Event ID: _____

AHRQ Common Formats for Event Reporting – Diagnostic Safety Version 1.0

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 Users' Guide before you begin. Terms that appear here with Capitalized First Letters are defined in the Users' Guide.
- The word "patient" includes or means the patient's parent, guardian, representative and/or family where applicable.
- Optional: Use the Brief Narrative in Section 5 to provide additional details and/or offer observations (e.g., what went wrong and why, what might be learned from this event).

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1.0 THE ACCURATE (FINAL) DIAGNOSIS

1.1 What was the accurate (final) diagnosis or explanation of the health problem? CHECK AND COMPLETE ONLY ONE:

a. ☐ Diagnostic label and ICD-10 code (Include more than one ONLY if relevant to this event). PLEASE SPECIFY:

_____

OR

b. ☐ Describe the accurate (final) explanation of the patient's health problem if it is not an ICD diagnosis. PLEASE SPECIFY:

_____

1.2 Specify the approximate date the accurate (final) diagnosis was identified by a Treating Clinician (MM/DD/YYYY):

____ / ____ / _____
MM DD YYYY

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

a. ☐ Yes, without delay or other problems. (PLEASE SPECIFY OTHER DETAILS IF KNOWN, E.G., HOW COMMUNICATED, WHAT WAS COMMUNICATED)

_____

b. ☐ Yes, but there were delays and/or other problems. PLEASE EXPLAIN:

_____

c. ☐ Unknown or Unclear. PLEASE EXPLAIN:

_____

d. ☐ No. PLEASE EXPLAIN:

_____

1.4 In what setting was the accurate (final) diagnosis identified by Treating Clinician(s)?

ENTER CDC NHSN LOCATION CODE: ☐

OR

CHECK ONE:

a. ☐ Virtual care (e.g., video visit, telehealth, email, phone)
b. ☐ Home care
c. ☐ Primary care or other general medical outpatient setting (e.g., clinic, office, urgent care)
d. ☐ Specialty medical care in outpatient setting (e.g., specialty clinic, specialist's office)
e. ☐ Mental health/psychiatric specialty care in outpatient setting
f. ☐ Mobile Emergency Services/EMS
g. ☐ Hospital Emergency Department
h. ☐ Acute care hospital inpatient area
i. ☐ Radiology/imaging
j. ☐ Laboratory, including pathology
k. ☐ Freestanding ambulatory surgery, procedure or labor/delivery setting
l. ☐ Inpatient unit in non-acute care hospital (e.g., long-term care hospital, rehabilitation hospital)
m. ☐ Non-hospital residential facility (e.g., rehabilitation center, long-term care)
n. ☐ Autopsy
o. ☐ Other setting not listed above. PLEASE SPECIFY: _____

1.4.1 In what acute care hospital inpatient area was the accurate (final) diagnosis identified? CHECK ONE:

1. ☐ Inpatient non-intensive care area (e.g., adult or pediatric medical-surgical, maternity unit)
2. ☐ Inpatient mental health/psychiatry unit
3. ☐ Special care area (e.g., ICU, CCU, NICU, step-down unit)
4. ☐ Labor and delivery
5. ☐ Preoperative/pre-procedure area
6. ☐ Operating room
7. ☐ Procedure room (e.g., cardiac catheter lab, endoscopy area)
8. ☐ Interventional radiology procedure room
9. ☐ PACU or recovery area

1.5 Time to Accurate Final Diagnosis: Including the first Diagnostic Episode in this Event Trajectory, approximately how long did it take for the accurate (final) diagnosis to be identified by a Treating Clinician?

a. ☐ Unable to calculate as the timing of the initial presentation/first Diagnostic Episode is unknown → **SKIP TO QUESTION 1.7**

b. It took approximately this many:	
_____ **(ENTER THE NUMBER)**	☐ minutes ☐ hours ☐ days ☐ weeks ☐ months ☐ years **(CHECK ONE)**

1.6 In this Event Trajectory, approximately how many Diagnostic Episodes took place before the accurate (final) diagnosis was identified by a Treating Clinician? (Count the first and all subsequent Diagnostic Episodes up until/excluding the one where the accurate (final) diagnosis was identified). CHECK ONE:

a. ☐ One
b. ☐ Two
c. ☐ Three
d. ☐ Four
e. ☐ Five
f. ☐ More than five
g. ☐ Unknown

