Appendix 1. Characteristics of databases used in development of the Framework for PRDBs

Dataset characteristic	IHI national survey dataset[35]	Open Notes survey dataset[25]
Eligible survey respondents	2536	22,889
Patient-reported errors	559 (22%)	4831/22889 (21%)
Family-reported errors	475 (19%)	n/a
Total non-trivial errors available for analysis	1034	1749
Ambulatory errors	416 (40%)	1749 (100%)
Survey setting	General public – panel representing US population	Clinical: Patients reading office visit notes at 3 US sites
Method of survey administration	Online or by telephone	Online through the patient portal
Survey Language	English or Spanish	English
Year of survey	2017	2017

PRDB=Patient-Reported Diagnostic process-related Breakdown. Table created by the authors

Appendix 2. The Framework for Patient-Reported Diagnostic process-related Breakdowns in ambulatory care

I. PATIENT-REPORTED BREAKDOWN/PROBLEM:

ACCESS TO CARE: A problem or delay in accessing care including:

- Scheduling a medical appointment
- Getting to the appointment
- Difficulty paying for care
- Lack of interpreter
- Access, not further described

MEDICAL HISTORY: A problem or delay in gathering, understanding, or interpreting the medical history, including:

- Wrong symptoms or main concern:
    - Description of symptoms, course of illness ("history of present illness"), sequence, duration, location, severity, what makes symptoms better or worse
    - Discrepancy in symptoms or other history in one part of the note vs another
    - Incorrect location of recent care related to current problem
    - Missing or wrong interpretation of symptoms or history related to medications including:
        - History of medications: How long patient has been taking particular meds and/or description of their effects or side effects on the patient
        - Unrecognized effect or side effect of medication/unmonitored medication including medication interactions
- Inaccurate diagnostic history: Current or past diagnoses misidentified in the history; ie specific (named) conditions listed or omitted in error
    - Patient has a diagnosis that is missing (or not listed)
    - Patient is not aware of a diagnosis that is listed or does not have diagnosis
    - Patient has the condition but the wrong diagnosis/type is listed; ie type 1 vs type 2 diabetes
    - Billing codes (imply diagnosis that patient does not have/is not aware of)
- Inaccurate past medical history:
    - Prior medical problems or conditions (except those specifically named (see "current or past diagnosis"))
    - Dates or types of surgeries or dates of clinical course
    - Incorrect healthcare provider or healthcare facility involved in prior care
- Wrong side: The description of "right" vs "left" is incorrect (For example: "broke *right* leg," when it was really the *left* leg.)
- Wrong patient: The information is about the wrong patient or appears to be about someone else
- Inaccurate social habits and circumstances:
    - Alcohol use, smoking, drug use or other habits
    - Patient's or family job/employment, place of residence
    - Family members names, ages, place of residence, employment, family structure
- Inaccurate family history: Inaccurate or missing family medical conditions: especially history of cancer, diabetes, other heritable diseases
- Something important is missing
    - Incomplete information in the records or from prior organization (ie records not sent or incomplete) or missed by provider
- Inaccurate patient characteristics: Inaccurate preferred name, age, gender, sexual orientation, race, ethnicity or other such description
- Medical history, not further described

PHYSICAL EXAM: A problem or delay related to the physical exam, including:
- Inaccurate description of physical exam
- Documentation of parts of exam that patient perceives were not done or missing physical exam
- Physical Exam, not further described

TESTS AND REFERRALS: A problem or delay in planning, completing, interpreting or communicating about medical tests, results, diagnostic procedures or referrals, including:

- Ordering/scheduling:
    - Wrong test or referral ordered
    - Delayed test or referral: delay in ordering test or in getting appointment/test/procedure due to system issue, such as lack of necessary paperwork to obtain recommended tests
- Completing:
    - Problem or delay completing tests or referrals
- Follow up/Interpreting:
    - Test results not viewed or followed up
    - Healthcare provider not aware of more recent test results
    - Wrong healthcare provider receiving results/referral notes
    - Something important missing from tests, results, or referrals
- Communicating: Results not communicated appropriately to patient
- Tests/referrals, not further described

