Clinical Validation: The Next Level of CDI (January 2019 Update)

This Practice Brief supersedes the 2016 Practice Brief titled "Clinical Validation: The Next Level of CDI."

As healthcare continues to evolve and quality of care is tied to claims data and payment methodologies, payer expectations regarding what clinical documentation elements are necessary to support a claim have shifted. The goal of clinical documentation improvement (CDI) and health information management (HIM) coding professionals is to ensure the patient's clinical scenario is accurately captured in the health record. But as payer expectations change, so too does the concept of "accuracy." CDI and coding professionals are in a paradoxical situation; payers are limiting how they define a variety of clinical conditions, yet many of these conditions remain reportable under the ICD-10-CM Official Guidelines for Coding and Reporting and coding industry standards. Confirming a that documented diagnosis meets a particular clinical threshold is the basis of clinical validation. The clinical validation process requires collaboration among providers, quality professionals, CDI, and HIM. This process has become a very challenging task for most organizations, so it is important that each organization create their own policy and procedure related to the clinical validation process in both the inpatient and outpatient settings, based on industry guidance as established by this Practice Brief.

Depending on the needs of the organization, the clinical validation query (clarification) process is typically performed by CDI and coding professionals with a variety of backgrounds (registered nurse (RN), HIM coding, MD/DO, foreign medical graduate (FMG), etc.). As organizations may utilize a wide range of professionals with differing backgrounds and roles to send queries, this Practice Brief will refer to these professionals as query professionals throughout the rest of this document. CDI professionals have always employed clinical indicators to identify documentation gaps and/or discrepancies requiring additional clarification from the provider. Issuing a clinical validation query is simply requesting that the practitioner to confirm the presence of the condition and provide additional rationale for common scenarios such as:

- A diagnosis was documented, but the patient has an atypical presentation
- A diagnosis appears to lack the clinical indicators needed to meet organizational or payer criteria
- A documented diagnosis appears to be no longer valid, but the documentation does not show the condition as ruled out/eliminated/resolved

According to ICD-10-CM Official Guidelines for Coding and Reporting, "the term provider is used throughout the guidelines to mean physician or any qualified healthcare practitioner who is legally accountable for establishing the patient's diagnosis." Provider documentation should reflect and record the totality of clinical findings and medical decision-making. Validating a diagnosis is also the responsibility of the treating provider.

Those working in the role of query professional are not expected to establish diagnoses, but they can identify potential gaps in the clinical picture and send queries to clarify. Consequently, physician engagement is essential for a robust clinical validation process.

When a query professional writes a clinical validation query, they are not performing clinical validation. Rather, they

are highlighting a potential gap between a documented diagnosis and the clinical evidence in the health record. The diagnostic decision remains the responsibility of the treating provider.

The term “clinical validation” was introduced by the Centers for Medicare and Medicaid Services (CMS) within a 2011 Recovery Auditor Scope of Work. It is important to recognize that the process of clinical validation differs from the process of diagnosis-related groups (DRG) validation in the inpatient hospital setting. The *Pocket Glossary of Health Information Management and Technology, Fifth Edition*, gives the following definitions for these processes:[1]

- Clinical Validation: “The process of validating each diagnosis or procedure documented within the health record, ensuring it is supported by clinical evidence”

- DRG Validation: “The process in which the final DRG assignment is validated based upon the clinical documentation and the appropriate coding of the principal and secondary diagnoses, and any applicable procedures”

As DRG validation activities result in fewer denials for payers, many have turned their attention to clinical validation activities. Consequently, combating clinical validation denials is becoming a priority for many organizations. Clinical validation queries allow the provider the opportunity to “think in ink” when the relationship between the clinical scenario and the ensuing diagnosis may be somewhat ambiguous.

Who Should Write a Clinical Validation Query?