1.7 In general terms, what prompted discovery of the accurate (final) diagnosis and/or recognition of this Diagnostic Safety Event? CHECK ALL THAT APPLY:

a. ☐ Patient's original symptoms or signs did not resolve
b. ☐ Deterioration/evolution of the original symptoms or signs
c. ☐ "Fresh eyes" looking at the original picture **in the same location** (e.g., evaluated by another Clinician, consultant, trainee, etc.)
d. ☐ Discovered **after care transition to a different location** (e.g., patient hospitalized, patient transferred from ER to inpatient unit or from inpatient unit to ICU, etc.)
e. ☐ Clinician discovered as a result of planned follow-up with patient
f. ☐ Clinician/staff discovered new or previously unseen/overlooked clinical data

1.7.1 How did the Clinician/staff discover new or previously unseen/overlooked clinical data? CHECK ONE:

1. ☐ By chance
2. ☐ After the Clinician requested a search
3. ☐ As a result of intentional tracking, monitoring, utilization review or quality/safety improvement activity
4. ☐ Other. PLEASE SPECIFY:

_____

g. ☐ Patient initiated

1.7.2 How did the patient initiate discovery of the accurate (final) diagnosis/recognition of this event? CHECK ONE:

1. ☐ Patient called provider's attention to new or previously unseen clinical data
2. ☐ Patient called provider's attention to existing clinical data
3. ☐ Patient requested pursuit of a different diagnosis
4. ☐ Other. PLEASE SPECIFY:

_____

h. ☐ Complaint, claim, or lawsuit
i. ☐ Patient died

1.7.3 How was the cause of death determined? CHECK ONE:

1. ☐ Autopsy determined cause of death
2. ☐ Cause of death documented without autopsy

j. ☐ Other. PLEASE SPECIFY:

_____

k. ☐ Not able to be determined

2.0 DETAILS ABOUT ONE DIAGNOSTIC EPISODE WITH MISSED OPPORTUNITIES

2.1 How certain are you that there were Missed Opportunities to pursue or identify the accurate (final) diagnosis during this Diagnostic Episode? CHECK ONE:

a. ☐ **Definitely**: There were clearly Missed Opportunities (e.g., "red flags" were clearly present and missed; diagnostic test report was completed but unavailable to the Treating Clinician or misinterpreted).

b. ☐ **Fairly certain**: It is fairly certain there were Missed Opportunities (e.g., key information was missed, but the clinical presentation was somewhat atypical).

c. ☐ **Uncertain**: There were probably Missed Opportunities, but it is hard to know for sure (e.g., it depends on whether a relevant physical exam finding was truly negative as documented, or actually positive and should not have been missed with an adequate physical exam).

2.2 In what setting did this Diagnostic Episode with Missed Opportunities occur?

ENTER CDC NHSN LOCATION CODE: ☐

OR

CHECK ONE:

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

b. ☐ Home care

c. ☐ Primary care or other general medical outpatient setting (e.g., clinic, office, urgent care)

d. ☐ Specialty medical care in outpatient setting (e.g., specialty clinic, specialist's office)

e. ☐ Mental health/psychiatric specialty care in outpatient setting

f. ☐ Mobile Emergency Services/EMS

g. ☐ Hospital Emergency Department

h. ☐ Acute care hospital inpatient area

i. ☐ Radiology/imaging

j. ☐ Laboratory, including pathology

k. ☐ Freestanding ambulatory surgery, procedure or labor/delivery setting

l. ☐ Inpatient unit in non-acute care hospital (e.g., long-term care hospital, rehabilitation hospital)

m. ☐ Non-hospital residential facility (e.g., rehabilitation center, long-term care)

n. ☐ Other setting not listed above. PLEASE SPECIFY:

_____

2.2.1 In what acute care hospital inpatient area was the accurate (final) diagnosis identified? CHECK ONE:

1. ☐ Inpatient non-intensive care area (e.g., adult or pediatric medical-surgical, maternity unit)
2. ☐ Inpatient mental health/psychiatry unit
3. ☐ Special care area (e.g., ICU, CCU, NICU, step-down unit)
4. ☐ Labor and delivery
5. ☐ Preoperative/pre-procedure area
6. ☐ Operating room
7. ☐ Procedure room (e.g., cardiac catheter lab, endoscopy area)
8. ☐ Interventional radiology procedure room
9. ☐ PACU or recovery area

2.3 What explanation for the health problem (if any) was documented during this Diagnostic Episode with Missed Opportunities? CHECK ONE:

a. ☐ An **inaccurate** diagnosis. PLEASE SPECIFY DIAGNOSTIC LABEL AND ICD-10 CODE:

_____

b. ☐ A differential, working, or "rule-out" set of diagnoses.

