Measure of Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures:

Chapter 6, Deliverable #28A

Centers for Medicare & Medicaid Services: Measure Instrument Development and Support

Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Year 4

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Measure of Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures:

Measure Methodology Report

Version 1.0

Submitted by:

Yale New Haven Health Services Corporation – Center for Outcomes Research & Evaluation (YNHHSC/CORE)

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1. Executive Summary

1.1 Overview of Report

In this document, we provide a detailed description of the process and key decisions related to the development and testing of the Measure of Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures (hereinafter referred to as, Quality of Informed Consent Documents Measure). We also provide measure results for development and testing samples of hospitals. This Executive Summary reviews, at a high level, the measure goal, rationale, development, and specifications. The remainder of the report provides complete details on all aspects of measure development and testing, consisting of

- The rationale for the measure (Section 2)
- The approach to measure development (Section 3)
- The measure specifications including the data source, cohort of patients, outcome definition, the approach for scoring the quality of informed consent documents (Abstraction Tool score) and for aggregating document scores to reflect hospital performance (measure score) (Section 4)
- The measure results for an eight-hospital development sample and a 25-hospital testing sample (Section 5)
- The results of measure testing for reliability, feasibility, and validity (Section 6)
- Report conclusions (Section 7)

The Appendices contain supplemental information, consisting of

1. Appendix A: Acknowledgment details
2. Appendix B: Glossary of key terminology
3. Appendix C: Guidelines and standards of informed consent reviewed
4. Appendix D: Taxonomy development
5. Appendix E: Taxonomy of quality informed consent elements
6. Appendix F: Abstraction Tool development
7. Appendix G: Abstraction Tool and instructions manual
8. Appendix H: Planned readmission algorithm overview

1.2 Goal of Measure

The goal of this measure is to support national strategies to promote patient-centered decision making. A measure of the quality of hospitals' informed consent documents is a first step towards increasing the attention and effort that hospitals dedicate to providing high-quality informed

consent, thereby supporting patient autonomy – a critical element of patient-centered decision making.

1.3 Background and Rationale

Informed consent, an ethical obligation and legal mandate intended to uphold patient autonomy, is a standard part of clinical practice, performed prior to most procedures and therapies with material risks. In the process of consenting patients for elective procedures, information should be communicated about the associated risks and benefits, alternative treatment options, and about what to expect during and after the procedure. Sharing the informed consent document with the patient is a critical component of this communication that is necessary, though not sufficient, for the patient to make an informed decision. Specifically, informed consent documents that are sensitive to patients' decisional needs can improve patient comprehension and satisfaction, and support patients in making decisions that are aligned with their expectations, preferences, and goals.

Yet despite standards for informed consent documents set forth by CMS and the Joint Commission, and recommendations for best practices, most informed consent documents do not meet a minimum patient-centered standard to support informed decision-making. By current standards, hospitals are expected to develop their own informed consent processes and forms, with written language referencing that the elements of informed consent were discussed. Accordingly, in most hospitals, informed consent documents are structured to contain generic language that meet this standard along with open space for clinicians to input the name, purpose and risks of the procedure. Yet there is no standardization, and often the most important information about the procedure is missing, illegible, or incomprehensible due to the use of acronyms and medical jargon. [1] Moreover, the documents are often shared minutes before the start of a procedure, a time when patients are vulnerable and least likely to ask questions.

Therefore, the development of a Quality of Informed Consent Documents measure is an opportunity to extend the minimum standard for informed consent documents in order to advance patient-centered decision making. The measure has been demonstrated to be feasible to implement, to discern quality of informed consent documents within and between hospitals, and to incur minimal burden for hospitals. The measure fully aligns with other regulatory standards as well as state laws, and is not duplicative or contrary to current guidelines.

1.4 Approach to Measure Development

CMS contracted with the Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE) in 2013 to develop the conceptual framework and specifications of the measure. CORE first conducted an extensive literature review and environmental scan, and an exploratory study of informed consent documents associated with elective cardiovascular procedures to inform feasibility. Next, CORE convened a nine-member Working Group composed of

patients and patient advocates with the goal of first developing a broad taxonomy of quality elements of informed consent documents, and of then narrowing this broad taxonomy to a reasonable (minimum) set of standards for quality of informed consent documents that were meaningful to patients, feasible to evaluate, and consistent with the recommendations set forth by government agencies and professional societies. Additionally, the Working Group provided input on all aspects of measure development.

To capture hospital performance on this patient-centered set of standards, CORE iteratively developed and validated an Abstraction Tool to assess the presence of these key elements in informed consent documents provided to patients undergoing hospital-performed elective procedures (Appendix G). This Tool was first developed using informed consent documents from eight hospitals. The Tool was then tested in a sample of 25 additional hospitals. The results of the development and testing work are presented in this report. From these activities, CORE confirmed that specific aspects of document quality (content, presentation, and timing) could feasibly and reliably be evaluated.

The final specifications of the Quality of Informed Consent Documents measure were developed with input from the Working Group and with feedback from a nationally convened Technical Expert Panel (TEP) comprised of a diverse stakeholder group.

1.5 Measure Specifications

This measure will assess the quality of informed consent documents associated with elective procedures performed among Medicare fee-for-service (FFS) patients aged 18 years and older hospitalized at acute care hospitals. The list of elective procedures that are eligible for inclusion in the cohort is broad, capturing 10 surgical specialties and various levels of invasiveness (for example, electively-performed knee replacements and coronary artery bypass surgeries). Additionally, the measure was developed such that it could be expanded to include elective procedures performed in hospital outpatient and ambulatory settings, and for non-Medicare beneficiaries (such as an all-payer cohort). As currently proposed, implementation of this measure will involve the use of administrative claims to select a random sample of procedures that is representative of the types of procedures performed in each hospital. The procedures selected for inclusion are those performed during hospitalizations for non-acute conditions. The informed consent documents associated with these procedures will be reviewed and abstracted by trained personnel using the Abstraction Tool described above. The measure development process also produced standardized training materials to support measure implementation. Document scores from the data abstraction will then be aggregated to calculate hospital-level scores on the measure. The measure is not risk adjusted, since demographic and clinical factors should not impact informed consent document quality.

2. Measure Rationale

2.1 Background

CMS contracted with CORE to develop a hospital-level measure of informed consent document quality for elective, hospital-based procedures.

The informed consent process is a well-ingrained part of clinical care, grounded in the ethical and legal principles of patient autonomy and beneficence.[2,3,4,5,6,7] When conducted as intended, the informed consent process should: 1) provide patients with information about the proposed procedure (nature of the procedure; reasonable alternatives to the procedure; and the relevant risks, benefits, and uncertainties related to the procedure); 2) ensure patient understanding; and 3) confirm the acceptance of the intervention by the patient.[2,6,8,9,10,11,12,13,14,15,16,17,18,19] In this process, patients have an opportunity to reflect on their values and goals to develop informed preferences. Reasonably, patients should be able to review the information and ask questions. In doing so, they may learn more about their prognosis and can signal concerns about safety and post-operative recovery. For these reasons, informed consent is also important for promoting patient safety, reducing medical error, and supporting transparency, open communication, and trust between the clinician and patient.[6,20,21,22,23,24,25,26,27]

To achieve its purpose, the informed consent process must be sensitive to *what* information is presented, *how* it is presented, and *when* it is presented. A critical component of this practice is reviewing an informed consent document with the patient.[12,27] When constructed in alignment with the perspective of a patient, the informed consent document provides the foundation for a meaningful informed consent discussion.[17,23,24] Informed consent documents that are sensitive to patients' decisional needs and health literacy can improve patient comprehension and satisfaction, and support patients in making decisions that are aligned with their values, preferences, and goals.[17,21,25,26,27,28,29] However, existing requirements do not ensure that informed consent documents contain these specific elements.

CMS's Conditions of Participation only require written documentation referencing that the elements of informed consent were discussed with the patient.[30] CMS's Hospital Interpretive Guidelines for Informed Consent and Informed Decision Making support that a properly executed informed consent document should reflect the process for obtaining the patient's consent, including information similar to that which the clinician communicated to the patient as part of informed consent discussions.[30,31] Additionally, existing guidance reinforces that sufficient time should be allowed for patients to consider the information,[22,27,32,33] but this criterion is not required and rarely followed. Finally, the informed consent document is a signal that communication about a given procedure occurred and a historical record to which patients, clinicians, and others can reference.[30,34] In fact, in 2007, Washington State passed legislation incentivizing clinicians to use a certified decision aid to facilitate shared decision making, instead of a traditional informed consent

document and process. [35,36] Clinicians who practice shared decision making will be presumed to have engaged patients in an informed consent process regarding the elective procedure and will be provided with increased protection against any ensuing litigation based on failure to inform. Such legislation affirms the importance of sharing information with patients in written and other contextual forms, and underscores the primacy of respect for patient autonomy in the decision-making process. [12,21,27,29,30]

This measure evaluates a minimum standard of quality of informed consent documents. Quality is evaluated using an Abstraction Tool that was developed through a consensus process and is firmly based in the ethical and legal principles of informed consent. The goal of the measure is to transform the informed consent document from a transactional form used to attain a patients' signature to a meaningful resource that supports patients in the decision-making process. This informed consent document quality measure is a first step towards improving the practice of informed consent, and may compliment or serve as a platform for other measures of high-quality, patient-centered decision making.

2.2 Measure Importance

Based on Medicare FFS data from 2012 and 2013, approximately 11 million elective procedures are performed in the Medicare population annually, with about a quarter being performed in the hospital setting. Therefore, this measure has the potential to improve a process that affects a significant proportion of Medicare beneficiaries.

We focused on the completed informed consent document as a feasible data source for this measure. During our preliminary measure development work, we found that several components of the quality of informed consent documents could be gleaned when reviewing patients' medical records. [1] In addition, the Working Group of patients and patient advocates endorsed the measure concept and the use of informed consent documents as a focus for quality measurement. While the document alone cannot capture all aspects of the informed consent process, a well-executed informed consent document should capture key aspects of the informed consent process, promoting transparency, patient autonomy, safety, beneficence, and respect. By providing high-quality informed consent documents in a timely fashion to all patients undergoing elective procedures, hospitals can ensure that their patients have the information they need in a readable form and with time to consider their options.

A measure of informed consent document quality aligns with national strategies aiming to promote patient-centered decision making. The Institute of Medicine (IOM)'s Six Aims for Improvement and the Affordable Care Act's National Quality Strategy both emphasize the importance of honoring a patient's autonomy through practicing patient-centered care. [37,38,39] It also aligns with the National Quality Forum's (NQF's) "Safe Practices for Better Healthcare," a report documenting best practices that should be "universally utilized in applicable healthcare settings to reduce the risk of harm

resulting from processes, systems, and environments of care." [40] Voluntary consensus standards for informed consent were among the 30 NQF-endorsed practices detailed in the NQF's report. The goals of these standards are to promote patient-centered care for a range of clinical areas and to protect patients who are particularly vulnerable to receiving low-quality care and/or experiencing medical errors because of communication barriers. [21,41]

2.3 Quality & Measurement Gaps

The process of informed consent has often been relegated to a perfunctory transaction necessary for attaining a patient's signature. [42,43,44] Prior studies, lawsuits, and patient testimonies reflect a process that is often broken, void of meaningful information for patients to develop informed preferences, and which sometimes jeopardizes patient safety. [33,42,45] To better understand the quality and measurement gaps related to informed consent, we conducted an environmental scan on existing guidance for surgical informed consent and any associated quality measures; completed an exploratory medical record review at a single institution; [1] and performed a literature review of studies that evaluated the effectiveness of interventions aimed to improve informed consent documents and the informed consent process.

2.3.1 *Current Informed Consent Document Guidance*

We conducted an environmental scan, assessing relevant, publicly available guidance on informed consent. First, we sought to identify the standards set by regulatory agencies such as CMS and the Joint Commission. Next, we explored statements on informed consent put forth by professional societies so as to better understand the overarching standard of care. Lastly, we reviewed published recommendations for constructing patient education/informed consent materials. We also considered several laws of informed consent, which vary by state.

Standards from CMS emphasize that informed consent documents should include the name of the hospital, procedure, and practitioner performing the procedure along with a statement certifying that the procedure, anticipated benefits, material risks, and alternative treatment options were explained to the patient or the patient's legal representative. [30,46]

The Joint Commission mandates that hospitals develop informed consent processes and forms, and that those forms reference that a discussion took place between the clinician and the patient about the risks, benefits, and alternatives to the proposed procedure, including the option to elect to receive no treatment. [47]

We also found that several professional societies have published best practices for informed consent. For example, the American College of Surgeons recommended that informed consent include: a written description about the basic procedures involved in the operation; when the patient can expect to resume normal activities; and how the operation is expected to improve the patient's health or quality of life (Appendix C). [48]

In addition to recommendations published by professional societies, a 2014 webinar hosted by the Institute of Medicine (IOM) convened several experts to share best practices to support health literacy. [37,38,43,44,48,49,50,51,52] These included: presenting content in various modalities; setting a maximum reading level of material; minimizing language barriers; focusing on patient desired outcomes; and beginning the informed consent process in advance of the procedures to allow patients to better prepare, ask questions, and deliberate the decision. [33,51]

Certain organizations provided guidance on the presentation or format of patient education resources/informed consent documents. For example, several organizations gave recommendations for the reading level of healthcare documents for patients, varying from below a fifth-grade reading level to below an eighth-grade reading level. [4,21,31,53,54] In addition, the NQF suggests that informed consent materials be made available in the patient's primary language, and include only information that is useful to the patient. [21]

In the U.S., each state has its own legal interpretation of informed consent. State laws are classified around two standards for defining what information should be included in the risks, benefits, and alternatives of informed consent: a physician-based standard (25 states) and a patient-based standard (23 states and the District of Columbia). Two states have a mixture of both. Yet these standards do not define what should be included in the informed consent document. [55] One state, Louisiana, mandates that the specific risks of the procedure are listed. In 2007, Washington State passed legislation that shared decision making with a certified decision aid is a favorable alternative to traditional informed consent documents and processes for preference-sensitive conditions. [36] Other states are non-prescriptive in what should be included in the consent forms.

Overall, the recommendations and laws governing informed consent are broad, allowing for substantial variation in interpretation and implementation. As such, they serve as guideposts for establishing standards upon which to evaluate the current quality of informed consent and benchmarks for developing high-quality informed consent documents and processes.

2.3.2 *Gaps in Informed Consent Document Quality*

There are significant gaps in informed consent document quality and highly variable compliance with informed consent guidelines. [6,56,57,58] Hospitals often follow legal precedent, which results in perfunctory consent documents that convey the minimum amount of information necessary for compliance without providing patient-centered information that fosters patient autonomy or choice. [18,42,55,59,60,61]

In a single-institution exploratory study conducted prior to measure development, we found several basic components were missing from informed consent documents, including the rationale for performing the procedure, a description of potential risks and benefits of the procedure, and alternatives to the procedure. [1] Through this study, we also determined that

most of the consent documents contained hand-written information that was often illegible, and that the majority of documents were signed by patients fewer than 30 minutes prior to the start of the procedure. [62] Sharing important information about an invasive but planned procedure shortly before the procedure does not allow sufficient time for patients to consider or deliberate their options. [16]

2.3.3 *Gaps in Quality Measurement*

Despite the perceived quality gaps, there were no existing measures to assess the quality of informed consent or mechanisms for collecting information about the informed consent process as of the beginning of measure development in September 2014.

More specifically, there are currently no hospital performance measures of informed consent document quality. There is an Agency for Healthcare Research and Quality (AHRQ) measure of the proportion of healthcare professionals who affirm on a safety culture survey that "in their unit or area steps are always taken to ensure that patients have understood the risks and complications before they sign the informed consent form." [63,64] We did not identify any measures of patient-reported experiences with informed consent or of informed consent document quality, though some instruments have been used in research to evaluate informed consent discussions and aspects of shared decision making. [65,66,67,68]

After confirming this measurement gap, we sought to understand if any other quality improvement efforts, beyond measurement, addressed informed consent. We identified several concurrent efforts to advance shared decision making including research projects, [28,69,70,71,72,73,74] Washington state's new law that patient decision aids may be used in lieu of informed consent documents for elective procedures; [35] CMS's payment model for a screening CT scan to detect lung cancer and for left atrial appendage repair as a strategy to prevent thromboembolic events in people with atrial fibrillation, tying reimbursement to the documentation of a discussion about risks, benefits, and alternative treatment options; [75] and NQF's efforts to support the measurement of patient-reported outcomes and use of patient decision aids. [76]

The informed consent document measure highlights a critical moment in the decision-making process, thereby providing a targeted opportunity for future quality measures that are complementary to both the informed consent process and the aforementioned ongoing quality improvement efforts. Therefore, this measure represents a meaningful and feasible first step to improving informed consent.

2.4 Measure Limitations

We recognize that an informed consent document alone cannot capture all facets of decisional quality or patient autonomy. Nonetheless, we see this measure contributing to CMS's larger efforts

dedicated to promoting patient-centeredness. This measure represents a foundation on which to expand measurement of the informed consent process.

In addition, we are aware that the current measure captures some but not all of the components of the informed consent document quality that patients would like to see measured. At this time the Abstraction Tool evaluates fundamental, patient-prioritized components of informed consent that are feasible to measure, including aspects of content, presentation, and timing. [77] Evaluating these components can ensure that patients receive the basic information necessary to make an informed decision, and can help drive quality improvements in the informed consent process. [16,23]

Several concerns about this measure have been voiced in prior public comment: the measure does not capture all aspects of decisional quality, such as engagement in shared decision making; the measure, as currently envisioned, places some additional burden on hospitals to abstract their own informed consent documents and provide these data to CMS for reporting; the measure has not yet been proven to improve patient experience or outcomes. Others commented on the timing item, which standardizes sharing the informed consent document at least one day prior to the procedure and is supported by patients, would be too disruptive to hospital workflow. While we acknowledge these concerns, the measure offers a first step towards improving informed consent which is currently not assessed through any existing measures. It evaluates only a parsimonious number of aspects of the informed consent document that were strongly supported by patients, feasible to reliably measure, and require minimal hospital burden to evaluate. Moreover, we tested the measure in 33 hospitals and found that most informed consent documents fail to meet the minimum standards set forth in this measure. The development of this measure and potential for future implementation is firmly supported by patients, and is a critical first step towards ensuring that patients receive basic information in a written format that is readable and will allow sufficient time for questions and deliberation. Additionally, the measure compliments ongoing efforts to implement and measure shared decision making. As currently envisioned, this measure should evolve over time. It will help to pave the way for future measures that evaluate other components of the informed consent process, including patient-reported input and shared decision making.

3. Approach to Measure Development

At the outset of measure development (September 2014), no standardized tools existed to assess the quality of informed consent documents. Thus, CORE developed and validated an instrument (Abstraction Tool) to assess the quality of informed consent documents for elective procedures. As the foundation for Abstraction Tool development, CORE first identified components of informed consent and created a taxonomy of elements of high-quality informed consent documents.

