Framework for Measurement of Diagnostic Quality

Potential definitions of **diagnostic quality**:

- *The degree to which an accurate and timely explanation of a patient's health problems has been (1) established and (2) communicated to the patient.*[1]
- *The degree to which the healthcare system can be relied upon to establish an accurate and timely explanation of a patient's health problem and to communicate that explanation to the patient.*[1]
- *The degree to which diagnosis-related systems, processes, and behaviors increase the likelihood of desired health outcomes and are consistent with current professional knowledge.*[1]

Efforts to improve diagnostic quality should also address the six dimensions of quality identified by the IOM:[2]

- Safe: Avoiding harm to patients from the care that is intended to help them.
- Effective: Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and misuse, respectively).
- Patient-centered: Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- Timely: Reducing waits and sometimes harmful delays for both those who receive and those who give care.
- Efficient: Avoiding waste, including waste of equipment, supplies, ideas, and energy.
- Equitable: Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

This framework for measuring diagnostic quality is based largely on the National Academy of Medicine's conceptual model of the diagnostic process. For the purposes of identifying, categorizing, and prioritizing measures, elements of the NAM model have been set within Donabedian's organizing concepts of structure, process and outcome.[1]

[1] Donabedian, A. (1988). *"The quality of care: How can it be assessed?"*. *JAMA*. **260** (12): 1743–8.

Structure

The **Structure** domain of the framework comprises aspects or attributes of the work system in which diagnosis occurs; these attributes may include the presence/availability of material or human resources, the characteristics of organizations involved in the diagnostic process, and social or environmental factors that have an impact on diagnosis.

Structural measures addressing diagnostic quality may be categorized using six subdomains:

- **People**: Addresses factors related to the diagnostic team, which includes patients and their families as well as all health care professionals involved in their care.
- **Tasks**: Addresses the extent to which the work system enables or impedes the various actions and processes involved in diagnosis. This subdomain is not intended to address whether the appropriate actions and processes have themselves occurred—this is covered in the Process domain—but rather the degree to which organizational systems, policies, and procedures have established conditions under which these tasks are likely to be executed successfully.
- **Technologies and Tools**: Addresses the availability and adequacy of tools used in the diagnostic process, including health information technology (HIT), laboratory and imaging resources, data tools, and other resources used by diagnostic team members to reach an accurate and timely diagnosis.
- **Organizational Characteristics**: Addresses organizational attributes that affect diagnostic performance, including culture, leadership, and policies and procedures related to diagnosis.
- **Physical Environment:** Addresses the extent to which the physical environment (e.g., facility layout, lighting, distractions, etc.) facilitates or constrains diagnostic performance.
- **External Environment:** Addresses the extent to which the external environment (e.g., legal factors, policies, regulations, payment models, etc.) facilitates or constrains diagnostic performance..

Process

The process domain of the framework addresses whether actions or processes supporting accurate and timely diagnosis are being performed safely, effectively, and as appropriate.

Process measures addressing diagnostic quality may be categorized using six subdomains:

- **Patient engagement:** Addresses actions, processes, and behavior related to engagement of patients and families in the diagnostic process, including ensuring timely access to care and patient behavior.
- **Information gathering/diagnostic evaluation:** Addresses the actions, processes, and behavior involved in gathering information and carrying out an initial diagnostic evaluation.
- **Information interpretation/hypothesis generation:** Addresses the actions, processes, and behavior involved in interpreting information gathered through diagnostic evaluation and generating a hypothesis to explain the patient's health problem.
- **Information integration/hypothesis confirmation & revision:** Addresses the actions, processes, and behavior involved in confirming and revising diagnosis over time; this subdomain includes communication of diagnosis-related information between healthcare providers.

- **Communication of the diagnosis to the patient:** Addresses the actions, processes, and behavior involved in communicating with patients about their diagnosis (or information relevant to their diagnosis) in a timely and effective way.
- **Quality improvement and learning activities:** Addresses actions, processes, and behaviors undertaken to monitor and improve diagnostic performance.

Outcome

The outcome domain of the framework addresses outcomes associated with diagnosis, or the effects of diagnosis-related activities on the health status of patients.

Diagnostic outcome measures can be categorized using four subdomains:

- **Intermediate outcomes:** When measuring the quality of healthcare, an intermediate outcome is typically defined as a change in physiologic state that leads to a longer-term health outcome for the patient (e.g., improvement in HbA1c levels for a patient with diabetes). In the case of diagnostic quality, we are using 'intermediate outcome' to address the extent to which an accurate and timely diagnosis, or explanation of the patient's health problem, has been achieved.
- **Patient outcomes:** Addresses changes in patients' health status that can/may be linked to the quality of diagnostic care.
- **Patient experience:** Addresses patients' experiences with their care, as it relates to diagnosis or the diagnostic process
- **System outcomes:** Addresses outcomes for the healthcare system as a whole (or individual health systems), including costs, resource use, patient trust/confidence, and other system outcomes related to diagnosis

Illustrative Examples

The charts below provide examples of measurement areas and measure concepts that could be associated with each domain/subdomain.