2.3.1 Did it include the accurate (final) diagnosis?
CHECK ONE:
1. ☐ Yes
2. ☐ No

PLEASE SPECIFY ALL DIAGNOSTIC LABELS AND ICD-10 CODES:

_____

c. ☐ Determination about patient's diagnosis or medical condition was unclear. PLEASE EXPLAIN:

_____

d. ☐ Other. PLEASE EXPLAIN:

_____

2.4 Was a plan for follow-up and/or further work-up specified during this Diagnostic Episode with Missed Opportunities? (e.g., a timeframe for the patient to be re-evaluated if the problem continued). CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

2.5 Was there a key piece of information – in existence at the time – that could have led to the accurate (final) diagnosis during this Diagnostic Episode if it had been available to or appreciated by the Treating Clinician(s)?

a. ☐ No
b. ☐ Unknown

SKIP TO QUESTION 2.6

c. ☐ Yes

If YES, find and select the row for that type of information in the table below and enter a brief description of the key piece of information. SELECT MORE THAN ONE ONLY IF EQUALLY KEY/SIGNIFICANT:

a. ☐ Chief complaint; PLEASE SPECIFY:	
b. ☐ Medications and/or allergies; PLEASE SPECIFY:	
c. ☐ Other history/information offered or provided by patient/representative; PLEASE SPECIFY:	
d. ☐ Previous documentation in the medical record; PLEASE SPECIFY:	
e. ☐ Vital signs; PLEASE SPECIFY:	
f. ☐ Physical exam findings; PLEASE SPECIFY:	
g. ☐ Lab/pathology results; PLEASE SPECIFY:	☐ Check here if this was an incidental finding
h. ☐ Imaging results; PLEASE SPECIFY:	☐ Check here if this was an incidental finding
i. ☐ Other Clinical Test results; PLEASE SPECIFY:	☐ Check here if this was an incidental finding
j. ☐ Other. PLEASE SPECIFY:	

2.6 Identify the specific diagnostic process(es) that involved Missed Opportunities during this Diagnostic Episode.

CHECK ALL THAT APPLY:

a. ☐ History
b. ☐ Vital signs
c. ☐ Physical exam
d. ☐ Lab tests/Pathology
e. ☐ Imaging
f. ☐ Other clinical tests (non-laboratory, non-imaging)
g. ☐ Consultations/referrals
h. ☐ Follow-up/tracking

Each diagnostic process listed in 2.6 above has a corresponding blue bar below. Under each bar is a list of factors that may have played a role in Missed Opportunities during that diagnostic process.

Find the blue bar for the diagnostic process(es) selected above in 2.6 (skip past the other blue bars). Select applicable factors from the lists under it only if these details are known based on information from the patient, Clinicians and/or other individuals involved, medical and other records, and/or other facts.

a. History (2.6.1)

If "a. History" was selected in 2.6, CHECK ALL THAT APPLY:

a. ☐ **Communication**
(e.g., communication gap between/among individuals)

b. ☐ **Access to Care Factors**

c. ☐ **Patient Factors**
(e.g., complex presentation)

d. ☐ **Clinician Factors**
(e.g., technique, completeness, documentation, issue with EMS/triage/pre-op information)

e. ☐ **Work environment/equipment**
(e.g., space, lighting, noise, privacy)

f. ☐ **Work processes/workflow**
(e.g., interruptions, processes for collecting/documenting clinical information used by Clinicians)

g. ☐ **Health Information Technology**
(e.g., design/usability of entry screens, availability/organization/display of content, problem list, copy/paste)

h. ☐ **Other.** PLEASE SPECIFY:
_____

2.6.1.1 CHECK ALL THAT APPLY:

1. ☐ **Patient/family circumstances**
(e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)
2. ☐ **Health coverage issue**
(e.g., uninsured, underinsured, network restrictions, insurer denial)
3. ☐ **Making appointments**
(e.g., user-friendliness of appointment system, appointment not timely available or offered)
4. ☐ **Communication assistance**
(e.g., usability or effectiveness of communication assistance needed by patient related to disability, health literacy or primary language, cultural competency of staff)
5. ☐ **Problem with patient contact information**
(e.g., unable to reach patient after extensive efforts)
6. ☐ **Organization's Health Information Technology**
(e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)
7. ☐ **Other.** PLEASE SPECIFY:
_____

b. Vital signs (2.6.2)

