DS DIAGNOSTIC SAFETY

1.0 Definition of Event

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).

2.0 Circumstances of Event

2.1 The accurate (final) diagnosis

- 2.1.1 Accurate (final) diagnosis – diagnostic label with ICD-10 code or explanation of health problem if not an ICD 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 delay or other problems
  - 2.1.3.2 Accurate (final) diagnosis communicated to patient but there were delays/other problems
  - 2.1.3.3 Unknown or Unclear whether accurate (final) diagnosis communicated to patient
  - 2.1.3.4 Accurate (final) diagnosis not communicated to patient
- 2.1.4 Setting of accurate (final) diagnosis (CDC NHSN Location Code OR setting selected from the following list)
  - 2.1.4.1 Virtual care (e.g., video visit, telehealth, email, phone)
  - 2.1.4.2 Home care
  - 2.1.4.3 Primary care or other general medical outpatient setting (e.g., clinic, office, urgent care)
  - 2.1.4.4 Specialty medical care in outpatient setting (e.g., specialty clinic, specialist's office)
  - 2.1.4.5 Mental health/psychiatric specialty care in outpatient setting
  - 2.1.4.6 Mobile Emergency Services/EMS

2.1.4.7 Hospital Emergency Department

2.1.4.8 Acute care hospital inpatient area

2.1.4.8.1 Inpatient non-intensive care area (e.g., adult or pediatric medical-surgical, maternity unit)

2.1.4.8.2 Inpatient mental health/psychiatry unit

2.1.4.8.3 Special care area (e.g., ICU, CCU, NICU, step-down unit)

2.1.4.8.4 Labor and delivery

2.1.4.8.5 Preoperative/pre-procedure area

2.1.4.8.6 Operating room

2.1.4.8.7 Procedure room (e.g., cardiac catheter lab, endoscopy area)

2.1.4.8.8 Interventional radiology procedure room

2.1.4.8.9 PACU or recovery area

2.1.4.9 Radiology/imaging

2.1.4.10 Laboratory, including pathology

2.1.4.11 Freestanding ambulatory surgery, procedure or labor/delivery setting

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

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

2.1.4.14 Autopsy

2.1.4.15 Other setting not listed above

2.1.5 Approximate length of time from first Diagnostic Episode in Event Trajectory to accurate (final) diagnosis

2.1.6 Approximate number of Diagnostic Episodes from first Diagnostic Episode in Event Trajectory to accurate (final) diagnosis

2.1.7 Circumstance(s) that prompted discovery of accurate (final) diagnosis/recognition of event

2.1.7.1 Patient's original symptoms or signs did not resolve

2.1.7.2 Deterioration/evolution of original symptoms or signs

2.1.7.3 "Fresh eyes" looking at original picture in the same location (e.g., evaluated by another Clinician, consultant, trainee, etc.)

2.1.7.4 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.)

2.1.7.5 Clinician discovered as a result of planned follow-up with patient

2.1.7.6 Clinician/staff discovered new or previously unseen/overlooked clinical data

2.1.7.6.1 By chance

2.1.7.6.2 After Clinician requested a search

2.1.7.6.3 As a result of intentional tracking, monitoring, utilization review or quality/safety improvement activity

2.1.7.6.4 Other

2.1.7.7 Patient initiated

2.1.7.7.1 Patient called provider's attention to new or previously unseen clinical data

2.1.7.7.2 Patient called provider's attention to existing clinical data

2.1.7.7.3 Patient requested pursuit of a different diagnosis

2.1.7.7.4 Other

2.1.7.8 Complaint, claim, or lawsuit

2.1.7.9 Patient died

2.1.7.9.1 Autopsy determined cause of death

2.1.7.9.2 Cause of death documented without autopsy

2.1.7.10 Other

2.1.7.11 Not able to be determined

2.2 Details About One Diagnostic Episode with Missed Opportunities

2.2.1 Level of certainty about Missed Opportunities

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

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

2.2.1.3 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).

