

Summary: This paper discusses the concept of clinical validation as it has evolved through CMS regulations and coding guidance. It also attempts to establish consensus about how CDI professionals should incorporate clinical validation into their practice.

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Introduction

Not all words written in the health record translate into ICD-CM/PCS or HCPCS coded data. Coders must determine when documented conditions meet reportable claims data requirements. As the role of coded data expands beyond statistical reporting and diagnosis-related groups to accurate depictions of clinical scenarios, it is becoming increasingly difficult to determine when a condition reaches a reportable threshold. Both government and commercial insurers rely on administrative data in the form of codes to measure the quality of care provided to their beneficiaries. Coded data is also used to validate the medical necessity of rendered services. Medical necessity has always been a CMS and private payer requirement, but advances in technology and data mining techniques have made it easier for payers to identify claims vulnerable to payment errors as well as trends associated with questionable coding practices. Criteria used to determine patient status or validate a service as a covered benefit are often independent of code assignment, making it a challenge to address medical necessity vulnerabilities.

The CDI specialist is uniquely positioned to unify efforts to report claims data that accurately reflects the clinical scenario and the provider’s intent within the constructs of the ICD-10-CM/PCS code set. To fulfill this role, the CDI specialist must understand the role of clinical validation as it relates to payment denials and quality measure performance validation.

Although guidance on clinical validation is extant in the Official Guidelines for Coding and Reporting, AHA Coding Clinic, AHIMA practice briefs, and ACDIS and AHIMA publications and resources, it often appears contradictory and leads to struggles for many CDI and coding professionals. The goal of this paper is to help standardize how CDI and coding professionals define and apply clinical validation techniques to accurately reflect clinical scenarios and minimize denials.

The case for clinical validation

The Recovery Auditor program was established to identify improper payments (overpayments and underpayments) on healthcare claims paid by Medicare Part A and Part B. Validation has traditionally revolved around the DRG because of its

“DRG validation is the process of reviewing physician documentation and determining whether the correct codes and sequencing were applied to the billing of a claim on prospective payment services (PPS), and as appropriate, reviewing the record’s DRG accuracy” (ACDIS, 2015).

direct relationship to payment. “DRG validation is the process of reviewing physician documentation and determining whether the correct codes and sequencing were applied to the billing of a claim on prospective payment services (PPS), and as appropriate, reviewing the record’s DRG accuracy” (ACDIS, 2015). In DRG validation, the focus is on the correct assignment of the principal diagnosis, procedure, and reportable secondary diagnoses based on the Official Guidelines for Coding and Reporting (hereinafter referred to as “Coding Guidelines”).

The Coding Guidelines reference the Uniform Hospital Discharge Data Set (UHDDS) as the criteria coders (and CDI specialists) must use when reporting diagnoses. The UHDDS definitions were developed to standardize reported inpatient data elements. The UHDDS defines the principal diagnosis as “that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care” (UHDDS, 1985). Additionally, the Coding Guidelines state, “In determining principal diagnosis, coding conventions in the ICD-10-CM, the Tabular List, and Alphabetic Index take precedence over these official coding guidelines (See Section I.A., Conventions for the ICD-10-CM).” (CDC, 2016)

Accurate principal diagnosis assignment is vital for several reasons. First, under DRG reimbursement mechanisms (i.e., MS-DRG and APR-DRG), the principal diagnosis establishes the base DRG, which can be modified by the presence of “other diagnoses” and procedures. The Medicare Claims Processing Manual (Chapter 23, Fee Schedule Administration and Coding Requirements) states the following:

“The principal diagnosis is the condition established after study to be chiefly responsible for the admission. Even though another diagnosis may be more severe than the principal diagnosis, the principal diagnosis, as defined above, is entered. Entering any other diagnosis may result in incorrect assignment of a Medicare Severity - Diagnosis Related Group (MS-DRG) and an incorrect payment to a hospital under PPS.” (CMS, n.d.b)

Second, principal diagnosis selection often influences the medical necessity of patient status determinations. Finally, the principal diagnosis is the basis of cohort selection for many quality measures.