3.1 Identifying Components of Informed Consent Quality

We conducted an extensive literature review and environmental scan to examine informed consent standards and quality gaps. This work included the review of published, peer-reviewed, and grey literature and discussions with content experts.

We then reviewed clinical and legal standards for informed consent documents at the state and national level, in addition to statements from regulatory agencies (such as CMS and the Joint Commission) and professional societies (as previously discussed in Section 2.3.1). We also compiled federal recommendations for patient education materials in order to better understand the standards for plain language and appropriate methods for assessing readability.

This work demonstrated that the existing standards for informed consent vary and are often open to broad interpretation. Overall, the standards focused on the content of informed consent documents.

To assess the feasibility of measurement and the variation in quality of informed consent documents among elective, hospital-based procedures, we conducted an exploratory study to empirically assess informed consent documents associated with three cardiovascular procedures performed at a single hospital. In this study, we reviewed 150 informed consent documents. [1]

This study confirmed that an informed consent document quality measure is feasible. Informed consent documents were easily located and extracted from medical records and quality information was easily abstracted from the informed consent documents by a non-clinical person.

3.2 Collaboration with Patient/Patient Advocate Working Group

We assembled a Working Group of patients and patient advocates (Table A.1) to ensure the representation of the patient perspective throughout measure development. The patients and patient advocates came from diverse backgrounds and had prior knowledge of or experiences with informed consent, either as patients, caregivers, advocates for vulnerable populations, legal representatives, or patient safety experts.

Based on the findings of the literature review and environmental scan, informed consent standards, and the exploratory study of medical records, we identified three domains of quality which formed

the basis for a taxonomy, or classification system for characterizing aspects of informed consent document quality. With the Working Group's input, we developed the taxonomy as a comprehensive list of 53 components of informed consent documents that reflect the decisional needs of patients. The process of co-developing the taxonomy with the Working Group is outlined in Appendix D and the final taxonomy is included in Appendix E.

3.3 Development of an Instrument (Abstraction Tool) to Evaluate Informed Consent Document Quality

CORE identified a subset of elements from the taxonomy that are representative of the minimum standards for informed consent document quality, feasible to measure, and consistent with the recommendations set forth by government agencies and professional societies. These elements were also supported by the Working Group as being meaningful components of informed consent document quality from the patient perspective.

From these elements, CORE constructed items for inclusion in the Abstraction Tool, an instrument designed to assess the quality of informed consent documents. The items were iteratively refined over 7 cycles of testing using documents from the development sample. Specifically, 10 documents per cycle were purposefully selected from a sample of 800 documents from 8 hospitals based on diversity in procedure type and quality. During this process of item construction and iterative testing, CORE developed a training manual with detailed descriptions about the intent of the items, what qualified and what did not qualify, and examples of each. The final version of the Abstraction Tool met the standards of acceptable reliability and validity. The process of Abstraction Tool development is described in Appendix F and the Abstraction Tool and accompanying instructions manual is found in Appendix G.

3.4 Development of Final Measure

After finalizing the Abstraction Tool, CORE continued to work with patients, methodological experts and our TEP to determine how the measure result would be calculated. This included defining a scoring algorithm for items in the Abstraction Tool based upon its performance characteristics in the development sample and additional patient and TEP input. Next, we explored multiple approaches to calculating the final hospital-level score. This included mean Abstraction Tool score, reporting the proportion of a hospital's documents that met a minimum threshold score, and identifying critical items in the Tool, based upon patient input, without which hospitals would 'fail' the measure. Based upon usability, item-level and overall measure result reliability, and face validity as assessed by our patient Working Group and TEP, the final specification is to report the proportion of a hospital's documents that meet a minimum threshold quality score. Further details are provided in Appendix F.

4. Measure Specifications

4.1 Overview of Measure

CORE's current proposed measure specifications to evaluate hospital-level quality of informed consent documents identify each of the following:

- **The data sources** for the measure are 1) administrative claims data, which are used to identify the cohort and 2) hospitals' informed consent documents.
- **The cohort** is a subset of procedures for Medicare FFS beneficiaries who have undergone an elective procedure in a hospital setting. From this cohort, CMS will select a random sample, stratified on the type of procedure, to be included in the measure. Hospitals will abstract the sample of informed consent documents and send the results to CMS.
- **The measure outcome** is the informed consent document quality. Each consent document is evaluated using the Abstraction Tool, a checklist for assessing the quality of each informed consent document (Section 6).
- **The hospital-level measure result** is the proportion of a hospital's sampled informed consent documents that meet a minimum threshold score of 10 points.

4.2 Data Sources

The measure uses two types of data sources: administrative claims and hospitals' informed consent documents. Elective procedures are identified in the administrative claims from the Medicare Provider Analysis and Review (MedPAR) as described in Section 4.3. [78] Using administrative data to identify medical records of elective procedures ensures that a representative sample of informed consent documents will be submitted for review and reduces the chance of selection bias. The hospitals will score the sampled informed consent documents and send the results to CMS for calculation of the hospital-level measure result.

4.2.1 *Development Sample*

Data from 800 informed consent documents from 8 hospitals were used to develop the Abstraction Tool. These hospitals varied in size, with bed capacity ranging from fewer than 100 to more than 600 beds. In addition, these hospitals were geographically distributed across the United States and varied in their urban/rural location [urban (n=7), rural (n=1)] and teaching status [major teaching (n=5), minor teaching (n=2), non-teaching (n=1)]. [79] The number of elective procedures performed in 2013-2014 across the eight hospitals ranged from 167 to 4,953 procedures.

The procedures for which informed consent documents were selected for the development samples were identified using administrative claims from 2013 [Chronic Conditions Data Warehouse (CCW)] and 2014 [Medicare Provider Analysis and Review (MedPAR)]. [78,80] We provided each hospital with a randomly selected sample of 200 eligible procedures and

requested copies (paper and/or electronic) of informed consent documents, operative reports, and other informed consent-related documentation for at least 100 of the 200 patient records. This allowed for the possibility that some records may not be able to be located and that some are written in non-English languages. The development sample was used for Abstraction Tool development and testing (Appendix F) and for calculating the preliminary hospital measure results.

4.2.2 *Testing Sample*

After we developed the Abstraction Tool and scoring algorithm, we pilot tested the tool in an independent sample of 2480 documents from 25 hospitals. To recruit hospitals, CORE contracted with Health Services Advisory Group (HSAG) and Premier Inc. HSAG recruited 10 hospitals from their network in 4 states: Arizona, California, Florida, and Ohio. Premier recruited fifteen hospitals from a diverse group of hospitals from seven states: Colorado, Louisiana, Maryland, Montana, Nebraska, Texas, and Washington. In order to evaluate a sample of 100 consent forms per hospital from among a representative group of each hospitals' procedures, CORE provided hospitals with a list of approximately 150 patients and the name and date of the qualifying elective procedure performed in their hospital, derived from more recent Medicare Part A claims data 2013-2015. Hospital staff were instructed to identify the corresponding medical record and the informed consent document and operative note associated with the qualifying procedure for the first 100 of the 150 patients on the list. If a medical record could not be identified or if the consent form was in a language other than English, the staff were instructed to substitute that record with one from the latter 50 on the list that was in the same surgical division as the one being substituted. Hospital staff sent all identified consent forms and operative reports to either HSAG or Premier for review. Staff at HSAG and Premier, all of whom had some clinical background and research experience, were trained to use the Abstraction Tool using the approach previously described (Section 3.3). They evaluated each consent form and sent their ratings, documented in a Microsoft Access database, and the documents to CORE.

4.3 Cohort Definition

The measure cohort is comprised of informed consent documents associated with a subset of elective, hospital-based inpatient procedures performed in Medicare FFS beneficiaries, aged 18 years and over, and for which informed consent is considered standard practice. The measure is broadly applicable to a range of procedures, including elective cardiac, orthopedic, and urological procedures.

We focused on informed consent documents for elective procedures for several reasons. We expect informed consent to be standard practice for these procedures. More importantly, patients undergoing elective procedures would greatly benefit from a measure aimed at optimizing communication about the risk, benefits, and purpose of the procedure because elective procedures are generally considered 'preference-sensitive' (meaning there are reasonable alternatives to the

procedure) and different patients may choose different options depending on their preferences, values, and goals.

Though currently specified for inpatient procedures, review of outpatient procedure codes and preliminary measure testing indicate that the measure could feasibly be expanded to include outpatient hospital-based procedures without impacting the validity of the measure (Section 6).

4.3.1 *Procedures Included in the Measure*

The quality of informed consent documents is assessed among:

- Qualifying elective procedures performed in the hospital inpatient setting during the measurement period among Medicare FFS patients aged 18 years and older who are enrolled in Part A at the time of the procedure.

Qualifying elective procedures are defined as procedures occurring during admissions for non-acute conditions, identified using the Planned Readmission Algorithm.[94] This approach aims to capture procedures that are:

- Defined in the Planned Readmission Algorithm as "always" or "potentially" planned procedures. (Appendix H)
- Not associated with an acute medical discharge diagnosis code from the Planned Readmission Algorithm.
- Procedures for which informed consent is standard practice.

The following elective procedures are not considered qualifying elective procedures and were subsequently omitted from the cohort:

- Organ transplant procedures
  - Rationale: Organ transplants are commonly performed on an emergent basis and typically use unique informed consent processes.
- Non-invasive radiographic diagnostic tests (for example, CT Scan with contrast)
  - Rationale: Informed consent standards may be different than standards for invasive procedures and surgeries.
- Procedures that are conducted over several encounters (for example, dialysis, chemotherapy, and radiation therapy)
  - Rationale: Informed consent is likely only conducted prior to the first encounter.
- Procedures performed during the same encounter as another already selected procedure. We will select the first procedure in the encounter, chronologically; if more than one procedure is performed on the same date, we will provide hospitals with all

procedures performed on that same date and ask hospitals to select the procedure that best matches the informed consent document in the medical record.

- Rationale: Two procedures performed during the same encounter are commonly performed together, and thus may not have distinct informed consent documents. Additionally, subsequent procedures performed after the initial procedure but in the same encounter may not be elective.

The final list of procedures used to identify informed consent documents for the measure cohort is presented in Table 1. The procedures are organized into 130 Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS) procedure categories within 10 specialty divisions, derived from the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10 codes) based on AHRQ CCS list and related ICD-10 codes are included in a supplemental Excel spreadsheet (CCS to ICD-10 exclusions_Final.xls). These divisions were created during development of the Hospital-Wide Readmission Measure which identified and then classified each major surgical procedure CCS into one of 10 surgical divisions based on surgical service-line; these groupings were reviewed by three practicing clinicians with expertise in measure development as well as by the TEP.

Table 1. Procedures Included in Cohort – updated to reflect ICD-10 classification

Specialty Division	Procedure	CCS Procedure Category
Neurosurgery	Incision and excision of CNS	**1**
	Insertion; replacement; or removal of extracranial ventricular shunt	**2**
	Excision destruction or resection of intervertebral disc	**3**
	Diagnostic spinal tap	**4**
	Insertion of catheter or spinal stimulator and injection into spinal canal	**5**
	Decompression peripheral nerve	**6**
	Other diagnostic nervous system procedures	**7**
	Other non-OR closed therapeutic nervous system procedures	**8**
	Other OR therapeutic nervous system procedures	**9**
Ophthalmology	Procedures typically performed for glaucoma	**14**
	Lens and cataract procedures	**15**
	Repair of retina	**16**
	Destruction of lesion of retina and choroid	**17**
	Diagnostic procedures on eye	**18**
	Other therapeutic procedures on eyelids; conjunctiva; cornea	**19**
	Other intraocular therapeutic procedures	**20**
	Other extraocular muscle and orbit therapeutic procedures	**21**
Otolaryngology (Ear/Nose/Throat)	Thyroidectomy; partial or complete	**10**
	Tympanoplasty	**22**
	Mastoidectomy	**24**
	Other therapeutic procedures on the ear nose and sinus	**26**
	Dental procedures	**29**
	Tonsillectomy and/or adenoidectomy	**30**
	Other non-OR procedures on mouth and throat	**32**
	Other OR procedures on mouth and throat	**33**
	Tracheoscopy and laryngoscopy with biopsy	**35**
Cardiothoracic	Lobectomy or pneumonectomy	**36**
	Other diagnostic procedures on the respiratory system and mediastinum	**40**
	Other non-OR therapeutic procedures on respiratory system and mediastinum	**41**
	Other OR Rx procedures on respiratory system and mediastinum	**42**
	Heart valve procedures	**43**
	Coronary artery bypass graft (CABG)	**44**
	Percutaneous transluminal coronary angioplasty (PTCA) with or without stent placement	**45**

Specialty Division	Procedure	CCS Procedure Category
	Insertion; revision; replacement; removal of cardiac pacemaker or cardioverter/defibrillator	**48**
	Other OR heart procedures	**49**
	Aortic resection; replacement or anastomosis	**52**
	Other diagnostic cardiovascular procedures	**62**
	Other non-OR therapeutic cardiovascular procedures	**63**
Vascular	Endarterectomy; vessel of head and neck	**51**
	Varicose vein stripping; lower limb	**53**
	Peripheral vascular bypass	**55**
	Other vascular bypass and shunt; not heart	**56**
	Other OR procedures on vessels of head and neck	**59**
	Embolectomy and endarterectomy of lower limbs	**60**
	Other OR procedures on vessels other than head and neck	**61**
General	Diagnostic endocrine procedures	**11**
	Therapeutic endocrine procedures	**12**
	Bone marrow transplant	**64**
	Procedures on spleen	**66**
	Other procedures; hemic and lymphatic systems	**67**
	Esophageal dilation	**69**
	Gastrostomy; temporary and permanent	**71**
	Colostomy; temporary and permanent	**72**
	Ileostomy and other enterostomy	**73**
	Gastrectomy; partial and total	**74**
	Small bowel resection	**75**
	Colorectal resection	**78**
	Excision (partial) of large intestine (not endoscopic)	**79**
	Cholecystectomy and common duct exploration	**84**
	Inguinal and femoral hernia repair	**85**
	Other hernia repair	**86**
	Laparoscopy (GI only)	**87**
	Abdominal paracentesis	**88**
	Exploratory laparotomy	**89**
	Excision; lysis peritoneal adhesions	**90**
	Other bowel diagnostic procedures	**92**
	Other non-OR upper GI therapeutic procedures	**93**
	Other OR upper GI therapeutic procedures	**94**
	Other non-OR lower GI therapeutic procedures	**95**
	Other OR lower GI therapeutic procedures	**96**
	Other gastrointestinal diagnostic procedures	**97**

Specialty Division	Procedure	CCS Procedure Category
	Other non-OR gastrointestinal therapeutic procedures	**98**
	Other OR gastrointestinal therapeutic procedures	**99**
	Other diagnostic procedures on musculoskeletal system	**159**
	Breast biopsy and other diagnostic procedures on breast	**165**
	Lumpectomy; quadrantectomy of breast	**166**
	Mastectomy	**167**
	Other non-OR therapeutic procedures on musculoskeletal system	**163**
	Other OR therapeutic procedures on musculoskeletal system	**164**
Urology	Endoscopy and endoscopic biopsy of the urinary tract	**100**
	Transurethral excision; drainage; or removal urinary obstruction	**101**
	Nephrotomy and nephrostomy	**103**
	Nephrectomy; partial or complete	**104**
	Genitourinary incontinence procedures	**106**
	Extracorporeal lithotripsy; urinary	**107**
	Procedures on the urethra	**109**
	Other diagnostic procedures of urinary tract	**110**
	Other non-OR therapeutic procedures of urinary tract	**111**
	Other OR therapeutic procedures of urinary tract	**112**
	Transurethral resection of prostate (TURP)	**113**
	Open prostatectomy	**114**
	Diagnostic procedures; male genital	**116**
	Other non-OR therapeutic procedures; male genital	**117**
	Other OR therapeutic procedures; male genital	**118**
Obstetrics/Gynecology	Oophorectomy; unilateral and bilateral	**119**
	Other operations on ovary	**120**
	Ligation or occlusion of fallopian tubes	**121**
	Other operations on fallopian tubes	**123**
	Hysterectomy; abdominal and vaginal	**124**
	Other excision of cervix and uterus	**125**
	Dilation and curettage (D&C)	**127**
	Repair of cystocele and rectocele; obliteration of vaginal vault	**129**
	Other diagnostic procedures; female organs	**130**
	Other non-OR therapeutic procedures; female organs	**131**
	Other OR therapeutic procedures; female organs	**132**
	Cesarean section	**134**
Orthopedics	Partial excision bone	**142**
	Fracture treatment including reposition with or without	**144**

Specialty Division	Procedure	CCS Procedure Category
	fixation; facial fracture or dislocation	
	Fracture treatment including reposition with or without fixation; radius or ulna fracture or dislocation	**145**
	Fracture treatment including reposition with or without fixation; hip or femur fracture or dislocation	**146**
	Fracture treatment including reposition with or without fixation; lower extremity fracture or dislocation (other than hip or femur)	**147**
	Fracture treatment including reposition with or without fixation of other fracture or dislocation	**148**
	Arthroscopy	**149**
	Division or release of joint capsule; ligament or cartilage	**150**
	Arthroplasty knee	**152**
	Hip replacement; total and partial	**153**
	Arthroplasty other than hip or knee	**154**
	Injections and aspirations of muscles; tendons; bursa; joints and soft tissue	**156**
	Amputation of lower extremity	**157**
	Spinal fusion	**158**
	Other therapeutic procedures on muscles and tendons	**160**
	Other OR therapeutic procedures on bone	**161**
	Other OR therapeutic procedures on joints	**162**
Plastic Surgery	Incision and drainage; skin subcutaneous tissue and fascia	**168**
	Excision of skin	**170**
	Repair of skin subcutaneous tissue and fascia	**171**
	Skin graft	**172**
	Other diagnostic procedures on skin subcutaneous tissue fascia and breast	**173**
	Other non-OR therapeutic procedures on skin subcutaneous tissue fascia and breast	**174**
	Other OR therapeutic procedures on skin subcutaneous tissue fascia and breast	**175**

We excluded procedures that are likely to have been done on an urgent or emergent basis (Examples provided in Table 2). For a full table of excluded procedures, see supplemental Excel spread sheet (CCS to ICD-10 exclusions_Final.xls).

Table 2. Examples of Procedures Not Included in Cohort of Eligible Elective Procedures

Procedures that are related to:	
Control of Hemorrhage	For example, bleeding related to heart, GI procedures, and urologic procedures
Hemodynamic support	For example, pulsation balloon implant; percutaneous heart assist system
Irrigation; introduction/infusion of medications, fluids, etc.	For example, irrigation of nasal passage
Removal/revision of drainage or monitoring devices via external approach	For example, removal of nasogastric drain; revision of arterial monitoring device

4.3.2 *Additional Exclusions from the Cohort*

The measure additionally excludes the following types of informed consent documents associated with qualifying elective procedures since they are not feasible to evaluate:

- Informed consent documents for patients who are not the primary FFS Medicare beneficiary, as indicated by their health insurance claim (HIC) number

  -Rationale: Claim information for patients who are not the primary beneficiary of the FFS Medicare plan cannot always be reliably matched to informed consent documents in the medical record.