Establishing clinical criteria/indicators is beyond the scope of the American Hospital Association’s *Coding Clinic* guideline publication. This criterion typically comes from professional medical guidelines, consensus, and evidence-based sources. However, not all patients will display the same indicators of a diagnosis. Therefore, clinical validation query activities require careful review by a qualified professional with demonstrable clinical knowledge application irrespective of credential.

An organization should determine who will be performing clinical validation. As a best practice, a person performing clinical validation should ask themselves whether a different practitioner would arrive at the same conclusion based on the totality of the health record, and if the documented diagnosis can withstand an audit.

As a continuous process improvement, organizations should also develop internal guidelines defining those diagnoses most vulnerable for denials from payers, and/or compliance. The criteria should be created in collaboration with all applicable staff such as the medical staff, CDI, coding, compliance, and quality professionals. The goal of these guidelines is to promote consistency among providers when making a diagnosis and among query professionals in identifying diagnoses that appear to lack clinical evidence prior to code assignment.

The clinical validation process involves a clinical review of the case to identify any potential gaps between the diagnoses documented in the health record and the clinical evidence. The qualifications of a professional who can send clinical validation queries will vary by setting and organization. Many organizations support both CDI and coding professionals as authors of clinical validation queries. Adequately trained query professionals should not be prevented from writing clinical validation clarification queries based on their credentials and/or background (e.g., HIM coding background versus clinical background). All diagnoses documented in the patient’s health record should be substantiated by clinical criteria generally accepted by the medical community or a specific payer.

Clinical Validation Processes

Determining the clinical validity of a reported condition is subjective, which is why denials are plentiful. Although it is tempting for query 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 the 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.[2] It is also important to recognize that while quality measures may be helpful to determine clinical indicators, this is not the same as clinical validation and sources must be considered.

What is the required threshold necessary to clinically validate a diagnosis? CMS states, "As with all codes, clinical evidence should be present in the medical record to support code assignment."[3] 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.
>
> 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, compliance, 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."[4]

As discussed above, clinical validation denials may result in a DRG change from an external auditing entity. 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, acute kidney injury/renal failure, acidosis, and severe malnutrition.

There are four key areas to consider when developing a clinical validation process: building the clinical validation team, education, physician engagement, and denials management. Although some would argue that every CDI review includes clinical validation, some organizations may create a dedicated clinical validation team that performs second-level reviews, which may or may not also include DRG validation depending on the structure of the team. Cases that need closer scrutiny include those with any diagnosis or procedure that is vulnerable to denial as unsubstantiated by the record as well as those where performance on a quality of care measure would be impacted.

Building a Clinical Validation Team

Steps to building a clinical validation team include the following:[5]

- Create goals and establish workflow
- Engage a physician champion for complex reviews
- Analysis to determine trends by service, DRG, query, vulnerable diagnoses, or procedures with query, billed, and denied claims data
- Determine high-risk principal diagnoses
- Evaluate the team's knowledge base in recognition of clinical criteria and the coding classification system
- Evaluate the clinical support for documented diagnoses
- Re-evaluate processes
    - Determine effectiveness of processes
    - Evaluate need for revisions or deletion of workflow processes

Clinical Validation Education

To perform a thorough clinical validation review it is important that the query professional has initial and ongoing training in clinical concepts such as pathophysiology, pharmacology, diagnostic testing, anatomy, and physiology.

Topics that should be addressed during education include:[6]

- The need for clinical validation and awareness of process change
- Providers must receive continued support and feedback for positive outcomes of clinical validation
- Education on new procedures, treatments, and changes to coding guidelines for diagnosis/procedure code selection
- Ongoing education to target clinical validation of high-risk diagnoses
- Training on how to construct compliant clinical validation queries

Physician engagement strategies include:[7]

