

# Public Comment Summary Report

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## Project Title:

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

## Dates:

The Call for Public Comment ran from July 18, 2016 to August 17, 2016.

The Public Comment Summary was made on September 14, 2016.

## Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with *Yale New Haven Health Services Corporation - Center for Outcomes Research & Evaluation (YNHHSC/CORE)* to develop a *Measure of Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures*. The contract name is Development, Reevaluation, and Implementation of Hospital Outcome/Efficiency Measures, Option Year 2. The contract number is HHSM-500-2013-13018I- Task Order HHSM-500-T0001. As part of its measure development process, CMS requests interested parties to submit comments on the proposed measure.

## Project Objectives:

- The goal of this measure of informed consent document quality is to support national strategies to promote patient-centered decision making. In evaluating hospitals' informed consent document quality, CMS seeks to increase the attention and effort that hospitals dedicate to providing high-quality informed consent, thereby supporting patient autonomy.
- The public comment period for this project was focused on gathering feedback on the current methodology and future work for the informed consent document quality measure from patients and patient advocates, hospitals, physicians, and other stakeholders.

## Information About the Comments Received:

- Public comments were solicited by:
  - Email notifications to CMS listserv groups;
  - Email notification to the informed consent document quality measure development Technical Expert Panel (TEP) and Working Group; and
  - Web posts on the CMS Public Comment website.
- 16 response letters were received.
  - Within these responses, there were over 125 individual comments covering a broad range of categories. (Note: This count does not include comments that were not relevant to measure development.)

- Responses were received from ten individuals, representing patients, patient advocates, and clinicians, two patient/consumer advocacy organizations, one hospital association, one physician professional society, one government organization, and one quality improvement organization.
- We have categorized these comments by topic and summarized them within each topic, as shown in the subsequent sections of this report:
  - [Measure Concept and Goals](#)
  - [Measured Entity](#)
  - [Measure Development Process](#)
  - [Measure Cohort](#)
  - [Abstraction Tool Concept and Goals](#)
  - [Abstraction Tool Items](#)
  - [Abstraction Tool Scoring](#)
  - [Abstraction Tool Validity and Reliability](#)
  - [Risk Adjustment](#)
  - [Hospital Results](#)
  - [Implementation](#)
  - [Overall Analysis of Stakeholder Comments and Recommendations](#)
- The full set of original comments can be found at the end of this report ([Public Comment Verbatim Report](#))

## **Stakeholder Comments and CMS Responses**

### **Measure Concept and Goals**

- We received supportive feedback about the importance of developing a measure to evaluate and improve informed consent for elective procedures.
  - Many felt informed consent was an important area of focus (six commenters), and that improvements to informed consent documents could make them more patient- and family-centered and elevate them to a more of meaningful part of the informed consent process (three commenters). Some commented that the measure fills an important gap in quality (three commenters), and that improvements to informed consent could ensure that patients fully understand the procedure, risks, and benefits (three commenters).
  - We received comments that starting with a measure of the quality of consent documents was important, and that the measure will improve the quality of informed consent documents (two commenters).
  - One commenter emphasized that this measure, when implemented, should hold hospitals accountable for the quality of processes and accuracy of information that is presented to patients, regardless of workflow.

### **CMS Response**

CMS appreciates the support for the importance of the measure. The measure under development is an important first step that, if successful, will provide patients with important information to support decision making. CMS believes that hospitals can and should be held accountable for the quality of informed consent documents shared with patients.

- Several commenters expressed concern that the measure, as specified, will not successfully evaluate the quality of, nor improve the informed consent process (six commenters). Specifically, commenters had concerns about (1) the outcome (measuring only the quality of the informed consent documents) and (2) the tool used to assess the quality of the documents.

### **CMS Response**

CMS thanks responders for this input and responds to the direct concerns in the sections: [Abstraction Tool Concept and Goals](#) and [Abstraction Tool Items](#), below.

- We also received suggestions to measure other aspects of the informed consent process:
  - Five commenters expressed a desire for a measure focused on shared decision making directly or the quality of the discussion between the patient and provider. Conversely, one commenter questioned the assumption that patients want to be involved in shared decision making.
  - One commenter noted that sources other than the consent document commonly summarize discussions between providers and patients (e.g., progress notes written by surgeons).
  - One commenter suggested evaluating the informed consent process directly from the patient's perspective. Similarly, one commenter called specifically for developing a patient-reported outcome (PRO) measure, suggesting a standardized set of patient-reported questions around shared decision making.
  - One commenter suggested the development of a template for informed consent documents instead of measuring the quality of currently used consent documents

### **CMS Response**

CMS believes that the measure represents an important first step forward in improving high-quality decision making and will fill a significant gap in the quality of the informed consent documents.

As the commenters noted, this measure evaluates the quality of informed consent documents only. It does not measure the quality of the communication between a clinician and a patient, and it does not measure the quality of the decision. However, one measure cannot capture all aspects, and we received broad support from patients and the majority of members of the TEP that the document is an important component of informed consent quality. Patients want something tangible that they can read at their own pace, take home, and share with others. This was especially articulated by the Working Group of patients and patient advocates who affirmed the importance of the proposed measure concept—measurement of the quality of informed consent documents.

CMS also acknowledges that not all patients want to be involved in shared decision making. This measure ensures that patients, at a minimum, have information about the basic aspects of a procedure, and its inherent risks, benefits and alternatives. High quality informed consent documents can facilitate patient participation in the informed consent process to the extent that is comfortable for them. While this measure is not evaluating shared decision making, CMS believes that all people should have the opportunity to engage in shared decision making if desired.

CMS recognizes the importance of measuring patient-reported outcomes and of evaluating the quality of shared decision making. CMS does not see the informed consent measure as a substitute for evaluating shared decision making or other related components of the informed consent process. CMS believes this measure will help pave the way for such measures.

CMS also recognizes that some may want for CMS to develop a template that represents a high-quality informed consent document. However, CMS believes there are many different approaches to achieving high-quality documents that, at the very least, meet the minimum standards specified in this measure. CMS encourages innovation in informed consent documents and evaluation of best practices.

