SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

Diagnostic Safety Event Reporting

Coalition to Improve Diagnosis Meeting

June 22, 2021

Agenda

- Welcome
- Coalition Strategy Around Diagnostic Safety Event Reporting
- Common Formats
  - What they are and why they are important
  - Diagnostic Safety Event Common Formats
    - What's in them?
    - Opportunities for Improvement
    - Discussion
  - How to Submit Comments
- Next Phase of Initiative
- Comments/Questions

SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

Diagnosis is Complex

- It always involves uncertainty
- Diseases present differently in different patients
- Diseases present differently at different times for a single patient
- Consensus on what constitutes a timely diagnosis is lacking
- A clinician’s approach to a patient’s diagnosis can have many appropriate permutations

The Situation

- The local burden of diagnostic error is unknown as measurement systems are immature.
- Operational tools are lacking
  - Dashboards are still experimental at best
  - Incident reporting systems often lack a Dx category
- Event learning is fragmented, e.g., peer review versus RCA
- Data elements used to describe diagnostic safety events vary greatly
- Feedback mechanisms to clinical teams regarding diagnostic quality are missing
- Patient inputs are not generally integrated
- Learning networks struggle with the lack of information

The Opportunity

- AHRQ, by proposing a safety event reporting system, has created an opportunity for the field to reach consensus on how to document, investigate and learn from such events.
- Optimal data elements can be identified.
- Definitions of terms can be standardized.
- Solutions can be practical, scalable allowed to evolve over time.

The Current Task

- Leverage the current opportunity to begin creating a consensus approach to event reporting, investigation and learning.
- Ensure we are steeped in today's reality.
- Design the future system with the future of diagnosis in mind
  - Diagnosis is a team sport
  - Patients are the only common denominator across multiple care settings
  - New modalities, e.g., TeleDx
  - New tools, e.g., CDSS
- Design what we need, not what we can do, but provide for an evolving approach.

Common Format review and analysis

- Work to date:
  - Interviews and e-mail exchanges with 8 Coalition members to solicit feedback on formats.
  - Engagement of Patient Groups not part of Coalition to educate them about Common Formats & solicit feedback.
  - Their insights will guide today's discussion.
- Today: walk through of Formats
  - Discussion of opportunities for improvement, and potential guidance to offer NQF and AHRQ.
  - How to submit comments.

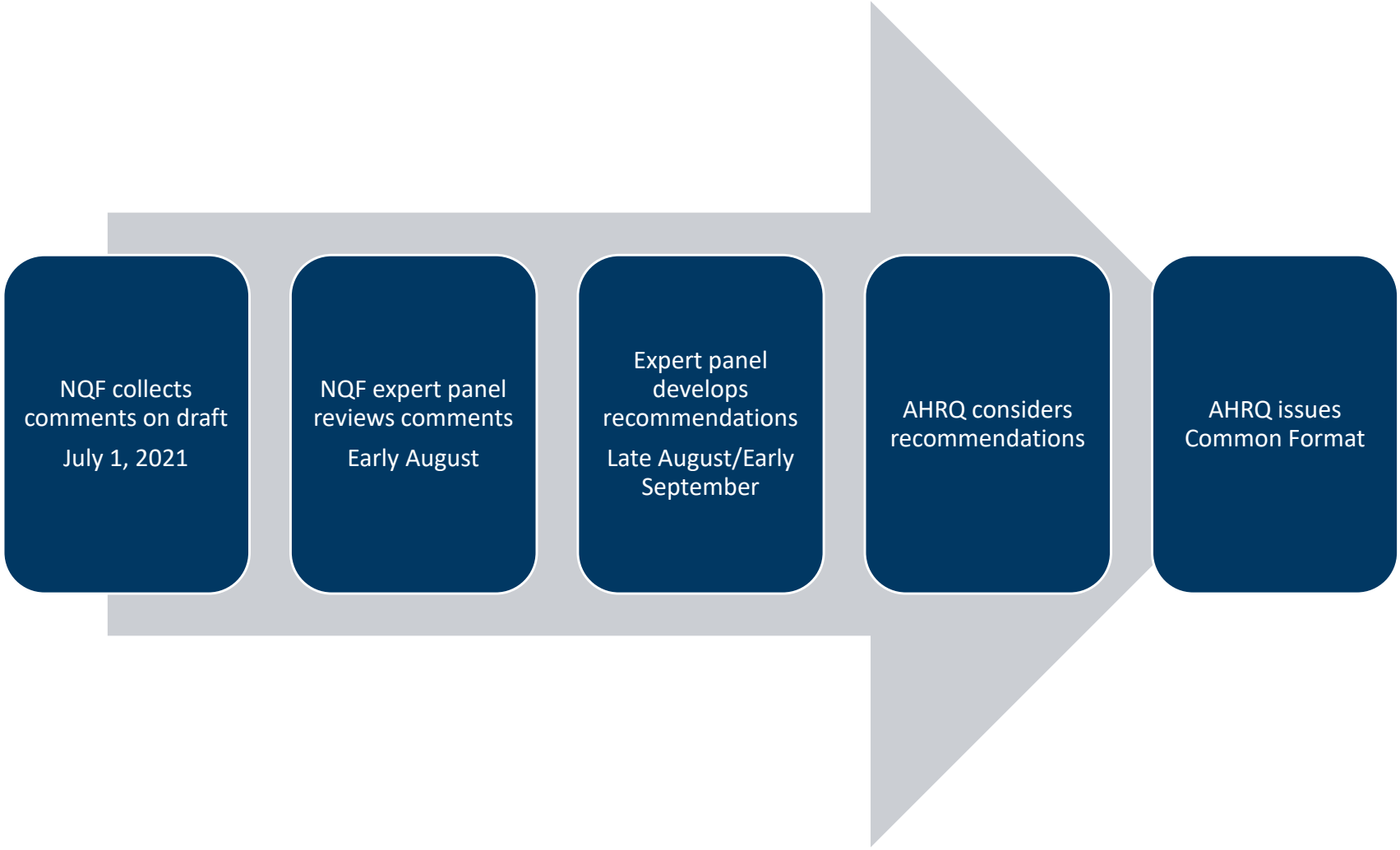
SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