- Discuss CDI initiatives for quality and accuracy of clinical documentation
- Discuss current query practices and evaluate effectiveness
- Discuss physician workflow processes and evaluate need for process change
- Discuss effectiveness of communication tools for physicians and CDI/coding
- Encourage documentation of clinical signs and symptoms as well as care for each confirmed, probable, and likely diagnosis
- Encourage confirmation of ruled-in or ruled-out diagnoses with clarification of present on admission
- Encourage documentation based on Uniform Hospital Discharge Data Set (UHDDS) guidelines
- Introduce awareness of ICD-10-CM and ICD-10-PCS coding guidelines and *Coding Clinic* as tools for coding and CDI professionals to consult when assigning codes
- Collaborate on available clinical criteria for top ten diagnoses at high risk for denials
- Educate medical staff on vulnerable diagnoses, documentation requirements, and clinical criteria
- Emphasize only providers who are legally accountable to diagnose patients, per the organization's bylaws and state licensure regulations; CDI and coding professionals have an ethical obligation to accurately assign codes based on documentation

Denials Management

In order to bring awareness of payer expectations, collaboration and participation in denials management is imperative for those who lead the clinical validation team. Although clinical validation impacts the coding process (e.g., whether the condition is reportable and which code(s) should be used to report it) it is also a coverage and medical necessity issue. CDI and coding professionals need to be aware of which payers, if any, have established

clinical criteria for particular diagnoses and evaluate how well organizational culture and provider documentation reflect these criteria.

CDI/coding/denials management collaboration processes include:[8]

- Define individual roles based on organization policies
- Determine best practices for communication between members of the clinical validation team
- Determine workflow practices
- Determine educational goals
- Determine escalation processes

Second-Level Reviews

A clinical validation team should perform a second-level review of cases which may include, but is not limited, to the following:

- Opportunity for clarity in vulnerable diagnoses
- Only one diagnosis with financial or quality impact documented
- Sign and Symptom code assignment
- High risk of denial for principal diagnosis
- High risk of denial for secondary diagnosis(es)

Please refer to the CDI and Coding Collaboration in Denials Management Toolkit for more information regarding the denials process.

Compliance Can Support Clinical Validation

Organizations must perform clinical validation to ensure documentation is complete and accurate, as well as appropriately reflects the patient's clinical conditions while abiding by relevant statutes, regulations, policies, and guidelines. 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.

Performing audits on the CDI process is beneficial in establishing and maintaining a compliant program. The audit process can be incorporated into the organization's compliance department or be managed by the CDI program. If the audit process is independent of the organization's compliance department, it is still important to have open communication with the compliance department to identify all of the components that should be audited. The audit process should include the clinical validation procedure. The compliance department 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. Examples of procedures that support a thorough auditing process include:

- Monitoring and auditing queries to ensure they do not incorrectly or unduly influence health record documentation
- Development of an auditing process to continuously monitor and analyze samples of queries and the utilization of query templates
- The use of the results for development of improvement plans and education for all involved in the query process (e.g., practitioners, coding professionals, CDI professionals)
- Collaborate with other departments when developing an audit process to identify the documentation elements

that impact their outcomes

Query Escalation

There may be times when although a provider confirms a diagnosis, the query professional still does not feel the diagnosis is supported by the clinical evidence. As stated in the ICD-10-CM Official Guidelines for Coding and Reporting: "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis."[9] This guidance instructs coding professionals to code all documented diagnoses, but it does not restrict the use of queries or policies to address clinical validation concerns.

To address when a query professional has continuing concerns regarding the provider's response to a clinical validation query, an organization can develop written escalation procedures. This will typically include a supervising physician or physician advisor who can have a peer-to-peer conversation with the treating provider to discuss the case. It is still the treating provider's responsibility to confirm or rule out a diagnosis. If the treating provider still feels the diagnosis is relevant after the escalation procedure is followed, the diagnosis should be reported.

When escalation procedures for clinical validation queries are initiated, it is important to document the outcome. If the case is denied at a later date, this documentation can be used for future education and demonstrate compliance with industry guidance. It would not be appropriate to initiate a query to address a denial; rather, it should be used for prevention training for providers and appropriate staff. See the side bar below for an example of a clinical validation query escalation policy.

