

Clinical Validation: the Next Level of CDI (December 2016 update)

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One of the more challenging tasks for both coding and clinical documentation improvement (CDI) professionals is clinical validation. This is a relatively new responsibility that has evolved as CDI programs mature and CDI and coding professionals advance their knowledge and collaboration on clinical care.

As explained in the 2008 Practice Brief “Managing an Effective Query Process:”

Providers often make clinical diagnoses that may not appear to be consistent with test results. For example, the provider may make a clinical determination that the patient has pneumonia when the results of the chest x-ray may be negative. Queries should not be used to question a provider’s clinical judgment, but rather to clarify documentation when it fails to meet any of the five criteria listed [here]—legibility, completeness, clarity, consistency, or precision.

A query may not be appropriate simply because the clinical information or clinical picture does not appear to support the documentation of a condition or procedure (e.g., documentation of acute respiratory failure in a patient whose laboratory findings do not appear to support this diagnosis). In situations where the provider’s documented diagnosis does not appear to be supported by clinical findings, a healthcare entity’s policies can provide guidance on a process for addressing the issue without querying the attending physician.

This advice was revised in the 2013 Practice Brief “Guidelines for Achieving a Compliant Query Practice,” which stated a query is appropriate when the health record documentation “provides a diagnosis without underlying clinical validation.” The article adds the additional statement, “When a practitioner documents a diagnosis that does not appear to be supported by the clinical indicators in the health record, it is currently advised that a query be generated to address the conflict or that the conflict be addressed through the facility’s escalation process.”

However, the original 2013 Practice Brief (updated in 2016) didn’t provide advice on how to determine if a documented diagnosis is supported by clinical indicators. Coding professionals may default to the American Hospital Association’s (AHA) *Coding Clinic* for clarification regarding how and when to assign a code, but the updated 2016 Practice Brief also highlights the following:

Although AHA’s *Coding Clinic*® for ICD-10-CM and ICD-10-PCS often references clinical indicators associated with particular diagnoses, it is not an authoritative source for establishing the clinical indicators of a given diagnosis. A recent *Coding Clinic*® issue also stated that it is not intended for such a purpose. Clinical indicators should be derived from the specific medical record under review and the unique episode of care. Clinical indicators supporting the query may include elements from the entire medical record, such as diagnostic findings and provider impressions.

It is also important to note that clinical validation is a somewhat subjective concept as practitioners often disagree how to define conditions such as severe malnutrition and acute respiratory failure.

Let’s take a closer look at the concept of clinical validation by examining how it is defined by the Centers for Medicare and Medicaid Services (CMS) as referenced in the Recovery Audit Contractor (RAC) Scope of Work (SOW) document from 2013:

Clinical validation is an additional process that may be performed along with DRG validation. Clinical validation involves a clinical review of the case to see whether or not the patient truly possesses the conditions that were documented in the medical record. Recovery Auditor clinicians shall review any information necessary to make a prepayment or post-payment claim determination. Clinical validation is performed by a clinician (RN, CMD or

therapist). Clinical validation is beyond the scope of DRG (coding) validation, and the skills of a certified coder. This type of review can only be performed by a clinician or may be performed by a clinician with approved coding credentials.

Based on CMS's guidance, it appears clinical validation may be most appropriate under the purview of the CDI professional with advanced clinical education and a background in conducting clinical reviews. Individual facilities need to establish their own criteria for the credentials, education, and experience required of their CDI professionals and develop processes to ensure collaboration between CDI and coding professionals. Additionally, it is important for coding professionals to increase their clinical knowledge as suggested in the Journal of AHIMA article "Taking Coding to the Next Level through Clinical Validation," so they can accurately refer cases to CDI professionals or a physician advisor as necessary. Per the new FY 2017 ICD-10-CM Official Coding Guideline A.19. and reiterated in the AHA Coding Clinic (Fourth Quarter 2016, pp. 147-149), clinical validation is a separate function from the coding process. The codes assigned by the coding professional are based on the documentation by the physician, not on a particular clinical definition or criteria. This guidance emphasizes the need for facilities to have a process in place to validate the patient's clinical conditions prior to completing the coding process.