AHRQ Common Formats for Event Reporting (CFER)

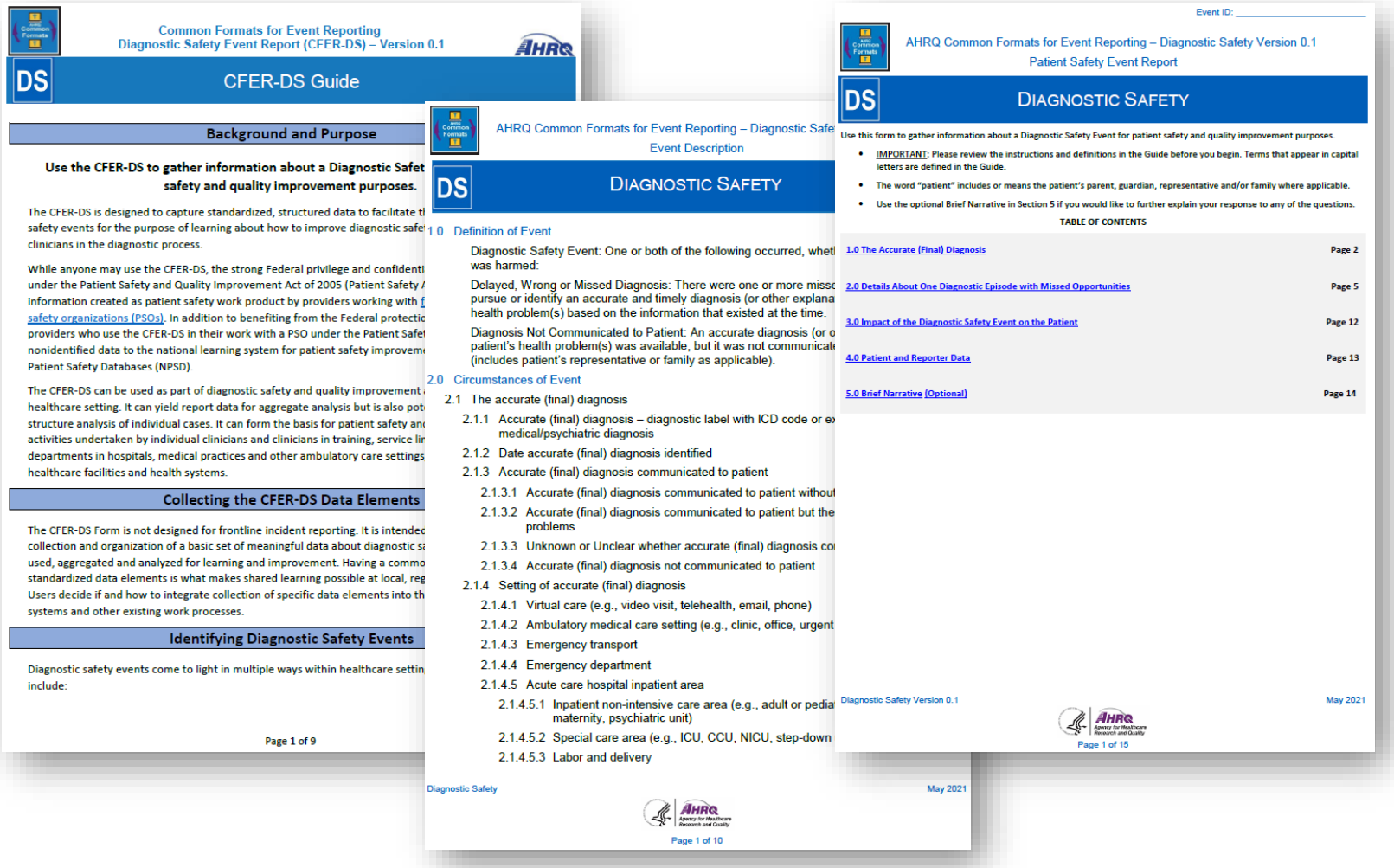
- Standardized definitions and categorizations to collect, aggregate, and analyze patient safety events
- Not a reporting system
- Used by healthcare providers that work with PSOs to report patient safety events
- Available in the public domain
- Event-specific modules for hospitals and nursing homes