Clinical Validation Query Escalation Policy Example

a. Departmental leadership/appointee determines if the case should be referred to the appropriate administrative representative (such as a physician advisor/physician champion, the medical director or designee) for further review if the query resulted in no response or a disagreement.

- The physician advisor notifies appointee of their concurrence with documenting practitioner. The diagnosis would then be coded as documented.
- The physician advisor does not agree with the existing documentation and discusses the case with the practitioner. The practitioner provides clarifying documentation within the health record, so the diagnosis can be coded.
- If significant disagreement cannot be resolved by the physician advisor, the case escalates to the appropriate medical staff or administrative physician leader for further review until a final determination is made per the organization's policy.

b. Steps in the escalation process are tracked for internal compliance purposes, such as in a query tracking log, or CDI worksheet/internal coding worksheet communication.

Alternatively , an organization may wish to implement a multi-disciplinary committee (consisting of physicians and quality, compliance, and HIM staff) to review cases submitted by CDI and coding staff where diagnoses are inconsistent with the patient's clinical picture, or the clinical picture is inconsistent with the diagnoses and provider is not in agreement with the clinical validation query. The committee can provide guidance on the best course of action on a case-by-case basis.

Gaining Consensus on Clinical Validation

CDI and coding professionals are united by the goal of ensuring accurate clinically valid documentation and reporting, which drives hospital and physician profiling comparatives, patient severity/mortality depiction, and financial outcomes—all of which are critical to the healthcare facility's survival. The roles of coding and CDI professionals are vital to the organization's patient care and national profiles, compliance with regulatory mandates, and financial stability. Though the two professions are complementary, they often operate from different perspectives. Developing a culture of collaboration and workflow processes with clearly defined expectations to achieve common goals of mutual respect, transparency, compliance, and data integrity are the key elements for achieving successful consensus.

Together, CDI and coding professionals play a crucial role in meeting quality standards that improve clinical and financial performance. Both must operate with mutual respect and understanding of the two perspectives, objectives, and the overarching goals; gaining consensus is built upon these principles. Teamwork between the physicians and CDI and coding staff is essential for resolving DRG mismatches and clinical validation issues. The coding professional is responsible for accurately reporting the diagnoses supported in the health record following UHDDS guidelines for reporting and adherence to ICD-10-CM/PCS coding guidelines. The CDI specialist is responsible for reviewing the health record to identify gaps within the documentation that are inconsistent, conflicting, or lacking in clinical significance. CDI specialists are not members of the patient's treatment team and therefore should not render clinical opinions for diagnoses. Ultimately, their job is to communicate with care providers—either verbally or via written queries—to clarify documentation in the health record to get to the clinical truth of the patient's condition(s) that will ensure the highest level of quality clinical documentation. Coding professionals, on the other hand, bear the ultimate responsibility for final coding and assignment of the Medicare Severity (MS)-DRG or All Patient Refined (APR)-DRG.

The best practice for optimal outcomes and reaching consensus is first understanding that identifying these differences between physicians, CDI, and coding professionals in a healthy, professional manner leads to bridging the gap and finding solutions collaboratively. For the sake of compliance, clinical validation should precede final coding and should involve the healthcare provider team to ensure documented conditions are clinically valid and supported in the medical record.

Some key areas where improvement may be needed to facilitate collaboration between CDI and coding staff that will support team building and camaraderie include:

- **Increased education for staff.** The increased specificity of the ICD-10-CM/PCS code set has required both CDI and coding professionals to strengthen their foundational knowledge. Moreover, additional education will be needed for CDI professionals with a 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.
- **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 the latest *Coding Clinic* publications, as well as 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 Major Complications and Comorbid Conditions/Complications and Comorbid Conditions (MCC/CC) discrepancies. Invite clinical providers to the coding/CDI meetings to discuss clinical indications or specific diseases.