The goal of clinical validation is to ensure that the health record is not only coded accurately, but also accurately reflects the clinical scenario within the health record, which requires collaboration among providers, CDI professionals, and coding professionals. The importance of accurately capturing the clinical scenario through the available code set continues to grow as CMS revises its payment methodologies, tying quality of care to reimbursement. Clinical validation is also a frequent reason for payment denials.

Figure 1: Guidelines for Building Consensus on Challenging Clinical Cases

Collaborative CDI/Coding Meetings

A collaborative meeting should occur on a regular basis to discuss ongoing documentation issues and provide coding and CDI education. These meetings should be designed to:

- Improve mechanics of the concurrent joint review process
- Enhance ongoing clinical education such as reviewing topics or introducing new procedures or medications
- Share changes in the Official Coding Guidelines
- Strategize to address physician concerns such as uncooperative or unresponsive physicians
- Understand and discuss educational opportunities related to DRG assignment
- Create a forum for asking questions concurrently rather than retrospectively
- Educate on opportunities for querying physicians as well as tactics and methodologies to elicit physician response

Second Level Reviews

Second level reviews are designed to provide CDI and coding professionals with a mechanism for ensuring accuracy and validation of the clinical picture for challenging cases or instances of discrepancies.

Health records that may be referred for a second level review can include:

- Cases where there is an opportunity for a MCC/CC
- Cases with only one MCC/CC
- Cases where a Sign and Symptom DRG has been assigned
- Cases where the "Working DRG" and "Final DRG" do not match
- Cases where the operating room procedure is unrelated to the principal diagnosis (DRGs 981-989)

Upon completion of reviewing a health record that meets the criteria listed above, the CDI or coding professional should refer the record to the designated Second Level Reviewer (SLR). This individual will:

- Review the record to validate an accurate and complete clinical picture

- Note where opportunities for additional documentation or clarification exist
- Provide feedback to the CDI and/or coding professional

Compliance Can Support Clinical Validation

AHIMA has published the “Ethical Standards for Clinical Documentation Improvement Professionals” and “Standards of Ethical Coding” to offer professional guidance for addressing issues like compliance, decision-making processes and actions, expectations for making ethical decisions in the workplace, and demonstrating the professionals’ commitment to integrity. Additionally, as a cooperating party with CMS, the AHA, and the National Center for Health Statistics (NCHS), AHIMA is able to set professional practice expectations for proper ICD-10-CM/PCS coding. AHIMA guidance applies not only to those who are AHIMA members or HIM professionals, but is relevant to all clinical documentation improvement professionals and those who manage the CDI function, regardless of the healthcare setting in which they work or their credentials. CDI professionals have an obligation to demonstrate actions that reflect ethical principles and guidelines.

For documentation to be considered high quality, it must be legible, complete, timely, reliable, consistent, precise, and clear. CMS encourages providers to ensure all entries are congruent with other parts of the health record (assessments, treatment plans, physician orders, nursing notes, medication and treatment records, etc.). Whenever an entry is made that contradicts documentation found elsewhere in the record, clarification should be obtained from the attending physician. CMS requires that any information that affects billed services and is acquired after the health record is complete must be added to the existing documentation in accordance with accepted standards for amending health record documentation.

Compliance, whether it’s a formal compliance department that understands compliant coding or coding management performing quality audits, can support the clinical validation process. Compliance can assist in developing a standardized query policy that applies to all who perform the query process within the organization regardless of the department in which they are located. Monitoring and auditing queries to ensure they do not incorrectly or unduly influence health record documentation is also a function of compliance. Auditing a small sample (i.e., 15 records per year) of coded records by each coding professional (both contract and employed) is one way to ensure that each coding professional is given some education on clinical validation.