The UHDDS also establishes criteria for the reporting of “other diagnoses,” which are commonly referred to as secondary diagnoses by CDI and coding professionals. Coding Guidelines reference UHDDS criteria instructing coders to report “additional conditions that affect patient care in terms of requiring: clinical evaluation; or therapeutic treatment; or diagnostic procedures; or extended

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length of hospital stay; or increased nursing care and/or monitoring.” (CDC, 2016) Additionally, the Medicare Claims Processing Manual adds the following requirement: “The provider reports the full codes for up to twenty-four additional conditions if they coexisted at the time of admission or developed subsequently, and which had an effect upon the treatment or the length of stay” (CMS, n.d.b).

There are many examples where CMS contractors, such as Recovery Auditors, make a DRG adjustment because the reported principal diagnosis is “not substantiated.” For example, a Medicare Quarterly Provider Compliance Newsletter describes the problem as:

There are many examples where CMS contractors, such as Recovery Auditors, make a DRG adjustment because the reported principal diagnosis is “not substantiated.”

“Recovery Auditors validated Medicare Severity-Diagnosis Related Group (MS-DRG) 189 (Respiratory Failure), specifically the principal diagnosis and any secondary diagnoses affecting or potentially affecting the DRG. The purpose of this study was to determine that the principal diagnosis and all secondary diagnoses identified were actually present, correctly sequenced, coded and clinically validated. When a patient is admitted to the hospital, the condition established after study found to be chiefly responsible for occasioning the admission to the hospital should be sequenced as the principal diagnosis. ... After physician and auditor review, it was determined that the clinical evidence in the medical record did not support respiratory failure, despite physician documentation of the condition. ... The auditor deleted acute respiratory failure and changed the principal diagnosis to COPD Exacerbation. The auditor deleted respiratory failure code 518.81 (ICD-10 = J9690) and changed the principal diagnosis to hypoxemia code 799.02 (ICD-10 = R0902). This resulted in a MS-DRG change from 189 to 192—Chronic Obstructive Pulmonary Disease without CC/MCC. This change resulted in an overpayment.” (CMS, 2011)

The same newsletter offered the following guidance on how to avoid these problems:

- *“The condition chiefly responsible for a patient’s admission to the hospital should be sequenced as the principal diagnosis, and the other diagnoses identified should represent all CC/MCC present during the admission that affect the stay. Code only those conditions documented by the physician.*
- *Refer to the Coding Clinic guidelines and query the physician when clinical validation is required.*
- *Inquire about conflicting documentation.” (CMS, 2011)*

Medicare contractors have also excluded secondary diagnoses that affect MS-DRG assignment by adding a CC or MCC due to a lack of clinical validity of the secondary diagnosis.

Unfortunately, clinical validation was not defined by the Medicare Quarterly Provider Compliance Newsletter. The most commonly referenced source for clinical validation is the Statement of Work for the Recovery Audit Program, which states the following: “Clinical validation is a separate process [from DRG validation], which involves a clinical review of the case to see whether or not the patient truly possesses the conditions that were documented” (CMS, n.d.c). The guidance continues with what some consider to be a controversial statement: “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” (CMS, n.d.c).

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It is beyond the scope of this paper to specify who, within each healthcare organization, can or should perform clinical validation. As a reminder, this guidance was directed toward Recovery Auditor practices and staffing, who are also required to employ certified coders to perform DRG validation. Each organization must develop a policy that works within its culture—this policy should identify who (i.e., which job roles) perform clinical validation and querying. For some organizations this may be clinical staff, and for others it may be a combination of clinical and HIM.

Industry guidance

Leaders in coding and CDI have issued professional guidance on clinical validation, but the apparent inconsistency of this guidance has led to confusion. For example, the 2008 AHIMA Practice Brief, “Managing an Effective Query Process,” discouraged issuing a query when the clinical information or clinical picture does not appear to support the documentation of a condition (and when no other issues are present). Contrast this perspective with the 2013 ACDIS/AHIMA Practice Brief, “Guidelines for Achieving a Compliant Query Practice” (updated for 2016), which includes documentation of a “diagnosis without underlying clinical validation” as an appropriate reason to generate a query (ACDIS/AHIMA, 2016).