### **Measured Entity**

- We received mixed feedback about measuring informed consent document quality at the level of the hospital.
  - Some agreed that provider-level measurement of document quality allows for hospital and physician comparisons and can incentivize improvement (two commenters).
  - Others suggested that the measure capture informed consent at the level of the individual surgeon in order to enhance the patient-provider relationship (two commenters).
  - One commenter suggested aggregating decision quality information at the physician-level for identification of feedback and quality improvement opportunities.

### **CMS Response**

Consistent with the goals of outcome measures, CMS' intention is to evaluate hospital performance and provide feedback on performance to hospitals, enabling them to compare their performance to others, and to innovate and improve in ways that are best-suited for them.

This measure was developed for a hospital inpatient reporting program, and therefore the measured entity is hospitals. The measure promotes hospital improvements to the informed consent document. CMS believes that hospitals can and should be held accountable for the quality of informed consent documents shared with patients. This does not exclude the potential to adapt the measure to evaluate surgeon-specific performance, however, more work needs to be done to ensure fairness and reliability.

## **Measure Development Process**

- We received mostly positive feedback on the measure development process, though some concerns were raised.
  - Specifically, one commenter acknowledged the excellent work that has been done by the measure development team, and many commenters appreciated the opportunity to participate in measure development during the public comment period (seven commenters).
  - One commenter suggested including additional peer-reviewed literature on informed consent to further inform measure development; the same commenter also expressed concern that the exploratory study of medical records was conducted in a single institution rather than a range of institutions.
  - There was also concern about the perceived separation of experts and patient advocates in the Working Group and TEP (one commenter).

### **CMS Response**

CMS will review the suggested additional peer-reviewed literature, many of which were included in prior developmental work of the measure, and incorporate into the methodology report.

CMS appreciates the concern raised about the initial exploratory study which was conducted in a single site, which has limitations related to the lack of diversity in consent forms and potential homogeneity of consent processes. This exploratory study of the quality of consent forms from a single site was conducted solely as a proof-of-concept. A subsequent pilot project was conducted with 8 diverse hospitals and hospital systems, providing a broader range of informed consent documents across multiple procedure types, and was used to inform measure development and testing. Still, CMS recognizes the need for broader testing and is currently partnering with an additional set of 25 hospitals.

As is standard with all CMS measures, the measure developer worked with multiple stakeholders as part of a TEP that included patients and caregivers in addition to clinicians, bioethicists, attorneys, and other healthcare professionals. In addition, the measure developer sought to collaborate with a distinct group of patients and patient advocates that were purposefully not part of the TEP in order to foster a safe and constructive space for sharing stories that might influence the measure, and to provide personalized, in-depth feedback. The measure developer collaborated with the National Partnership for Women and Families to review best practices in patient engagement and to recruit nine patients and patient advocates to participate in a Working Group. During seven meetings, the measure developer with the Working Group co-developed a taxonomy of informed consent document quality and discussed key aspects of measure development and measure specifications. CMS was present, though did not participate on these calls. CMS believes that their input deeply strengthened the measure, and will continue to collect and evaluate feedback from the Working Group and other stakeholders about this measure.

## **Measure Cohort**

- We received a few comments about the approach to sampling elective procedures for measurement.
  - One commenter suggested sampling an equal number of each procedure types as opposed to sampling the proportions of procedure types that are reflective of the procedure-mix of the hospital.
  - Commenters recommended that steps be taken to reduce risk of gaming (hospital bias). Specifically, they supported the idea of random sampling and not allowing hospitals to select cases that have particularly high-quality consent documents (two commenters).
  - One commenter proposed restricting the cohort to procedures for which a pre-procedure visit is standard practice. The rationale for this suggestion was the concern that Item 8 (the timing of the patient signature on the consent document) would not apply to minor procedures for which there is not a strong precedent for signing the document at least one day in advance of the procedure.

## **CMS Response**

Several decisions were made during the measure development process – either to develop a measure for a few high-volume procedures which would limit the number of hospitals included in the measure, or to develop a measure that captured a broad group of procedures and thus, reached more hospitals and patients. CMS' preference was to capture a broad group of procedures. However, because the types and volume of elective procedures performed varies within each hospital, it may not be feasible to select the same number of documents for each procedure type across all hospitals. Moreover, CMS believes the measure should evaluate the procedure mix that is unique to each hospital.

Accordingly, CMS has revised the sampling approach that was used for the pilot project. The current approach is a stratified sampling method to capture a set of diverse procedures from each hospital that is representative of the procedure mix performed at that hospital. With this approach, procedures are categorized into ten common specialties. The relative proportion of procedures within each of these ten specialties will be calculated for each hospital, and a sample of procedures will be randomly selected in proportion to each hospital's procedure mix. This approach additionally ensures that hospitals are not able to game the measure by selecting only high-quality informed consent documents. Hospitals will be required to provide copies of the informed consent documents for the sample of procedures provided by CMS. Replacement procedures would be provided in the case that the patient medical record cannot be located or that the informed consent document is not written in English.

This revised approach to selecting the measure cohort received support from the patient and patient advocate Working Group and was viewed by the measure developers as fair and feasible for hospitals. In the upcoming TEP meeting, the measure developers will seek further feedback about this approach. Additionally, in the next year, CMS will further develop the sampling approach with the goal of including hospitals with small procedure volume; this will involve additional testing in order to determine the minimum number of informed consent documents needed to produce reliable hospital level performance estimates.

CMS understands the concern raised that a patient signature may not typically be obtained at least one day in advance of minor procedures that typically do not require a pre-procedure visit. The current cohort does not include minor procedures which may or may not require informed consent (such as minor procedures commonly performed at the bedside or by allied health professionals). However, for other minor procedures (and other electively performed procedures) with sufficient invasiveness or risk to require informed consent as standard practice, CMS believes that it is important to give patients the opportunity to review the informed consent document prior to the day of the procedure. Setting the criteria to at least one day in advance ensures that patients are not learning about the procedure (and the associated risks/benefits/alternatives) for the first time on the day of the procedure. With that said, some patients may not want information beforehand; the measure allows for patients to opt out of this requirement.

- We received one comment that expressed concern that the measure will not help individuals who speak little to no English or have cognitive deficiencies or other limitations.