Due to an increase in the number of denials for lack of clinical validity in the health record, CMS stated that recovery auditors may use clinical review judgment to assist in making payment determination. The CMS Medicare Learning Network Quarterly Compliance Newsletter, “Guidance to Address Billing Errors,” shared RAC audit findings on several targeted areas. One of the targeted areas was acute hypoxic respiratory failure. After review of one case, it was determined that the clinical evidence in the health record did not support reporting of respiratory failure, despite physician documentation of the condition. Unfortunately, the article did not elaborate regarding the specific shortcomings of the clinical evidence nor did it specify the minimum threshold of clinical evidence to support the diagnosis of acute hypoxic respiratory failure. The result of the audit was deletion of the acute respiratory failure code, changing the principal diagnosis to chronic obstructive pulmonary disease (COPD) exacerbation. This resulted in a MS-DRG change and an overpayment.

Identifying Clinical Indicators

Determining the clinical validity of a reported condition is subjective, which is why denials are plentiful. Although it is tempting for CDI and coding professionals to define diagnoses for providers, doing so is beyond their scope. For example, it is not appropriate for a CDI or coding professional to omit the diagnosis of malnutrition when it is based on the patient’s pre-albumin level rather than American Society for Parenteral and Enteral Nutrition (ASPEN) criteria. Many practicing physicians have not adopted ASPEN criteria and there is no federal or American Medical Association (AMA) requirement stating that ASPEN criteria must be utilized by a physician in making the diagnosis of malnutrition.

Establishing clinical indicators is also beyond the scope of the *Coding Clinic*. In fact, according to CMS’ Official Coding Guidelines, “The term provider is used throughout the guidelines to mean physician or any qualified health care practitioner who is legally accountable for establishing the patient’s diagnosis.” Neither CDI professionals nor coding professionals are qualified to establish diagnoses. Some CDI professionals do possess a medical degree, but should not be diagnosing the patient if they are not a member of the treating medical team.

So what is the required threshold necessary to clinically validate a diagnosis? CMS only states, “As with all codes, clinical evidence should be present in the medical record to support code assignment.” Typically, CMS does not define diagnoses unless specified in a National Coverage Determination (NCD) or Local Coverage Determination (LCD). Otherwise, CMS requires the following:

All entries in the medical record must be complete. A medical record is considered complete if it contains sufficient information to identify the patient; support the diagnosis/condition; justify the care, treatment, and services; document the course and results of care, treatment, and services; and promote continuity of care among providers. With these criteria in mind, an individual entry into the medical record must contain sufficient information on the matter that is the subject of the entry to permit the medical record to satisfy the completeness standard.

A good practice is for the person performing clinical validation to ask themselves whether other providers would come to the same conclusion based on the same information. Is the diagnosis a reasonable conclusion based on the totality of the health record? Organizations are also well served to develop internal guidelines defining those diagnoses most vulnerable to denials. The criteria should be created in collaboration with the medical staff, CDI professionals, coding professionals, and quality of care professionals. The goal of these guidelines is to promote consistency among CDI and coding professionals in identifying diagnoses that appear to lack sufficient clinical evidence.

Watch for Vulnerable Diagnoses

As discussed above, clinical validation denials typically result in a DRG change from an external auditing entity. They are usually addressed to facility leadership and routed to the HIM department, case management, or CDI department to review and develop a collaborative response. Coding professionals often feel caught in the middle because, traditionally, if a diagnosis was documented in the health record it was coded as long as it met Uniform Hospital Discharge Data Set (UHDDS) criteria for reporting as a secondary diagnosis. However, the concept of clinical validation is subjective since many diagnoses lack a standardized definition agreed upon by all practitioners. In situations where the provider’s documented diagnosis does not appear to be supported by clinical findings, internal policies can provide guidance, if available, outlining a process for addressing these specific cases.

In addition to addressing retrospective denials, front-end process changes and education for the appropriate audience may assist with ensuring complete and accurate clinical documentation. While coding and CDI staff continue to educate providers on the importance of documentation, it is equally important to encourage providers to emphasize the clinical evidence they relied upon to make the diagnosis. Some of the specific conditions that could be vulnerable to challenge include: sepsis, acute respiratory failure, metabolic encephalopathy, and severe malnutrition.