If "b. Vital signs" was selected in 2.6, CHECK ALL THAT APPLY:

a. ☐ **Communication**
(e.g., communication gap between/among individuals)

b. ☐ **Access to Care Factors**

c. ☐ **Patient Factors**
(e.g., physiologic/pharmacologic factor affecting vital signs)

d. ☐ **Clinician Factors**
(e.g., technique, interpretation, documentation)

e. ☐ **Performing Clinician/Personnel Factors**
(e.g., technique, completeness, documentation)

f. ☐ **Work environment/equipment**
(e.g., space, lighting, noise, privacy; availability/usability of equipment/supplies, equipment quality, maintenance, calibration)

g. ☐ **Work processes/workflow**
(e.g., timing for optimal accuracy, interruptions)

h. ☐ **Health Information Technology**
(e.g., accuracy, design/usability of display screens, availability/organization/display of content)

i. ☐ **Other.** PLEASE SPECIFY:
_____

2.6.2.1 CHECK ALL THAT APPLY:

1. ☐ **Patient/family circumstances**
(e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)
2. ☐ **Health coverage issue**
(e.g., uninsured, underinsured, network restrictions, insurer denial)
3. ☐ **Making appointments**
(e.g., user-friendliness of appointment system, appointment not timely available or offered)
4. ☐ **Communication assistance**
(e.g., usability or effectiveness of communication assistance needed by patient related to disability, health literacy or primary language, cultural competency of staff)
5. ☐ **Problem with patient contact information**
(e.g., unable to reach patient after extensive effort)
6. ☐ **Organization's Health Information Technology**
(e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)
7. ☐ **Other.** PLEASE SPECIFY:
_____

c. Physical Exam (2.6.3)

If "c. Physical Exam" was selected in 2.6, CHECK ALL THAT APPLY:

a. ☐ **Communication**
(e.g., communication gap between/among individuals)

b. ☐ **Access to Care Factors**

c. ☐ **Patient Factors**
(e.g., adequate physical exam not possible or permitted)

d. ☐ **Clinician Factors**
(e.g., technique, completeness, documentation)

e. ☐ **Work environment/equipment**
(e.g., space, lighting, noise, privacy; availability/usability of equipment/supplies, equipment quality, maintenance, calibration)

f. ☐ **Work processes/workflow**
(e.g., patient flow, throughput, interruptions, availability of support staff)

g. ☐ **Health Information Technology**
(e.g., accuracy, design/usability of entry screens, availability/organization/display of content, copy/paste)

h. ☐ **Other.** PLEASE SPECIFY:
_____

2.6.3.1 CHECK ALL THAT APPLY:

1. ☐ **Patient/family circumstances**
(e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)
2. ☐ **Health coverage issue**
(e.g., uninsured, underinsured, network restrictions, insurer denial)
3. ☐ **Making appointments**
(e.g., user-friendliness of appointment system, appointment not timely available or offered)
4. ☐ **Communication assistance**
(e.g., usability or effectiveness of communication assistance needed by patient related to disability, health literacy or primary language, cultural competency of staff)
5. ☐ **Problem with patient contact information**
(e.g., unable to reach patient after extensive effort)
6. ☐ **Organization's Health Information Technology**
(e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)
7. ☐ **Other.** PLEASE SPECIFY:
_____

d. Lab Tests/Pathology (2.6.4)

If "d. Lab Tests/Pathology" was selected in 2.6, CHECK ALL THAT APPLY:

a. ☐ **Communication**
(e.g., communication gap between/among individuals)

b. ☐ **Access to Care Factors**

c. ☐ **Patient Factors**
(e.g., unable to provide specimen, declined, physiologic/pharmacologic factor affecting lab values)

d. ☐ **Ordering Clinician Factors**
(e.g., appropriate test(s) not selected/ordered, provision of clinical information needed by lab)

e. ☐ **Performing/Interpreting Clinician/Personnel Factors**
(e.g., Ordered tests not processed, performed, or interpreted completely/correctly)

f. ☐ **Ordered test(s) false positive or false negative**
PLEASE SPECIFY:
_____

g. ☐ **Work environment/equipment**
(e.g., needed test not available; space, lighting, noise, privacy; availability/usability of equipment/supplies, equipment quality, maintenance, calibration)

h. ☐ **Work processes/workflow**
(e.g., ordered test not performed or resulted, specimen lost or mishandled, report or specimen processing issue, discrepant initial vs. final result, misidentification)