### **CMS Response**

CMS acknowledges that a limitation of the measure is its inability to assess the quality of documents that are not written in English. Currently, informed consent documents written in a language other than English are excluded from scoring because the measure is specified and tested in English documents only. We hope to evaluate the feasibility of expanding the measure to address this limitation in future measure reevaluation work.

We agree that individuals with cognitive deficiencies or other limitations represent vulnerable populations at risk for low-quality informed consent. We feel that patient-specific factors should not impact informed consent document quality. Moreover, caregivers and other surrogates of patients with cognitive deficits are supportive of the measure, as there is a need for greater written information about the choices they are making on behalf of the patient.

### **Abstraction Tool Concept and Goals**

- We received mixed support for the concept and goals of the Abstraction Tool, the instrument used to assess the quality of informed consent documents.
  - CMS was commended for its decision to require highly ethical, patient-centered informed consent documents that are legible, describe the treatment/procedure, and identify the risks, benefits (one commenter).
  - Two commenters noted the effort put into developing a rigorous and objective instrument (the Abstraction Tool).
  - One commenter felt that the Abstraction Tool is very fundamental and would not be able to differentiate quality among documents.
  - Suggestions were made for the measure developer to continue to refine the Abstraction Tool. Specifically,

- One commenter felt that the items included on the Abstraction Tool are more provider-centered than patient- or family-centered and will not capture items that could be of value to patients.
- One commenter expressed concern that the Abstraction Tool may encourage hospitals to add standardized language to consent documents that will not actually be meaningful to patients.
- One commenter suggested including only the elements from the taxonomy that are most important and understandable to the patient.

### **CMS Response**

We recognize that an informed consent document alone cannot capture all facets of decisional quality or patient autonomy and that the Abstraction Tool captures only a portion of possible quality elements of informed consent documents. Nonetheless, the items included in the Abstraction Tool stem from a fuller taxonomy of informed consent document quality that was co-developed by the measure developer and the patient and patient advocate Working Group, and represent important elements of informed consent documents that are fundamental to the ethical and legal standards of quality. The measure developer collaborated with the Working Group to ensure that the standards for each item in the Abstraction Tool are meaningful to patients, and feasible to measure.

CMS acknowledges that there is discordance about how expansive the Abstraction Tool should be in capturing quality – some stakeholders feel the Abstraction Tool is too basic, while others believe that a measurement tool should evaluate only the most important elements of quality. CMS believes that the present Abstraction Tool effectively and concisely captures key elements of informed consent document quality that represent a minimum standard for informed consent documents that are meaningful to patients. Moreover, in a pilot of 8 hospitals, it was found that even the basic elements of informed consent are often not met. While the Abstraction Tool could go further in evaluating other quality elements, CMS believes this is a first start, and the Abstraction Tool can be expanded with time.

Highlighting gaps in fundamental concepts of informed consent can generate awareness of their importance and can help drive higher standards of quality that promote patient-centered decision making. Preliminary measure testing showed that the Abstraction Tool is able to distinguish between high- and low-quality documents. While the results from the pilot project demonstrated that, overall, the informed consent documents did not meet minimum standards of quality, there was a range of performance both within and between hospitals. The measure is undergoing additional testing in a larger sample of hospitals.

As suggested, CMS will continue to collect and evaluate feedback from stakeholders and consider commenters’ suggestions to refine the Abstraction Tool during ongoing measure reevaluation work.

### **Abstraction Tool Items**

- We received several comments related to specific items in the Abstraction Tool. Most commenters suggested that the criteria for each item in the Abstraction Tool be expanded in

order to evaluate the quality of the content in greater depth, and to ensure its accuracy. We outline feedback received on the items in the Abstraction Tool:

- Item 1 (basic description of the procedure)
  - One commenter noted that the description of the procedure should be provided in plain language and that the use of graphics or pictures could aid in patient understanding. The commenter suggested that these be evaluated as sub-items for item 1 rather than whether the information is typed.
  - Two commenters suggested that item 1 also evaluate the description of implants and medical devices that will be used during the procedure, when applicable.
- Item 2 (description of how the procedure will be performed)
  - Two commenters agreed that the informed consent document should include a detailed description of the procedure.
- Item 3 (rationale for the procedure)
  - One commenter emphasized the importance of patients understanding the nature of their clinical condition and reason for treatment.
- Items 4, 5, and 6 (benefits and risks of the procedure)
  - Two commenters agreed that patients need to know the risks and alternatives to decide whether to undergo an elective surgery.
  - Several commenters suggested evaluating whether the risks and benefits provided were generic or personalized (three commenters).
  - Four commenters suggested evaluating whether the patient was given accurate and complete information on procedure-specific, patient-specific, and provider-specific risks and outcomes.
  - Two commenters suggested evaluating the source of the risk and benefit information (that is, whether it is specific to the surgeon or institution, or if it is from medical literature). One commenter suggested the use of a validated risk calculator.
  - Two commenters suggested that this item also evaluate whether the discussion was tailored to the risks of the individual patient.
  - One commenter supported the requirement to document the qualitative and quantitative risks of a procedure.
- Item 7 (alternatives to the procedure)
  - Three commenters suggested expanding this item to ask whether the informed consent document includes all potential alternatives to the procedure and the risks and benefits of each alternative. One commenter suggested using a “reasonable patient standard” to evaluate this.
  - One commenter suggested including an item to assess whether the rationale for selecting the procedure instead of other alternatives is given on the informed

- consent document. Similarly, one commenter suggested that the document should note specifically if there is no evidence to support having the procedure other than physician recommendation.
- Three commenters proposed evaluating whether the informed consent document describes medical guidelines or best practices for the procedure and reasons for following or not following them.
  - Two commenters proposed including an item to measure whether the informed consent document includes a description of the consequences of no treatment.
- Item 8 (timing of the patient signature on the informed consent document)
- Two commenters affirmed the importance of providing adequate time for the patient to review the informed consent document and make a decision prior to the procedure.
  - One commenter supported the proposed timeframe of at least one day prior to the procedure.
  - We also received several comments raising concerns about the timing item:
    - One commenter disagreed with this item, noting that despite seeming intuitive, there is little evidence that signing or distributing the consent document in advance of the procedure improves informed consent.
    - One commenter noted this item could be problematic since the informed consent discussion could happen after the decision has been made to perform a procedure, during the scheduling process, or the day prior to an unexpected opening in a surgeon’s schedule.
    - One commenter recommended that patients sign the informed consent document one week prior to the procedure in order to give patients adequate time to digest the information.
    - One commenter did not support this item’s “opt-out” option, as it might diminish the act of signing “the consent document to a purely administrative act, separate from the informed consent conversation between the provider and the patient.” Additionally, it might place negative pressure on patients to consent on the day of the procedure.