Example of Documentation and Query with Diagnosis of Sepsis

The following is an example of documentation associated with the diagnosis of sepsis. The clinical scenario is as follows:

78-year-old female presents with a change in mental status, fever/chills, painful urination and feeling weak all over. Physician exam reveals tachycardia with a temperature of 102 degrees, with all other systems within normal limits. Admit diagnosis: Sepsis due to UTI. Day 1 Progress note: Patient less confused; frequent & painful urination; started on oral antibiotics. Day 2 Progress note: WBC within normal limits; temperature 99 degrees, continue with course of antibiotics and discharge. Discharge Diagnosis: Sepsis.

The question that needs to be asked is "Do the clinical indicators overwhelmingly support the diagnosis of sepsis, which is frequently challenged for a lack of clinical significance?" It could be argued that sepsis is not supported by the totality of the record due to lack of IV antibiotics, lack of an infectious disease consult, lack of sustained abnormal clinical values and short length of stay. Consequently, the physician should be queried to validate the diagnosis of sepsis.

Sample Query

Sepsis was documented as a discharge diagnosis in this patient with the following clinical scenario (see above). Based on standard recognized clinical criteria for sepsis... [Note: include documentation here of facility criteria or other standard criteria for sepsis]. Can you please clarify the status of sepsis, as follows:

- ☐ ☐ Sepsis was confirmed
- ☐ ☐ Sepsis was ruled out
- ☐ ☐ Sepsis was without clinical significance
- ☐ ☐ Unable to determine
- ☐ ☐ Other _____

Refer to [Appendix A](#) for additional clinical validation query examples.

Gaining Consensus on Clinical Validation

Many organizations struggle with CDI and coding collaboration. This collaboration is becoming even more challenging as more employees work remotely, making communication more cumbersome. Organizations are well served to clearly define the expectation of both CDI and coding efforts in regard to clinical validation. The coding professional is responsible for accurately reporting the diagnoses associated with the claim as coded data, but clinical validation precedes code assignment since ensuring the condition meets UHDDS guidelines for reporting and adherence to coding guidelines is no longer the only consideration.

Specifically, organizations need to consider how to address the following types of discrepancies and develop processes to tackle the potential obstacles. Identifying discrepancies during the DRG reconciliation process is too late; billing has already occurred. Discrepancies need to be recognized and dealt with prior to billing to avoid potential rebilling or future denials. One such discrepancy is when the CDI professional determines a documented diagnosis is not supported in the health record. First, that discrepancy must be discussed with the attending physician, through the query process, and any changes properly documented in the health record. Also, the coding professional needs access to the CDI review so they can see the changes that occurred and understand why there were changes to the documentation. This workflow should be a seamless part of the coding process so that it doesn't impact coder productivity.

Another discrepancy occurs when the CDI professional identifies and reports a diagnosis classified as a complication or comorbidity (CC) or major complication or comorbidity (MCC), but the coding professional determines the diagnosis is not clinically supported by the health record. In this type of situation, what is the resolution? Is the CDI professional required to query the provider for clarification at the coding professional's request? Does the coding professional query the provider? Is a query necessary if the CDI professional is qualified to complete a clinical validation review? Failure to establish a precise process can negatively impact collaborative efforts as CDI professionals might feel ignored and coding professionals may feel compromised. Refer to Figure 1 above for some best practice guidelines for building consensus between CDI and coding on challenging clinical cases.