Professional guidance in regard to coders changed once again with the FY 2017 Coding Guideline I.A.19 “Code Assignment and Clinical Criteria,” which again stated that “code assignment is not based on clinical criteria used by the provider to establish the diagnosis.” (CDC, 2016) This new advice was also addressed in AHA Coding Clinic, Fourth Quarter 2016, which states the following:

“Coding must be based on provider documentation. This guideline is not a new concept, although it had not been explicitly included in the official coding guidelines until now. Coding Clinic and the official coding guidelines have always stated that code assignment should be based on provider documentation. As has been repeatedly stated in Coding Clinic over the years, diagnosing a patient’s condition is solely the responsibility of the provider. Only the physi-

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cian, or other qualified healthcare practitioner legally accountable for establishing the patient's diagnosis, can "diagnose" the patient. As also stated in Coding Clinic in the past, clinical information published in Coding Clinic does not constitute clinical criteria for establishing a diagnosis, substitute for the provider's clinical judgment, or eliminate the need for provider documentation regarding the clinical significance of a patient's medical condition.

The guideline noted [in the original question] addresses coding, not clinical validation. It is appropriate for facilities to ensure that documentation is complete, accurate, and appropriately reflects the patient's clinical conditions. Although ultimately related to the accuracy of the coding, clinical validation is a separate function from the coding process and clinical skill. The distinction is described in the Centers for Medicare & Medicaid (CMS) definition of clinical validation from the Recovery Audit Contractors Scope of Work document and cited in the AHIMA Practice Brief ("Clinical Validation: The Next Level of CDI") published in the August issue of JAHIMA. While physicians may use a particular clinical definition or set of clinical criteria to establish a diagnosis, the code is based on his/her documentation, not on a particular clinical definition or criteria. In other words, regardless of whether a physician uses the new clinical criteria for sepsis, the old criteria, his personal clinical judgment, or something else to decide a patient has sepsis (and document it as such), the code for sepsis is the same—as long as sepsis is documented, regardless of how the diagnosis was arrived at, the code for sepsis can be assigned. Coders should not be disregarding physician documentation and deciding on their own, based on clinical criteria, abnormal test results, etc., whether or not a condition should be coded. For example, if the physician documents sepsis and the coder assigns the code for sepsis, and a clinical validation reviewer later disagrees with the physician's diagnosis, that is a clinical issue, but it is not a coding error." (AHA, 2016)

The FY 2017 Coding Guidelines, as well as guidelines from prior years, state:

"A joint effort between the healthcare provider and the coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. These guidelines have been developed to assist both the healthcare provider and the coder in identifying those diagnoses that are to be reported. The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation accurate coding cannot be achieved. The entire record should be reviewed to determine the specific reason for the encounter and the conditions treated." (AHA, 2016)

CDI professionals can fulfill this requirement for collaboration, as they are increasingly responsible for communicating with the provider to impart education as well as obtain clarification when ambiguity exists in the health record. Providers often describe their findings using signs and symptoms instead of diagnoses, and they often lack knowledge of the coding terminology required by the ICD-10-CM conventions to accurately reflect a patient's condition.

Regardless of whether an organization includes clinical validation as part of routine CDI review or considers it a special function performed in conjunction with DRG validation, the focus is the same: ensuring documented conditions are supported by the totality of the health record.

Traditionally, the query process has focused on adding specificity to an already-documented diagnosis or obtaining a diagnosis based on clinical evidence within the health record. However, providers are increasingly documenting diagnoses without corroborative clinical evidence. The reasons include electronic health records with limited free-text documentation fields and the prevalence of CDI educational efforts that encourage the documentation of specific diagnoses. CDI professionals review the entire medical record to identify clinical indicators, evaluation, monitoring, and treatment that supports diagnoses and conditions documented by the provider. But the same use of provider notes, medication administration records, labs, diagnostics, and ancillary notes results in the identification of clinical diagnoses that often lack sufficient supporting clinical indicators, monitoring, and/or treatment to meet the UHDDS definition of reportable diagnosis. As such, some argue that CDI professionals address clinical validity issues with each record review, making clinical validation inherent to the CDI process rather than an additional function. Clinical validation as a second-level review process will be discussed in further detail later in this white paper.