EXPLANATION AND NEXT STEPS: A problem or delay in explaining the symptoms in a timely manner, or communicating the explanation to the patient/family; or in communicating, coordinating, or arranging next steps, including:

- Problem or delay in reaching a final diagnosis
    - Failure to consider alternate explanations of symptoms or bias toward a fixed but unproven explanation such as all symptoms seen through the lens of pre-existing diagnosis (i.e., depression)
    - Disagreement between clinicians about diagnosis, or treatment resulting in confusing/conflicting information for patient/family
    - Other failure or delay, not otherwise described
- Problem or delay with communicating the diagnosis to the patient
- "Diagnosis," not further described
    - ie Patient comment that uses the words diagnosis or misdiagnosis/misdiagnosed
- Next steps not communicated to patient or does not match patient understanding
- Something important missing from next steps or care plan
- Problem or delay of treatment (including clinician planning or coordination)
    - Wrong treatment
    - Other failures or delays related to clinician planning for next steps
    - Inadequate coordination of care between providers or between visits
- Care plan/treatment/coordination, not further described

COMMUNICATION AND RESPECT: A problem or delay related to communication specifically described by the patient or family, including:

- Patient not listened to/not heard Patient specifically (subjectively) states that they felt unheard

  - Healthcare provider unresponsive/fails to communicate upon request
  - Patient concern or knowledge dismissed, ignored, not taken seriously, not 'believed'
  - Patient's request to address a perceived problem was ignored
- Misalignment between patient and clinician about symptoms, events, or significance of these: A mismatch between patient and provider about significance of a new or persisting problem. Misalignments may vary in degree and may not be recognized by the patient or the clinician at the time of the visit. Patient objectively states a mismatch. Although misalignment may coexist with "Patient not listened to/not heard," in some instances clinician may have listened but not remembered, etc. In other words, some patients may not report that they feel unheard, but could independently report misalignment).
  - Misalignment about problem significance or failure to address patient's main concern; for example, patient specifically reports that the description of the main problem in the note does not match their experience of illness
  - Misaligned emotional factors related to a problem, (such as patient fear of diagnostic test)
  - Misaligned memory of visit related to a problem: Something written that patient believes "did not happen at visit" such as documentation of counseling or other discussion that patient perceives did not occur
  - Lack of Shared Decision Making: Explanation of health issues, elicitation of patient preferences, integration of patient preferences in choosing next steps including note indicates that patient declined a treatment, test, or surgery, but patient disagrees
- Lack of transparency from provider: Lack of access to the right information at the right time
  - Lack of access to health information
  - Lack of open and honest communication (including after harmful event)
  - "Selective" documentation (litigious influences/pressures); Misrepresentation of documentation: 'if something looks like harm it does not go into the record'
- Ineffective or inadequate communication about uncertainty to patient or between providers: Missing or incorrect communication by or between healthcare providers related to uncertainty about diagnosis, care plan, or other aspects of care
- Experience of disrespect: A specific experience of disrespect with a stated or implied negative impact (ie offended) described by the patient such as being: belittled, mocked, ignored, short-changed, mistreated, manipulated, deceived, treated rudely, labeled or stereotyped (including race/ethnicity, "Young (biased as healthy)", female, on pain medications, mental health, gender non-conforming, substance abuse or mental health disorder, or other specific characteristic)
- Communication, not further described: Wrong or missing information related to communication that is specifically mentioned by the patient but not otherwise detailed

OTHER BREAKDOWN POTENTIALLY RELATED TO THE DIAGNOSTIC PROCESS: A breakdown not represented in the above categories but related to the diagnostic process; such as:

- Error stemming from copy/paste documentation
- Incorrect billing (diagnostic) code (implying a wrong diagnosis)
- Technology or telemedicine related*: poor access, inadequate physical exam, impaired communication, or inadequate follow up
- Other breakdown related to the diagnostic process, not further described

NOT APPLICABLE: Patient report is not applicable due to:

- Insufficient information to categorize the breakdown
- Breakdown is not directly related to the diagnostic process such as medications/allergies or non-diagnostic procedural problems

II. PATIENT-REPORTED CONTRIBUTING FACTORS

CLINICIAN FACTORS: Problem or delay in timely and/or accurate clinician evaluation due to a clinician factor such as:

- Failure to consider alternate explanation(anchoring), implicit or explicit bias
- Disagreement or miscommunication between clinicians about history, diagnosis, or treatment
- Failure to educate patient on life-threatening symptoms, and actions to take if they arise
- Lack of clinician engagement of patient or care partner in care and/or care decisions to the degree desired by patient/family
- Clinician factor, not further described

PATIENT FACTORS: Patient-related problem affecting access, adherence, communication, or care, such as:

- Barriers to communication or speaking up
- Power hierarchy, fear of judgment, fear of being a troublemaker
    - Too sick, anxious or confused
    - Not sure if important
    - Patient-provider relationship problem: pre-existing distrust, unmet or unrealistic expectations, or other relational challenge
- Social determinants: Language, literacy, culture, social norms and attitudes, education, employment, transportation, housing, child/elder care, cost, or other inadequate resources
- Physical barriers (i.e, experienced by persons with disabilities)
- Privacy concerns
- Prior distressing experience with healthcare, harm or medical error
- Lack of knowledge about how to escalate concerns about worsening or persistent symptoms
- Patient factor, not further described

SYSTEMS FACTORS: Organizational or technical factor, such as:

- Inappropriate copy/paste or use of templates
- EHR problem or glitch such as wrong or missing data due to new or updated EHR
- Problematic hospital/practice policies that prevent patients/families from completing next steps
- Insurance problem or delay
- Failure to provide access to test results, medical notes, and other relevant health information
- System factor, not further described

III. PATIENT-REPORTED IMPACT:

PATIENT ACTIVATION or MITIGATION: Patient describes an increased level of activation, strengthened healthcare relationship, or problem resolution, such as:

- Increased patient activation or engagement as a result of the breakdown
- Positive impact on patient-healthcare provider relationship
- Mitigation of perceived breakdown

NEGATIVE PATIENT IMPACT: Patient describes a negative effect on care or care experience related to the perceived error, such as:

- Negative physical impact
    - Incorrect or delayed diagnosis or treatment
    - Worsening of health condition
    - Additional care, admission, or prolonged treatment required
    - Other negative impact on adherence, partnership; referral/work up/care plan
- Negative emotional or psychological impact
    - Increased worry
    - Privacy concerns
    - Frustration (i.e. failed attempt to correct the problem or healthcare provider not responsive to concerns) explicitly stated or reflected in tone of the report
    - Repeated breakdown (happened more than once)
- Negative impact on patient-healthcare provider relationship; decreased trust
- Negative impact on relationships including effects on family of social interactions
- Negative financial impact including insurance, disability or legal issues
- Patient Disengagement including:
    - Hopelessness, sense of futility or overwhelm with healthcare system
    - Despair or “no meaningful change” after reporting/sharing information
- Decision to leave care/Change provider
- Negative impact, not further described

Appendix created by the authors

Appendix 3: Inter-coder reliability testing of the PRDB framework breakdown categories in two datasets

Dataset	Reliability testing across 7 breakdown categories	Kappa (95% CI)	AC1 (95% CI)
1 (n=416)	MD1 vs MD2 (raw data)	0.84 (0.81,0.86)	0.95 (0.95, 0.96)
	Adjudicated MD vs patient coder	0.85 (0.83,0.88)	0.96 (0.95, 0.97)
2 (n=1749)	MD1 vs MD2 (10% raw data)	0.77 (0.73,0.81)	0.93 (0.92,0.94)
	MD vs patient coder	0.64 (0.62,0.66)	0.89 (0.89,0.90)

PRDB=Patient-Reported Diagnostic process-related Breakdowns. Table created by the authors.

Appendix 4: How clinicians and systems can help avoid patient-reported ambulatory diagnostic pitfalls: Six features of strong patient-provider diagnostic teams

Figure created by the authors.