- Informed consent documents written in a language other than English

  -Rationale: At the present time, the measure is specified and tested in English language documents only.

4.3.3 *Sampling*

The types and volume of elective procedures performed varies within each hospital. For this reason, the measure uses a sampling method to capture a set of procedures from each hospital that is representative of the types of procedures performed at that hospital during the measurement period. Specifically, a sample of cases is generated for each hospital using random sampling stratified on specialty; the number of cases sampled from each of the 10 specialties is proportional to the total number of cases at the hospital in each category. The hospital receives a list of the selected cases and sends copies of the informed consent document and face sheet of the associated operative report from the patient medical record for each requested case. The hospital sample includes 50 surplus cases to account for the possibility that it is unable to locate the medical record or that the identified consent document is in a language other than English.

Sample Size

Based on measure testing to date, the required minimum sample size is anticipated to be approximately 100 documents. If possible, smaller sample sizes will be utilized. The final sample size will be finalized and announced through the rulemaking process prior to measure implementation. In determining the sample size, we will consider both reliability of the measure score, which typically increases with larger sample size, the number of hospitals with enough cases, which decreases with larger sample size, and hospital burden. Hospitals with fewer than the required minimum sample size will not be included in the measure.

4.4 Outcome Definition

The outcome is the quality score of the informed consent document. Each document will be scored using the Abstraction Tool developed by CORE. Informed consent document quality scores will be aggregated to derive a hospital-level performance score.

4.4.1 *Overview of Abstraction Tool*

The Abstraction Tool is a checklist for evaluating the presence of the following items in the consent document:

- Description of the procedure
- How the procedure will be performed
- Rationale for why the procedure will be performed
- Risks, benefits, and alternatives to the procedure
- An item to assess the timing of the patient's signature on the consent document in relation to the procedure date

Items that were selected for inclusion in the Abstraction Tool were:

- Important to patients
- Supported by evidence in the literature and published standards and guidelines
- Applicable to the cohort of elective procedures
- Easily abstracted from medical records without undue burden on patients and hospitals
- Feasibly measured with high reliability

The Abstraction Tool scores consent documents on a scale of 0-20, with a higher score indicating better quality (Table 3). Points were assigned to each item by considering patient and TEP input as well as performance characteristics, such as reliability in empiric testing. Of note, the timing item is assigned the greatest number of points because members of the Working Group and TEP considered this to be the most critical item for patient-centered decision making. The timing item could also be easily abstracted and reliably measured.

Table 3. Abstraction Tool Item Scoring

Item	Response	Points
Description of Procedure		
1) Is language describing *what* the procedure is (beyond the medical name) provided for the patient?	"Yes"	2
	"No"	0
1t) If provided, is it typed?	"Yes"	1
	"No"	0
	"N/A"	0
2) Is a description of *how* the procedure will be performed provided for the patient?	"Yes"	2
	"No"	0
2t) If provided, is it typed?	"Yes"	1
	"No"	0
	"N/A"	0
Rational for Procedure		
3) Is the clinical rationale (condition-specific justification) for *why* the procedure will be performed provided?	"Yes, context and condition given and fully meet criteria"	2
	"Context and condition given, but do not fully meet criteria"	1
	"No, no rationale given"	0
Patient-Oriented Benefit(s)		
4) Is any patient-oriented *benefit* provided (intended impact on patient's health, longevity, and/or quality of life)?	"Yes"	2
	"No"	0
Probability of Procedure-Specific Risks		
5) Is a *quantitative probability* provided for any procedure-specific *risk*?	"Yes"	2
	"No"	0
6) Is a *qualitative probability* provided for any procedure-specific *risk*?	"Yes"	1
	"No"	0
Alternative(s) to the Procedures		
7) Is any *alternative* provided for the patient?	"Yes"	2
	"No"	0
Timing		
8a) Date consent document was shared with the patient (usually indicated by patient's/proxy's signature) 8b) Date of procedure 8c) Patient opted-out of receiving the consent document at least one day prior to the procedure	At least one day before procedure **OR** patient opted out of viewing the informed consent document at least 1 day prior	5
	Less than 1 day before procedure	0
	Missing either date of patient's/proxy's signature or missing date of procedure	0
Maximum Quality Score		20

4.4.2 *Abstraction Tool Implementation*

The Abstraction Tool is a Microsoft Access form that allows trained abstractors to enter responses for each item evaluated in the informed consent document. The Tool is supported by standardized training materials consisting of an instruction manual that provides guidance and examples of what meets criteria for each item in the Abstraction Tool, a training video, and sample test documents. The Abstraction Tool and instructions manual are presented in Appendix G. Following training, the abstractors score the set of sample test documents to demonstrate that they can correctly use the Abstraction Tool before beginning abstraction for the measure.

4.5 Measure Calculation

The final hospital-level measure result is calculated by aggregating the scores of the sample of hospitals' informed consent documents, as assessed using the Abstraction Tool. In accordance with feedback from the Working Group and TEP, and consistent with other measures of patient-centered practices, the hospital-level score will be calculated as the percentage of a hospital's documents that exceed a specific quality threshold score. Based upon input from our Working Group, we are proposing a minimally acceptable document score threshold of 10 out of the possible 20 points on the Abstraction Tool. Using this threshold, we observe significant inter-hospital variation in the quality of informed consent documents.

4.6 Risk Adjustment

Risk adjustment is used to account for differences in patient case mix that may impact clinical outcomes and obscure assessment of care quality. Risk adjustment is not appropriate for an informed consent document quality measure because patient-specific factors should not impact informed consent document quality. Therefore, the measure outcome is not risk adjusted.

5. Measure Results

Below we report measure results for the development and testing samples.

5.1 Development Sample

Hospital measure results were calculated in the development sample as part of measure development by scoring a sample of 100 completed informed consent documents for each of eight hospitals (total=800). We calculated the number of individual Abstraction Tool items that each hospital received credit for, as well as the distribution of the document score, mean document score for each hospital, and proportion of documents reaching a specified scoring threshold for each hospital.

5.1.1 *Abstraction Tool Item Results by Hospital*

We assessed hospital performance on each item in the Abstraction Tool (Table 4). The results demonstrate substantial deficiencies among all hospitals on most items included in the Abstraction Tool. Only one document reported any quantitative risks, such as the percent of patients who develop an infection during the post-operative period. Few included mention of any patient-oriented benefits, such as pain relief or prolonged survival, or procedure-specific alternative treatment options, such as medication therapy. In four of the hospitals, the content items were only handwritten and never typed. The majority of documents were signed by patients more than 24 hours prior to the procedure in most hospitals. Overall, there was variation among hospitals in performance on each item in the Abstraction Tool, with substantial variation on items describing the procedure and the rationale for the procedure.

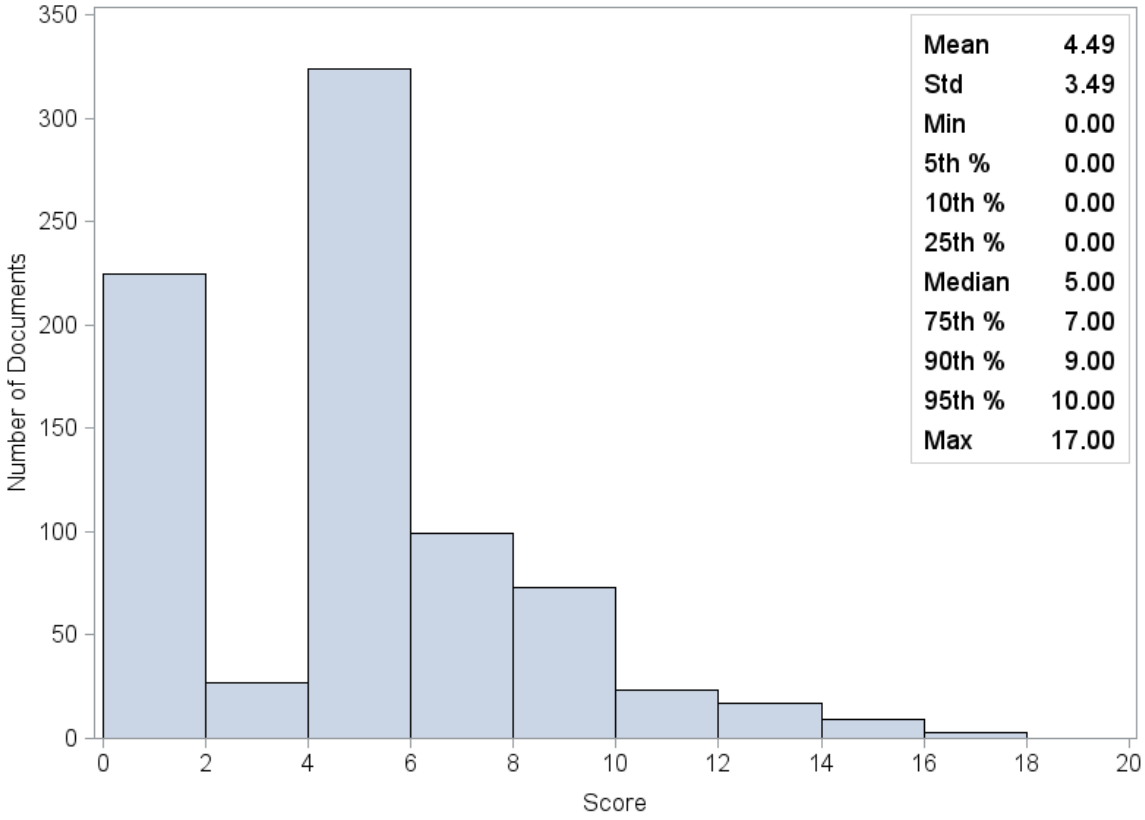
Table 4. Overall Item-Level Performance across Hospitals

Abstraction Tool Item	Overall Document Performance (N=800) n (%)	Range in Hospital Performance (Minimum to Maximum % correct)
1) **What** the procedure is		
Documents that received credit	224 (28%)	3% - 67%
1t) If provided, is it **typed**?		
Documents that received credit	112 (14%)	0% – 60%
2) **How** the procedure will be performed		
Documents that received credit	130 (16%)	0% – 59%
2t) If provided, is it **typed**?		
Documents that received credit	116 (15%)	0% – 55%
3) **Why** the procedure will be performed		
Documents that received credit	140 (18%)	1% – 70%
4) Patient-oriented **benefit**		
Documents that received credit	24 (3%)	0% – 10%
5) Quantitative procedure-specific **risk** probability		
Documents that received credit	1 (0%)	0% – 1%
6) Qualitative procedure-specific **risk** probability		
Documents that received credit	45 (6%)	0% – 24%
7) **Alternative** to procedure		
Documents that received credit	45 (6%)	0% – 33%
8) Consent document shared at least one day before procedure		
Documents that received credit	436 (55%)	33% – 77%

5.1.2 *Distribution of Document Scores*

Document scores are calculated based on performance on each individual item as described in Table 3. The mean document score was 4.5. The median score was 5 and the inter-quartile range was [0 ,7]. The minimum score was 0 and the maximum score was 17.

Figure 1. Distribution of Document Scores



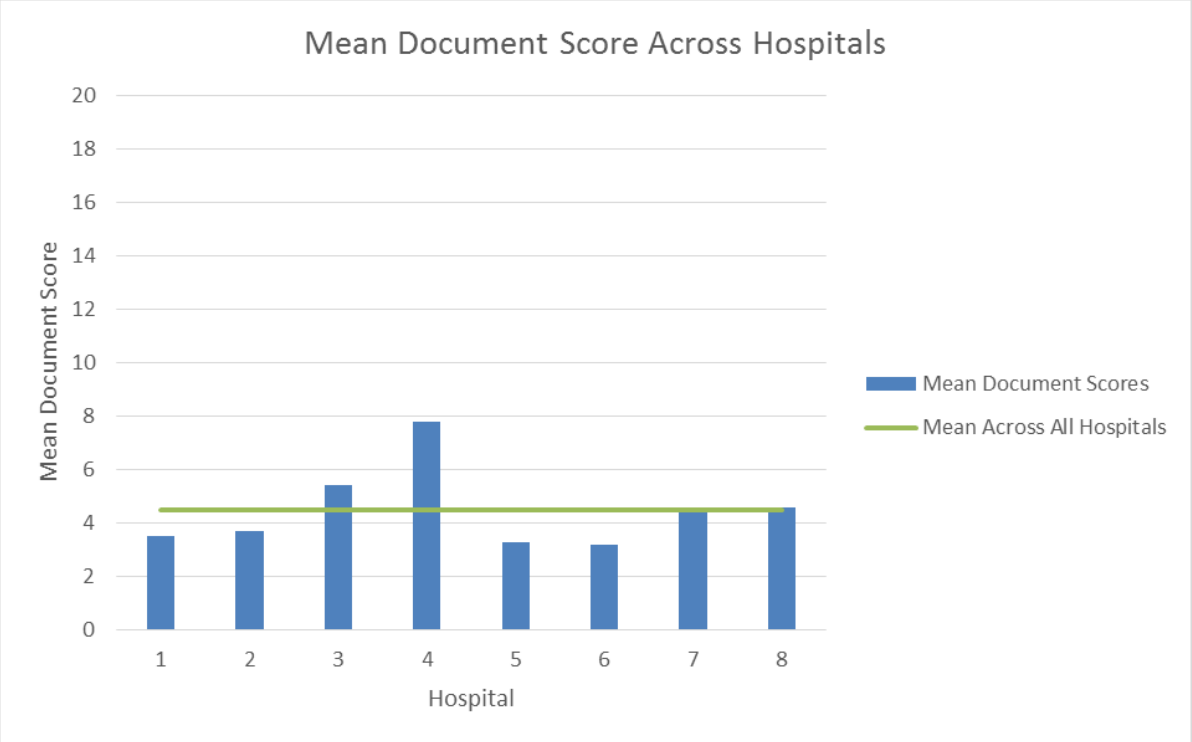
5.1.3 *Distribution of Hospital Measure Performance Using Mean Document Score*

Hospital performance was measured first by taking the mean of all document scores at each hospital. These hospital-level scores are shown in Table 5 and Figure 2. The mean scores ranged from 3.2 (95% Confidence Interval (CI): 2.6 – 3.8) for Hospital 6 to 7.8 (95% CI: 7.1 – 8.5) for Hospital 4 (Table 5).

Table 5. Hospital-Level Mean Document Score Results in the Development Sample

	Hospital Site #							
	1	2	3	4	5	6	7	8
Hospital-level mean score (N= 100 documents)	3.5	3.7	5.4	7.8	3.3	3.2	4.4	4.6
95% CI	3.0-4.1	3.2 -4.2	4.9 -5.9	7.1-8.5	2.9 -3.8	2.6 -3.8	3.6 -5.2	3.8.-5.4

Figure 2. Hospital-Level Mean Document Scores



5.1.4 *Distribution of Hospital Measure Performance Using Document Threshold Approach*

The proportion of documents meeting or surpassing a quality threshold of 5, 10, and 15 points (out of 20 points total) are presented in Table 6 and Figure 3, Figure 4, and Figure 5. All hospitals had 50% or more of their documents reaching a scoring threshold of greater than or equal to 5 points, but there was a range in performance. In Hospital 4, 86% of documents met this threshold, as compared with 55% of documents in Hospital 6. Five

hospitals had at least some documents score greater than or equal to 10 points and only two hospitals had any documents greater than or equal to 15 points.

Table 6. Hospital-Level Results Using Three Possible Document Threshold Values in the Development Sample

	Hospital Site # (N= 100 documents per site)							
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Proportion of documents scoring equal to or above threshold (%)	Threshold of 5 points							
	62	66	77	86	65	55	60	58
	Threshold of 10 points (proposed reporting threshold)							
	0	**0**	**3**	**29**	**0**	**2**	**8**	**10**
	Threshold of 15 points							
	0	0	0	6	0	0	1	0

Figure 3. Hospital-Level Performance at a Document Threshold of 5 Points

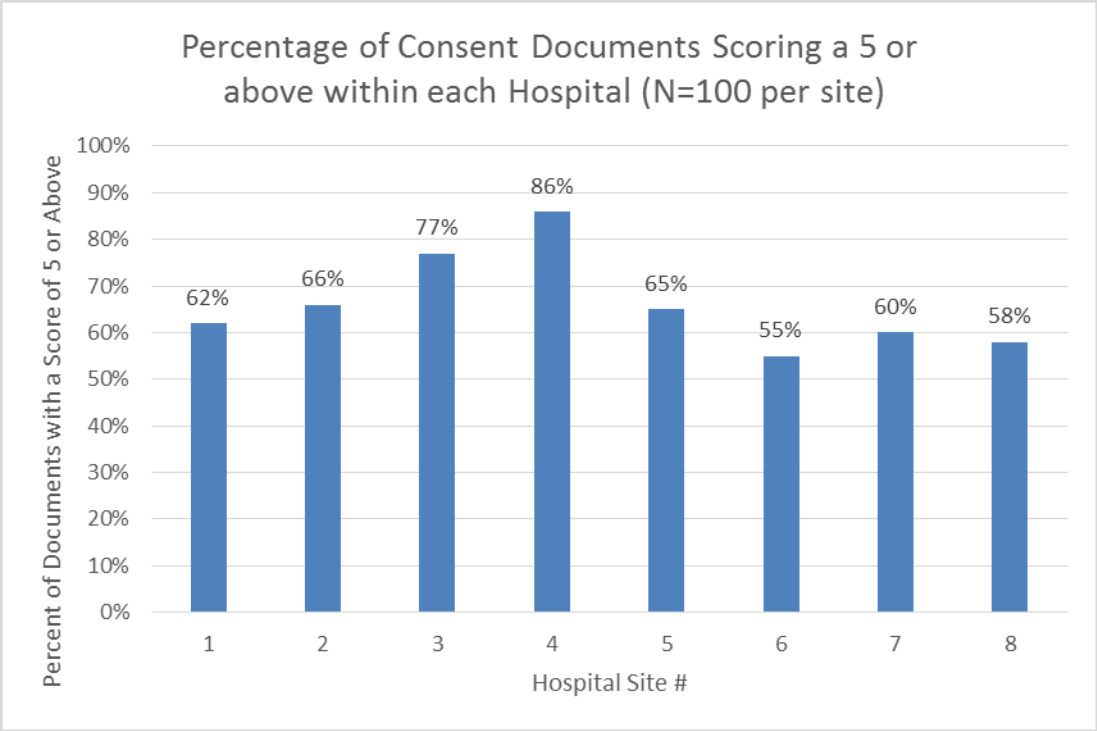


Figure 4. Hospital-Level Performance at a Document Threshold of 10 Points (proposed reporting threshold)