### **CMS Response**

CMS appreciates the commenters’ support of specific Abstraction Tool Items. This feedback is consistent with support that we have received from the patient and patient advocate Working Group and providers and experts that were consulted during the measure development process.

CMS recognizes some commenters’ desire that the criteria for meeting each item in the Abstraction Tool be more fitted for evaluating specific procedures. In most cases, evaluating the comprehensiveness and accuracy of the items would require information from data sources beyond those currently used in the measure (informed consent documents and CMS claims data). It also requires a process for certifying the accuracy of the information and

ensuring that the information is up to date. In developing this measure, CMS assumes that hospitals' that change their consent documents to conform to the standards set in this measure will continue to meet the legal standards of their State and hospital, and will be accountable to clinicians and patients for the integrity of the information provided in the documents. CMS appreciates that consent documents need to be complete in their description of the risks, benefits and alternatives. For the reasons stated above, this measure will not evaluate the accuracy of the information; however this does not remove hospitals' or clinicians' obligation to provide accurate information. CMS supports tailoring the risks and benefits, and the likelihood of their occurrence to the patient, procedure and hospital, when these data are available.

CMS agrees that the alternatives should be well-described, including a description of the natural consequences of no treatment, and the rationale for proceeding with one option over another should be included. CMS will consider evaluating the feasibility of capturing this in a future iteration of the measure.

CMS acknowledges that the appropriate amount of time to share the informed consent document with a patient may vary by procedure and patient preference. The developers discussed this item in detail with the Working Group, TEP, and other experts in the field. The item aims to avoid consent documents being signed on the day of the procedure, a time when patients are most vulnerable and least likely to ask questions. The Abstraction Tool allows for patients to opt-out of this timing requirement. While it is possible that the opt-out approach may be used to pressure patients, the measure will enable CMS to observe hospitals which are outliers on this item, suggesting that these hospital may discourage sharing informed consent documents prior to the day of the procedure.

### **Additions to the Abstraction Tool Items**

- Several commenters suggested the addition of items to the current Abstraction Tool to evaluate the following components of informed consent:
  - *Shared decision making*
    - Three commenters suggested including an item to capture whether a decision aid was used.
    - One commenter suggested assessing whether the informed consent document included the patient's treatment preferences.
  - *Quality of patient-clinician discussions and patient understanding*
    - Four commenters suggested assessing the patient's understanding of the procedure, risks, and/or available alternatives.
    - One commenter suggested having an additional requirement for the provider to sign the form to confirm that that the informed consent discussion took place and that the patient expressed comprehension and consent after an opportunity to ask questions.
    - Two commenters suggested including an item to assess whether the consent document allowed the patient to indicate if they wanted a second opinion.

- Two commenters suggested including an item to assess whether the consent document allowed the patient to indicate if wanted more time to explore alternatives or options.
- *Disclosure of hospital and clinician conflicts of interest, credentials, and experience*
  - One commenter suggested assessing whether the patient was informed of any conflicts of interest held by the hospital or surgeons, particularly with regard to medical devices or pharmaceuticals used in the procedure.
  - Three commenters recommended evaluating whether the patient was provided with accurate description of the experience and credentials of all clinicians participating in the surgery.
- *Disclosure of individuals involved in the procedure*
  - Six commenters suggested that the Abstraction Tool should include an item to capture whether the informed consent document lists all individuals who will be involved in the procedure and what each person's role will be (for example, performing the procedure, supervising a resident or student, or representing a medical device company).
  - One commenter recommended assessing whether the informed consent conversation takes place between the patient and the surgeon who will be performing the procedure.
- *Disclosure of information pertaining to medical devices*
  - One commenter proposed evaluating whether the informed consent document lists off-label devices used in the procedure and the risks and benefits of each.
- *Disclosure of data/tissue being used for research investigation*
  - One commenter felt that the Abstraction Tool should include an item to assess whether the patient received full disclosure if their case was part of any study or trial collecting data.
- *Other*
  - One commenter suggested assessing the presence of information describing plans for follow-up visits and post-operative care.
  - One commenter agreed with the measure not including the costs of the procedure.
  - One commenter emphasized the importance of measuring anesthesia consent.
- One commenter had several concerns about items in the taxonomy (Appendix F of the Draft Methodology Report) that are not currently included in the measure. The commenter indicated that including some of the elements could result in extraneous information that might not be important to patients, might be difficult for patients to interpret, and might detract from the goal of the informed consent measure. The same commenter noted that the additional elements could result in excessively long consent documents.

## **CMS Response**

We received mixed comments about what should be included from the broader taxonomy (of informed consent document quality) in the final Abstraction Tool. Some respondents wanted to see broader inclusion of quality items though others raised concerns that there was no evidence to support that including these items would improve decision making. There was further concern that including additional criteria such as physician-level or hospital-level data could distract rather than support the goals of informed consent. We are aware that the current measure captures some but not all of the components of informed consent document quality that commenters would like to see measured. At this time the Abstraction Tool evaluates aspects of several key components that meet five element selection criteria: importance 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, and feasibly measured with high reliability. While the quality of consent for anesthesia was raised by the Working Group and included in our taxonomy, early work by the measure developers found this to be a distinct part of the consent process with unique challenges for measurement. CMS will consider future work in this area.

CMS recognizes the desire to capture the use of patient decision aids. This may be feasible in the future; however, at the current time, without standards for certification of decision aids, decision aids may be biased or otherwise of low quality. As such, CMS had reservations about capturing their use. CMS will continue to evaluate their inclusion as well as other elements of high-quality informed consent documents, as suggested above.