Some key areas where improvement may be needed to facilitate collaboration between the CDI and coding staff include:

- **Increased education for staff.** The increased specificity of the ICD-10 code set has required coding professionals to strengthen their foundational knowledge in pathophysiology, anatomy, and pharmacology. Moreover, additional education will be needed for CDI professionals with a solid clinical background that may not have adequate coding knowledge to be able to identify when a diagnosis requires further clarity to code the record. The ability of coding and CDI staff to understand one another's perspective will be helpful in clearing the path for building consensus for clinical validation.
- **Develop an effective query process.** The additional education and sharpened skill set should help to effectively identify when there are gaps in documentation to support a diagnosis and a query of the physician is necessary. Organizations should develop standards for identifying the need for queries based on high-risk, problematic, or confusing conditions.
- **Conduct regular meetings to discuss documentation issues.** Collaborative meetings between coding and CDI professionals should occur on a regular basis to discuss ongoing documentation issues and provide additional education.

Select cases for review where there are differences in the working DRG and the final DRG. During the meeting, have an open dialogue of how and why the specific principal diagnosis was obtained and review any MCC/CC discrepancies. Inviting clinical providers to the coding/CDI meetings to discuss clinical indications or specific disease processes or procedures is also very valuable.

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Appendix A: Clinical Validation Query Examples

Acute Respiratory Failure

Clinical Scenario

73-year-old man presents with difficulty breathing and confusion. Physical exam reveals tachypnea, wheezing, and cyanosis. Admission diagnosis: Acute respiratory distress secondary to COPD. Day 1 Progress note: Tachypnea and cyanosis still noted. Patient confused and cannot speak in full sentences. Pulse oximetry at 92 percent on 2 liters of oxygen. Day 2 Progress note: Patient doing better. Day 3 Progress note: Patient continues to improve. Day 4 Progress note: ABG normal. Discharge patient. Discharge diagnosis: Acute respiratory distress.

Sample Query:

Based on the patient's signs, symptoms, and treatments above are you able to further clarify the patient's diagnosis? Possible diagnoses include, but are not limited to:

- Chronic Respiratory Failure
- Acute COPD Exacerbation
- Acute Respiratory Failure

- *Acute-on-Chronic Respiratory Failure*
- *Respiratory Acidosis Alkalosis*
- *Respiratory Acidosis or Alkalosis*
- *Metabolic Acidosis or Alkalosis*
- *Acute Respiratory Insufficiency*
- *Acute Respiratory Distress*
- *Other*
- *Unable to determine*

If one of the above conditions is the source of the respiratory symptoms, please also document the acuity, severity, and type or cause if known.

Metabolic Encephalopathy

Clinical Scenario

85-year-old female presents with altered mental status and a UTI. Physical exam reveals poor coordination of movements. Admit patient with IV-ANTIBX. Day 1 Progress note: Patient still confused. Day 2 Progress note: Encephalopathy cleared; discharge patient.

The diagnosis of encephalopathy may be obvious in the provider's mind but often the specificity of a diagnosis is left out of the documentation. Clinical indicators of altered mental status and poor coordination of movements do not provide a clear picture of the type of encephalopathy the patient has and the provider should be queried.

Encephalopathy was documented in the health record. Based on the patient's clinical presentation are you able to clarify the type of encephalopathy you are treating? Examples include but are not limited to:

- ☐ *Subacute spongiform encephalopathy*
- ☐ *Wernicke's encephalopathy*
- ☐ *Subacute necrotizing (Leigh's) encephalopathy*
- ☐ *Hypertensive encephalopathy*
- ☐ *Post contusional (post-concussion) syndrome (encephalopathy)*
- ☐ *Alcoholic encephalopathy*
- ☐ *Hepatic encephalopathy (specify underlying cause) _____*
- ☐ *Post radiation encephalopathy*
- ☐ *Encephalopathy caused by infection (specify underlying infection) _____*
- ☐ *Toxic (metabolic or septic) encephalopathy (specify cause) _____*
- ☐ *Acute necrotizing hemorrhagic encephalopathy (specify post infectious vs. post immunization vs. other specified etiology vs. unknown) _____*
- ☐ *Paraneoplastic limbic encephalopathy (document underlying neoplasm) _____*
- ☐ *Other encephalopathy (specify) _____*
- ☐ *Unable to determine*

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Acknowledgements

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