Clinical validation/review

Regardless of whether an organization includes clinical validation as part of routine CDI review or considers it a special function performed in conjunction with DRG validation, the focus is the same: ensuring documented conditions are supported by the totality of the health record. The goal of clinical validation is ensuring that “the health record is not only coded accurately, but also accurately reflects the clinical scenario within the health record” (Denton et al., 2016). A thorough clinical validation review includes searching the health record for contradictory clinical indicators that might make a diagnosis vulnerable to clinical validation denial. For example, documentation in the review of systems may describe a patient's general appearance as “within normal limits” or “good,” rendering a diagnosis of moderate or severe protein-calorie malnutrition suspect to an auditor.

Regarding diagnoses that are most vulnerable to clinical validation denials (e.g., acute respiratory failure, encephalopathy, sepsis, and severe protein-calorie malnutrition), supportive documentation from multiple members of the healthcare

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team, including providers and clinicians, should be in evidence—or, at the very least, the documentation should not cast doubt on the validity of the documented diagnosis.

Clinical validation review processes must confirm that the provider’s clinical criteria can be easily linked to the corresponding diagnosis. Regardless of their professional background, not all CDI professionals will feel comfortable with this task. “Clinical Validation: The Next Level of CDI” states that clinical validation “is usually considered an advanced skill requiring a strong understanding of clinical pathology, finesse when constructing a query, and excellent communication skills to avoid conflicts with the provider” (Denton et al., 2016).

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Regarding medical necessity of setting reviews, CMS allows auditors to infer the severity of the patient’s condition based on documentation of the patient’s history and comorbidities. Otherwise, “CMS only states, ‘As with all codes, clinical evidence should be present in the medical record to support code assignment’” (Denton et al., 2016). This threshold can vary by payer because there is often little agreement among medical professionals about when or how to diagnose a condition. This makes the clinical validation process inherently subjective—for example, two providers can use different criteria when rendering the same diagnosis. Consequently, this white paper does not aim to tell organizations what clinical criteria or indicators their providers should use for making their diagnoses. “Clinical Validation: The Next Level of CDI” advises the following:

“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. ... 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?” (Denton et al., 2016)

In order to minimize clinical variations of care, providers should base decisions around diagnosis definitions grounded in evidence-based medicine and the respective colleges’ recommendations. AHA Coding Clinic has inherent limitations as discussed in the ACDIS/AHIMA Practice Brief, “Guidelines for Achieving a Compliant Query Practice”:

“Although AHA’s Coding Clinic for ICD-9-CM 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.” (ACDIS/AHIMA, 2016)

Contrary to many organizational practices, diagnoses need not be documented in the discharge summary to be reportable—AHA Coding Clinic has consistently reinforced that diagnoses can be obtained from any part of the health record if they meet UHDDS criteria.

Organizationally established guidelines and clinical indicators created in collaboration with the medical staff, CDI specialists, and coders for problematic or high-risk diagnoses can help support CDI professionals and coders in the clinical validation process. The purpose of these definitions is not to limit how a diagnosis can be defined, but rather to promote consistency among CDI specialists in determining whether a minimal threshold of support is present within the health record. CDI specialists may wish to encourage providers who use nontraditional criteria to include the rationale for their conclusion, since the attendings are ultimately responsible for managing their patients (CMS, n.d.a). The query process, which will be discussed later in this white paper, can only attempt to clarify the status of what appears to be an unsubstantiated diagnosis. A provider cannot be forced to recant a questionable diagnosis to avoid its reporting when it meets UHDDS criteria. Consequently, physician education (intervention) should reaffirm the importance of including the clinical decision-making related to the clinical indicators and criteria used to reach a diagnosis. Doing so not only supports clinical validation efforts, but also provider evaluation and management billing. Because a diagnosis is not always established in a linear fashion with a clear cause-and-effect relationship, documentation from the provider’s initial contact with patients may result in a list of differential diagnoses that include signs and symptoms. As patients undergo workup, clinical documentation should reflect the evolution of symptoms into diagnoses that speak to a patient’s underlying acute condition, comorbidities, and reason for inpatient care.