## **Abstraction Tool Scoring**

We received feedback on the current approach to scoring the Abstraction Tool. Specifically:

- Items 1 and 2 (basic description of the procedure and description of how it will be performed)
  - One commenter proposed giving extra credit points for consent documents that include pictures or videos that could aid in patient understanding.

## **CMS Response**

CMS appreciates this suggestion and will consider ways to incorporate the presence and quality of supplemental graphics, videos, tables, or other educational materials.

- Items 1t and 2t (whether the information for items 1 and 2 is typed)
  - One commenter felt that giving points for items 1t and 2t, the “typed” items is not necessary; instead, the commenter suggested that illegible consent documents lose 5 points from the total score.
  - One commenter felt that legibility is a less important criteria than other items on the Abstraction Tool, and therefore should not be assigned the same number of points.

- One commenter expressed concern about hospitals being required to type specific components of consent documents, particularly in the event that hospital computer systems are not functioning. The commenter suggested that this is taken into consideration when assigning points for items 1t and 2t.

### **CMS Response**

In the pilot study, assessment of the legibility of hand-written information varied between and among raters, and thus was not feasible to measure. Moreover, we received support from the TEP that with electronic health records and digital communication, there is no reason that the information could not be typed.

Additionally, CMS acknowledges the potential for human and system error that can impact the capacity to meet all items on the Abstraction Tool. The sampling approach ensures that hospitals receive a reliable score that is indicative of the general quality of documents at their institution.

- Items 4, 5, and 6 (benefits and risks of the procedure)
  - One commenter suggested the qualitative and quantitative risks be assigned the same number of points.
  - One commenter recommended that the qualitative risk be assigned the same or more points than the quantitative risk.

### **CMS Response**

The developers elicited a lot of feedback from the Working Group and TEP members about the importance of quantitative and qualitative risks. Nearly all acknowledged the importance of providing both – qualitative risks can be more interpretable, especially for people with limitations in numeracy; quantitative probabilities can allow patients to interpret for themselves whether a risk is sufficiently meaningful. The current scoring approach assigns more points to quantitative probabilities, reflective of the weight of the feedback. However, CMS will revisit this scoring approach in future work.

- Item 8 (timing of the patient signature on the informed consent document)
  - Two commenters recommend reducing the number of points assigned to this item.

### **CMS Response**

CMS acknowledges that there are several different approaches to scoring each item. The developers sought input from the Working Group and TEP specifically on the item of timing. Some suggested that the document should not receive a passing score unless the timing criterion of one day was met. Some suggested removing the timing item. The Working Group ultimately agreed that 5 points (or ¼ of the total score) be given to timing. CMS appreciates the feedback on the number of points assigned to timing and will consider these comments in future work.

## **Abstraction Tool Validity and Reliability**

- We received support that the Abstraction Tool can work [to evaluate quality of the informed consent documents] when applied as planned (one commenter).
- One commenter expressed concern that the process of validity testing did not adequately incorporate expert assessment, which may have resulted in inaccurate results.

### **CMS Response**

The Abstraction Tool was developed in consultation with experts in survey development. In accordance with expert guidance, the measure developers engaged in an iterative process to develop each item on the Abstraction Tool, and the associated definitions/criteria for assessing each item. Moreover, they developed and tested a training kit which consisted of a one-hour video and the review of a sample of 10 informed consent documents. Tests of reliability between two independent abstractors (not a part of the measure development team or organization) with a set of 50 documents demonstrated excellent reliability. In addition, the measure developer compared the score obtained using the Abstraction Tool with a qualitative assessment of informed consent documents, and shared these findings with the Working Group – who further endorsed the validity of the Abstraction Tool to discriminate quality.

Still, CMS recognizes the commenter’s concern that the Abstraction Tool validity testing did not include external expert assessment as to the accuracy of the content provided; for example, the accuracy of risk probabilities provided in the consent documents were not evaluated. The measure developers and clinician/non-clinician experts felt that while this was feasible in evaluating a few procedures, it was not feasible to evaluate the accuracy of the breadth of procedures captured in this measure. CMS opted for breadth rather than depth, entrusting that the clinicians and hospitals are still accountable, both professionally and legally, for providing patients with accurate information. We are currently engaging 25 additional hospitals to pilot and test the measure; during this time CMS will consider more broadly testing the Abstraction Tool in the future.

## **Risk Adjustment**

- We received support for not risk-adjusting the measure (two commenters).

### **CMS Response**

CMS agrees that the measure should not be risk-adjusted because we feel that patient-specific factors should not impact informed consent document quality.

## **Hospital Results**

- We received some comments about hospital-level results from the 8-hospital pilot study:
  - Acknowledgment that most hospitals included in the preliminary measure results performed poorly (one commenter).

- Preference for reporting the percent of documents reaching a threshold score for each hospital (one commenter).
- Preference for a mean document score for each hospital (one commenter).

### **CMS Response**

CMS recognizes that most hospitals will not meet the minimum standards set forth in this measure; however, this indicates room for improvement.

The developers presented the hospital-level performance to the TEP and to the Working Group as both a mean score and a threshold score, and explicitly asked for their feedback. The developers received overwhelmingly more support for the threshold approach. There are advantages and disadvantages to both. The mean score enables hospitals to compare themselves against a national average; however, hospital performance may be misleading for patients if the distribution of scores is uniformly low. For example, hospitals may perform better than the mean, but if the mean is a low-score, this may not reflect quality. The threshold approach sets an external standard for quality. While this standard will need to be set by consensus, the standard can increase as hospitals gain more experience with the measure. CMS will seek more input on scoring approaches in the future.

### **Implementation**

- We received some general comments related to implementation of the measure.
  - One commenter recommended that the measure be included in CMS initiatives to pilot innovative measures and encouraged CMS to collect data for patient-reported outcomes. This commenter suggested this could improve data collection rates and lower costs.
  - One commenter encouraged CMS and the Office of the National Coordinator for Health Information Technology to create interoperability standards for electronic health records (EHRs) for easier collection of informed consent data. This would reduce any biases and the burden on hospitals to perform chart abstraction. This commenter suggested using an application program interface to pull data.

### **CMS Response**

CMS appreciates that this is a novel measure with the potential to impact millions of patients undergoing elective procedures.

