens, but an EMS visit can occur without transport. Need to revise to include EMS encounter.

2.1.7.7 Patient initiated

- Suggest adding a fourth answer option to cover cases in which the patient or family identifies the diagnosis and asks the clinician to confirm or deny. This is different than a patient pushing to find a new diagnosis.

2.2.3 Documented explanation of health problem for this Diagnostic Episode with Missed Opportunities

- Suggest adding a second question asking what was communicated (if anything) to patients/families.

2.2.5 Key information in existence at the time that could have led to accurate (final) diagnosis

- Recommend including "problem list" and "medication list."

2.2.6.4 Lab Tests

- 2.2.6.4 Lab Tests can be combined with 2.2.6.5 Imaging/Other Diagnostic Testing to simplify. Combining all test options into a single section would be beneficial, but collecting the nature of the test would then need to be added as a subpart, i.e., clinical pathology, anatomic pathology, imaging, electrophysical, etc.

2.2.6.4.4 Performing/interpreting Clinician factors (e.g., ordered tests not performed or interpreted completely/correctly

- Could also be interpreted correctly, but not acted upon in a timely fashion.

2.2.7 Factors Contributing to Missed Opportunities

- The differentiation between 2.2.7.3 Overall safety climate/organizational culture and 2.2.7.4 Safety climate/organizational culture surrounding missed/delayed/wrong diagnoses may be difficult to distinguish for some. To differentiate items more clearly might reword the 2.2.7.4 as: Diagnosis-related safety climate/organizational culture surrounding raising, investigating, learning from missed/delayed/wrong diagnoses.
- Other contributing factors to include which are currently included in the Common Formats for Event Reporting – Hospital Version 2.0a Event Description (Supplemental) are 2.3.5 Human factors (e.g., fatigue, stress, inattention, cognitive factors) and 2.3.9 Health Information Technology (HIT) especially as they relate to clinical decision support and access to electronically stored information.

3.2 Patient gender

- People who are "in transition" biologically would be categorized as “Other” here but it is an example of one category that could be very relevant to interpretation of laboratory results. As you have done in other parts of the form, we recommend that “Other” carry a request to “Please Specify, e.g., in gender transition, on hormones” and that there be a line for open text.

3.5.1 Probable impact, severity unquantifiable

- Suggest rewording as follows to clarify: Probably had an impact, but severity unquantifiable: Condition probably worsened to a clinically meaningful extent due to circumstances related to the Diagnostic Safety Event (e.g., delays, risk from unnecessary interventions) but the impact cannot be objectively observed or quantified.

3.7 Other ways the Diagnostic Safety Event affected the patient/family

- The failure to communicate diagnosis of a diagnostic event related to a hereditary disorder to family members can have a harmful impact on the care of other family members. This currently would be captured in item 3.7.4 Other impact on patient’s family. Given the role that family history is a key piece of information that could lead to accurate diagnosis, suggest adding “Impact on patient’s family medical history.”

NEW ITEMS

The patient is part of every step of the diagnostic process and often the only constant across multiple settings and interactions. The Guide should explicitly suggest that key elements of the event and investigation should be reviewed with the patient or their family/representative. Discrepancies should be resolved if possible. We understand that this might not always be practical, but there should be a YES/NO question in the form that asks “Were the relevant elements of the event reviewed with the affected patient or their family/representative? (yes/no)” and “Were discrepancies resolved to both parties’ satisfaction? (yes/no).” It is not the intent of this comment to recommend an action that might invalidate the protections of the PSQIA.