AHRQ Patient Safety Organization (PSO) Program – Common Formats Overview: https://www.pso.ahrq.gov/common-formats/overview

Commenting Process



Common Formats for Event Reporting –Diagnostic Safety (CFER-DS) Ver. 0.1



Common Formats for Event Reporting
Diagnostic Safety Event Report (CFER-DS) – Version 0.1

DS CFER-DS Guide

Background and Purpose

Use the CFER-DS to gather information about a Diagnostic Safet safety and quality improvement purposes.

The CFER-DS is designed to capture standardized, structured data to facilitate t safety events for the purpose of learning about how to improve diagnostic safe clinicians in the diagnostic process.

While anyone may use the CFER-DS, the strong Federal privilege and confidenti under the Patient Safety and Quality Improvement Act of 2005 (Patient Safety information created as patient safety work product by providers working with safety organizations (PSOs). In addition to benefiting from the Federal protectic providers who use the CFER-DS in their work with a PSO under the Patient Safe nonidentified data to the national learning system for patient safety improve Patient Safety Databases (NPSD).

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

Collecting the CFER-DS Data Elements

The CFER-DS Form is not designed for frontline incident reporting. It is intended collection and organization of a basic set of meaningful data about diagnostic s used, aggregated and analyzed for learning and improvement. Having a commo standardized data elements is what makes shared learning possible at local, re Users decide if and how to integrate collection of specific data elements into th systems and other existing work processes.

Identifying Diagnostic Safety Events

Diagnostic safety events come to light in multiple ways within healthcare settin include:

Page 1 of 9

AHRQ Common Formats for Event Reporting – Diagnostic Safe
Event Description

DS DIAGNOSTIC SAFETY

1.0 Definition of Event

Diagnostic Safety Event: One or both of the following occurred, whet was harmed:

Delayed, Wrong or Missed Diagnosis: There were one or more misse pursue or identify an accurate and timely diagnosis (or other explana health problem(s) based on the information that existed at the time.

Diagnosis Not Communicated to Patient: An accurate diagnosis (or patient's health problem(s) was available, but it was not communicat (includes patient's representative or family as applicable).

2.0 Circumstances of Event

2.1 The accurate (final) diagnosis

2.1.1 Accurate (final) diagnosis – diagnostic label with ICD code or e medical/psychiatric diagnosis

2.1.2 Date accurate (final) diagnosis identified

2.1.3 Accurate (final) diagnosis communicated to patient

2.1.3.1 Accurate (final) diagnosis communicated to patient without

2.1.3.2 Accurate (final) diagnosis communicated to patient but the problems

2.1.3.3 Unknown or Unclear whether accurate (final) diagnosis co

2.1.3.4 Accurate (final) diagnosis not communicated to patient

2.1.4 Setting of accurate (final) diagnosis

2.1.4.1 Virtual care (e.g., video visit, telehealth, email, phone)

2.1.4.2 Ambulatory medical care setting (e.g., clinic, office, urgent

2.1.4.3 Emergency transport

2.1.4.4 Emergency department

2.1.4.5 Acute care hospital inpatient area

2.1.4.5.1 Inpatient non-intensive care area (e.g., adult or pedia maternity, psychiatric unit)

2.1.4.5.2 Special care area (e.g., ICU, CCU, NICU, step-down

2.1.4.5.3 Labor and delivery

Diagnostic Safety May 2021

Page 1 of 10

Event ID: _____

AHRQ Common Formats for Event Reporting – Diagnostic Safety Version 0.1
Patient Safety Event Report

DS DIAGNOSTIC SAFETY

Use this form to gather information about a Diagnostic Safety Event for patient safety and quality improvement purposes.