CMS agrees that interoperability standards for electronic health records would enable easier collection of informed consent data. Until this happens, the developers have set forth a process that is mindful of the feasibility and burden to hospitals and have tested the measure to ensure these standards. While the measure will ensure that basic components of informed consent are met, the measure, as currently specified, will not evaluate the accuracy of the content provided. The measure developers are conducting further testing in an additional 25 hospitals. As technological capacity evolves, CMS will consider alternative mechanisms for acquiring and evaluating informed consent data with the goal of collecting high-quality data and reducing burden to hospitals.

## **Preliminary Recommendations**

CMS will continue to evaluate the current informed consent document quality measure. As the measure evolves and input from stakeholders is received, CMS will continue to consider improvements to the informed consent document quality measure methodology.

CMS has made updates to the measure that address comments received, including:

- Changing the method of sampling procedures from the cohort. Commenters expressed concern about the possibility of hospitals selecting their own consent documents and supported the idea of random sampling to prevent gaming. After conducting additional analyses and consulting the Working Group, CMS has revised the sampling approach and the measure will now use a stratified random sampling method (see description [here](#)).
- CMS has reviewed the additional peer-reviewed literature suggested by commenters and, where appropriate, incorporated into the methodology report.

In response to comments received, CMS will consider the following additional work in future years:

- Evaluating the feasibility of expanding the measure to include non-English informed consent documents.
- Revisiting the Abstraction Tool scoring approach to consider weighing qualitative and quantitative risk probabilities equally and decreasing the number of points assigned to the timing item.
- Evaluating the feasibility of capturing additional criteria in the Abstraction Tool.
  - As standards for certification of decision aids develop, CMS will consider evaluating the use of patient decision aids.
  - If appropriate data become available, CMS will consider evaluating whether the consent documents include patient-, procedure-, and hospital-specific risks and benefits and the likelihood of their occurrence; the natural consequences of no treatment; and the rationale for proceeding with one procedure option over another.
- Evaluating the feasibility and validity of adapting the measure to evaluate surgeon-specific performance.

In addition, CMS will continue to consider measures aimed at capturing patient-reported outcomes and shared decision making as part of its measure development work.

## **Overall Analysis of Stakeholder Comments and Recommendations**

Most commenters supported the measure goal of improving informed consent, but nine alternative approaches to improve the informed consent process were proposed, such as measures of the quality of the discussion and patient reported outcome measures.

CMS recognizes the importance of other measures of decisional quality and does not see the informed consent document quality measure as a substitute for evaluating shared decision making or other related components of the informed consent process. CMS believes this measure is a first step that, if successful, will provide patients with important information to support decision making. In

evaluating hospitals' informed consent document quality, CMS seeks to increase the attention and effort that hospitals dedicate to providing high-quality informed consent, thereby supporting patient autonomy.

Most comments applied to the items captured by the Abstraction Tool:

- Many commenters suggested that the Abstraction Tool assess the accuracy and comprehensiveness of the content provided in the informed consent document.
- Several commenters emphasized the need for the Abstraction Tool to measure patient understanding.
- Several commenters expressed concern that the timing item on the Abstraction Tool (Item 8a-c), could impede hospital workflow, may not be appropriate for all elective procedures, and may have unintended negative consequences for patients.

Several commenters suggested that the Abstraction Tool assess procedure-, patient-, and hospital-specific risks and benefits, and whether or not a shared decision making tool was used. Some commenters recommended including information about cost, medical devices and conflict of interest, though other suggest against this level of detail.

In summary, CMS is pleased that stakeholders are committed to improving informed consent. In developing this measure, CMS is supporting hospital efforts to launch novel improvements to informed consent. The comments received are valued by CMS and supportive of our goals to improve patient-centered decision making. While this measure evaluates basic components of informed consent documents, a first step to improving this process, the measure is not at the expense of other measures or efforts that aim to expand this work and address shared decision making.

CMS will consider the suggestions made in future measure development work.

## Public Comment Verbatim Report

Please note that CMS’s recommendations and actions taken in response to all comments can be found in the [Stakeholder Comments and CMS Responses](#) section of the report above.

**Table 1. Verbatim Comments**

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
7/28/2016	<p>Enclosed please find my suggestions for making the scoring system genuinely patient centered.</p> <p>Comments on Informed Consent Tool for hospital elective surgery</p> <p>The team has performed a great deal of background research and demonstrated that the proposed tool can work when applied as planned. Unfortunately, the tool and scoring system fall short of the stated goal of “support[ing] patient autonomy and patient-centered decision making for the elective procedures by assessing the quality of informed consent documents.” Patient autonomy and decision making in the face of possible elective surgery must include the following, which are missing from the abstraction tool:</p> <ol style="list-style-type: none"> <li>1. What are all my options and what is the risk and benefit of each option. How is the risk-benefit known (ie. Is it specific to the surgeon, institution, or from medical literature)? This should also include a description of the risks and benefits of robotic surgery vs. laparoscopic surgery if appropriate. Each option should be described in sufficient detail to reasonably inform the patient.</li> <li>2. Who will be involved in key aspects of my procedure and what is their specific role. This is especially important in teaching hospitals where poorly supervised residents may be doing a procedure for the first time.</li> <li>3. Medical guidelines are the underpinning of best practices (aka, evidence-based medicine). The patient should know which guidelines are being followed for her specific condition. If the care needs to deviate from guidelines, then the physician performing the invasive procedure must state why the guidelines are not being followed. If there is no guideline, then that should be explicitly stated in the IC document.</li> </ol>	John James, PhD, Patient Safety America	Patient/ Consumer Advocacy Organization	See Pages 3, 8, 10, 11, and 13-15