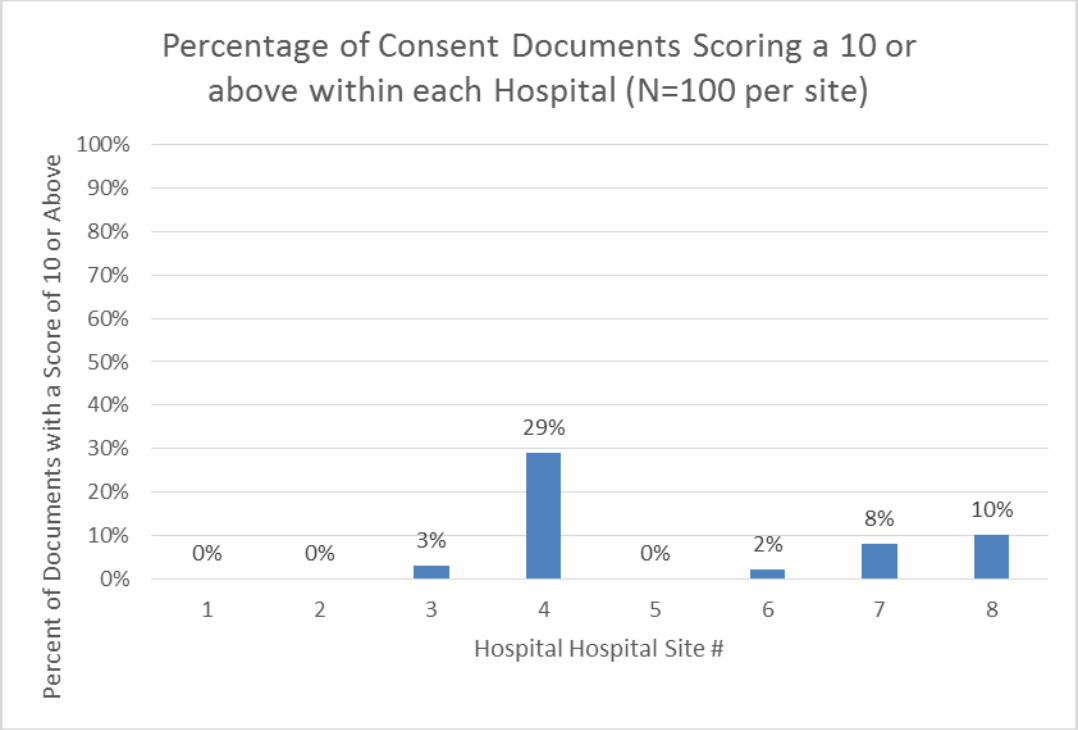
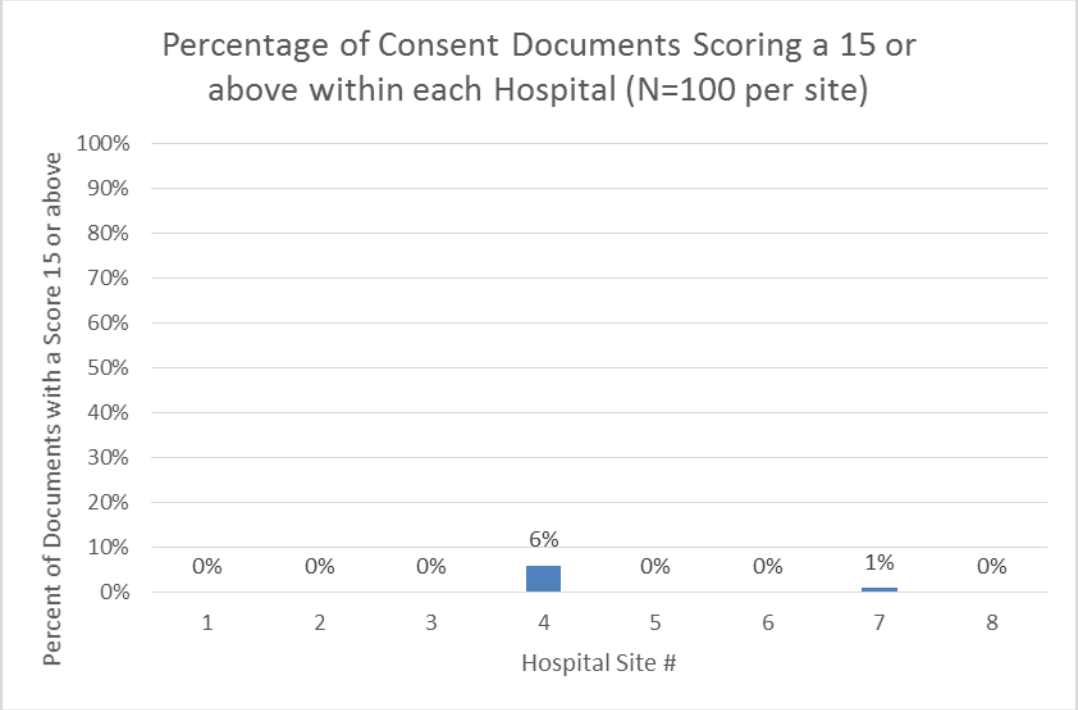


Figure 5. Hospital-Level Performance at a Document Threshold of 15 Points



5.2 Testing Sample Results

5.2.1 *Abstraction Tool Item Results by Hospital*

As described above, we tested the final Abstraction Tool on informed consent documents from an independent sample of 25 hospitals. For this testing sample, we also assessed hospital performance on each item in the Abstraction Tool (Table 7), and evaluated hospital level scores. Among documents, the distribution was similar to those in the development sample, with document scores ranging from 0 to 20, with a median of five. The results demonstrate substantial deficiencies among all hospitals, with the majority of documents failing to receive credit on most items.

Table 7. Overall Item-Level Performance across Hospitals in the Testing Sample

Abstraction Tool Item	**Overall Document Performance** (N=2480) n (%)	**Range in Hospital Performance** (Minimum to Maximum % correct)
1) **What** the procedure is		
Documents that received credit	755 (30%)	0%—94%
1t) If provided, is it **typed**?		
Documents that received credit	453 (18%)	0%—88%
2) **How** the procedure will be performed		
Documents that received credit	276 (11%)	0%—79%
2t) If provided, is it **typed**?		
Documents that received credit	216 (9%)	0%—79%
3) **Why** the procedure will be performed		
Documents that received credit	563 (23%)	0%—71%
4) Patient-oriented **benefit**		
Documents that received credit	131 (5%)	0%—83%
5) Quantitative procedure-specific **risk** probability		
Documents that received credit	49 (2%)	0%—12.8%
6) Qualitative procedure-specific **risk** probability		
Documents that received credit	585 (24%)	0%—100%
7) **Alternative** to procedure		
Documents that received credit	421 (17%)	0%—92%
8) Consent document shared at least one day before procedure		
Documents that received credit	1106 (46%)	6%—88%

5.2.2 *Distribution of Hospital Measure Performance Using Mean Document Score*

The aggregated hospital-level scores are shown below. We calculated the mean score for a sample of 100 documents and the mean score for the total number of documents submitted by hospitals that had fewer than 100 documents.

Hospital mean performance scores ranged from 0.8 (95% Confidence Interval (CI): 0.4 – 1.1) for Hospital 3 to 10.8 (95% CI: 10.0 – 11.6) for Hospital 9 (Table 8).

Table 8. Hospital-Level Mean Document Score Results in Testing Sample

Hospital Site #	Total Number of Documents Submitted	Hospital-level mean score (N= 100 documents)*	95% CI
1	100	2.0	1.5-2.5
2	150	2.0	1.5-2.4
3	100	0.8	0.4-1.1
4	95	1.02	0.6-1.4
5	100	3.5	2.6-3.5
6	99	1.9	1.4-2.4
7	148	6.3	5.3-7.2
8	99	0.9	0.5-1.2
9	100	10.8	10.0-11.6
10	100	0.6	0.3-0.9
11	51	2.8	2.2-3.5
12	101	3.7	3.1-4.2
13	100	8.6	7.8-9.5
14	50	9.8	9.1-10.6
15	76	8.6	7.6-9.7
16	111	5.3	4.6-6.1
17	101	1.5	1.1-2.0
18	101	3.7	2.9-4.5
19	100	5.0	4.4-5.6
20	100	5.3	4.8-5.9
21	100	7.7	7.0-8.5
22	98	5.4	4.7-6.2
23	98	5.3	4.7-5.9
24	101	5.9	5.1-6.7
25	101	7.8	7.2-8.4

* * Hospitals 4, 6, 8, 11, 14, 15, 22, and 23 had fewer than 100 documents. The mean score and CI for these hospitals were calculated based on the total number of document.

5.2.3 *Distribution of Hospital Measure Performance Using Quality Threshold Approach*

The proportion of documents meeting or surpassing a quality threshold of 5, 10 (proposed for reporting), and 15 points (out of 20 points total) are presented in Table 9 based on up to 100 documents per hospital.

Table 9. Hospital-Level Results Using Three Possible Quality Threshold Values in the Testing Sample

	Hospital Site #*																							
Proportion of documents scoring equal to or above threshold (%)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**
	Threshold of 5 points																								
	35	38	15	14	61	31	76	14	91	6	51	63	87	94	83	63	23	33	72	72	80	59	68	60	84
	Threshold of 10 points (proposed threshold for reporting)																								
	0	**0**	**0**	**0**	**0**	**0**	**25**	**0**	**79**	**0**	**0**	**1**	**46**	**84**	**47**	**15**	**0**	**14**	**6**	**1**	**24**	**14**	**9**	**30**	**39**
	Threshold of 15 points																								
	0	0	0	0	0	0	4	0	14	0	0	0	9	0	13	2	0	4	0	0	0	0	0	0	1

* Hospitals 4, 6, 8, 11, 14, 15, 22, and 23 had fewer than 100 documents

5.3 Summary of Measure Results

These results demonstrate that, overall, most hospitals in the development and testing samples perform poorly on the measure, as expected based upon our literature review and discussions with patients. For example,

- Only one document in the development sample (0%) and only 49 (2%) documents (Table 4 and Table 7) in the testing sample reported any quantitative risks; however, both quantitative and qualitative risks were asserted to be important by the Working Group and TEP. Moreover, the surgical community is increasingly using evidence-based calculators to estimate personalized risk.
- Few informed consent documents reported any patient-oriented benefits or procedure-specific alternative treatment options, though this was asserted to be an important component of informed consent by the Working Group and TEP and in feedback received during the public comment period.
- In most hospitals, the content items relating to the name of the procedure and how it is performed were never typed.
- The timing item was met by the majority of documents in most hospitals, though overall measure results show opportunity for improvement.

Despite the universally inadequate performance, we observed substantial inter-hospital variation in performance on each Abstraction Tool item and in overall document scores, demonstrating the potential to detect differences in informed consent document quality between hospitals. The mean document score (based on a scale of 0 to 20, with 20 representing high quality informed consent documents) ranged from 3.2 (95% CI: 2.6 -3.8) to 7.8 (95% CI: 7.1-8.5) in the development sample and from 0.75 (95% CI: 0.4-1.1) to 10.8 (95% CI: 10.0-11.6) in the testing sample. While these results reflect only a limited number of hospitals, these hospitals were geographically dispersed with different state informed consent laws and diverse in size, teaching status, and utilization of different informed consent templates.

The results from the testing sample also affirm that setting a quality threshold of 10 out of 20 points enables hospitals to compare themselves against an established standard as well as to other hospitals. Most hospitals had at least some of their documents score more than 10, demonstrating that this score is attainable, but only two hospitals had more than 50% of their documents score above a 10-point threshold, demonstrating significant opportunities for improvement. Thresholds for quality can progressively increase in response to public feedback and hospital performance, setting higher standards for informed consent documents over time. In setting a threshold score of 10 out of 20 points, this measure highlights that few hospitals offer patients a minimum standard of written information about their elective procedure. As hospital performance improves, CMS can solicit additional stakeholder feedback on changing the threshold or scoring approach as appropriate.

6. Measure Testing

NQF considers the scientific acceptability of measures in terms of reliability and validity.[81] Specifically, they require measure developers to establish the reliability and validity of both the component data elements that make up a measure, as well as the measure score itself. NQF also considers the feasibility of the measure in terms of the availability of the data and possibility for use for performance measurement.

The Abstraction Tool and measure results were tested for reliability in the development and testing samples. The face validity of the measure concept as well as the face validity of the final measure specifications were tested following completion of measure development and prior to testing. Finally, the feasibility of the measure was tested in the development and testing samples.

6.1 Reliability Testing

To assess the reliability of the Abstraction Tool, CORE examined the inter-rater reliability of each item on the Abstraction Tool as well as the overall informed consent document scores produced by the Tool for 10% (n=80) of the 800 documents received from the 8 hospitals in the development sample, and after further revisions to the Abstraction Tool Manual, reassessed reliability among 10% (n=250) of the 2480 documents from the 25 hospitals in the testing sample.

In the development phase, we trained two abstractors using a recorded webinar that reviewed the Tool and instructions. These individuals work in the medical records division of a hospital. They had not previously abstracted documents during the development of the Abstraction Tool; additionally, they had no knowledge that CMS was developing an Informed Consent Document Quality measure. As part of the training, we conducted a trial run with a test set of 10 completed informed consent documents; differences between the two were discussed and resolved through consensus. After completion of their training, the paired abstractors reviewed two sets of the same 40 informed consent documents (5 documents per hospital per set); one set represented the first 40 out of 800 documents, and the other set represented the last 40 out of 800 documents evaluated by the abstractors (Section 5.1), Sample A and Sample B. We then calculated percent agreement and Cohen's kappa for each item, and Spearman's correlation and Fleiss' ICC [2,1] for the document scores, to assess agreement between the two raters.

Based on these findings, we made further revisions to the Abstraction Tool Manual, and then trained 2 new raters using the methods described above. These raters evaluated 250 additional informed consent documents from the testing sample. We calculated percent agreement and Cohen's kappa for each item, and Spearman's correlation and Fleiss' ICC [2,1] for the document scores, to assess agreement between the two raters.

6.1.1 *Development Sample: Reliability of the Abstraction Tool*

For each Abstraction Tool item, we calculated the percent agreement, as well as the inter-rater reliability (Cohen's kappa). For the overall document score (derived based on the scoring approach presented in Table 10), we calculated the intra-class correlation (ICC) and Spearman's rank order correlation. The results of the reliability testing for the Abstraction Tool items are provided in Table 11.

From the development sample, the results for item reliability demonstrate excellent agreement between the two abstractors. Agreement reached >90% in testing sample A and 70% in testing sample B for all items on the Tool. Inter-rater reliability ranged from a Cohen's kappa statistic 0.45 to 0.94. The kappa values ranged from 0.45 to 1.0 in Sample A and 0.18 to 1.0 in Sample B; values between 0.0 and 0.2 are conventionally considered as "slight" inter-rater agreement, values between 0.2 and 0.4 are considered "fair" agreement, values above 0.4 are considered "moderate" agreement, and values in the range of 0.6 to 0.8 are considered "substantial" agreement. [82] Several items had insufficient variation within or between abstractors to calculate the kappa statistic. These items are marked with a Not Available (N/A). The high percent agreement but low kappa for statistic for several of the items is a statistical phenomenon due to the low prevalence of the positive answer and not an indication of inadequate reliability of the item. [83]

Table 10. Inter-rater Reliability in Abstraction Tool Item Results Between Two Abstractors: Development Sample

Abstraction Tool Item	Testing Sample A (N=40)		Testing Sample B (N=40)	
	% Agreement	Kappa	% Agreement	Kappa
1) **What** the procedure is	90.0	0.71	70.0	0.32
1t) If provided, is it **typed**?	95.0	0.77	92.5	0.36
2) **How** the procedure will be performed	92.5	0.73	97.5	0.90
2t) If provided, is it **typed**?	95.0	0.77	97.5	0.84
3) **Why** the procedure will be performed	90.0	0.45	70.0	0.18
4) Patient-oriented **benefit**	100.0	N/A	95.0	N/A
5) Quantitative procedure-specific **risk** probability	100.0	N/A	100.0	N/A
6) Qualitative procedure-specific **risk** probability	100.0	1.00	100.0	1.00
7) **Alternative** to procedure	95.0	0.48	97.5	N/A
8a,b) Consent document shared at least one day before date of procedure	97.5	0.94	97.5	0.95
8c) Patient opted-out of receiving the consent document at least one day prior to the procedure	100.0	N/A	100.0	N/A

In the development sample, the Spearman correlation between overall document scores was 0.81 for Sample A and 0.70 for Sample B. The ICC [2,1] was 0.81 for Sample A and 0.70 for Sample B (Table 11). These are conventionally considered as "strong" to "very strong" correlations. [84]

Table 11. Inter-rater Reliability of Abstraction Tool Document Scores Between Two Abstractors: Development Sample

Sample A (N=40)		Sample B (N=40)	
Spearman Correlation	ICC	Spearman Correlation	ICC
0.81	0.81	0.70	0.70

6.1.2 *Testing Sample: Reliability of the Abstraction Tool*

To further assess reliability, two experienced external abstractors re-abstracted a subset of previously abstracted documents from the testing sample; none of the documents had been previously abstracted by either of these two abstractors. In addition, both abstractors worked as abstractors within a hospital system; one of the two abstractors had previously abstracted informed consent documents using the Abstraction Tool while the second was entirely new to the work and received only an hour of standard training prior to performing the abstraction. CORE randomly selected 10 informed consent documents from each hospital for the two abstractors to review (total of 250 documents). Agreement reached >90% for all items on the Tool. Inter-rater reliability ranged from a Cohen's kappa statistic 0.53 to 0.95. Values between 0.0 and 0.2 are conventionally considered as "slight" inter-rater agreement, values between 0.2 and 0.4 are considered "fair" agreement, values above 0.4 are considered "moderate" agreement, and values in the range of 0.6 to 0.8 are considered "substantial" agreement. [82] Several items had insufficient variation within or between abstractors to calculate the kappa statistic. These items are marked with a Not Available (N/A). The high percent agreement but low kappa for statistic for several of the items is a statistical phenomenon due to the low prevalence of the positive answer and not an indication of inadequate reliability of the item. [83]

The Spearman correlation between document scores was 0.92. The ICC [2,1] was 0.92 (Table 12). These are conventionally considered as "very strong" correlations. [84] Not only were the testing results robust, they support that experienced abstractors who receive minimal training in the Abstraction Tool can produce reliable results.

Table 12. Inter-rater Reliability in Abstraction Tool Item Results Between Two Abstractors: Testing Sample

Criterion/Question on Abstraction Tool	Agreement between 2 Raters (N=250)	
	% Agreement	Kappa
1) Is language describing "WHAT is the procedure" (beyond the medical name) provided for the patient?	92.0	0.81
1t) If provided, is it typed?	96.4	0.89
2) Is a description of HOW the procedure will be performed provided for the patient?	96.8	0.89
2t) If provided, is it typed?	98.0	0.92
3) Is the clinical rationale (condition-specific justification) for WHY the procedure will be performed provided?	92.6	0.75
4) Is any patient-oriented benefit provided (intended impact on patient's health, longevity, and/or quality of life)?	96.8	0.76
5) Is a QUANTITATIVE probability provided for any procedure-specific risk?	97.6	0.61
6) Is a QUALITATIVE probability provided for any procedure-specific risk?	94.8	0.53
7) Is any alternative provided for the patient?	98.8	0.95
8a,b) Was the informed consent document shared with the patient at least one day before date of procedure, if the patient did not opt out of signing at least one day in advance?	95.2	0.88
8c) Did the patient opt out of signing at least one day in advance	100.0	NA
Document score agreement		
Spearman correlation	0.9164	
ICC	0.9159	

6.2 Validity Assessment

The validity of a measurement is the degree to which "the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality." [85] As with prior CMS outcome measures, in the absence of existing quality "gold standards," we evaluated the face validity of the measure concept as well as the face validity of the final measure specifications.