- IMPORTANT: Please review the instructions and definitions in the Guide before you begin. Terms that appear in capital letters are defined in the Guide.
- The word "patient" includes or means the patient's parent, guardian, representative and/or family where applicable.
- Use the optional Brief Narrative in Section 5 if you would like to further explain your response to any of the questions.

TABLE OF CONTENTS

Diagnostic Safety Version 0.1 May 2021

Page 1 of 15

NQF Common Formats for Patient Safety Data – Common Formats Open for Comment: https://www.qualityforum.org/Project_Pages/Common_Formats_for_Patient_Safety_Data.aspx

SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

CFER-DS Guide – Identifying Diagnostic Safety Events

- Patients through communication with clinicians, event reporting, experience of care surveys, complaints, and claims and litigation
- Quality and patient safety improvement activities
- Risk management and peer review processes
- Incident reporting systems

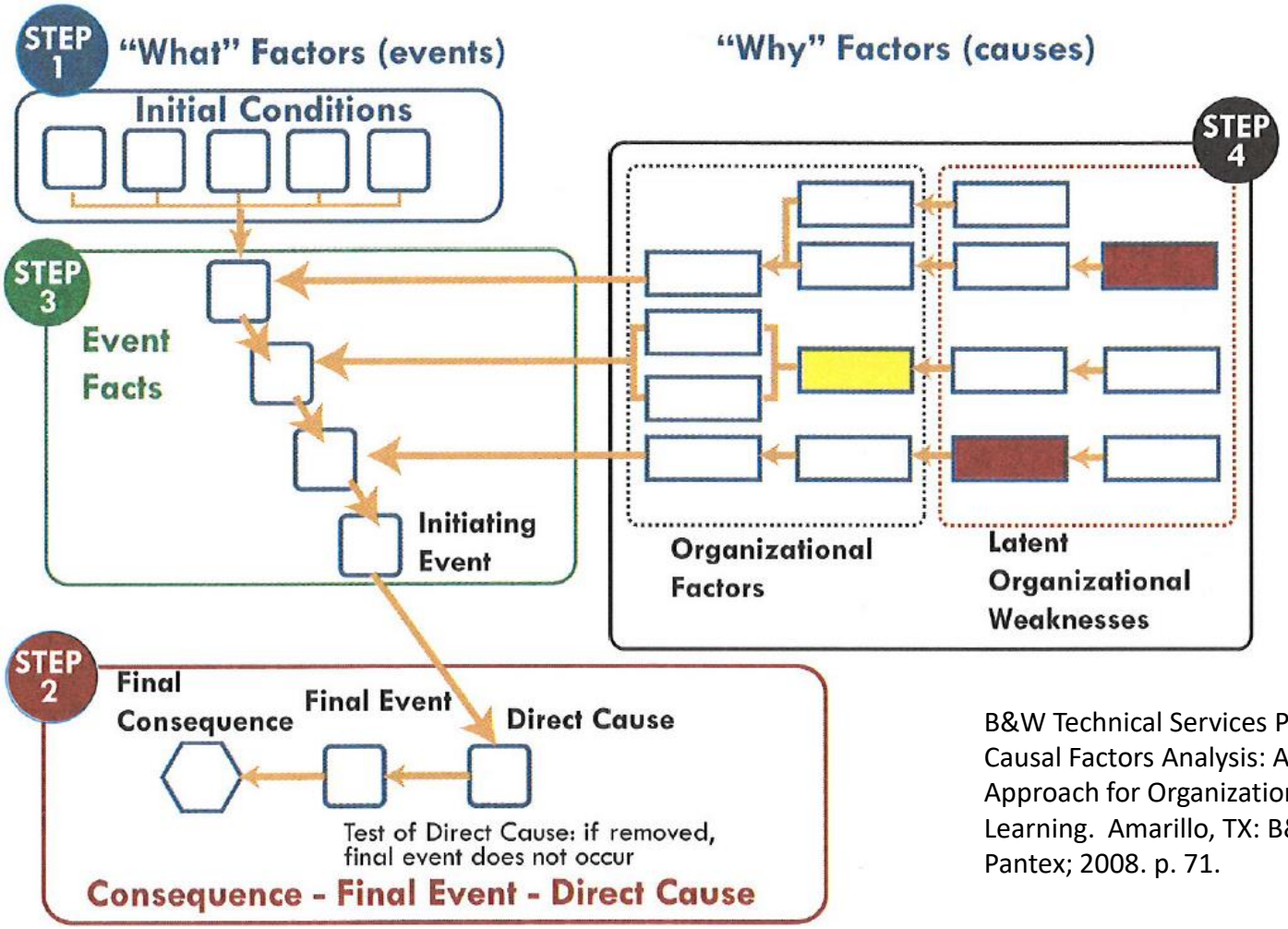
Diagnostic Safety Event - Defined

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.