2.2.2 Setting of Diagnostic Episode with Missed Opportunities (CDC NHSN Location Code OR setting selected from the following list)

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

2.2.2.2 Home care

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

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

2.2.2.5 Mental health/psychiatric specialty care in outpatient setting

2.2.2.6 Mobile Emergency Services/EMS

2.2.2.7 Hospital Emergency Department

2.2.2.8 Acute care hospital inpatient area

2.2.2.8.1 Inpatient non-intensive care area (e.g., adult or pediatric medical-surgical, maternity unit)

2.2.2.8.2 Inpatient mental health/psychiatry unit

2.2.2.8.3 Special care area (e.g., ICU, CCU, NICU, step-down unit)

2.2.2.8.4 Labor and delivery

2.2.2.8.5 Preoperative/pre-procedure area

2.2.2.8.6 Operating room

2.2.2.8.7 Procedure room (e.g., cardiac catheter lab, endoscopy area)

2.2.2.8.8 Interventional radiology procedure room

2.2.2.8.9 PACU or recovery area

2.2.2.9 Radiology/imaging

2.2.2.10 Laboratory, including pathology

2.2.2.11 Freestanding ambulatory surgery, procedure or labor/delivery setting

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

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

2.2.2.14 Other setting not listed above

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

2.2.3.1 Inaccurate diagnosis (diagnostic label and ICD-10 code)

2.2.3.2 Differential, working or “rule-out” set of diagnoses (diagnostic label and ICD-10 code)

2.2.3.2.1 Included accurate (final) diagnosis

2.2.3.2.2 Did not include accurate (final) diagnosis

2.2.3.3 Determination about patient’s diagnosis or medical condition was unclear

2.2.3.4 Other

2.2.4 Plan for follow-up/further work-up specified

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

2.2.5.1 Chief complaint

2.2.5.2 Medications and/or allergies

2.2.5.3 Other history/information offered or provided by patient/ representative

2.2.5.4 Previous documentation in the medical record

2.2.5.5 Vital signs

2.2.5.6 Physical exam findings

2.2.5.7 Lab/pathology results, indicate if incidental finding

2.2.5.8 Imaging results, indicate if incidental finding

2.2.5.9 Other Clinical Test results, indicate if incidental finding

2.2.5.10 Other

2.2.6 Diagnostic process(es) with Missed Opportunities

2.2.6.1 History

2.2.6.1.1 Communication (e.g., communication gap between/among individuals)

2.2.6.1.2 Access to Care Factors

2.2.6.1.2.1 Patient/family circumstances (e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)

2.2.6.1.2.2 Health coverage issue (e.g., uninsured, underinsured, network restrictions, insurer denial)

2.2.6.1.2.3 Making appointments (e.g., user-friendliness of appointment system, appointment not timely available or offered

2.2.6.1.2.4 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)

2.2.6.1.2.5 Problem with patient contact information (e.g., unable to reach patient after extensive efforts)

2.2.6.1.2.6 Organization's Health Information Technology (e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)

2.2.6.1.2.7 Other

2.2.6.1.3 Patient factors (e.g., complex presentation)

2.2.6.1.4 Clinician factors (e.g., technique, completeness, documentation, issue with EMS/triage/pre-op information)

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

2.2.6.1.6 Work processes/workflow (e.g., interruptions, processes for collecting clinical information used by Clinicians)

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

2.2.6.1.8 Other

2.2.6.2 Vital signs

2.2.6.2.1 Communication (e.g., communication gap between/among individuals)

2.2.6.2.2 Access to Care Factors

2.2.6.2.2.1 Patient/family circumstances (e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)

2.2.6.2.2.2 Health coverage issue (e.g., uninsured, underinsured, network restrictions, insurer denial)

2.2.6.2.2.3 Making appointments (e.g., user-friendliness of appointment system, appointment not timely available or offered

2.2.6.2.2.4 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)

2.2.6.2.2.5 Problem with patient contact information (e.g., unable to reach patient after extensive efforts)

2.2.6.2.2.6 Organization's Health Information Technology (e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)

2.2.6.2.2.7 Other

2.2.6.2.3 Patient factors (e.g., physiologic/pharmacologic factor affecting vital signs)

2.2.6.2.4 Clinician factors (e.g., technique, interpretation, documentation)

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

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

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

2.2.6.2.8 Health Information Technology (e.g., design/usability of entry screens, availability/organization/display of content)

2.2.6.2.9 Other

2.2.6.3 Physical Exam

2.2.6.3.1 Communication (e.g., communication gap between/among individuals)

2.2.6.3.2 Access to Care Factors

2.2.6.3.2.1 Patient/family circumstances (e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)

2.2.6.3.2.2 Health coverage issue (e.g., uninsured, underinsured, network restrictions, insurer denial)

2.2.6.3.2.3 Making appointments (e.g., user-friendliness of appointment system, appointment not timely available or offered