Educational efforts and problem list templates should encourage providers to document when a diagnosis has been ruled out. It is not uncommon for diagnoses to be documented at the beginning of a stay, but fail to be carried through the record into the discharge summary. Contrary to many organizational practices, diagnoses need not be documented in the discharge summary to be reportable—AHA Coding Clinic has consistently reinforced that diagnoses can be obtained from any part of the health record if they meet UHDDS criteria. But failure to carry a diagnosis through to discharge, in conjunction with cessation of the treatment course targeting that diagnosis, can signal that the diagnosis was ruled out and thus should not be reported. For example, it may be prudent for the CDI specialist to validate the diagnosis of sepsis in a patient when aggressive antibiotics are

stopped and future documentation refers to the patient's pneumonia. Again, all diagnoses not carried through the health record require clinical validation, but a change in or discontinuation of treatment can be an indicator of a ruled-out or resolved diagnosis.

Timing of clinical validation (concurrent vs. retrospective)

The timing of clinical validation largely depends on an organization's resources and the skill set of its CDI professionals. This paper has described a retrospective clinical validation process employed by Recovery Auditors and denials management. Concurrent review of the record to obtain the most accurate, compliant documentation and enable capture of codes portraying the severity of illness and risk of mortality also contains a clinical validation component. Concurrent review and validation is recommended for every record reviewed by CDI. Because retrospective clinical validation can be a labor-intensive process, it may be restricted to those diagnoses most vulnerable to denial, rather than all diagnoses, except when the lack of clinical support is obvious during a typical CDI review process. Some organizations may choose to take a more specialized approach, limiting clinical validation to a post-discharge, pre-bill process or to a second-level review process.

Organizations should strive to implement a pre-bill clinical validation process rather than a post-bill process so that needed changes can be made prior to claim submission. This is echoed by "Clinical Validation: The Next Level of CDI," which states that "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" (Denton et al., 2016). Organizations can benefit by developing an ongoing interdepartmental committee comprising leadership representation from the CDI, coding, quality, and compliance departments. The committee should also include a physician advisor or champion, who can complete second-level reviews when a coding or CDI professional identifies an opportunity for clinical validation following assignment of final codes. Organizations might also opt for a second-level review process when coding and/or CDI professionals identify or request a review of a diagnosis.

To support clinical validation reviews, facilities may wish to consider having a dedicated physician advisor to review a chart when there is a question on the clinical indicators needed for a certain documented diagnosis. Coding Clinic, Fourth Quarter 2016 explains that "clinical validation involves a clinical review of the case to see whether or not the patient truly possesses the conditions that were

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documented in the medical record” (AHA, 2016). This second-level review may be done by a physician advisor, a physician champion, a chief resident, service line leadership, compliance staff, or a multidisciplinary second-level review team. The review process should address clinical denials, analyze organizational trends, and establish processes related to clinical validation. The multidisciplinary team should also foster provider engagement and education related to clinical validation. The resulting education to both parties by a designated second-level reviewer not only builds a cooperative and collegial environment, but also addresses clinical validation issues and facilitates additional internal guidelines for problematic diagnoses.

The use of queries as a tool in addressing clinical validation

Deployment of clinical validation queries is a complex issue and can be challenging for an organization. This paper recommends strong collaboration with providers, CDI, coding, and quality of care professionals to develop criteria for when a clinical validation query should occur. “The goal of these guidelines is to promote consistency among CDI and coding professionals in identifying diagnoses that appear to lack sufficient clinical evidence” (Denton et al., 2016).

Queries play an important role in addressing clinical validation. A lack of supporting clinical indicators for a diagnosis presents the CDI professional with a clinical validation query opportunity. When a CDI professional identifies a diagnosis without supporting clinical evidence, he or she should query the provider for clinical validity. This is not done to challenge the clinical knowledge of the provider, but rather to ensure the diagnoses and procedures documented in the record are clearly supported by clinical indicators to allow for accurate ICD-10-CM/PCS code assignment. Doing so will result in improved accuracy and completeness in documentation, coding, reimbursement, and severity of illness/risk of mortality classifications (Arrowood et al., 2016).