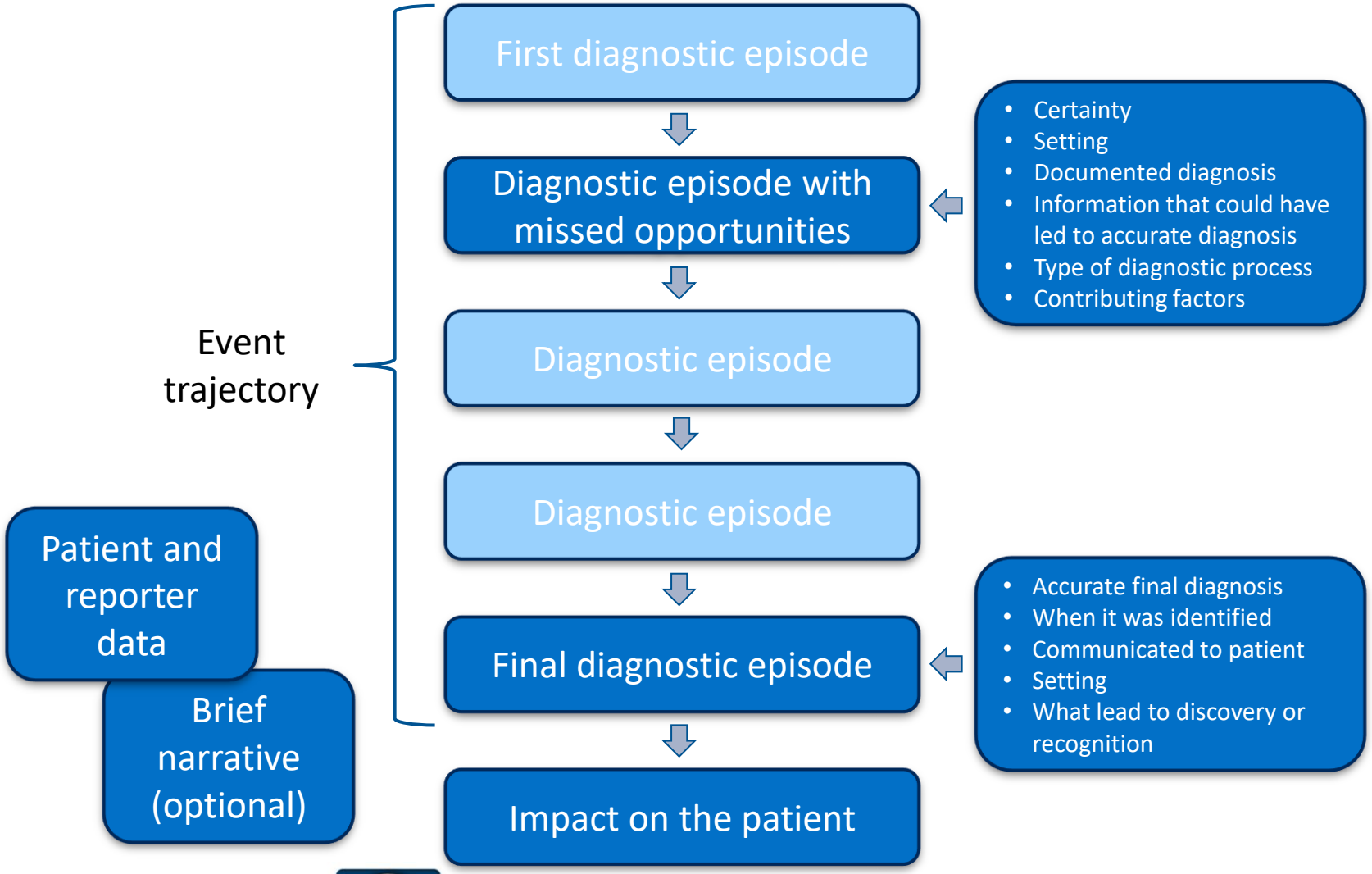
DIAGNOSIS NOT COMMUNICATED TO PATIENT: An accurate diagnosis (or other explanation) of the patient's health problem(s) was available, but it was not communicated to the patient (includes patient's representative or family as applicable).

Traditional Approach to Contributing Factor Analysis



B&W Technical Services Pantex. Causal Factors Analysis: An Approach for Organizational Learning. Amarillo, TX: B&W Pantex; 2008. p. 71.