6.2.1 *Data Element Validity: Validity of the Abstraction Tool*

After development of the Abstraction Tool, we presented the Tool and testing results to the Working Group and TEP and solicited feedback through public comment. The Working Group affirmed that the items included in the Tool represented key elements of informed consent that are important to patients, lending support that this measure meets criteria for construct validity. However, some Working Group and TEP members and members of the public proposed additional elements from the taxonomy that they would like to see incorporated.

6.2.2 *Measure Result Validity*

We also asked the TEP to evaluate the final face validity of the measure. We surveyed the TEP and asked each member to rate six statements using a six-point scale (1=Strongly Agree, 2=Moderately Agree, 3=Somewhat Agree, 4=Somewhat Disagree, 5= Moderately Disagree, and 6=Strongly Disagree).

1. Measuring the quality of informed consent is important.
2. The quality of informed consent documents is an important component of the informed consent process.
3. Measuring the quality of the informed consent document is a valid approach for assessing an aspect of informed consent quality.
4. Improving the quality of informed consent documents could meaningfully improve one aspect of the informed consent process for patients.
5. The Abstraction Tool, as currently specified, provides a valid assessment of the basic elements of informed consent documents.
6. The measure, as currently specified, provides a valid assessment of the quality of hospitals' informed consent documents.

Seven of thirteen TEP members responded to the survey. All TEP members supported the validity of the measure concept (items 1-3 above), including the importance of measuring informed consent, the importance of informed consent documents as a component of the informed consent process, and the validity of measuring the quality of informed consent documents as a way of assessing an aspect of informed consent quality. The TEP members agreed that improving the quality of informed consent documents could meaningfully improve one aspect of the informed consent process for patients. Six of the seven TEP members supported that the Abstraction Tool provides a valid assessment of the basic elements of informed consent documents and five agreed that the measure, as currently specified provides a valid assessment of the quality of hospitals' informed consent documents.

While we did not specifically survey hospitals in the testing sample, participating staff noted that the hospitals engaged during measure testing were enthusiastic about the project and felt that they learned a lot about their informed consent process. CORE recognizes that these hospitals self-selected to participate in this study; nonetheless, this feedback helps to confirm that this

measure can be a tool for hospitals to reflect on their own informed consent documents and processes, and innovate in novel ways that not only conform to the minimum standards set forth in this measure, but also meet a more patient-centered standard.

6.3 Feasibility Assessment

Measure feasibility is the extent to which the required data are readily available, can be retrieved without undue burden, and can be implemented for performance measurement. [81] Prior to developing this measure, we had evaluated feasibility in an exploratory study of a single institution's informed consent documents. [1] From this study, we learned that it is feasible to abstract aspects of informed consent document quality related to the content, timing and presentation.

The feasibility of implementing the informed consent document quality measure was formally assessed by surveying the eight hospitals of the development sample following data collection and abstraction of the informed consent documents. Data collectors typically needed 1-1.5 days to identify and create electronic copies of 150 informed consent documents from the medical charts. We did not encounter any challenges in this phase. In our survey of abstractors, we found that after abstractors completed approximately three hours of training, which included reviewing the standardized instructions presented on paper and by video, and using the Abstraction Tool with 10 test documents followed by audit review with CORE, the abstraction time per document is under five minutes.

Among the 25 additional hospitals in the testing sample, the process of identifying, collecting and abstracting a subset of informed consent documents representative of a hospitals' case-mix was viewed as feasible. Participating hospitals did not report any confusion about the instructions for identifying the procedures and associated documents. With respect to the amount of time needed to evaluate each informed consent document using the Abstraction Tool, both HSAG and Premier abstractors noted taking about 5-10 minutes for the first few informed consent documents from a single hospital, after which the rest of the documents took approximately 3 minutes to complete. Both HSAG and Premier found the Abstraction Tool Manual easy to use.

7. Summary

In developing the Quality of Informed Consent Documents measure we engaged with multiple stakeholders to rigorously develop the measure concept, identify quality and measurement gaps in informed consent documents and develop and test Abstraction Tools to assess document quality, and create a methodology for assessing hospital performance based on a sample of their informed consent documents. This work was accomplished in collaboration with a patient and patient advocate Working Group and was vetted throughout development with a nationally convened TEP.

This measure assesses informed consent documents associated with a cohort of Medicare FFS beneficiaries who have elective procedures performed during an inpatient encounter. We anticipate the measure could be expanded to include outpatient procedures performed in both hospital and ambulatory care settings, as well as in non-Medicare beneficiaries (an all-payer cohort). The measure will not be risk-adjusted since patient characteristics should not influence the quality of the informed consent documents.

The quality of the informed consent documents is rated using an Abstraction Tool, an instrument that evaluates a minimum standard that all informed consent documents should meet. The Abstraction Tool was developed with substantial input from experts in survey development, the Working Group and TEP, and involved iterative reliability and validity testing in a development sample of eight hospitals and in a testing sample of 25 distinct hospitals. This testing also demonstrated the feasibility of this measure and expected burden to hospitals. Abstractors were trained to use the Abstraction Tool to assess the quality of informed consent documents and were able to abstract documents at a rate of approximately three minutes per document. We developed a rubric for scoring the Abstraction Tool. Document scores are aggregated to calculate hospital-level performance on the measure. Hospital results are presented as the percent meeting a quality threshold of 10 out of a possible 20 points.

Hospital-level results from the development and testing samples demonstrate substantial deficiencies in quality. Even with the overall poor performance, we observed variation in informed consent document quality among hospitals, demonstrating the potential to detect differences in informed consent document quality within and between hospitals.

Hospitals and other healthcare systems can directly impact the quality of informed consent documents to meet a more patient-centered, ethical standard that aligns with state laws and hospital policies. This measure will illuminate hospital-level deficiencies and variation in the quality of informed consent documents. It will also increase the attention and effort that hospitals dedicate to high-quality informed consent documents and processes that support patient autonomy.

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Appendix A. Acknowledgement Details

We would like to acknowledge the ongoing support from our consultants and technical experts. These individuals generously gave their time, providing guidance on key measure development decisions. In addition to the patient advocates on our Working Group (Table A.1) and the members of our Technical Expert Panel (TEP) (Table A.2), we would like to thank the following consultants:

Leslie Curry, PhD, MPH – Senior Research Scientist in and Lecturer in Public Health (Health Policy); Co-Director, Robert Wood Johnson (RWJ) Clinical Scholars Program, Yale School of Public Health

Mary Dixon-Woods, DPhil, MSc – Professor of Medical Sociology, Department of Health Sciences, University of Leicester, UK

Carol Oladele, PhD, MPH – Associate Research Scientist in Medicine, Equity Research and Innovation Center (ERIC), Yale School of Medicine

Table A. 1. Working Group Members

Name	Title and Organization
Ellen Andrews, PhD	Executive Director, Connecticut Health Policy Project
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Larry Bocchiere III	Founder and President Emeritus, Well Spouse Association
Jonathan Delman, PhD, JD, MPH	Research Assistant Professor at the University of Massachusetts Medical School, Department of Psychiatry
Gaye Hyre	Founder and Executive Director, ArtBra New Haven
Marilyn Mann, JD	Editor, Circulation: Cardiovascular Quality and Outcomes Caregiver Viewpoint section
Chris Norton, MA	Co-founder and President, Minnesota Breast Cancer Coalition
Patty Skolnik, BASW	Founder and Director, Citizens for Patient Safety
Amos Smith, MSW	President & CEO, Community Action Agency of New Haven, CT

Table A. 2. TEP Members

Name	Organization (Title)	Location
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Tina Weinstein, JD, BSN	Montefiore Health System (Assistant Vice President of Counsel Claims and Risk)	Bronx, NY

Appendix B. Glossary of Key Terminology

In this report, we used specific terminology from the qualitative literature to guide our measure development process. We define these terms here for the reader:

Abstraction Tool – A standardized instrument for evaluating specific elements of quality from informed consent documents. The Abstraction Tool will be used to evaluate the quality of hospital's informed consent documents. The quality scores generated using the Abstraction Tool will be aggregated to calculate the hospital-level score for the measure. The Tool and instructions manual can be found in Appendix G.

Beneficence – An action in health care in which the patient's decision is respected, the patient is protected from harm and their well-being is secured. [86]

Confidence Interval (CI) – A statistical value for an interval estimate of the 'true' value. That is, if a different sample of values from the same hospital (for example) was evaluated, there is 95% confidence that the mean value from that second sample would fall within the confidence interval.

Informed Consent Document – A written document that accompanies a verbal description of the informed consent process. The document should include information necessary for a patient to make a fully informed decision about whether to proceed with a healthcare intervention. The patient (or their healthcare proxy) sign the document to indicate that they have received the information and voluntarily agree to proceed with the healthcare intervention.

Informed Consent Process – The informed consent process is a widely accepted legal, ethical, and regulatory requirement for most research and healthcare interventions. In this measure, however, we focus only on informed consent processes that are associated with healthcare interventions and specifically only interventions that are elective. Information about the healthcare intervention (elective procedure) and its inherent risks, benefits, and alternatives is shared with the patient so that they may make an informed decision about whether to proceed. Ultimately, the informed consent process is intended to support patient autonomy – or the patients' right to self-determination.

Informed Consent Document Quality Measure Working Group – A diverse and independent group of patients and patient advocates who worked closely with CORE during all phases of measure development. The Working Group co-developed the taxonomy of informed consent document quality elements, as described in Appendix D.

Inter-Quartile Range – A measure of statistical dispersion around the median. The 25th percentile (quartile 1) is mid-way between the lowest value and the median value. The 75th percentile (quartile 3) is mid-way between the median value and the highest value. The range is calculated by subtracting quartile 1 from quartile 3.

Inter-rater Reliability (Cohen's kappa statistic) – A statistical value that calculates the degree of agreement between the two abstractors. This value indicates the rate of inter-rater agreement.

Intra-Class Correlation (ICC) – A statistical value that demonstrates agreement in overall document scores. An ICC describes how well values from the same group tend to be similar.

Material risks - Risks with either a high degree of likelihood but a low degree of severity or a very low degree of likelihood but high degree of severity (CMS Regulations and Interpretive Guidelines).[30]

Mean – A statistical value that represents an average. It is calculated by summing the values of the total parts and dividing by the number of parts of the total.

Measure Cohort – Patients included in the measure. For this measure, the cohort includes patients who have undergone an elective, hospital-based inpatient procedure for which informed consent is considered standard practice. Patients included in the measure development cohort will be Medicare FFS beneficiaries aged 18 years and over.

Measure Specifications – The specific criteria used to define the measure, such as the measure cohort and outcome.

Median – A statistical value determined by ordering a set of data from lowest to highest and selecting the middle score. The median is considered the 50th percentile, meaning that half of the values are below the median and half of the values are above the median.

Medicare fee-for-service (FFS) – Original Medicare plan in which providers receive a fee or payment for each individual service provided directly from Medicare. Only beneficiaries in Medicare FFS, not in managed care (Medicare Advantage) will be included in the measure.

Patient Autonomy – The right of patients to make decisions about their medical care without their healthcare provider trying to influence the decision. Patient autonomy allows for healthcare providers to educate the patient but does not allow the healthcare provider to make the decision for the patient.[87]

Percent Agreement – A numeric value calculated by summing the total number of times the two abstractors scored an item with the same score, divided by the total number of items.

Planned Readmissions Algorithm – An algorithm developed for CMS's hospital readmission measures (CMS's Planned Readmission Algorithm Version 3.0). In brief, the algorithm is a set of criteria for classifying admissions as planned or unplanned using Medicare claims.

Reliability – When the instrument (or measure) produces similar results under the same conditions.

Sampling – The set of data or values in a study of which the results are determined.

Spearman Correlation – A statistical value that measures the relationship between two variables. A correlation value of 1 demonstrates a perfect relationship between the two variables.

Standard Deviation – A statistical test measuring the amount of variation around the mean. Large standard deviations indicate that there is a large spread of variation around the mean. Small standard deviations indicate that there is a small amount of variation around the mean, or that most data in the set are close to the mean.

Technical Expert Panel (TEP) – This panel is composed of clinicians, patient advocates, hospital administrators, attorneys, and experts in bioethics. Collectively, the TEP members bring expertise and perspectives in informed consent and ethical decision making; patient care, engagement, and communication; hospital administration and risk management; psychometric tool development; and performance measurement and quality improvement.

Taxonomy – The hierarchical identification or classification structure of key aspects of informed consent document quality. We refer to the following specific components of the taxonomy: domains, dimensions, and elements. Elements are nested within dimensions and dimensions are nested within domains. Taxonomy development is outlined in Appendix D and the full taxonomy of informed consent document quality can be found in Appendix E.

- **Domains** – The first tier of the taxonomy. The domains in the taxonomy include: content, presentation and timing. These three domains capture all key themes and concepts of informed consent document quality identified during the development of the informed consent document quality measure conceptual framework.
- **Dimensions** – The second tier of the taxonomy. Dimensions describe one or more key aspects of a domain. For example, the content domain includes several dimensions such as “Description of Procedure” and “Rationale for Procedure.”
- **Elements** – The third tier of the taxonomy. Elements describe one or more key aspects of a dimension. Elements represent specific quality standards that will be considered for inclusion in the Abstraction Tool.

Appendix C. Guidelines and Standards for Informed Consent

Table C. 1. Source Documents for Guidelines and Standards of Informed Consent

Organization	Title of Source Document
Centers for Medicare & Medicaid Services	Regulations and Interpretive Guidelines for Hospitals [30]
The Joint Commission	The Joint Commission 2009 Requirements Related to the Provision of Culturally Competent Patient-Centered Care Hospital Accreditation Program (HAP) [2]
National Quality Forum	Improving Patient Safety Through Informed Consent for Patients with Limited Health Literacy [21]
American Medical Association	AMA Opinion 2.1.1 – Opinions on Consent, Communication, and Decision Making [88]
American College of Surgeons	Statements on Principles: Relation of the Surgeon to the Patient- Informed Consent [48]
American Academy of Orthopedic Surgeons	Orthopedic Surgical Consent: The First Step in Safety [16]
American Association of Neurological Surgeons	AANS Guide to Informed Consent [43]
American College of Obstetricians and Gynecologists	ACOG Committee Opinion No. 439: Informed Consent [44]
American Society of Anesthesiologists	Manual For Anesthesia Department Organization and Management [46]
American Association of Neurological Surgeons	AANS Clinical Ethics in Neurosurgery: Module 1 [89]
American Association of Nurse Anesthetists	AANA Standards for Nurse Anesthesia Practice [52]
State of Florida Legislature	The 2015 Florida Statutes: Title XLV TORTS [51]
State of New York Department of Health	New York State Surgical and Invasive Procedure Protocol [90]
Minnesota Alliance for Patient Safety	Minnesota Alliance for Patient Safety (MAPS) Informed Consent: A Model Facility Policy [91]

Appendix D. Taxonomy Development

The measure outcome is based on the quality of the informed consent documents. A first step in developing the measure was creating an expansive, comprehensive list of components of high-quality informed consent documents. Working closely with the patient and patient advocate Working Group, we created a taxonomy of consent document components that reflect the decisional needs of patients. Following completion of the taxonomy, individual elements of the taxonomy were selected for inclusion in the Abstraction Tool, as described in Appendix F.

This section describes our approach to development of the taxonomy of informed consent document quality.

Taxonomy Development

The taxonomy was developed based on the findings of the literature review and environmental scan, informed consent standards, and the exploratory study of medical records along with significant input from the Working Group. First, we identified three "domains" of quality which formed the basis for a taxonomy, or classification system for characterizing aspects of informed consent document quality.

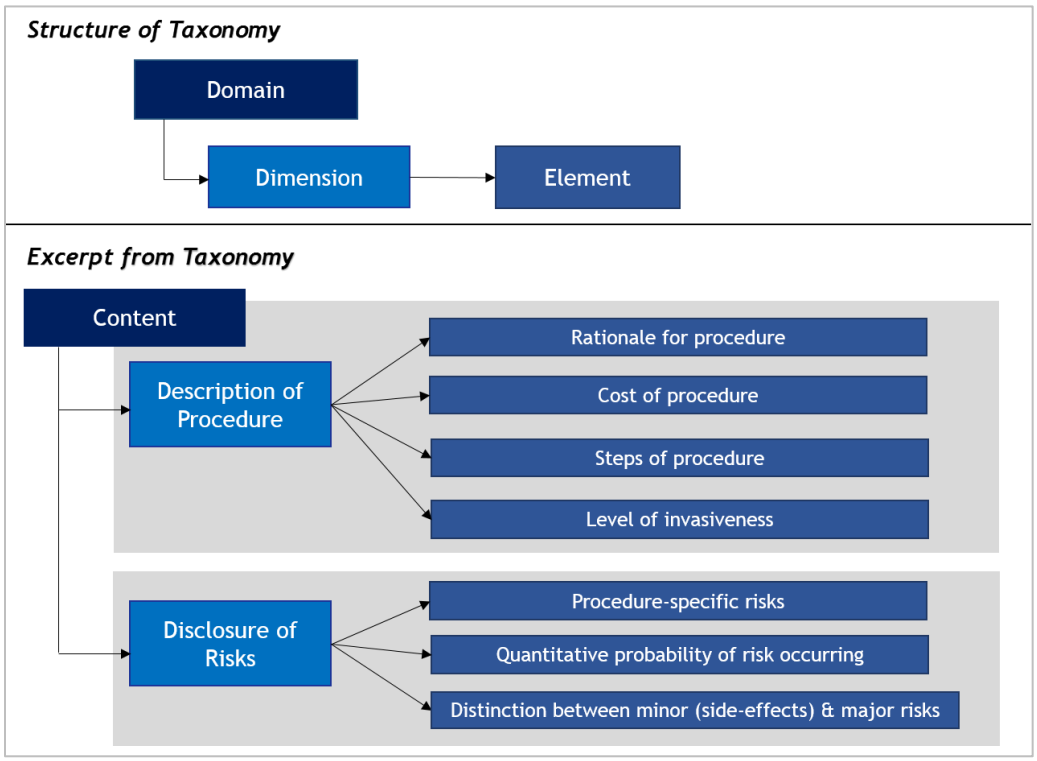
These three domains were content, presentation, and timing.

- **Content**: what information is provided to the patient, including explanations of the procedure and the risks, benefits, alternative treatment options, and expected results.
- **Presentation**: how the document displays the information, including legibility, readability, use of lay language, and non-text information such as figures.
- **Timing**: when the informed consent document is presented and discussed with the patient.

These domains were then subdivided into "dimensions." These dimensions were then expanded into "elements" through close collaboration with our Working Group. Figure D.1 depicts the structure of the taxonomy as well as provides an excerpt as an example of the level of detail reflected by each element.