The wording of queries for clinical validation deserves careful consideration. Present complete information in an objective manner when querying the provider. Queries should be focused on clarifying the presence of a diagnosis and requesting additional clinical evidence or decision-making. Helping providers understand that clinical validation is related to denials mitigation may enhance their engagement in the query process.

For example, a CDI specialist reviews a medical record with documentation of “severe protein-calorie malnutrition” in the H&P. The consultation report, however, states that the patient is “well developed” and “well nourished” on physical exam. The patient has a BMI of 32, and there are no chronic conditions or weight loss

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documented. No dietitian assessment or monitoring was done during the patient's admission, and a regular diet was ordered without dietary supplements. Perform a query to clinically validate the documented "severe protein-calorie malnutrition" to ensure the final coded data reflects the most accurate reportable diagnoses for the patient (refer to the query example below).

Writing a validation query and appropriate responses

Clinical validation queries that simply confirm the presence of a diagnosis are not sufficient; the query should also request additional documentation of clinical data or clinical decision-making by the provider to support the diagnosis. An alternate response to the query would be to negate the diagnosis as erroneous or ruled out. Clinical validation responses should also be reflected in subsequent progress notes and be carried through to discharge, or (if the diagnosis is possible, probable, suspected, or likely) into the discharge summary.

If the attending physician responds to the clinical validation query by validating a diagnosis without adding clinical indicators to support it, the diagnosis is at risk for denial. A written query that is made part of the permanent medical record demonstrates to all auditors that the CDI professional completed his or her obligation in clarifying the diagnosis with the attending provider (Ericson, 2015). All queries sent—regardless of whether they are replied to or agreed with—should be maintained for compliance and future review purposes. Although some organizations choose to keep queries as part of the business record, this process can lead to vulnerabilities in regard to clinical validation queries.

CDI professionals may wish to issue verbal queries for clinical validation. Verbal queries allow the CDI professional to discuss a documented diagnosis with the attending provider. This type of query can create an opportunity to explain to the provider why clinical validation is needed for his or her documented diagnosis. These queries also allow the CDI professional to provide real-time education using a record example that is directly applicable to the provider. Clinical validation can make providers feel their diagnosis is being challenged; the real-time explanation that occurs with a verbal query can help prevent this negative reaction. Rather than insinuating that the physician's judgment is in question, the CDI specialist can offer education on the importance of documenting clinical indicators for a diagnosis to assist in creating a denial-proof medical record. After a discussion with the provider, the provider must update the documentation in the medical record, and the CDI specialist should document the verbal query per the organization's established policies (ACDIS/AHIMA, 2016).

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Furthermore, organizations should consider developing an algorithm or escalation process for clinical validation query responses. If a CDI specialist feels the query should be placed, follow-up is critical to obtain a physician response. Timely presentation of the query may result in a higher response rate. In general, physicians prefer to answer queries while they are working in the patient record. Even if the patient has already been discharged, physicians want to have queries presented to them while the case is top of mind (e.g., while they are discussing the patient or involved in dictation). “In my experience, it doesn’t matter whether that query is presented remotely or on the floor. ... The timing of the query is the key factor in ensuring a physician provides an answer” (Chapman, 2015).

Tracking trends and education

CDI programs need to track trends in documentation of all diagnoses, including those without supporting indicators and treatment. A second-level review committee can review these trends and use them as a basis for ongoing provider education. An organization’s provider CDI education process should also include taking action on identified trends. The provider education process might include use of a physician advisor or champion to educate providers on overuse of clinical diagnoses by reviewing clinical validation queries and feedback on denials. CDI leaders and CDI specialists can also provide CDI-related education for providers as well as daily coaching and mentoring related to common documentation issues, including clinical validation.

CDI programs can proactively promote quality documentation by educating providers to not only document a medical diagnosis in the medical record, but also include their clinical decision-making as well as the treatment plan for the condition. Continued documentation of how the patient is responding to the treatment plan in subsequent progress notes also facilitates quality of care (Prescott, 2016).