Notes

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Additional Resources

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Appendix A: Sample Queries and Disclaimers

Disclaimer Examples

When sending queries, facilities may decide to include a disclaimer, to reflect the intention of the query. Below are some examples of such disclaimers, if the organization chooses to include one.

- We are committed to accurately capturing the acuity and complexity of your patient and the quality of your care. The medical record reflects the following clinical findings, treatment, and risk factors.
- When responding to this query, please exercise your professional judgment. When a question is asked, it does not imply that any particular answer is desired or expected. Thank you for your clarification on this issue.

Query Examples

Below are some examples of compliant clinical validation queries. (Please refer to the "Guidelines for Achieving a Compliant Query Practice (2016 Update)" Practice Brief at http://library.ahima.org/doc?oid=301357 to review the components of a compliant query.)

Acute Respiratory Failure Query Example

Dr. Jones:

60-year-old male with COPD admitted via the ED for COPD Exacerbation. PMH documents chronic respiratory failure and states the patient requires 2L NC 24 hours.

ED MD documents 'some mild dyspnea, but speaking in mostly full sentences'. RR recorded as 22, normal mentation.

ABG shows pH 7.40, pCO2 52 mmHg, and pO2 70 mmHg; bicarbonate level on BMP is elevated at 42

QUERY:

Patient placed on 3L NC for 2 hours, after which this was reduced to 2L NC.

ED MD documents 'respiratory distress' due to COPD as impression; H&P documents 'Acute on Chronic Respiratory Failure'.

Based on the indicators and your professional judgement, please clarify the diagnosis of Acute on Chronic Respiratory Failure.

Please complete by selecting one of the options below:

- Acute on Chronic Respiratory Failure (if confirmed, please add additional supporting information in the medical record)
- Chronic Respiratory Failure without Acute Component
- Other explanation of clinical finding: _____
- Unable to determine

Encephalopathy Query Example

Dr. Jones:

69-year-old male admitted from SNF for complicated UTI. Per multiple recorded assessments, not meeting internal criteria for Sepsis. Known history of dementia per PMH. Per family members and SNF Notes, patient is known to be frequently confused, hostile, exhibiting disruptive behavior as consequences of dementia.

QUERY:

H&P documents patient is confused and hostile with 'Encephalopathy in the setting of infection" and states patient is trying to bite staff. RNs record GCS scores ranging from 12 to 14. Mental status does not change with treatment of UTI.

Based on the indicators and your professional judgement, please clarify the diagnosis of Encephalopathy.

Please complete by selecting one of the options below:

- Encephalopathy is/was present (if confirmed, please add additional supporting information in the medical record and indicate type)
- Dementia with Behavioral Disturbance
- Other explanation of clinical finding: _____
- Unable to determine

Severe Protein Calorie Malnutrition Query Example

Dr. Jones:

73-year-old man presents with small bowel obstruction and is newly diagnosed with primary cancer of the small bowel. The MD progress note on 9/14/18 documents 'severe protein-calorie malnutrition' and this condition is repeated per daily progress notes.

QUERY:

Progress note documents severe protein calorie malnutrition. The H&P documents a patient that is 'well developed' and 'well nourished', but also noted to be 'somewhat underweight'. The H&P documents a BMI of 18 and Prealbumin of 13.0.

The RD assesses the patient, documenting a 5% loss of weight in the past month with mild loss of subcutaneous fat from the triceps, with patient at 93% of usual body weight and Ensure is being provided as a supplement. The patient is described as consuming 80% of their estimated energy requirement for the 3 days prior to this admission.

Based on the indicators and your professional judgement, please clarify the diagnosis of Severe Protein-Calorie Malnutrition.

Please complete by selecting one of the options below:

- Severe Protein-Calorie Malnutrition is confirmed (if confirmed, please add additional supporting information in the medical record)
- Protein-Calorie Malnutrition of other severity (Please document severity)
- Protein-Calorie Malnutrition, unknown severity
- Underweight w/o form of Malnutrition
- Other
- Unable to determine

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