With the Working Group's input, we sought to make the taxonomy as expansive as possible in order to comprehensively reflect the decisional needs of patients. The final taxonomy (Appendix E) included three domains, 20 dimensions, and 53 elements.

Figure D. 1. Overview of Taxonomy for Elements of High-Quality Informed Consent Documents



Input from Working Group

We conducted a series of seven 90-minute meetings with the Working Group, the first five of which were focused on developing the taxonomy.

In the first meeting, we introduced the measure concept and rationale and encouraged Working Group members to share their backgrounds, experiences, and perspectives relevant to informed consent. Over the course of the following three meetings, we presented each domain (Meeting 2: Content; Meeting 3: Presentation; Meeting 4: Timing). For each domain, we presented the associated quality dimensions and elements. We invited discussion around each dimension and element.

Based on these discussions, we refined the taxonomy by further specifying the dimensions and elements and adding new dimensions and/or elements when appropriate. We surveyed the Working Group members between meetings to obtain additional insight and feedback. We summarized this expanded taxonomy and presented it for feedback to the Working Group members through a final web-based survey.

From these discussions and the survey, Working Group members consistently emphasized the importance of dimensions and elements that:

- Facilitate patient understanding (for example, receiving the document with sufficient time for review; plain language descriptions of procedures)
- Promote transparency about the frequency and magnitude of benefits/risks
- Communicate what the patient can expect following the procedure (for example, need for follow-up visits, recovery time, post-operative need for a family caregiver)
- Ensure patient safety (for example, patient-specific risk information; knowledge of anticipated mode of anesthesia)

During the fifth meeting, we presented the revised taxonomy, which incorporated their prior input, and solicited the Working Group's final approval. We also asked them to complete a survey selecting dimensions that were of highest priority.

We re-engaged with the Working Group for meetings six and seven after developing the Abstraction Tool to ensure that we captured these priority elements (or if the elements were not captured we explained why not they were not feasible to measure) and to ensure that the items in the Abstraction Tool accurately reflected what was important to them.

Appendix E. Taxonomy of Quality Informed Consent Elements

Table E. 1. Taxonomy of Quality Informed Consent Elements

Domain (N=3)	Dimension (N=20)	Element (N=53)
CONTENT	Description of Procedure	1. Rationale for the procedure
		2. Level of invasiveness
		3. Steps of the procedure
	Post-operative Expectations for Procedure	4. Estimated recovery time
		5. Estimated time before the patient can return to work or normal activity
		6. Whether there is need for a family caregiver following the procedure
		7. Description of how the procedure will influence future care (for example, follow-up visits)
	Goals (Benefits) of Procedure	8. What the patient hopes to get out of the procedure, tied to patient's care plan
		9. What the procedure will *not* achieve
		10. Procedure-specific benefits
		11. General quantitative probabilities of benefits occurring
	Disclosure of Risks/ Side-effects	12. Procedure-specific risks
		13. General quantitative probabilities of risks occurring
		14. Distinction between minor risks (side-effects) and major risks
	Alternatives to Procedure	15. Potential alternative treatment options (for example, medication/physical therapy, alternative procedure, watch and wait, no treatment)
		16. Anticipated outcomes associated with potential alternative treatment options
	Hospital-specific and/or Physician-specific Performance	17. Procedure volume (that is, the number of procedures performed) by physician/at hospital
		18. Procedure success rate of physician/hospital
		19. Procedure complication rate of physician/hospital, including post-operative complications (for example, infection)
		20. Cost of the procedure (for example, may refer to hospital's base cost, noting that this is not the cost to the patient)
	Patient Safety Check	21. Review of medications taken by patient, including over-the-counter medications
		22. List of allergies
		23. Note of prior reactions to anesthesia (yes/no)

Domain (N=3)	Dimension (N=20)	Element (N=53)
		24. Agreement between operative report and consent document, with caveat for unexpected findings/complications during procedure
CONTENT	Additional Resources	25. Invitation for others, such as family caregivers, spouse, child, to be included in informed consent discussion
		26. Invitation for additional medical consultation (for example, discussion with primary care provider or a second opinion)
		27. Reference to decision aids, patient education brochures, videos, or links to relevant webpages
		28. Phone numbers for support (for example, hospital's Patient Relations, nurse/physician hotline, or Department of Public Health)
		29. Referral to patient peer groups
	Opt-out or Strikeout Instructions	30. Presence and role of students and trainees
		31. Permission to take pictures or video for educational, advertising, and/or other public purposes
		32. For-profit use of tissue/specimen
		33. Blood transfusion with description of risks if patient opts out
	Type of Anesthesia	34. Description of anticipated type of anesthesia: a. Conscious sedation* b. Local anesthesia* c. Regional anesthesia (for example, spinal, epidural)* d. General anesthesia* e. Local nerve block*
	Description of Risks of Anesthesia	35. General risks of anticipated type of sedation/pain control
		36. Patient-specific risks of anticipated type of sedation/pain control
	Post-operative Expectations	37. Recovery time from anesthesia (for example, duration of unconsciousness, somnolence, and cognitive effects)

* We acknowledge that the use of plain language is critical for all elements of informed consent document quality.

Domain (N=3)	Dimension (N=20)	Element (N=53)
	for Anesthesia	38. Disclaimer that recovery time may vary by patient 39. Instructions on immediate follow-up (for example, driving; operating machinery)
	Format	40. Identification of the method of distribution: patient portal, website link, electronic copy received via email, paper copy distributed at office, paper copy mailed to patient
		41. Alignment with the patient's preferred method for reviewing the document (may be more than one format)
CONTENT	Accessibility	42. Notation that the patient was offered: a. Braille or audio version of the document b. Large-font document c. Document in patient's preferred language d. Language interpretation/translation services
PRESENTATION	Legibility	43. All information is typed
		44. Minimum font size
		45. Minimum resolution (that is, visual clarity of language, avoiding blurred or overexposed printed/written language)
	Readability	46. Plain language and medical terms provided for the name of the procedure
		47. Written at or below a 6-8th grade reading level 48. Written at a reading level that is compliant with the state's recommended reading level for Medicaid patients
	Organization	49. Use of: a. Subheadings b. Checkboxes c. Bullet points
		50. Diagrams, figures, graphs, or pictures
	Length	51. Limit on the number of pages
		52. Limit on the average time required for a patient to read/review the document
TIMING	Time to Review	53. Time stamp that indicates document received at least 72 hours (business days) prior to the procedure date, unless patient opts out of review time in order to have the procedure sooner
	Consistency over Time	54. Checkbox on consent document indicates consistency between document received prior to the procedure and the document the patient signs

Appendix F. Abstraction Tool Development

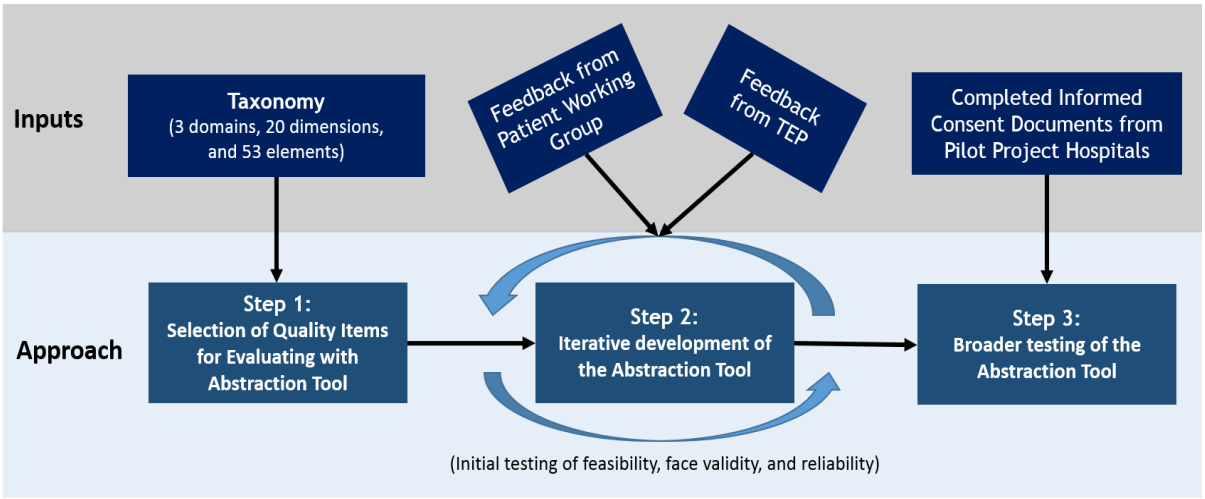
The measure outcome is based on the quality of the informed consent documents. At the outset of measure development (September 2014), no standardized tools existed to assess the quality of informed consent documents. Thus, CORE developed and validated the Abstraction Tool to assess the quality of informed consent documents for elective procedures for Medicare FFS patients. This section describes our approach to development and testing of the Abstraction Tool.

Abstraction Tool Development

As referred to above, taxonomy was used to inform the development of the Abstraction Tool to rate the quality of informed consent documents received from hospitals. Hospital performance on the informed consent document quality measure is based on the quality of the informed consent documents of patients in the cohort. These details are further described in the measure specification section below.

- **Step 1:** Selection of "elements" from the taxonomy, to be operationalized into items for evaluating with the Abstraction Tool;
- **Step 2:** Iterative development of the Abstraction Tool, testing the reliability and face validity of the items of the Tool; and
- **Step 3:** Broader testing of the Abstraction Tool items using a larger sample of completed informed consent documents received from hospitals participating in the development sample (Section 6).

Figure F. 1. Approach to Abstraction Tool Development and Testing



Step 1: Selection of "Elements" from the Taxonomy for Evaluating with the Abstraction Tool

To select elements from the taxonomy for possible inclusion in the Abstraction Tool, we first identified five principles important for defining the measure outcome (Table F.1). Thirteen

clinician and non-clinician researchers at CORE reviewed each element, evaluating its alignment with these principles. The 16 elements selected using this approach were then operationalized into items for inclusion in the first draft of the Tool. Excluded elements will be re-evaluated for inclusion in a future (Version 2.0) Abstraction Tool if there is reason to believe that an element's ability to meet the element selection principles (Table F.1) has improved.

Table F. 1. Principles to Select Taxonomy Elements for Abstraction Tool

Principle	Definition
Importance to patients	• Element should be important to patients, patients' family, friends, and/or caregivers. • Element should collectively represent a meaningful construct of informed consent document quality.
Evidence in support of the item (based on literature/ published standards)	• Element should be supported by consensus-based guidelines, documented best practices, or standards/benchmarks. In other words, published evidence and/or recommendations put forth by regulatory body, professional societies, or national institute should establish the element as a signal of quality.
Applicability to cohort	• Element should be relevant to informed consent documents for all elective procedures, irrespective of level of invasiveness or surgical specialty. • Element should be applicable to a broad range of patients with different characteristics.
Ease of collection	• Element should not place undue burden on patients and hospitals in regard to data collection. • Medical chart abstraction and data transfer require hospital resources.
Feasibility of reliable measurement	• Element can be defined and applied in a consistent way.

Step 2: Iterative Development of the Abstraction Tool

We constructed items for the Abstraction Tool based on the selected elements from the taxonomy in consultation with informed consent and measurement experts. For each Abstraction Tool item, we developed a set of instructions to explain what specifically would need to be present on the informed consent document to "qualify" as meeting the item criteria. These instructions also included a brief background on the intent of the item, as well as examples from actual informed consent documents of what would qualify for meeting the item and what would not. The Abstraction Tool was used to rate the quality of informed consent documents in cycles.

Following each cycle, the instructions were updated, clarifying what would and would not qualify and adding examples to facilitate operationalization.

The Abstraction Tool was implemented in Microsoft Access to enhance data quality and reliability. In the first cycles, abstractors (5 to 12 CORE team members per cycle; 17 total members participating across all cycles) used the Abstraction Tool to evaluate the quality of a sample of 10 informed consent documents from the development sample, selected for representativeness and variety of procedure type. After each cycle, we evaluated discrepancies between abstractors and revised the Tool and the accompanying instructions to achieve agreement among abstractors.

Before finalizing the Tool, we added an additional cycle of review in which three abstractors (including two prior abstractors and one new abstractor) re-rated the full development sample of 50 consent documents (with the first 10 documents used to train the abstractors on how to use the Tool using the most updated instructions). We utilized this last cycle to finalize the language of each item, refine our training approach, and clarify our abstraction instructions, ensuring the standardized application of the Abstraction Tool across the different abstractors. The abstraction training approach is described in detail in Section 6.1.1. Appendix G presents the Abstraction Tool and the instructions for evaluating each item. We also used this final cycle to perform preliminary reliability and validity testing of the Abstraction Tool (described below).

Preliminary Reliability (Agreement) Testing of Abstraction Tool Items

In the final cycle, we assessed item reliability by calculating agreement among the three abstractors. We defined agreement as the percentage of documents for which abstractor responses were the same. For example, if the abstractors agreed across half the documents in their responses to a given item, the agreement for that item would be 50%.

All items except for one, addressing the "purpose of the procedure" (agreement = 70%), met the agreement threshold of ≥80%. After discussion among abstractors and the CORE team, we revised the response choices of this item ("purpose of the procedure") to accommodate the uncertainty of whether a document met the criteria established for this item. We did not omit this item from the Tool because it is important to patients (and when well-described, meaningfully improves informed consent document quality) and because omission of this item might impact responses to other items.

The results of our preliminary reliability (agreement) testing of the Abstraction Tool items in the Development Sample are shown in Table F.2.

Table F. 2. Results of Preliminary Reliability (Agreement) of Abstraction Tool Items

Item on Abstraction Tool	Agreement (N=40)
1) Is language describing "*what* is the procedure" (beyond the medical name) provided for the patient?	80%
1t) If provided, is it typed?	90%
2) Is a description of *how* the procedure will be performed provided for the patient?	85%
2t) If provided, is it typed?	93%
3) Is the clinical rationale (condition-specific justification) for *why* the procedure will be performed provided?	70%
4) Is any patient-oriented benefit provided (intended impact on patient's health, longevity, and/or quality of life)?	100%
5) Is a *quantitative* probability provided for any procedure-specific risk?	100%
6) Is a *qualitative* probability provided for any procedure-specific risk?	100%
7) Is any *alternative* provided for the patient?	100%
8) Was the informed consent document shared with the patient at least one day before date of procedure, if the patient did not opt out of signing at least one day in advance?	98%

Preliminary Validity Testing of Abstraction Tool Items

Following the fifth cycle of our iterative Abstraction Tool development process, we sought feedback from the Working Group and TEP. We asked for feedback on the face validity of the items; that is, we asked the Working Group and TEP to examine if the items, as specified, were aligned with our element selection principles and were capturing the elements as represented in the taxonomy. Nearly all of the Working Group and TEP members affirmed that the items captured by the Abstraction Tool represented key elements of informed consent. However, some Working Group and TEP members proposed additional elements from the taxonomy that they would like to see included in the Abstraction Tool.

Step 3: Expanded and Future Testing of the Abstraction Tool

Broader testing of the Abstraction Tool using a larger sample of completed informed consent documents received from hospitals participating in the development sample is described in Section 7.

Abstraction Tool Scoring Approach

The final Abstraction Tool scores individual informed consent documents using the Abstraction Tool on a scale of 0-20 (Table F.3), with a higher score indicating better quality. In deciding how many points to assign to each item on the Abstraction Tool, we considered three principles:

1. Magnitude of evidence supporting the item
    a. The published informed consent standards and guidelines more strongly support the items related to the information (procedures description, rationale, risks, benefits, and alternative treatment options) included on the informed consent document than those related to the format (presentation) of the document or when it was given to the patient (timing).
2. Reliability of the item
    a. Partial points (or no points) could be given to items that did not achieve 80% agreement between abstractors.
3. Alignment of the item with patients' preferences
    a. Of note, the Working Group and patient representatives on the TEP emphasized the importance of all items on the Abstraction Tool.

We presented three scoring options to the Working Group and TEP: (1) assigning an equal number of points to each Abstraction Tool item (unweighted); (2) grouping items by the three domains of the taxonomy (content, presentation, and timing), and then, assigning the same number of overall points to all items within a given domain (domain-specific weighting); and (3) assigning points to each item individually (item-specific weighting). In vetting these options, we considered the challenge for hospitals to construct informed consent documents that meet the criteria established in the Abstraction Tool. While some items may be easier to achieve than others, we did not differentiate weights based on this principle, since patients supported all Abstraction Tool items as representing meaningful improvements to informed consent, and since all hospitals should be able to achieve all items.

The third option, assigning item-specific weights, best met the above document-level scoring principles. Moreover, this option was largely supported by the Working Group and TEP and was found to produce reliable individual consent document quality scores (Section 6). This final scoring of the Abstraction Tool items is given in Table F.3.