i. ☐ **Health Information Technology**
(e.g., Design/usability of order entry screens, clinical decision support, Laboratory Information System, availability/organization/display of content, alerts, copy/paste)

j. ☐ **Other.** PLEASE SPECIFY:
_____

2.6.4.1 CHECK ALL THAT APPLY:

1. ☐ **Patient/family circumstances**
(e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)
2. ☐ **Health coverage issue**
(e.g., uninsured, underinsured, network restrictions, insurer denial)
3. ☐ **Making appointments**
(e.g., user-friendliness of appointment system, appointment not timely available or offered)
4. ☐ **Communication assistance**
(e.g., usability or effectiveness of communication assistance needed by patient related to disability, health literacy or primary language, cultural competency of staff)
5. ☐ **Problem with patient contact information**
(e.g., unable to reach patient after extensive effort)
6. ☐ **Organization's Health Information Technology**
(e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)
7. ☐ **Other.** PLEASE SPECIFY:
_____

e. Imaging (2.6.5)

If "e. Imaging" was selected in 2.6, CHECK ALL THAT APPLY:

a. ☐ **Communication**
(e.g., communication gap between/among individuals)

b. ☐ **Access to Care Factors**

c. ☐ **Patient Factors**
(e.g., unable to prepare for or complete test, declined)

d. ☐ **Ordering Clinician Factors**
(e.g., appropriate test(s) not selected/ordered, provision of clinical information needed for test)

e. ☐ **Performing/Interpreting Clinician/Personnel Factors**
(e.g., ordered tests not performed or interpreted completely/correctly)

f. ☐ **Work environment/equipment**
(e.g., needed test not available; space, lighting, noise, privacy; availability/usability of equipment/supplies, equipment quality, maintenance, calibration)

g. ☐ **Work processes/workflow**
(e.g., delay or ordered test not performed or read, discrepant initial vs. final result, report processing, misidentification, patient flow, throughput, interruptions, availability of support staff)

h. ☐ **Health Information Technology**
(e.g., design/usability of order entry screens, clinical decision support, picture archiving and communication system (PACS), availability/organization/display of content, alerts, copy/paste, patient portal)

i. ☐ **Other.** PLEASE SPECIFY:
_____

2.6.5.1 CHECK ALL THAT APPLY:

1. ☐ **Patient/family circumstances**
(e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)
2. ☐ **Health coverage issue**
(e.g., uninsured, underinsured, network restrictions, insurer denial)
3. ☐ **Making appointments**
(e.g., user-friendliness of appointment system, appointment not timely available or offered)
4. ☐ **Communication assistance**
(e.g., usability or effectiveness of communication assistance needed by patient related to disability, health literacy or primary language, cultural competency of staff)
5. ☐ **Problem with patient contact information**
(e.g., unable to reach patient after extensive effort)
6. ☐ **Organization's Health Information Technology**
(e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)
7. ☐ **Other.** PLEASE SPECIFY:
_____

f. Other Clinical Tests (non-laboratory, non-imaging) (2.6.6)

If "f. Other Clinical Tests (non-laboratory, non-imaging)" was selected in 2.6, CHECK ALL THAT APPLY:

a. ☐ **Communication**
(e.g., communication gap between/among individuals)

b. ☐ **Access to Care Factors**

c. ☐ **Patient Factors**
(e.g., unable to prepare for or complete test, declined)

d. ☐ **Ordering Clinician Factors**
(e.g., appropriate test(s) not selected/ordered, provision of clinical information needed for test)

e. ☐ **Performing/Interpreting Clinician/Personnel Factors**
(e.g., ordered tests not performed or interpreted completely/correctly)

f. ☐ **Work environment/equipment**
(e.g., needed test not available; space, lighting, noise, privacy; availability/usability of equipment/supplies, equipment quality, maintenance, calibration)

g. ☐ **Work processes/workflow**
(e.g., delay or ordered test not performed or read, discrepant initial vs. final result, report processing, misidentification, patient flow, throughput, interruptions, availability of support staff)

h. ☐ **Health Information Technology**
(e.g., Design/usability of order entry screens, clinical decision support, availability/organization/display of content, alerts, copy/paste, patient portal)

i. ☐ **Other.** PLEASE SPECIFY:
_____

2.6.6.1 CHECK ALL THAT APPLY:

1. ☐ **Patient/family circumstances**
(e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)
2. ☐ **Health coverage issue**
(e.g., uninsured, underinsured, network restrictions, insurer denial)
3. ☐ **Making appointments**
(e.g., user-friendliness of appointment system, appointment not timely available or offered)
4. ☐ **Communication assistance**
(e.g., usability or effectiveness of communication assistance needed by patient related to disability, health literacy or primary language, cultural competency of staff)
5. ☐ **Problem with patient contact information**
(e.g., unable to reach patient after extensive effort)
6. ☐ **Organization's Health Information Technology**
(e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)
7. ☐ **Other.** PLEASE SPECIFY:
_____

g. Consultations/Referrals (2.6.7)