2.2.6.3.2.4 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)

2.2.6.3.2.5 Problem with patient contact information (e.g., unable to reach patient after extensive efforts)

2.2.6.3.2.6 Organization's Health Information Technology (e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)

2.2.6.3.2.7 Other

2.2.6.3.3 Patient factors (e.g., adequate physical exam not possible or permitted, access issue)

2.2.6.3.4 Clinician factors (e.g., technique, completeness, documentation)

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

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

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

2.2.6.3.8 Other

2.2.6.4 Lab Tests/Pathology

2.2.6.4.1 Communication (e.g., communication gap between/among individuals)

2.2.6.4.2 Access to Care Factors

2.2.6.4.2.1 Patient/family circumstances (e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)

2.2.6.4.2.2 Health coverage issue (e.g., uninsured, underinsured, network restrictions, insurer denial)

2.2.6.4.2.3 Making appointments (e.g., user-friendliness of appointment system, appointment not timely available or offered

2.2.6.4.2.4 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)

2.2.6.4.2.5 Problem with patient contact information (e.g., unable to reach patient after extensive efforts)

2.2.6.4.2.6 Organization's Health Information Technology (e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)

2.2.6.4.2.7 Other

2.2.6.4.3 Patient factors (e.g., unable to provide specimen, declined, physiologic/pharmacologic factor affecting lab values)

2.2.6.4.4 Ordering Clinician factors (e.g., appropriate test(s) not selected/ordered, provision of clinical information needed by lab)

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

2.2.6.4.6 Ordered test(s) false positive or false negative

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

2.2.6.4.8 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)

2.2.6.4.9 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)

2.2.6.4.10 Other

2.2.6.5 Imaging

2.2.6.5.1 Communication (e.g., communication gap between/among individuals)

2.2.6.5.2 Access to Care Factors

2.2.6.5.2.1 Patient/family circumstances (e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)

2.2.6.5.2.2 Health coverage issue (e.g., uninsured, underinsured, network restrictions, insurer denial)

2.2.6.5.2.3 Making appointments (e.g., user-friendliness of appointment system, appointment not timely available or offered

2.2.6.5.2.4 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)

2.2.6.5.2.5 Problem with patient contact information (e.g., unable to reach patient after extensive efforts)

2.2.6.5.2.6 Organization's Health Information Technology (e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)

2.2.6.5.2.7 Other

2.2.6.5.3 Patient factors (e.g., unable to prepare for or complete test, declined)

2.2.6.5.4 Ordering Clinician factors (e.g., appropriate test(s) not selected/ordered, provision of clinical information needed for test)

2.2.6.5.5 Performing/interpreting Clinician/Personnel Factors (e.g., ordered tests not performed or interpreted completely/correctly)

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

2.2.6.5.7 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)

2.2.6.5.8 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)

2.2.6.5.9 Other

2.2.6.6 Other Clinical Tests (non-laboratory, non-imaging)

2.2.6.6.1 Communication (e.g., communication gap between/among individuals)

2.2.6.6.2 Access to Care Factors

2.2.6.6.2.1 Patient/family circumstances (e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)

2.2.6.6.2.2 Health coverage issue (e.g., uninsured, underinsured, network restrictions, insurer denial)

2.2.6.6.2.3 Making appointments (e.g., user-friendliness of appointment system, appointment not timely available or offered

2.2.6.6.2.4 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)

2.2.6.6.2.5 Problem with patient contact information (e.g., unable to reach patient after extensive efforts)

2.2.6.6.2.6 Organization's Health Information Technology (e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)

2.2.6.6.2.7 Other

2.2.6.6.3 Patient factors (e.g., unable to prepare for or complete test, declined)

2.2.6.6.4 Ordering Clinician factors (e.g., appropriate test(s) not selected/ordered, provision of clinical information needed for test)

2.2.6.6.5 Performing/interpreting Clinician/Personnel Factors (e.g., ordered tests not performed or interpreted completely/correctly)

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

2.2.6.6.7 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)

2.2.6.6.8 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)