Conclusion

Providers hold the ultimate responsibility for both establishing a diagnosis and documenting the criteria that led to the establishment of said diagnosis. When the medical record appears to lack evidence-based clinical criteria for a diagnosis, CDI specialists must query the provider. Doing so provides the physician an opportunity to either add more clinical criteria to support the diagnosis, confirm the diagnosis as it stands, or confirm that the diagnosis was ruled out or is with-

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out clinical significance. Should the query remain unanswered, organizations must have an escalation policy in place to address the issue, which is best done peer-to-peer. In addition, it is best practice for an organization to put policies and procedures in place to address how to construct a clinical validation query, along with delivery methods of written and verbal queries.

Should the query remain unanswered, organizations must have an escalation policy in place to address the issue, which is best done peer-to-peer.

Organizations need to be transparent regarding the need for strong supporting clinical criteria in the medical record and the clinical validation process. All involved parties, including key provider representation, coding, CDI, and leadership, along with quality, denials management, and the compliance department, are encouraged to sit at the table and develop policies to ensure the creation of a medical record that precisely, completely, and accurately depicts the patient encounter.

This white paper has provided information and guidance on clinical validation, but it has only scratched the surface. Clinical validation will become more prominent in the industry as time progresses and denials mount. Watch for an industry survey on this subject in the future.

Note: This White Paper was drafted by the ACDIS CDI Practice Guidelines Committee. It was reviewed and approved by the ACDIS Advisory Board.

WHAT IS AN ACDIS WHITE PAPER?

An ACDIS white paper discusses CDI best practice, advances new ideas, increases knowledge, or offers administrative simplification. It can be written by an ACDIS Advisory Board member or a smaller subset of the board, or written by external sources subject to board approval. It is less formal than a position paper.

Appendix: Examples of clinical validation queries

Compliant validation queries follow the same guidance as any other type of query. They should be supported by providing the clinical indicators that were present but do not seem to support the diagnosis and the treatments that were not provided, as well as any corresponding clinical information that leads the writer to identify the potential diagnosis as not clinically supported.

Example #1

Severe Protein Calorie Malnutrition is documented in the patient's H&P. The patient was noted to be "well developed" and "well-nourished" on physical exam with a regular diet ordered. There was no dietician assessment and no information regarding chronic illness, weight loss, muscle or subcutaneous fat wasting or edema. Due to the conflicting clinical picture, please clarify the finding of severe protein calorie malnutrition:

- Severe protein calorie malnutrition is ruled out for this encounter
- Severe protein calorie malnutrition is a current condition for this admission. Please provide additional relevant clinical indicators: _____

- Other diagnosis explaining the findings _____

- Unable to clinically determine

Example #2

Patient has a documented diagnosis of severe protein calorie malnutrition (where/when) with a history of a "Roux-n-Y gastric bypass one month PTA, 38# wt loss, admitted for nausea, dehydration." Dietary consult classifies patient as "moderately compromised" and encouraged diet of protein rich foods with small, frequent oral intake to control nausea. Is severe protein calorie malnutrition an accurate diagnosis for this encounter?

- No, severe protein calorie malnutrition is not a valid diagnosis during this admission.
- Yes, severe protein calorie malnutrition is present/active during this admission. Please provide relevant additional clinical indicators: _____

- Other diagnosis explaining the findings _____

- Unable to clinically determine

Example # 3

Please clarify the accuracy of the diagnosis “acute respiratory failure” as documented (where/when) in this COPD patient with an SpO₂ of 90% on admission. The patient is on 2L of home oxygen and received a maximum of 3L of oxygen during the admission. The H&P Review of System includes documentation of the respiratory system “within normal limits” and the physical exam on January 21st documents “decreased bases with crackles.” The acute respiratory failure was:

- Confirmed/validated
- Ruled out
- Chronic respiratory failure only
- Without clinical significance
- Other diagnosis explaining the findings _____

- Unable to clinically determine

Example #4

The diagnosis of acute respiratory failure is documented (where/when), with SpO₂ recorded as 88-93%; the patient received a maximum 3L via nasal cannula during the admission and “No respiratory distress” was documented in the ED physician note. Is acute respiratory failure an accurate diagnosis for this encounter?

- No, acute respiratory failure is not a valid diagnosis during this admission.
- Yes, acute respiratory failure is present/active during this admission.
Please provide relevant clinical indicators: _____

- Other diagnosis explaining the findings _____

- Unable to clinically determine

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