If "g. Consultations/Referrals" was selected in 2.6, CHECK ALL THAT APPLY:

a. ☐ **Communication**
(e.g., communication gap between/among individuals)

b. ☐ **Access to Care Factors**

c. ☐ **Patient Factors**
(e.g., declined)

d. ☐ **Ordering Clinician Factors**
(e.g., appropriate specialty not selected/ordered, provision of clinical information needed by consultant/referral source, interpretation of results)

e. ☐ **Consulting/Referral Clinician Factors**
(e.g., reason for consult/referral not sufficiently addressed)

f. ☐ **Work environment/equipment**
(e.g., space, lighting, noise, privacy; availability of needed consultant/referral specialties)

g. ☐ **Work processes/workflow**
(e.g., processes for making referrals/obtaining consults)

h. ☐ **Health Information Technology**
(e.g., design/usability of order entry screens, availability/organization/display of content, copy/paste, patient portal)

i. ☐ **Other.** PLEASE SPECIFY:
_____

2.6.7.1 CHECK ALL THAT APPLY:

1. ☐ **Patient/family circumstances**
(e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)
2. ☐ **Health coverage issue**
(e.g., uninsured, underinsured, network restrictions, insurer denial)
3. ☐ **Making appointments**
(e.g., user-friendliness of appointment system, appointment not timely available or offered)
4. ☐ **Communication assistance**
(e.g., usability or effectiveness of communication assistance needed by patient related to disability, health literacy or primary language, cultural competency of staff)
5. ☐ **Problem with patient contact information**
(e.g., unable to reach patient after extensive effort)
6. ☐ **Organization's Health Information Technology**
(e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)
7. ☐ **Other.** PLEASE SPECIFY:
_____

h. Follow-up/tracking (2.6.8)

If "h. Follow-up/tracking" was selected in 2.6, CHECK ALL THAT APPLY:

a. ☐ **Communication**
(e.g., communication gap between/among individuals)

b. ☐ **Access to Care Factors**

c. ☐ **Patient Factors**
(e.g., changed provider)

d. ☐ **Clinician Factors**
(e.g., review/action/documentation related to test results)

e. ☐ **Work environment/equipment**
(e.g., space, lighting, noise, privacy)

f. ☐ **Work processes/workflow**
(e.g., dedicated/protected time and/or assigned staff for follow-up and tracking tasks; processes for closing the loop between Treating Clinician and other Clinicians, processes for closing the loop between Clinicians and patients, processes for follow-up/tracking of test results, return visits, from periodic screening, after discharge, etc.)

g. ☐ **Health Information Technology**
(e.g., availability/organization/display of content, alerts, patient portal)

h. ☐ **Other.** PLEASE SPECIFY:
_____

2.6.8.1 CHECK ALL THAT APPLY:

1. ☐ **Patient/family circumstances**
(e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)
2. ☐ **Health coverage issue**
(e.g., uninsured, underinsured, network restrictions, insurer denial)
3. ☐ **Making appointments**
(e.g., user-friendliness of appointment system, appointment not timely available or offered)
4. ☐ **Communication assistance**
(e.g., usability or effectiveness of communication assistance needed by patient related to disability, health literacy or primary language, cultural competency of staff)
5. ☐ **Problem with patient contact information**
(e.g., unable to reach patient after extensive effort)
6. ☐ **Organization's Health Information Technology**
(e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)
7. ☐ **Other.** PLEASE SPECIFY:
_____

2.7 Were there Missed Opportunities in the overall diagnostic assessment during this Diagnostic Episode? CHECK ONE:

a. ☐ Yes

b. ☐ No – the Missed Opportunities in this Diagnostic Episode were unrelated to the overall diagnostic assessment

c. ☐ Unable to determine

2.7.1 Select the item(s) that best summarize where there were Missed Opportunities in the overall diagnostic assessment during this Diagnostic Episode. CHECK ALL THAT APPLY:

1. ☐ Selecting/gathering the right information/clinical data
2. ☐ Information integration and interpretation
3. ☐ Generating/prioritizing hypotheses and working diagnoses
4. ☐ Recognizing/addressing urgency
5. ☐ Other. PLEASE SPECIFY:
_____