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
	<p>4. Decision aids are readily available for many procedure options. If I were a patient, I would want to know if such an aid were available and be allowed to view it and ask questions.</p> <p>5. Medical explanations and procedures can be complex. It is essential that the tool recognize this by scoring the patient’s understanding of her choices. This could be as simple as the patient writing in a few lines about why she chose the procedure that she and her doctor agreed upon. If the patient wants a second opinion, this would be the place to indicate that, perhaps by a check box.</p> <p>6. Comment on the scoring tool itself – giving any points for “typing” the IC scoring tool items 1 and 2 makes little sense to me. If the form is not easily read, then 5 points should be taken from the score for illegible writing. I trust this would be a rare happening.</p> <p>7. A recent UCLA settlement for off-label use of a glue during spine surgery indicates that the CMS IC document assessment tool should specifically ask for any off label use of devices, and if none are being used off label, then that should be indicated with the signature of the lead surgeon. If a device is being used off label, then a thorough description of the risks and benefits of the off label device must be present. Here is a link to the \$8.5 million settlement: Off label spinal glue.</p> <p>It is my opinion that as proposed, the tool and its associated scoring approach fail to protect the patient from bias on the part of the provider. A procedure could be easily sold to a patient that does not need it, and the IC score using the proposed plan would still be 20 points. That should not be able to happen with a patient-centered IC scoring system.</p>			
7/28/2016	<p>The proposed tool fails in its chief aim; to measure whether the patient was provided with sufficient information to make an informed decision. Offering one procedure and presenting one alternative is not sufficient in many cases. All reasonable procedures should be presented to the patient and documented as to the risks and benefits of each. If the physician is recommending one procedure, then there should be a clearly written rationale for performing that invasive operation in lieu of the alternatives.</p>	Dan Walter, Patient Safety Advocate	Individual	See Pages 8, 10, 11, and 13

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
7/29/2016	<p>I was devastatingly and permanently harmed at [REDACTED] by a surgeon, [REDACTED], head of his department, who was not board certified, was not credentialed, and was not privileged to use the da Vinci robot. He had not performed 1000 open and 1000 robotic prostatectomies as he stated to many of his patients who were also devastatingly harmed. Court records show he had performed no open procedures since his graduation from a foreign residency in [REDACTED] and had performed only a few hundred robotic procedures. He represented positive outcomes of 98% and 95% for continence and sexual potency. This was also false. He represented an [REDACTED] medical license in his application to CMS. The [REDACTED] Board stated he applied for an [REDACTED] Medical License but did not meet their minimum requirements. He claimed to be a member of the FACS which was false. He claimed to have been board certified by the [REDACTED] as well as the [REDACTED] – all false. The informed consent document upon which I wrote, “Only [REDACTED] is allowed to perform my surgery”, signed by me, my wife as witness, and [REDACTED], was “disappeared” by the [REDACTED] claiming they did not have patients sign informed consents for major complex surgeries. The [REDACTED] audit report and operating room log show no evidence that [REDACTED] was present at any time during my surgery, or hospitalization. Except for seeing the resident in the Operating Room who, over my objections that [REDACTED] was not present, directed I be given anesthesia, I never saw a physician or resident during my hospitalization. The surgeons attestation is blank. The op note was unsigned for two years until CMS investigated. The same day surgical episode document recertifying informed consent by [REDACTED] is blank, signed, and dated 7 weeks after my surgery. My op note states “150cc blood loss and no complications” even though I was administered 5500cc of colloids and crystalloids during my surgery. My labs show that my HCT was continuing to drop with each successive lab including my discharge lab—a drop of more than 12%. I was extreme ill and weak. All progress notes during my hospitalization were written by a second year resident and not co-signed as required. My discharge briefing to me and my wife was done by a nurse. Again, we never saw a physician. The discharge was signed by the second year resident and not cosigned as required. [REDACTED] was an employee of [REDACTED], for which he alleged received payments in money, stock, and stock options, a conflict of interest he did not reveal to his patients. CMS cited the [REDACTED] for performing robotic da Vinci procedures without patients knowledge or consent.</p> <p>I propose the following elements be included in informed consent:</p>	David Antoon	Individual	See Pages 10, 11, and 13

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
	<ol style="list-style-type: none"> <li>1. A full disclosure of all conflicts of interest held by the surgeons and the hospital any way related to medical devices or pharma to be used.</li> <li>2. A description of the valid credentialing, certification, and privileging of all surgeons participating in the surgery.</li> <li>3. A description of any device, including identification information for the device, which will be used on the patient.</li> <li>4. Accurate documented information stating the surgical outcomes by the surgeon who represents he will be the surgeon performing the procedure.</li> <li>5. Accurate documented information about the outcomes for the specific procedure at this hospital.</li> <li>6. Document identifying all personnel present during the entire procedure, including device reps.</li> <li>7. Document stating who will perform which portion of the procedure.</li> </ol> <p>Full disclosure if your case is part of any study or trial collecting data</p>			
8/2/2016	<p>I am writing as an individual and not on behalf of my organization.</p> <p>It is vitally important from a patient safety and QI standpoint that the informed consent for non-emergent procedures be centered on the patient and family and not on the healthcare provider. It is the patients who are best situated to determine whether non-emergent surgery should be done. The patient needs to know the risks and alternatives.</p> <p>I strongly recommend that you use the reasonable patient options for this work. This would include all options that a reasonable patient would expect, with clearly stated risks benefits of the planned intervention. There should be a detailed description of each procedure, with decision aids (if applicable). The patient should be made aware of which clinical guidelines or evidence is being used to make the recommendation for the procedure. Also, they patient should know and be aware if the recommended procedure is in an “evidence free” zone. Sometimes, clinician recommendation is the strongest evidence available and patients should know this. Finally, it is appropriate for forms to be available and reviewed with the patient at least 8, but preferably 24h prior to the procedure.</p>	<p>Greg Ogrinc, MD, MS, Senior Associate Dean for Medical Education, Interim, Geisel School of Medicine at Dartmouth; Associate Chief of Staff for Education, White River Junction VA Medical Center</p>	Individual	See Pages 10, 11, and 13