CFER-DS Conceptual Model



SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

CFER-DS Concepts and Definitions

Event Trajectory:

- Began the first time the patient presented (to any healthcare setting or location) for the purpose of diagnosing the health problem that is the subject of the Diagnostic Safety Event (this is the first Diagnostic Episode in the Event Trajectory); 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.

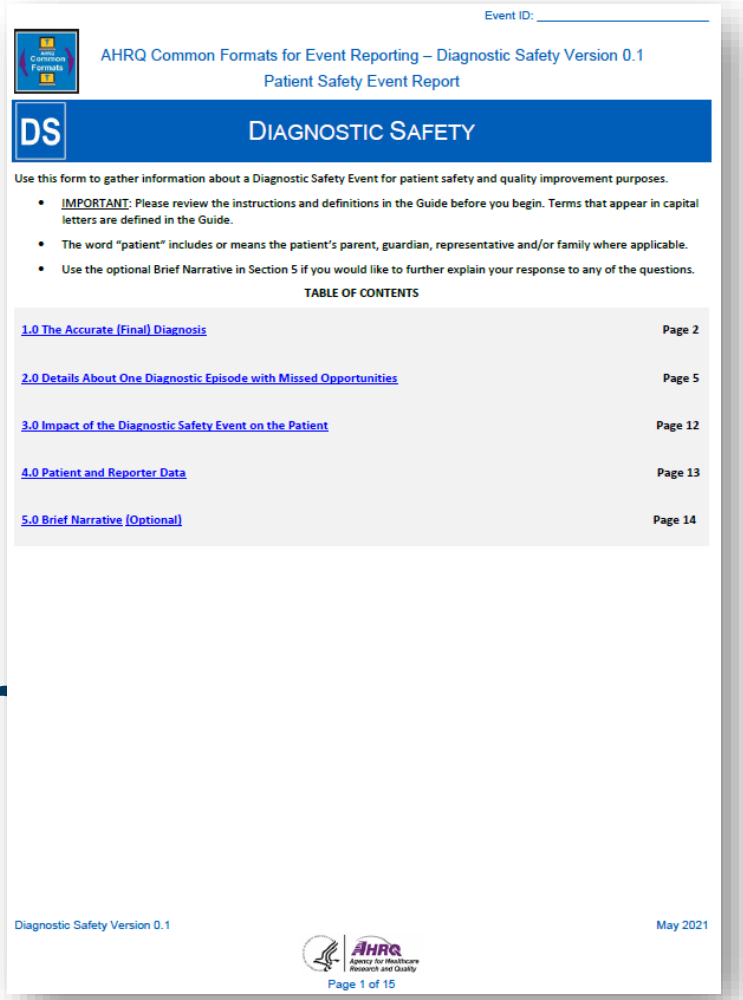
Diagnostic Episode: A Diagnostic Episode is a distinct point in time or period of time during the Event Trajectory when some explanation had been established for the health problem that is the subject of the Diagnostic Safety Event.

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.

CFER-DS Form Sections

1. The Accurate (Final) Diagnosis
2. Details about One Diagnostic Episode with Missed Opportunities
3. Impact of the Diagnostic Safety Event on the Patient
4. Patient and Reporter Data
5. Brief Narrative (optional)

CFER-DS Form Walkthrough



Event ID: _____

AHRQ Common Formats for Event Reporting – Diagnostic Safety Version 0.1
Patient Safety Event Report

DS DIAGNOSTIC SAFETY

Use this form to gather information about a Diagnostic Safety Event for patient safety and quality improvement purposes.

- IMPORTANT: Please review the instructions and definitions in the Guide before you begin. Terms that appear in capital letters are defined in the Guide.
- The word "patient" includes or means the patient's parent, guardian, representative and/or family where applicable.
- Use the optional Brief Narrative in Section 5 if you would like to further explain your response to any of the questions.