2.2.6.6.9 Other

2.2.6.7 Consultations/Referrals

2.2.6.7.1 Communication (e.g., communication gap between/among individuals)

2.2.6.7.2 Access to Care Factors

2.2.6.7.2.1 Patient/family circumstances (e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)

2.2.6.7.2.2 Health coverage issue (e.g., uninsured, underinsured, network restrictions, insurer denial)

2.2.6.7.2.3 Making appointments (e.g., user-friendliness of appointment system, appointment not timely available or offered

2.2.6.7.2.4 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)

2.2.6.7.2.5 Problem with patient contact information (e.g., unable to reach patient after extensive efforts)

2.2.6.7.2.6 Organization's Health Information Technology (e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)

2.2.6.7.2.7 Other

2.2.6.7.3 Patient factors (e.g., declined)

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

2.2.6.7.5 Consulting/Referral Clinician factors (e.g., reason for consult/referral not sufficiently addressed)

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

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

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

2.2.6.7.9 Other

2.2.6.8 Follow-up/Tracking

2.2.6.8.1 Communication (e.g., communication gap between/among individuals)

2.2.6.8.2 Access to Care Factors

2.2.6.8.2.1 Patient/family circumstances (e.g., care delayed due to transportation, work-related, childcare, financial or other barriers, access to information technology, personal reasons)

2.2.6.8.2.2 Health coverage issue (e.g., uninsured, underinsured, network restrictions, insurer denial)

2.2.6.8.2.3 Making appointments (e.g., user-friendliness of appointment system, appointment not timely available or offered

2.2.6.8.2.4 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)

2.2.6.8.2.5 Problem with patient contact information (e.g., unable to reach patient after extensive efforts)

2.2.6.8.2.6 Organization's Health Information Technology (e.g., design/usability of administrative/practice management/registration/appointment scheduling system, patient portal)

2.2.6.8.2.7 Other

2.2.6.8.3 Patient factors (e.g., changed provider)

2.2.6.8.4 Clinician factors (e.g., review/action/documentation related to test results)

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

2.2.6.8.6 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.)