Structure	
Subdomain	**Examples of measure concepts**
People • Patient factors • Workforce factors • Administrative and clinical support	• Staff involved in diagnosing patients have appropriate competency to do so • Provider mix involved in diagnosis are appropriate for the complexity of the case • Radiologists are available 24/7 to read stat diagnostic imaging studies in real time • Attending staff are on site to supervise trainees 24/7 • Support staff operate at the top of their license to free up cognitive load of the MD • Scribes, administrative staff are available to support diagnosis • Patients understand actions they can take to improve diagnostic performance

Tasks • Workflow • Communication • Diagnosis	• SOP's exist for triaging patients and assigning them to appropriate providers • Consult agreements exist between primary care and subspecialty consultants • SOP's are in place to ensure test results are communicated reliably • Second opinions and specialty consultation are available
Technologies and tools • Hardware and software • Clinical content of HIT (e.g., clinical decision support) • Human-computer interface • Availability of diagnostic resources	• The organization uses an interoperable and certified EHR with CDS functionality • Web-based decision support tools and online reference materials are available to all providers to aid differential diagnosis • Advanced imaging and laboratory diagnostics are available • The organization has an EHR data warehouse and informatics team to enable diagnostics measurement related to diagnostic safety (e.g., trigger tools) • Proportion of patients that have electronic portal access
Organizational Characteristics • Culture • Policies and procedures (e.g., time allocated for diagnosis, oversight of the process)	• Leadership understands that diagnostic error is a major safety concern that needs addressing • Healthcare organizations develop processes and procedures to identify and learn from cases of diagnostic error • The organization has an established mechanism for providing feedback when there is a significant change in diagnosis • The organization has expertise to conduct a comprehensive RCA in cases involving diagnostic error • The organization has someone designated to monitor and improve diagnostic performance
Physical Environment • Layout, noise, lighting • Distractions and interruptions • Workload and performance pressure	• Physicians have adequate time for diagnosis • The environment for diagnosis promotes quality (i.e., makes diagnosis easier, not harder)
External Environment • Payment • Care delivery system • Legal environment • Reporting environment	• Payment incentives promote quality over quantity • Care delivery system promotes primary care approach & care coordination • Care delivery is patient-centered, not physician-centered • The legal environment promotes case discussions, error reporting, and learning to improve diagnosis

Process

Subdomain	Examples of measure concepts
Patient engagement • Access to care • Patient behavior • Timing of presentation • Communication with patient	• Proportion of patients with appropriate compliance with cancer screening • Proportion of patients that actively use electronic portal access • Ease of getting an appointment • Patient access is expanded geographically and through extra hours nights, weekends
Information gathering/diagnostic evaluation • Eliciting patient history & performing the physical exam • Collecting existing data, old records • Connecting with family, caregivers, and primary care staff • Ordering the appropriate diagnostic tests • Technical errors in handling or processing of diagnostic tests	• Adequacy of documenting the initial findings; clarity and accuracy of the documentation • Adequacy of collecting available data; adequacy of connecting to other providers and the family • Adequacy of assessing patient literacy
Information interpretation/hypothesis generation • Interpretation of history, physical exam findings, test results • Weighting and prioritization of information • Integration of team-based information • Generating diagnostic possibilities that are rational, evidence-based if possible, and not inappropriately biased	• New problems generate a differential diagnosis • Clinical decision support is used appropriately to ensure diagnosis is comprehensive • Proportion of diagnostic evaluations with appropriate team involvement

Information integration/hypothesis confirmation & revision (diagnosis that plays out over time)
• Testing follow-up
• Consultation from specialists
• Time-related aspects of diagnosis: Watchful waiting, re-evaluation after tests and consults;
• Appropriate follow-up
	• Proportion of patients with timely follow up
	  ○ After an initial diagnosis
	  ○ After identification of a red flag condition
	  ○ After identification of incidental but possibly important findings
	• Proportion of patients diagnosed with a specified target disease of interest (e.g., known diagnostic dilemmas) who received a second opinion
	• Problem list is accurate and up-to-date
	• Diagnosis is timely:
	  ○ Proportion of laboratory test results or diagnostic imaging not performed within the expected turnaround time
	  ○ Proportion of abnormal diagnostic test results returned but not acted upon within an appropriate time window
	  ○ Proportion of clinical providers who identify a surrogate to review diagnostic test results while on vacation or when leaving employment
	  ○ Timeliness of cancer evaluation; e.g., time from positive blood in stool to colonoscopy

Communication of the diagnosis • Failure/delay in notification of patient • Incomplete explanation • Patient does not understand explanation	• Communication about the diagnosis is documented • Tests pending at discharge are followed-up • Revised reports from radiology and pathology are appropriately communicated • Critical results are reliably communicated • Communication accommodates patient literacy level
Quality improvement and learning activities • Monitoring diagnostic performance • Identifying diagnostic errors • Learning and improving	• Organization monitors adenoma detection rates and provides feedback to endoscopists • Organization measures diagnostic performance (lab, radiology, ER, selected specialties or clinical conditions) • Organization sponsors and encourages learning through M&M conferences, etc

Outcome	
Subdomain	**Examples of measure concepts**
Intermediate outcomes • Correctness/accuracy of diagnosis • Timeliness of diagnosis	• Proportion of patients with newly-diagnosed colorectal cancer diagnosed within 60 days of first presentation of known red flags • Discrepancy rate of pathological interpretations • Timeliness of diagnosing targeted diseases of interest (anemia, asthma, diabetes, COPD, etc)
Patient outcomes • Morbidity/mortality related to diagnostic error/failure • Harm to patients (e.g., physical, psychological, financial) resulting from diagnostic errors or failures	• Failure to rescue episodes • % of cancers diagnosed at late stage, or that should have been found through screening • # of diagnostic errors reported by MD's or patients • # of patients targeted through trigger tools designed to avoid harm
Patient experience • Patient surveys or other patient-focused assessments of diagnosis-related experience	• Patient satisfaction with the diagnostic process
System outcomes • Cost & resource use • Efficiency	• # of malpractice suits • # of re-visits and re-admissions related to diagnostic error • # of patients who leave the system to get diagnosed elsewhere