TABLE OF CONTENTS

High Level Initial Feedback from Coalition Members

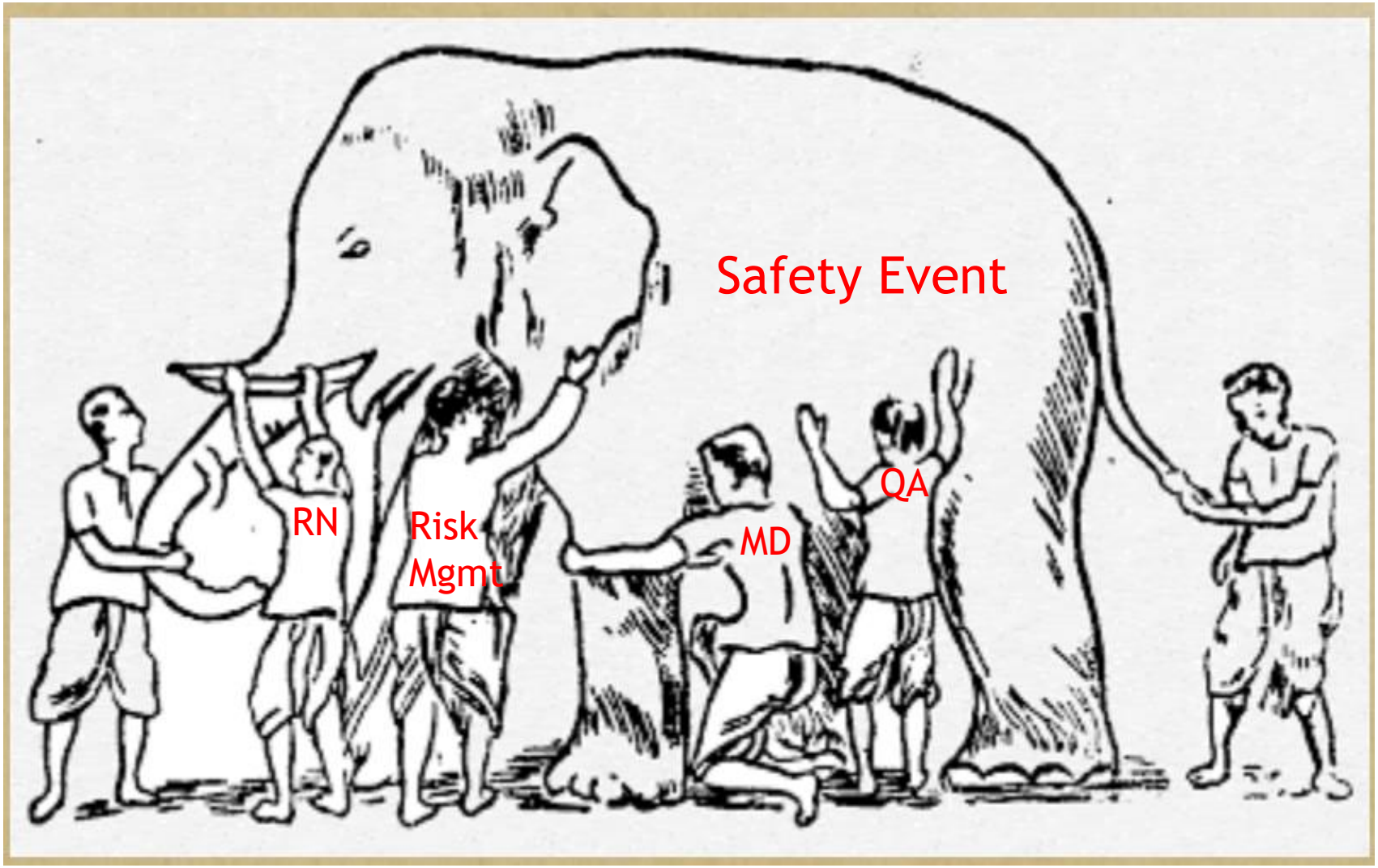
- Emphasize diagnostic safety reporting not errors, shared learning not measurement
- Physician-centric, other contributors to diagnosis not well specified (i.e., nursing, tech, etc.)
- Patient not listed as a contributor to the analysis
- Trajectory of event ends with “final diagnosis”
- Analysis may be resource intensive
- For hereditary conditions, family members can be impacted if not communicated
- Disparity and equity data for patients and providers
- Specific comments on data elements

Recap

- The long-term goal: Consensus approach to event reporting, investigation and shared learning
- The intermediate-term goal: Envision the “ideal” system and develop a roadmap to get there
  - Practical
  - Scalable
  - Flexible
- The short-term goal (1 week): Provide AHRQ/NQF feedback that identifies technical fixes to improve the “starting” point

SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

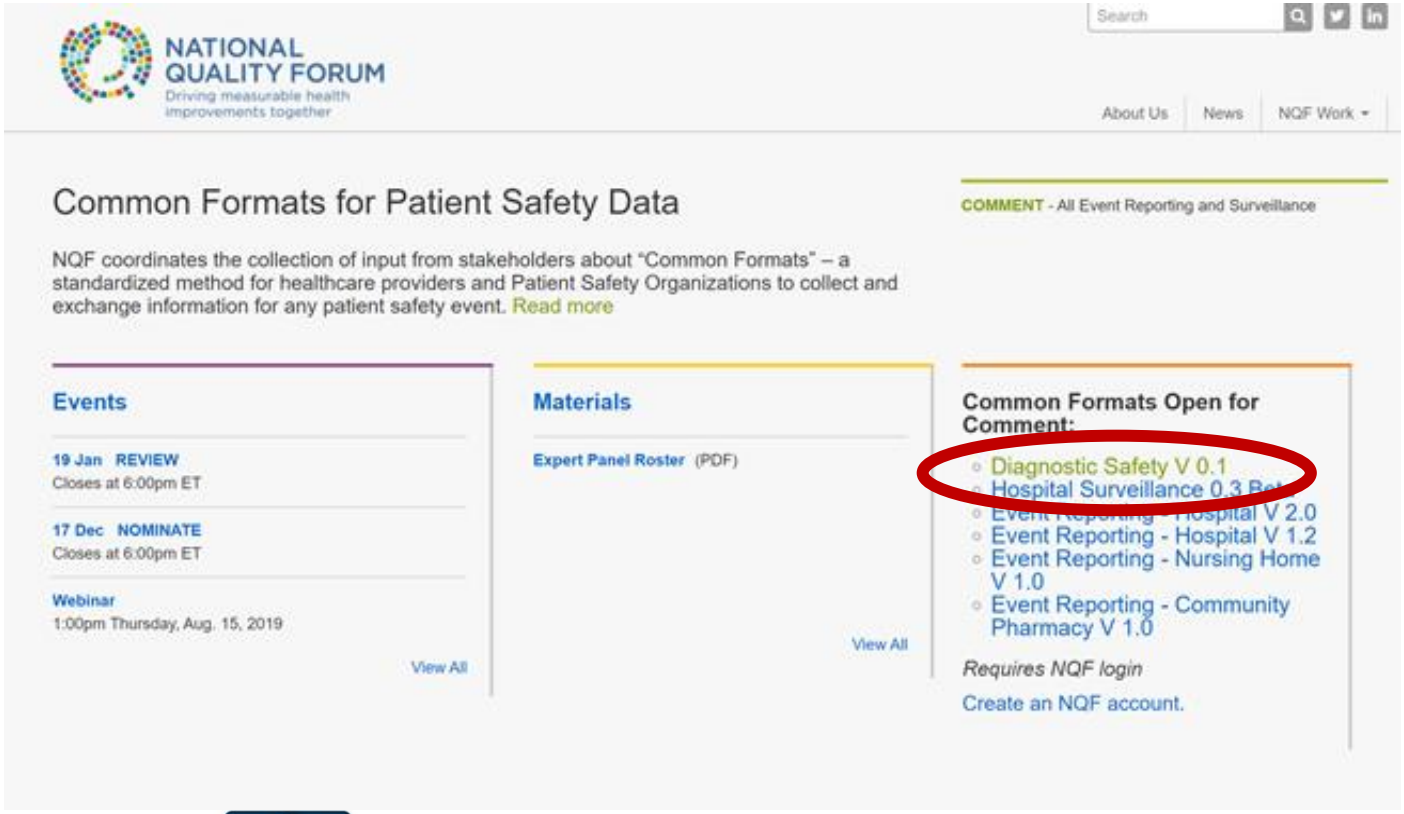
Many Stakeholders, Many Perspectives



Where's the Patient?

What's Next? Submit comments!

- Option 1: Submit your own comments
  - Visit: https://www.qualityforum.org/Common_Formats_for_Patient_Safety_Data.aspx



Next Steps – Option 1

- Create an NQF account (or sign in if you have an account).
- The webpage prompts you to enter comments in each section; we will share a video tutorial about this process.
- There is not a formal option to submit a letter.

If you submit comments, please let us know and send a copy of your comments to us!

SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

Next Steps – Option 2

- SIDM plans to submit a letter to accompany our technical comments.
- We welcome your **organization's sign-on to that letter**, as well as any substantive comments or issues you would like to include as an appendix in that communication.
- We will circulate a link to a simple online form that allows you to sign on and submit any substantive comments in a free text field.
- In order to meet the deadline for the comment submission, we ask that you complete your sign-on by June 29th.

SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

What's Next?

- Submit comments to NQF or sign-on to SIDM's letter
- What can you do?
  - Identify case studies and test them against the current Common Formats
  - Discuss with your stakeholders – needs & fears
- What will SIDM do?
  - Keep the conversation going
  - Collect the wisdom of the field
  - Leverages the Coalition to develop a whitepaper that defines the ideal state and the path to get there

SOCIETY to IMPROVE DIAGNOSIS in MEDICINE

Thank you!

Additional comments or questions? Contact:

Gerry Castro
Gerry.Castro@Improvediagnosis.org

Tina Huff
Tina.Huff@Improvediagnosis.org

SOCIETY to IMPROVE DIAGNOSIS in MEDICINE