2.8 Organizational Factors Contributing to Missed Opportunities: Identify the specific factors known to have contributed to the Missed Opportunities that occurred during this Diagnostic Episode based on information provided by individuals involved and/or other facts. CHECK ALL THAT APPLY:

a. ☐ Information not available → SKIP TO QUESTION 3.1

Communication in the Organization

b. ☐ In the particular unit/clinic/office/department/service
c. ☐ In the organization in general
d. ☐ Between/among organizational leaders and front-line staff

Safety climate/organizational culture - OVERALL

e. ☐ In the particular unit/clinic/office/department/service
f. ☐ In the organization in general

Safety climate/organizational culture – SPECIFIC TO DIAGNOSTIC SAFETY EVENTS

g. ☐ In the particular unit/clinic/office/department/service
h. ☐ In the organization in general

Resources/support for diagnostic safety improvement activities

i. ☐ In the particular unit/clinic/office/department/service
j. ☐ In the organization in general

Workload and staffing

k. ☐ Overall Clinician workload

Consideration of intensity of patient needs in scheduling/staffing

l. ☐ Clinician/medical staff (e.g., clinic or ER, hospitalists, on-call coverage)
m. ☐ Nursing and/or other health professional staff
n. ☐ Clinical support staff (e.g., nursing assistants, technicians, clerical)
o. ☐ Number of patients to be seen/length of time allotted per patient

Consideration of Clinician qualifications/proficiency to meet patient needs in scheduling/staffing

p. ☐ Clinician/medical staff (e.g., clinic or ER, hospitalists, on-call coverage)
q. ☐ Nursing and/or other health professional staff
r. ☐ Clinical support staff (e.g., nursing assistants, technicians, clerical)

Supervision and support

s. ☐ Support for personnel fatigue, stress, health issues
t. ☐ Personnel orientation, training, and related support

Clinical supervision

u. ☐ In the particular unit/clinic/office/department/service
v. ☐ In the organization in general

Policies, procedures, protocols

w. ☐ Availability/accessibility of policies/procedures/protocols
x. ☐ Availability/accessibility of resources or supplies needed to implement policies/procedures/protocols
y. ☐ Clarity/usability/clinical appropriateness of available policies/procedures/protocols

z. ☐ Availability/accessibility/effectiveness of training on policies/procedures/protocols

Handover, handoff, or care transition

aa. ☐ Missed Opportunity was related to a handover, handoff, or care transition

Crisis situation

bb. ☐ Missed Opportunity occurred during a crisis situation affecting the location/setting

Other

cc. ☐ Other. PLEASE SPECIFY:

_____

3.0 IMPACT OF THE DIAGNOSTIC SAFETY EVENT ON THE PATIENT

3.1 Impact on Patient's Condition: To what extent did the Diagnostic Safety Event – not the underlying disease itself – have an impact on the patient's medical (includes psychiatric) condition, even if temporary. For example, was there a delay in diagnosis that worsened the status or prognosis, or required additional medical or surgical intervention?

CHECK ONE:

a. ☐ Probable impact, 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

b. ☐ Death: Considering all available information, the occurrence of and/or timing of the patient's death seems related to circumstances specific to the Diagnostic Safety Event → SKIP TO QUESTION 3.3

c. ☐ Severe impact: Severe adverse impact on patient's condition, functional ability, quality of life, and/or shortened life expectancy; and/or patient requires life-saving or major treatment/intervention as a result of the event

d. ☐ Moderate impact: Serious adverse impact on patient's condition, functional ability and/or quality of life; and/or patient requires moderate level of treatment/intervention as a result of the event

e. ☐ Mild impact: Minimal adverse impact on patient's condition, functional ability and/or quality of life; and/or patient requires only observation or minimal intervention, if any, as a result of the event

f. ☐ None: The event appears to have had no impact on the patient's condition → SKIP TO QUESTION 3.3

g. ☐ Unknown/Unsure

3.2 What is the expected duration of the impact of this Diagnostic Safety Event – not the underlying disease itself – on the patient's medical (includes psychiatric) condition?