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

2.2.6.8.8 Other

2.2.7 Missed Opportunities in Overall Diagnostic Assessment

2.2.7.1 Selecting/gathering the right information/clinical data

2.2.7.2 Information integration and interpretation

2.2.7.3 Generating/prioritizing hypotheses and working diagnoses

2.2.7.4 Recognizing/addressing urgency

2.2.7.5 Unable to determine

2.2.7.6 Not applicable – the Missed Opportunities were unrelated to the overall diagnostic assessment

2.2.8 Organizational Factors Contributing to Missed Opportunities

2.2.8.1 Information not available

2.2.8.2 Communication in the organization

2.2.8.2.1 In the particular unit/clinic/office/department/service

2.2.8.2.2 In the organization in general

2.2.8.2.3 Between/among organizational leaders and front-line staff

2.2.8.3 Overall safety climate/organizational culture

2.2.8.3.1 In the particular unit/clinic/office/department/service

2.2.8.3.2 In the organization in general

2.2.8.4 Safety climate/organizational culture specific to diagnostic safety events

2.2.8.4.1 In the particular unit/clinic/office/department/service

2.2.8.4.2 In the organization in general

2.2.8.5 Resources/support for diagnostic safety improvement activities

2.2.8.5.1 In the particular unit/clinic/office/department/service

2.2.8.5.2 In the organization in general

2.2.8.6 Workload and staffing

2.2.8.6.1 Overall Clinician workload

2.2.8.6.2 Consideration of intensity of patient needs in scheduling/staffing

2.2.8.6.2.1 Clinician/medical staff (e.g., clinic or ER, hospitalists, on-call coverage)

2.2.8.6.2.2 Nursing and/or other health professional staff

2.2.8.6.2.3 Clinical support staff (e.g., nursing assistants, technicians, clerical)

2.2.8.6.2.4 Number of patients to be seen/length of time allotted per patient

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

2.2.8.6.3.1 Clinician/medical staff (e.g., clinic or ER, hospitalists, on-call coverage)

2.2.8.6.3.2 Nursing and/or other health professional staff

2.2.8.6.3.3 Clinical support staff (e.g., nursing assistants, technicians, clerical)

2.2.8.7 Supervision and support

2.2.8.7.1 Support for personnel fatigue, stress, health issues

2.2.8.7.2 Personnel orientation, training, and related support

2.2.8.7.3 Clinical supervision

2.2.8.7.3.1 In the particular unit/clinic/office/department/service

2.2.8.7.3.2 In the organization in general

2.2.8.8 Policies, Procedures, Protocols

2.2.8.8.1 Availability/accessibility of policies/procedures/protocols

2.2.8.8.2 Availability/accessibility of resources or supplies needed to implement policies/procedures/protocols

2.2.8.8.3 Clarity/usability/clinical appropriateness of available policies/procedures/protocols

2.2.8.8.4 Availability/accessibility/effectiveness of training on policies/procedures/protocols

2.2.8.9 Missed Opportunity related to handover, handoff, or care transition

2.2.8.10 Missed Opportunity occurred during a crisis situation affecting the location/setting

2.2.8.11 Other

3.0 Impact on Patient

3.1 Impact on Patient's medical (includes psychiatric) condition

3.1.1 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.

3.1.2 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.

3.1.3 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.

3.1.4 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.

3.1.5 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.

3.1.6 None: The event appears to have had no impact on the patient's medical condition.

3.1.7 Unknown/Unsure

3.2 Expected duration of impact on medical (includes psychiatric) condition

3.2.1 Expected to have a permanent impact

3.2.2 Not expected to have a permanent impact

3.3 Other ways Diagnostic Safety Event affected patient/family

3.3.1 Additional anxiety, emotional/psychological distress

3.3.2 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)

3.3.3 Other impact on patient's life, career, education, growth and/or development

3.3.4 Other impact on patient's family

3.3.5 Other

4.0 Patient Information

4.1 Patient age range at time of accurate (final) diagnosis

4.1.1 Neonate (<30 days)

4.1.2 Infant (≥30 days <1 year)

4.1.3 Early childhood (≥1 <5 years)

4.1.4 Late childhood (≥5 <13 years)

4.1.5 Adolescent (13-17 years)

4.1.6 Younger adult (18-35 years)

4.1.7 Adult (36-64 years)

4.1.8 Mature adult (65-74 years)

4.1.9 Older adult (75-84 years)

4.1.10 Aged adult (85+ years)

4.2 Patient race

4.2.1 American Indian or Alaska Native

4.2.2 Asian

4.2.3 Black or African American

4.2.4 Native Hawaiian or Other Pacific Islander

4.2.5 White

4.3 Patient ethnicity Hispanic or Latino

4.3.1 Hispanic or Latino ethnicity

4.3.2 Not Hispanic or Latino

4.4 Patient sex (assigned at birth)

4.4.1 Male

4.4.2 Female

4.5 Patient gender identity

4.5.1 Male

4.5.2 Female

4.5.3 Female-to-Male (FTM)/Transgender Male/Trans Man

4.5.4 Male-to-Female (MTF)/Transgender Female/Trans Woman

4.5.5 Genderqueer, neither exclusively male nor female, non-binary gender

4.5.6 Additional gender category or other

4.5.7 Choose not to disclose

4.6 Patient sexual orientation

4.6.1 Lesbian, gay, or homosexual

4.6.2 Straight or heterosexual

4.6.3 Bisexual

4.6.4 Something else

4.6.5 Choose not to disclose

4.7 Patient preferred language

5.0 Reporter Information

5.1 Job or position of reporter

5.1.1 Healthcare professional

5.1.1.1 Doctor, dentist (including student)

5.1.1.2 Nurse, nurse practitioner, physician assistant (including student or trainee)

5.1.1.3 Pharmacist, pharmacy technician (including student)

5.1.1.4 Allied health professionals (including paramedic, speech, physical, or occupational therapist, dietician)

5.1.2 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

5.1.3 Emergency service personnel (including police officer, fire fighter, or other emergency service officer)

5.1.4 Patient, family member/caregiver

5.2 Staff/position type contributing information about Diagnostic Episode with Missed Opportunities

5.2.1 Clinician(s) who identified the accurate (final) diagnosis

5.2.2 Clinician(s) involved in the Missed Opportunities

5.2.3 Supervisors of the Clinician(s) involved in the Missed Opportunities

5.2.4 Clinicians with expertise/interest in diagnostic safety improvement

5.2.5 Patient safety/quality improvement professional

5.2.6 Risk manager

5.2.7 Other

6.0 Brief Narrative (Optional)