Table F. 3. Abstraction Tool Scoring Approach (Item-Specific Weighting)

	Response	Points
Description of Procedure		
1) Is language describing *what* the procedure is (beyond the medical name) provided for the patient?	"Yes"	2
	"No"	0
1t) If provided, is it typed?	"Yes"	1
	"No"	0
	"N/A"	0
2) Is a description of *how* the procedure will be performed provided for the patient?	"Yes"	2
	"No"	0
2t) If provided, is it typed?	"Yes"	1
	"No"	0
	"N/A"	0
Rational for Procedure		
3) Is the clinical rationale (condition-specific justification) for *why* the procedure will be performed provided?	"Yes, context and condition given and fully meet criteria"	2
	"Context and condition given, but do not fully meet criteria"	1
	"No, no rationale given"	0
Patient-Oriented Benefit(s)		
4) Is any patient-oriented *benefit* provided (intended impact on patient's health, longevity, and/or quality of life)?	"Yes"	2
	"No"	0
Probability of Procedure-Specific Risks		
5) Is a *quantitative probability* provided for any procedure-specific *risk*?	"Yes"	2
	"No"	0
6) Is a *qualitative probability* provided for any procedure-specific *risk*?	"Yes"	1
	"No"	0
Alternative(s) to the Procedures		
7) Is any *alternative* provided for the patient?	"Yes"	2
	"No"	0
Timing		
8a) Date consent document was shared with the patient (usually indicated by patient's/proxy's signature)	≥1 day before (8a is *at least* 1 day before 8b) **OR** 8c is checked	5
8b) Date of procedure	<1 day before (8a is not *at least* 1 day before 8b)	0
8c) Patient opted-out of receiving the consent document at least one day prior to the procedure	Missing (either 8a or 8b is missing)	0
Maximum Quality Score		20

Appendix G. Abstraction Tool and Instructions Manual

Figure G. 1. Screenshot of the Abstraction Tool

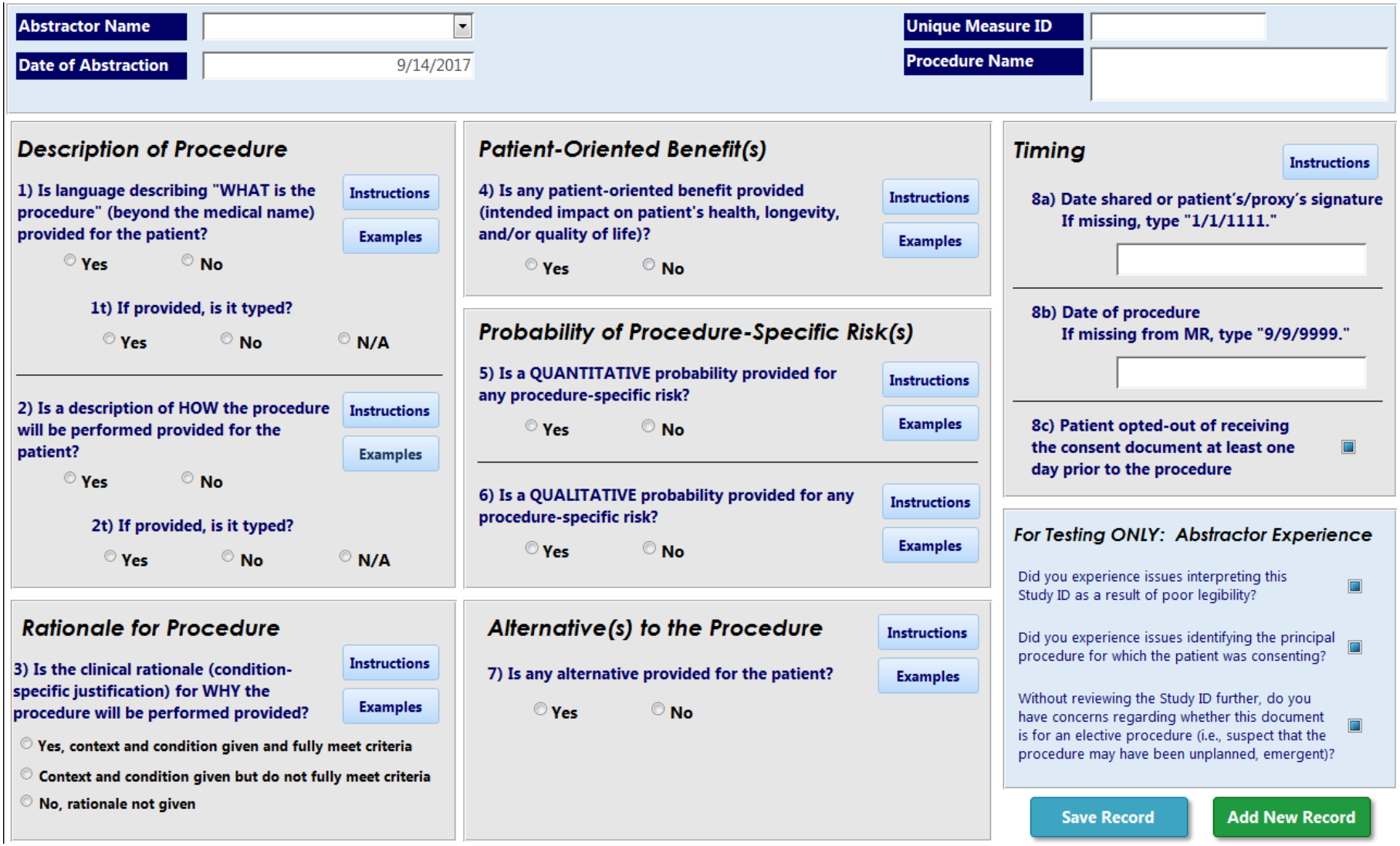


Figure G. 2. Instructions Manual – Item 1 (Part 1)

Item 1: Is language describing "WHAT is the procedure" (beyond the medical name) provided for the patient?

What qualifies?	• A description of the procedure in language a standard patient could understand (lay terms). • In the instance of multiple procedures written on a single consent form, ALL procedure names should be spelled out and described.
What does *not* qualify?	1. Name of the procedure is stated ***only*** in medical terms 2. Acronyms or abbreviations for which each letter is not defined (meaning, not spelled out **AND** not defined elsewhere on the form)

Figure G. 3. Instructions Manual – Item 1 (Part 2)

Examples	✓	✗

Cardiac (Heart) Procedures/Surgery	• Coronary Artery Bypass Surgery:
	  ○ Surgery to bypass a diseased heart artery
	  ○ Open heart surgery taking healthy arteries to bypass blocked arteries
	• Surgical or Transcatheter Aortic Valve Replacement:
	  ○ Replace a diseased valve with an artificial valve
		• Coronary artery bypass grafting
		• CABG (*not elsewhere spelled out and described*)
		• Open heart surgery (*without further description*)
		• Transcatheter aortic valve replacement (only the medical name given)

Hip Surgery	• Replace left/right hip joint • Hip Replacement • Damaged bone and cartilage from the hip are replaced with prosthetic material	• Left Total Hip Arthroplasty
Prostate Surgery	• Robotic Prostatectomy: Robot-assisted procedure to remove the prostate • Prostatectomy: This procedure involves removing portions of the prostate that block urine flow or cause other problems (*also qualifies for items 2 and 3*) • Cystoscopy: Your doctor will insert a small tube (scope) into your bladder through your urethra. • Transurethral Prostatectomy: removal of portions of the prostate through a catheter (tube) that is inserted through the urethra (*also qualifies for item 2*)	• Prostate-Prostatectomy Simple • TURP (*not elsewhere spelled out and described*) • Radical prostatectomy • Transurethral Prostatectomy
Spinal Surgery	• Procedure to relieve pressure on the nerves of the spinal cord (*also qualifies for item 3*) • Surgery to remove bone from the spine • Treatment for a herniated, bulging or degenerated disc.	• Posterior Cervical Decompression with Fusion (*not in laymen's terms*) • Laminectomy

Figure G. 4. Instructions Manual – Item 2 (Part 1)

Item 2: Is a description of "HOW the procedure will be performed" provided for the patient?

What qualifies?	• Language that explains to patients (in lay terms), "**HOW** the principal procedure will be performed?"
	  ○ In the instance of multiple procedure names, the document must describe how the "principal" procedure (often the first listed) will be performed in order to qualify as satisfying this question
	• The "**HOW**" of a procedure usually refers to a technical action/s, such as:
	  ○ Inserting a (tube into the artery)
	  ○ Connecting (an artery)
	  ○ Making an incision (in the abdomen)
	  ○ Bypassing (a blocked artery)
	  ○ Taking out (a mass)
	  ○ Passing a (tube/scope/camera into the xxx)

What does *not* qualify?	1. Information about the procedure that does **not** explain **HOW** the procedure will be performed

Figure G. 5. Instructions Manual – Item 2 (Part 2)

Examples	✓	✗
Cardiac (Heart) Procedures/Surgery	• Graft a healthy artery from a different part of the body to a blocked artery near the heart	• "My physician has explained to me and I understand the course of the procedure" (*generic language that does not specify how the procedure will be done*) • Open heart surgery (*without further description as to how the procedure will be done*)
Hip Surgery	• Damaged or diseased parts of the hip joint will be removed and replaced with a mechanical part • To perform a hip replacement your surgeon will make an incision over the front or side of your hip; remove diseased and damaged bone and cartilage, while leaving healthy bone intact; implant the prosthetic socket into your pelvic bone; and then replace the round top of your femur with the prosthetic ball	• Hip Replacement (*qualifies for Item 1, but does not indicate how the procedure will be done)* • Right Total Hip Replacement **with table anterior approach** (*this is not an adequate description since the 'how' is not described in lay terms, though it would still qualify for Item 1*)
Prostate Surgery	• Robotic-assisted instruments are inserted through several small abdominal incisions. The instruments are controlled by a surgeon who cuts out portions of or the entire prostate. • A single large incision (cut) is made in the lower abdomen to reach and remove the prostate gland. • A catheter (tube) is inserted into the bladder through the urethra (the small duct through which urine passes out of the body). An instrument is passed through the tube to cut out the portion of the prostate that is blocking the urethra and the passage of urine. These portions of the prostate are then removed through the tube	• Removal of prostate • Open prostatectomy • Robot-assisted prostatectomy • Nerve-sparing prostatectomy • Minimally invasive prostatectomy • Catheter-based prostatectomy • To resect prostate
Spinal Surgery	• Your surgeon will make an incision on the back of your neck, your muscles and blood vessels will be moved aside to expose your vertebrae, and a portion of the bone pushing on the nerves will be removed	• Removal of indwelling neuro-stimulator (*not in laymen's terms*)

Figure G. 6. Instructions Manual – Item 3 (Part 1)

Item 3: Is the clinical rationale (purpose) for "WHY the procedure will be performed" provided?

What qualifies and fully meets criteria?	• Language that explains "**WHY** the principal procedure will be performed? **WHY** is it necessary?" This refers to the medical purpose (intent) of the procedure as it relates to the patient's condition (disease or symptoms) • Look for both a "medical rationale" and a "condition" • The medical rationale usually refers to **one** of the following (or equivalent language): o to diagnose/rule out o to inform prognosis o to treat o to fix/replace/repair o to prevent o to improve a patient's clinical state or condition o to execute the patient's request • Medical terms are acceptable for this question since this refers to the medical rationale for the procedure.
What qualifies, but does not fully meet criteria?	• **Use this response choice if you are uncertain if the language fully meets the above criteria. In this case, the patient may still be unsure why the procedure is being performed.**
What does *not* qualify?	1. Rationale not specified 2. Condition (disease, symptoms) not specified 3. Generic language that states a range of intents, but does not specify which one applies to the patient

Figure G. 7. Instructions Manual – Item 3 (Part 2)

Examples	✓	✗
Cardiac (Heart) Procedures/Surgery	• To treat (***medical rationale***) a blockage or coronary artery disease (***condition***) • To improve (***medical rationale***) blood flow where there is a blockage (***condition***) • To bypass (***medical rationale***) the blocked vessel (***condition***) (*also qualifies for item 2*)	• To treat CAD (*acronym not known to patients*) • Coronary artery disease or myocardial infarction/heart attack (*these are conditions, but there is no information about the intent*)
Hip Surgery	• To treat or replace (***medical rationale***) a worn out joint/arthritic joint (***condition***) • Arthroplasty is being performed to replace worn out tissue, alleviate pain, and improve function (*also qualifies for item 4*)	• Arthritis • To replace the joint (*there is no condition; why the joint needs to be replaced is not explained*)
Prostate Surgery	• To remove/treat (***medical rationale***) cancer (***condition***) • To treat (***medical rationale***) an enlarged prostate (***condition***) • To treat/reduce (***medical rationale***) the blockage of urine (***condition, symptom***) • To reduce the size (***medical rationale***) of the prostate in order to relieve the blockage of urine (***condition, symptoms***)	• Prostate Cancer (this is the condition, but the medical rationale for the procedure is not clear) • Benign Prostatic Hypertrophy (this is the condition, but the medical rationale for the procedure is not clear) • To either treat prostate cancer or benign prostate hypertrophy (*this is generic and not specific to the patient*)
Spinal Surgery	• To prevent (***medical rationale***) paralysis (***condition***) • To remove (***medical rationale***) bone spurs in spine (***condition***) • To reduce (***medical rationale***) back pain (***condition, symptom***)	• Herniated disc • To remove the disc (*there is no condition; why the disc needs to be removed is not explained*)

Figure G. 8. Instructions Manual – Item 4 (Part 1)

Item 4: Is any patient-oriented benefit (intended impact on patient's health, longevity, and/or quality of life) provided for the patient?

What qualifies?	• Language that explains how the principal procedure will benefit the individual patient. The benefit is something that the patient will experience. For example,
	  ○ Reduced symptoms (e.g., pain, shortness of breath)
	  ○ Improved function (e.g., mobility, urination)
	  ○ Less chance of future problems (e.g., reduced risk of heart attack; prevent bone fracture)
	  ○ Improved chance of survival
	• The benefit to the patient may not be known. In these cases, it must be stated that the benefit is uncertain.

What does *not* qualify?	1. Language that refers only to the medical rationale (Q3), without referring to a positive effect of the procedure on the patient 2. Generic statement that the benefits were discussed with the patient 3. Language that states possible benefits, not defining the primary (intended) benefit(s)

Figure G. 9. Instructions Manual – Item 4 (Part 2)

Examples	✓	✗
Cardiac (Heart) Procedures/Surgery	• To alleviate chest pain • To alleviate chest pain and potentially reduce the risk of future heart attack • There may be no benefit to you • To reduce risk of heart failure • To improve longevity	• To improve blood flow to the heart (*qualifies for item 3 but does not explain how improving blood flow will help the patient*) • Benefits of the procedure were discussed with the patient
Hip Surgery	• Repair the torn ligament in order to improve exercise tolerance, mobility, flexibility, strength (*meets criteria for Q2, 3, and 4*) • To improve mobility • To reduce pain	• To treat diseased joint (*qualifies for item 3 but does not explain how improving blood flow will help the patient*)
Prostate Surgery	• This procedure may make it easier to urinate (*includes improvement of a specific symptom*) • This procedure may slow the growth of cancer • This procedure may prevent the recurrence of cancer • You may not feel any better but it may improve your chances of survival.	• To minimize the size of the prostate (*qualifies for item 3 but does not explain how improving blood flow will help the patient*) • To either improve urination or to prevent recurrent infection or to prevent the spread of cancer (*generic*)
Spinal Surgery	• To relieve back pain • To reduce risk of paralysis	• To remove a diseased disc (*benefit to the patient not explained*)

Figure G. 10. Instructions Manual – Item 5 (Part 1)

Item 5: Is a QUANTITATIVE probability provided for any procedure-specific risk?

What qualifies?	• A specific number or estimated range describing the likelihood of *any* **procedure-specific** risk occurring with the principal procedure
	  ○ Can be expressed as percentage or odds
	  ○ May be stated in words
	  ○ May be displayed graphically

What does *not* qualify?	1. Numeric prediction that states the risk is possible but provides no basis for comparison 2. Generic statement that the clinician discussed the risks with the patient

Figure G. 11. Instructions Manual – Item 5 (Part 2)

Examples	✓	✗

	• 1% (or less than 1% of patients)
	• 5 out of 10 patients
	• One in five patients
	• 1 in 10,000 patients
	• Or a graphic or other figure that illustrates the risk; e.g., 14 out of 100 people
	 
	• Common risks and complications (in approximately 5% of patients) include:
	  ○ Bleeding from the wound that may require blood transfusion.
	  ○ Heart rhythm changes, which are usually temporary.
	• Rare risks and complications (that can occur in less than 1% of patients undergoing the procedure) include:
	  ○ Heart attack
	  ○ Stroke
	  ○ Death
		• A greater than 0% chance of complication
		• < 5% - since the less than sign, "<," may not be understood
		• My physician has discussed the risks of the procedure with me
		• I understand that every procedure has risks

Figure G. 12. Instructions Manual – Item 6 (Part 1)

Item 6: Is a QUALITATIVE probability provided for any procedure-specific risk?

What qualifies?	• **QUALITATIVE** (non-numeric; non-graphical) **procedure-specific** descriptor of likelihood
What does *not* qualify?	1. Generic terms that lack relativity/comparability 2. Qualitative terms related to severity of risks (which do not indicate the likelihood of the risk occurring) 3. Generic statement that the clinician discussed the risks with the patient 4. **Procedure-Specific** risks that do not include likelihood

Figure G. 13. Instructions Manual – Item 6 (Part 2)

Examples	✓	✗
	• Common/rare • More frequent/less frequent • Likely/unlikely • On occasion • Major chance/minor chance of occurring • Minimal	• Uncertain, possible, or potential • Material risks include: • Serious or major/minor, not followed by term that indicates frequency • My physician has discussed the risks of the procedure with me • All procedures have risks, including: • Some risks associated with this procedure include: (*when no likelihood is attached, this does not qualify*)

Figure G. 14. Screenshot of the Instructions Manual – Item 7 (Part 1)

Item 7: Is any alternative provided for the patient?

What qualifies?	• Any alternative to the surgical procedure for which the patient is consenting
What does *not* qualify?	1. Generic statements about potential alternatives that are applicable across a range of surgical procedures 2. Generic statement that the clinician discussed the alternatives with the patient

Figure G. 15. Screenshot of the Instructions Manual – Item 7 (Part 2)

Examples	✓	✗
	• Medication for condition management • Watch-and-wait or observation • Alternatives include physical therapy and/or observation	• My provider and health care team have discussed possible alternative treatments, including no treatment • After discussing other options, including no treatment, with my doctor, I give permission…. • You have been told about reasonable therapeutic alternatives and material risks associated with such alternatives

Figure G. 16. Screenshot of the Instructions Manual – Items 8a, 8b, 8c

Item 8a: Timing – Date of patient/proxy's signature

What qualifies?	• MM/DD/YYYY that the patient or proxy **<u>received</u>** the document
	• If date received is not noted, then the MM/DD/YYYY that the patient or proxy signed the document
	  ○ Signature date *must* be labeled as the signature of the patient/proxy, unless one date is assigned to all signatures on the document, in which case, this signature date would be acceptable
	  ○ If missing, "01/01/1111"
	
	If the **patient** has signed the document at two different times and both are noted on the document, abstract the *earlier* of the two dates as this date reflects when the patient first "received" the document

What does *<u>not</u>* qualify?	1. Physician's signature 2. Witness's signature

Item 8b: Timing – Date of procedure

What qualifies?	• The date associated with when the procedures was performed, as noted in the Operative Report (OP)
	  ○ May be referred to as "Date of service" or "Date of operation," but does not necessarily have to be labeled as such
	  ○ May appear in the header of the operative report or in the body of the report
	  ○ If no date is available, "09/09/9999"
	• If a date is present but not labeled as the procedure date, use your best judgment. It is acceptable if the date for this question is not as explicitly labeled as the patient/proxy's signature date.

What does *<u>not</u>* qualify?	1. Date of dictation 2. Date of OP note 3. Date of Admission

Item 8c: Timing – Opt-out notation

What qualifies?	• Notation of patient's/proxy's decision to opt-out of receiving the document at least one day (24 hours) before the procedure ○ May include: signature, initials, or checkbox • Phone consent (presuming that the patient/proxy has opted out of receiving or signing the consent document in person)
What does *<u>not</u>* qualify?	1. Notation that indicates "rush for next day surgery," which would still satisfy the minimum standard to have the patient receive/sign the document at least one day before the procedure

Appendix H. Planned Readmission Algorithm

The CMS Planned Readmission Algorithm identifies a list of potentially planned procedures and a list of acute discharge diagnosis codes. Admissions that have a potentially planned procedure without an acute discharge diagnosis code are considered planned according to the CMS Planned Readmission Algorithm. The Quality of Informed Consent Documents measure does not use the Planned Readmission Algorithm to identify planned versus unplanned readmissions. The measure builds upon the vetted approach of the Planned Readmission Algorithm to identify only electively-performed procedures because planned procedures are also commonly electively-performed. We used clinical expert review to further narrow the list of potentially planned procedures from the Planned Readmission Algorithm to those which are consistently elective-performed and likely to have informed consent obtained prior to every procedure. We provide the details of the Planned Readmission Algorithm here for convenience.