CHECK ONE:

a. ☐ It is expected to have a permanent impact

b. ☐ It is not expected to have a permanent impact

c. ☐ Unknown

3.3 In what *other* ways did this Diagnostic Safety Event – not the underlying disease itself – affect the patient/family? CHECK ALL THAT APPLY:

a. ☐ Additional anxiety, emotional/psychological distress
b. ☐ Additional financial or time impact (e.g., resulted in additional health care co-pays, travel or childcare costs, time lost from work, school, usual activities)
c. ☐ Other impact on patient's life, career, education, growth and/or development
d. ☐ Other impact on patient's family
e. ☐ Unknown
f. ☐ Other. **PLEASE SPECIFY:**

_____

4.0 PATIENT AND REPORTER DATA

4.1 What was the patient's age at the time the accurate (final) diagnosis was identified? CHECK ONE:

a. ☐ Neonate (<30 days)
b. ☐ Infant (≥30 days <1 year)
c. ☐ Early childhood (≥1 <5 years)
d. ☐ Late childhood (≥5 <13 years)
e. ☐ Adolescent (13-17 years)
f. ☐ Younger Adult (18-35 years)
g. ☐ Adult (36-64 years)
h. ☐ Mature adult (65-74 years)
i. ☐ Older adult (75-84 years)
j. ☐ Aged adult (85+ years)
k. ☐ Unknown

4.2 What is the patient's race? CHECK ALL THAT APPLY:

a. ☐ American Indian or Alaska Native
b. ☐ Asian
c. ☐ Black or African American
d. ☐ Native Hawaiian or Other Pacific Islander
e. ☐ White
f. ☐ Unknown

4.3 Is the patient's ethnicity Hispanic or Latino? CHECK ONE:

a. ☐ Hispanic or Latino ethnicity
b. ☐ Not Hispanic or Latino
c. ☐ Unknown

4.4 What is the patient's sex (assigned at birth)? CHECK ONE:

a. ☐ Male
b. ☐ Female
c. ☐ Unknown

4.5 What is the patient's gender identity? CHECK ONE:

a. ☐ Male
b. ☐ Female
c. ☐ Female-to-Male (FTM)/Transgender Male/Trans Man
d. ☐ Male-to-Female (MTF)/Transgender Female/Trans Woman
e. ☐ Genderqueer, neither exclusively male nor female, non-binary gender
f. ☐ Additional gender category or other, PLEASE SPECIFY:
_____
g. ☐ Choose not to disclose
h. ☐ Unknown

4.6 What is the patient's sexual orientation? CHECK ONE:

a. ☐ Lesbian, gay, or homosexual
b. ☐ Straight or heterosexual
c. ☐ Bisexual
d. ☐ Something else, PLEASE DESCRIBE:
_____
e. ☐ Choose not to disclose
f. ☐ Unknown

4.7 What is the patient's preferred language?

a. PLEASE SPECIFY:
_____
b. ☐ Unknown

4.8 Who reported the Diagnostic Safety Event? CHECK ONE:

a. ☐ Healthcare professional
b. ☐ Healthcare worker, including nursing assistant, patient transport/retrieval personnel, assistant/orderly, clerical/administrative personnel, interpreter/translator, technical/laboratory personnel, pastoral care personnel, biomedical engineer, housekeeping, maintenance, patient care assistant, home assistant, administrator/manager, or volunteer
c. ☐ Emergency service personnel, including police officer, fire fighter, or other emergency service officer
d. ☐ Patient, family member/caregiver
e. ☐ Unknown
f. ☐ Other. PLEASE SPECIFY:
_____

4.8.1 What is the type of healthcare professional?
CHECK ONE:

1. ☐ Doctor, dentist (including student)
2. ☐ Nurse, nurse practitioner, physician assistant (including student or trainee)
3. ☐ Pharmacist, pharmacy technician (including student)
4. ☐ Allied health professional (including paramedic, speech, physical and occupational therapist, dietician)

4.9 Which of the following participated in or contributed information used to answer questions about the Diagnostic Episode(s) with Missed Opportunities described in this event report? CHECK ALL THAT APPLY:

a. ☐ The Clinician(s) who identified the accurate (final) diagnosis
b. ☐ The Clinician(s) involved in the Missed Opportunities
c. ☐ Supervisors of the Clinician(s) involved in the Missed Opportunities
d. ☐ Clinician(s) with expertise/interest in diagnostic safety improvement
e. ☐ Patient safety/quality improvement professional
f. ☐ Risk manager
g. ☐ Other. PLEASE SPECIFY: _____

5.0 BRIEF NARRATIVE (OPTIONAL)

If there is additional narrative information you would like to include as part of this event report, please enter it below. For example, you may want to provide more detail or relevant thoughts and observations about what went wrong and why, and what you would like others to learn from this event.

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