The Planned Readmission Algorithm is a set of criteria for classifying readmissions as planned among the general Medicare population using Medicare administrative claims data. For this measure, the Planned Readmission Algorithm is used to identify admissions for procedures as planned or unplanned. It was also used in specifying procedures that are typically considered planned, by AHRQ CCS category code [92], for the measure cohort inclusions criteria.

For more details on the Planned Readmission Algorithm Version 3.0, please see the report titled "2014 Measure Updates and Specifications Report Hospital-Wide All-Cause Unplanned Readmission" on the Readmission Measures Archived Resources page of QualityNet. [93] The Planned Readmission Algorithm Version 3.0 flowchart (Figure H.1) and associated code tables taken from this report are included below.

Planned Readmission Algorithm Version 3.0 – General Population

The Planned Readmission Algorithm uses a flow chart and four tables of specific procedure categories and discharge diagnosis categories to classify readmissions as planned. Readmissions that include certain procedures (Table H.1) or are for certain diagnoses (Table H.2) are always considered planned.

If the readmission does not include a procedure or diagnosis in Table H.1 or Table H.2 that is always considered planned, the algorithm checks if the readmission has at least one procedure that is considered potentially planned (Table H.3). If the readmission has no procedures from Table H.3, the readmission is considered unplanned. Table H.3 includes 55 AHRQ procedure CCS categories from among 231 AHRQ procedure CCS categories, plus 11 individual ICD-9-CM procedure codes. Two examples of potentially planned procedures are total hip replacement (Procedure CCS 153) and hernia repair (Procedure CCS 85).

If the readmission *does* have at least one potentially planned procedure from Table H.3, the algorithm checks for a primary discharge diagnosis that is considered acute (Table H.4). If the readmission has an acute primary discharge diagnosis from Table H.4, the readmission is considered unplanned. Otherwise, it is considered planned. The list of acute primary discharge diagnoses includes 101 diagnosis groups from among 285 AHRQ condition categories, plus six groupings of individual ICD-9-CM diagnosis codes that represent cardiac diagnoses that would not be associated with a planned readmission. Two examples of acute primary discharge diagnoses that identify readmissions with potentially planned procedures as unplanned are pneumonia (Diagnosis CCS 122) and cardiac arrest (Diagnosis CCS 107).

The informed consent document quality measure applied the Planned Readmission Algorithm to identify planned *admissions*, using the same steps and procedure and diagnosis codes as the Planned Readmission Algorithm Version 3.0 (Figure H.1).

Figure H. 1. Planned Readmission Algorithm Flowchart

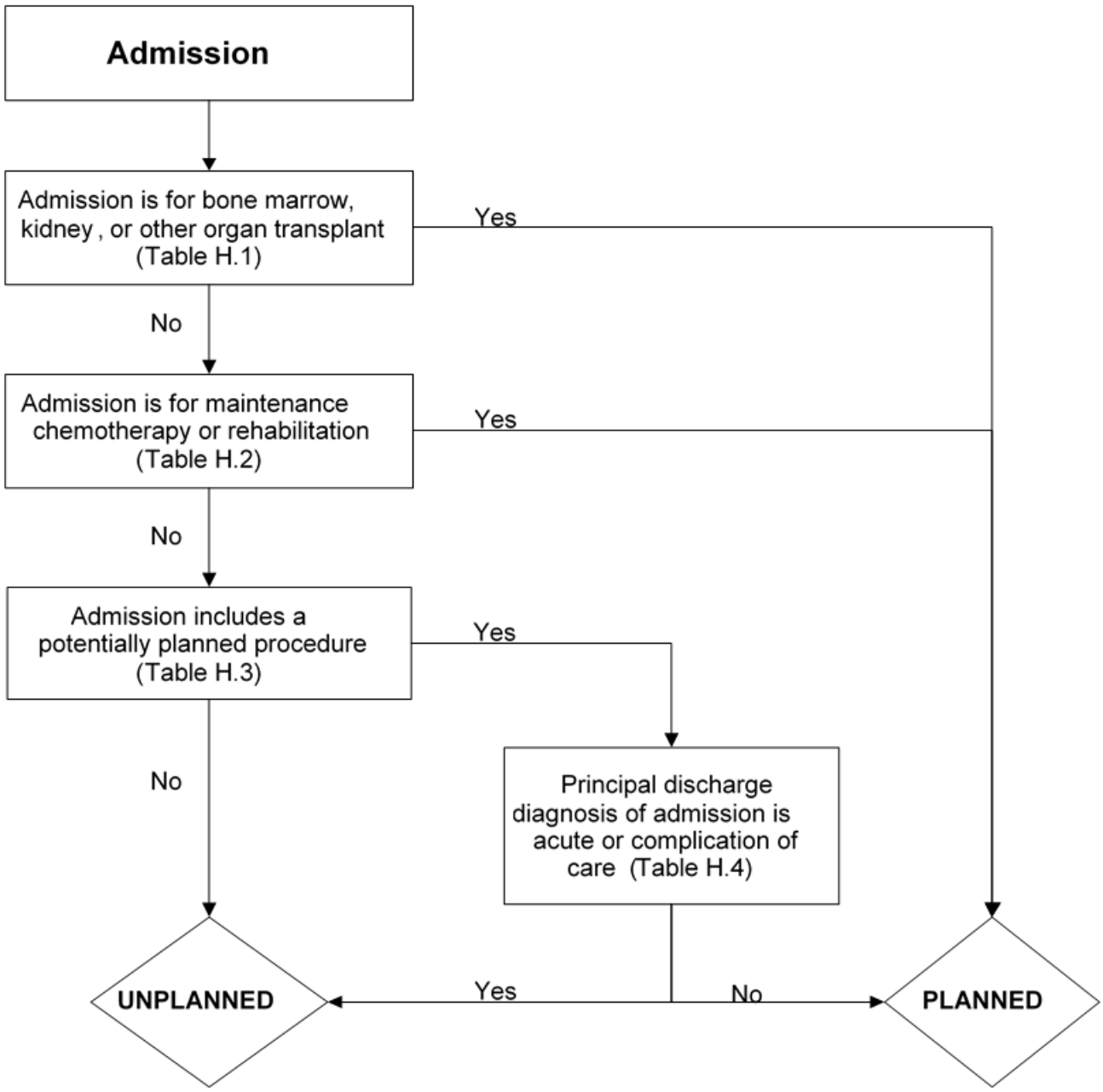


Table H. 1. Procedure Categories that are Always Planned (Version 3.0 - General Population)

Procedure CCS	Description
64	Bone marrow transplant
105	Kidney transplant
134	Cesarean section*
135	Forceps; vacuum; and breech delivery*
176	Other organ transplantation

Table H. 2. Diagnosis Categories that are Always Planned (Version 3.0 - General Population)

Diagnosis CCS	Description
45	Maintenance chemotherapy
194	Forceps delivery*
196	Normal pregnancy and/or delivery*
254	Rehabilitation

Table H. 3. Potentially Planned Procedure Categories (Version 3.0 - General Population)

Procedure CCS	Description
3	Laminectomy; excision intervertebral disc
5	Insertion of catheter or spinal stimulator and injection into spine
9	Other OR therapeutic nervous system procedures
10	Thyroidectomy; partial or complete
12	Other therapeutic endocrine procedures
33	Other OR therapeutic procedures on nose; mouth and pharynx
36	Lobectomy or pneumonectomy
38	Other diagnostic procedures on lung and bronchus
40	Other diagnostic procedures of respiratory tract and mediastinum
43	Heart valve procedures
44	Coronary artery bypass graft (CABG)
45	Percutaneous transluminal coronary angioplasty (PTCA)
47	Diagnostic cardiac catheterization; coronary arteriography
48	Insertion; revision; replacement; removal of cardiac pacemaker or cardioverter/defibrillator

*CCS to be included only in all-payer settings, not intended for inclusion in CMS' claims-based readmission measures for Medicare fee-for-service beneficiaries aged 65+ years

Procedure CCS	Description
49	Other OR heart procedures
51	Endarterectomy; vessel of head and neck
52	Aortic resection; replacement or anastomosis
53	Varicose vein stripping; lower limb
55	Peripheral vascular bypass
56	Other vascular bypass and shunt; not heart
59	Other OR procedures on vessels of head and neck
62	Other diagnostic cardiovascular procedures
66	Procedures on spleen
67	Other therapeutic procedures; hemic and lymphatic system
74	Gastrectomy; partial and total
78	Colorectal resection
79	Local excision of large intestine lesion (not endoscopic)
84	Cholecystectomy and common duct exploration
85	Inguinal and femoral hernia repair
86	Other hernia repair
99	Other OR gastrointestinal therapeutic procedures
104	Nephrectomy; partial or complete
106	Genitourinary incontinence procedures
107	Extracorporeal lithotripsy; urinary
109	Procedures on the urethra
112	Other OR therapeutic procedures of urinary tract
113	Transurethral resection of prostate (TURP)
114	Open prostatectomy
119	Oophorectomy; unilateral and bilateral
120	Other operations on ovary
124	Hysterectomy; abdominal and vaginal
129	Repair of cystocele and rectocele; obliteration of vaginal vault
132	Other OR therapeutic procedures; female organs
142	Partial excision bone
152	Arthroplasty knee
153	Hip replacement; total and partial
154	Arthroplasty other than hip or knee
157	Amputation of lower extremity
158	Spinal fusion
159	Other diagnostic procedures on musculoskeletal system
166	Lumpectomy; quadrantectomy of breast
167	Mastectomy
169	Debridement of wound; infection or burn
170	Excision of skin lesion

Procedure CCS	Description
172	Skin graft

ICD-9 Codes	Description
30.1, 30.29, 30.3, 30.4, 31.74, 34.6	Laryngectomy, revision of tracheostomy, scarification of pleura (from Procedure CCS 42- Other OR Rx procedures on respiratory system and mediastinum)
38.18	Endarterectomy leg vessel (from Procedure CCS 60- Embolectomy and endarterectomy of lower limbs)
55.03, 55.04	Percutaneous nephrostomy with and without fragmentation (from Procedure CCS 103- Nephrotomy and nephrostomy)
94.26, 94.27	Electroshock therapy (from Procedure CCS 218- Psychological and psychiatric evaluation and therapy)

Table H. 4. Acute Diagnosis Categories (Version 3.0 – General Population)

Diagnosis CCS	Description
1	Tuberculosis
2	Septicemia (except in labor)
3	Bacterial infection; unspecified site
4	Mycoses
5	HIV infection
7	Viral infection
8	Other infections; including parasitic
9	Sexually transmitted infections (not HIV or hepatitis)
54	Gout and other crystal arthropathies
55	Fluid and electrolyte disorders
60	Acute post-hemorrhagic anemia
61	Sickle cell anemia
63	Diseases of white blood cells
76	Meningitis (except that caused by tuberculosis or sexually transmitted disease)
77	Encephalitis (except that caused by tuberculosis or sexually transmitted disease)
78	Other central nervous system infection and poliomyelitis
82	Paralysis
83	Epilepsy; convulsions
84	Headache; including migraine
85	Coma; stupor; and brain damage
87	Retinal detachments; defects; vascular occlusion; and retinopathy
89	Blindness and vision defects
90	Inflammation; infection of eye (except that caused by tuberculosis or sexually transmitted disease)
91	Other eye disorders

Diagnosis CCS	Description
92	Otitis media and related conditions
93	Conditions associated with dizziness or vertigo
99	Hypertension with complications
100	Acute myocardial infarction (with the exception of ICD-9 code 410.x2)
102	Nonspecific chest pain
104	Other and ill-defined heart disease
107	Cardiac arrest and ventricular fibrillation
109	Acute cerebrovascular disease
112	Transient cerebral ischemia
116	Aortic and peripheral arterial embolism or thrombosis
118	Phlebitis; thrombophlebitis and thromboembolism
120	Hemorrhoids
122	Pneumonia (except that caused by TB or sexually transmitted disease)
123	Influenza
124	Acute and chronic tonsillitis
125	Acute bronchitis
126	Other upper respiratory infections
127	Chronic obstructive pulmonary disease and bronchiectasis
128	Asthma
129	Aspiration pneumonitis; food/vomitus
130	Pleurisy; pneumothorax; pulmonary collapse
131	Respiratory failure; insufficiency; arrest (adult)
135	Intestinal infection
137	Diseases of mouth; excluding dental
139	Gastroduodenal ulcer (except hemorrhage)
140	Gastritis and duodenitis
142	Appendicitis and other appendiceal conditions
145	Intestinal obstruction without hernia
146	Diverticulosis and diverticulitis
148	Peritonitis and intestinal abscess
153	Gastrointestinal hemorrhage
154	Noninfectious gastroenteritis
157	Acute and unspecified renal failure
159	Urinary tract infections
165	Inflammatory conditions of male genital organs
168	Inflammatory diseases of female pelvic organs
172	Ovarian cyst
197	Skin and subcutaneous tissue infections
198	Other inflammatory condition of skin

Diagnosis CCS	Description
225	Joint disorders and dislocations; trauma-related
226	Fracture of neck of femur (hip)
227	Spinal cord injury
228	Skull and face fractures
229	Fracture of upper limb
230	Fracture of lower limb
232	Sprains and strains
233	Intracranial injury
234	Crushing injury or internal injury
235	Open wounds of head; neck; and trunk
237	Complication of device; implant or graft
238	Complications of surgical procedures or medical care
239	Superficial injury; contusion
240	Burns
241	Poisoning by psychotropic agents
242	Poisoning by other medications and drugs
243	Poisoning by nonmedicinal substances
244	Other injuries and conditions due to external causes
245	Syncope
246	Fever of unknown origin
247	Lymphadenitis
249	Shock
250	Nausea and vomiting
251	Abdominal pain
252	Malaise and fatigue
253	Allergic reactions
259	Residual codes; unclassified
650	Adjustment disorders
651	Anxiety disorders
652	Attention-deficit, conduct, and disruptive behavior disorders
653	Delirium, dementia, and amnestic and other cognitive disorders
656	Impulse control disorders, NEC
658	Personality disorders
660	Alcohol-related disorders
661	Substance-related disorders
662	Suicide and intentional self-inflicted injury
663	Screening and history of mental health and substance abuse codes
670	Miscellaneous disorders

ICD-9 codes	Description
Acute ICD-9 codes within Diagnosis CCS 97: Peri-; endo-; and myocarditis; cardiomyopathy	
032.82	Diphtheritic myocarditis
036.40	Meningococcal carditis, unspecified
036.41	Meningococcal pericarditis
036.42	Meningococcal endocarditis
036.43	Meningococcal myocarditis
074.20	Coxsackie carditis, unspecified
074.21	Coxsackie pericarditis
074.22	Coxsackie endocarditis
074.23	Coxsackie myocarditis
112.81	Candidal endocarditis
115.03	Infection by Histoplasma capsulatum, pericarditis
115.04	Infection by Histoplasma capsulatum, endocarditis
115.13	Infection by Histoplasma duboisii pericarditis
115.14	Histoplasma duboisii, endocarditis
115.93	Histoplasmosis, unspecified, pericarditis
115.94	Histoplasmosis, unspecified, endocarditis
130.3	Myocarditis due to toxoplasmosis
391.0	Acute rheumatic pericarditis
391.1	Acute rheumatic endocarditis
391.2	Acute rheumatic myocarditis
391.8	Other acute rheumatic heart disease, unspecified
391.9	Acute rheumatic heart disease, unspecified
392.0	Rheumatic chorea with heart involvement
398.0	Rheumatic myocarditis
398.90	Rheumatic heart disease, unspecified
398.99	Other Rheumatic heart diseases
420.0	Acute pericarditis in diseases classified elsewhere
420.90	Acute pericarditis, unspecified
420.91	Acute idiopathic pericarditis
420.99	Other acute pericarditis
421.0	Acute and subacute bacterial endocarditis
421.1	Acute and subacute infective endocarditis in diseases classified elsewhere
421.9	Acute endocarditis, unspecified
422.0	Acute myocarditis in diseases classified elsewhere
422.90	Acute myocarditis, unspecified
422.91	Idiopathic myocarditis
422.92	Septic myocarditis
422.93	Toxic myocarditis
422.99	Other acute myocarditis
423.0	Hemopericardium
423.1	Adhesive pericarditis

423.2	Constrictive pericarditis
423.3	Cardiac tamponade
429.0	Myocarditis, unspecified
Acute ICD-9 codes within Diagnosis CCS 105: Conduction disorders	
426.0	Atrioventricular block, complete
426.10	Atrioventricular block, unspecified
426.11	First degree atrioventricular block
426.12	Mobitz (type) II atrioventricular block
426.13	Other second degree atrioventricular block
426.2	Left bundle branch hemiblock
426.3	Other left bundle branch block
426.4	Right bundle branch block
426.50	Bundle branch block, unspecified
426.51	Right bundle branch block and left posterior fascicular block
426.52	Right bundle branch block and left anterior fascicular block
426.53	Other bilateral bundle branch block
426.54	Trifascicular block
426.6	Other heart block
426.7	Anomalous atrioventricular excitation
426.81	Lown-Ganong-Levine syndrome
426.82	Long QT syndrome
426.9	Conduction disorder, unspecified
Acute ICD-9 codes within Diagnosis CCS 106: Dysrhythmia	
427.2	Paroxysmal tachycardia, unspecified
427.69	Other premature beats
427.89	Other specified cardiac dysrhythmias
427.9	Cardiac dysrhythmia, unspecified
785.0	Tachycardia, unspecified
Acute ICD-9 codes within Diagnosis CCS 108: Congestive heart failure; nonhypertensive	
398.91	Rheumatic heart failure (congestive)
428.0	Congestive heart failure, unspecified
428.1	Left heart failure
428.20	Systolic heart failure, unspecified
428.21	Acute systolic heart failure
428.23	Acute on chronic systolic heart failure
428.30	Diastolic heart failure, unspecified
428.31	Acute diastolic heart failure
428.33	Acute on chronic diastolic heart failure
428.40	Combined systolic and diastolic heart failure, unspecified
428.41	Acute combined systolic and diastolic heart failure
428.43	Acute on chronic combined systolic and diastolic heart failure
428.9	Heart failure, unspecified
Acute ICD-9 codes within Diagnosis CCS 149: Biliary tract disease	

574.00	Calculus of gallbladder with acute cholecystitis, without mention of obstruction
574.01	Calculus of gallbladder with acute cholecystitis, with obstruction
574.30	Calculus of bile duct with acute cholecystitis, without mention of obstruction
574.31	Calculus of bile duct with acute cholecystitis, with obstruction
574.60	Calculus of gallbladder and bile duct with acute cholecystitis, without mention of obstruction
574.61	Calculus of gallbladder and bile duct with acute cholecystitis, with obstruction
574.80	Calculus of gallbladder and bile duct with acute and chronic cholecystitis, without mention of obstruction
574.81	Calculus of gallbladder and bile duct with acute and chronic cholecystitis, with obstruction
575.0	Acute cholecystitis
575.12	Acute and chronic cholecystitis
576.1	Cholangitis
Acute ICD-9 codes with Diagnosis CCS 152: Pancreatic disorders	
577.0	Acute pancreatitis