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
8/2/2016	<p>I am writing to share my personal comments on the Measure of Informed Consent Document Quality Abstraction Tool. It was very disappointing to see patients and families and experts parsed into separate working groups for what should have been a co-designed instrument. Informed consent is a bi-directional process and both parties should be very clear with one another about the care expected to be delivered and the care expected to be received. Developing an abstraction tool with a mixed group of stakeholders would have achieved a more balanced instrument—elements important to providers and patients. The items on the proposed abstraction tool are very provider-centered and seems very fundamental—I can't imagine most standard consents not meeting the criteria of the abstraction tool and it will not differentiate the quality among consents. It will not capture items that could be of value to patients, e.g. "is there a space for patients to enter their preferences for treatment", "is there a space for patients to indicate they would like more time to explore alternatives or options", "are patients encouraged to get a second option or schedule a meeting with another provider", "is there a space for patients to indicate that they would like more time to consider options if they have questions" are a just a few questions that may be of interest from a patient's point-of-view. It is unfortunate that these types of questions are not included on the abstraction tool.</p> <p>Thank you for the opportunity to share my feedback.</p>	Kathryn A. Sabadosa, MPH	Individual	See Pages 5, 8, and 13
8/8/2016	<p>Thank you for this opportunity to comment on the proposed draft measures on informed consent. I am not an expert in this area, though I broadly follow issues related to being an "informed consumer". I am very supportive of the work at the Center for Outcomes Research &amp; Evaluation to make informed consent more meaningful to patients and families, however, I have the following concerns about the draft materials:</p> <ol style="list-style-type: none"> <li>1. As I read the materials, I found myself wondering: Why the focus on measuring document quality? It seems from the initial testing that you have done that informed consent documents are all over the map—and mostly would perform poorly against your measurement specs/abstraction tool. It seems a first, more reasonable step is to take the work that you have done, modify it based on the comments you receive and focus more on developing templates. These templates could initially be piloted—getting feedback from patients and families in particular, but also learning more about how and where they should be introduced into a patient/family decisionmaking process (more on that below). Then they could be widely distributed by</li> </ol>	Carol Cronin, Executive Director, Informed Patient Institute	Patient/ Consumer Advocacy Organization	See Pages 3, 5, 7, 10, 11, 13, and 16

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
	<p>CMS and other interested parties (State health organizations etc.). I think of these “informed consent” templates as similar to the federal “nutrition labels” or state-specific “advance directives” though I understand the complexity of elective surgery decision making limits the analogy.</p> <p>In short, it struck me that your report indicates that the state-of-the-art of informed consent is pretty dismal. Spending a lot of time and money to find out precisely how dismal it is doesn't seem very wise. That time and money might be better spent understanding what a good decision making process and a meaningful informed consent document look like. This, of course will take more time and money, but perhaps a group like PCORI could be involved (in the same way that they are funding multi-faceted research to better understand what a good “transition in care” from the hospital should look like).</p> <ol style="list-style-type: none"> <li>2. As referenced above, I also have concerns about the very narrow focus of the measures – on document quality. An informed consent document ideally should be the end of a meaningful process that encompasses real shared decision making – a much more robust set of steps that involve understanding of the preferences of a patient, the weighing of alternatives, and a considered decision that is ultimately documented in an informed consent document. I'm not sure your measure specs/abstraction tool will capture any of this?</li> <li>3. How would the proposed measures deal with issues of patients who don't speak English/speak limited English, have Alzheimers/other cognitive deficits or have other limitations.</li> <li>4. I also think that somewhere in the informed consent process and documentation should be an understanding and consent regarding WHO is going to be doing the procedure. Much of the focus in this measure is on documenting information related to the procedure itself. There is a growing awareness that many people are involved in surgery – sometimes residents/other trainees or other surgeons. The patient and their family should have a good understanding through a informed consent process and document of WHO is going to be doing the procedure that they have agreed to. They should also have access to information about the backgrounds and experience of their surgical team – ideally not minutes before the procedure as was noted in this recent JAMA article about a woman physician's</li> </ol>			

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
	<p>experience during a procedure:  <a href="http://jama.jamanetwork.com/article.aspx?articleID=2540406">http://jama.jamanetwork.com/article.aspx?articleID=2540406</a>.</p> <p>Thank you for the opportunity to comment on these measures.</p>			
8/15/2016	<p>I applaud that you are developing a quality measure for informed consent. However in its current form your tool does not include a patient-centered approach. In order to be patient-centered there should be items that show shared decision making did occur.</p> <p>I suggest you include items that describe</p> <ul style="list-style-type: none"> <li>• whether decision aid (either written, electronic, audiovisual, or web-based tool formats) were used including all options as per current guidelines,</li> <li>• who will perform the procedure (names of healthcare providers),</li> <li>• the form was offered at least 24 hours before or if not possible the reason why.</li> </ul> <p>Thanks for this opportunity to comment on this important work.</p>	<p>Marianne Baernholdt, PhD, MPH, RN, FAAN, Director Langston Center for Quality, Safety, and Innovation; Nursing Alumni Endowed Distinguished Professor, School of Nursing, Virginia Commonwealth University</p>	Individual	See Pages 3, 8, 10, 11, and 13
8/17/2016	<p>The Federation of American Hospitals (FAH) appreciates the opportunity to submit comments on the draft CMS Quality of Informed Consent Documents measure. FAH recognizes the need to ensure that the informed consent process is comprehensive and that patients fully understand the procedure, associated risks, and benefits prior to elective procedures. We strongly disagree that a measure focused solely on the quality of the documentation of an informed consent process will address these questions. The information provided by the developer on the evidence and opportunity for improvement is limited. We believe that CMS should invest time and resources on developing measures that focus on shared decision making and appropriateness of the procedure, particularly prior to when a patient arrives at the hospital for an elective procedure. Any PRO measure should be derived directly from the patient's voice and not by assessing the adequacy of documentation. Investing in the development and implementation of a measure that examines merely the quality of <u>documentation</u> does not provide any substantive value when addressing the quality of care provided to patients.</p>	<p>Jayne Chambers, Senior Vice President Quality, Federation of American Hospitals</p>	Hospital Association	See Pages 3-5
8/17/2016	<p>As a cardiologist and bioethicist, I have personal familiarity with both the conduct of informed consent processes for procedures and scholarship related to informed consent. As a member of the Technical Expert Panel for this project, I am supportive</p>	<p>Neal Dickert Jr, MD, PhD, Assistant Professor of Medicine,</p>	Individual	See Pages 3, 6-8, 10, 11, and 14

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
	<p>of the goals of this project and appreciate the work that has gone into trying to develop a rigorous and meaningful set of metrics by which consent practices can be evaluated. I have several comments related to the current draft.</p> <p>- I have some concern regarding the extent to which the requirement for exposure to the consent form more than 24 hours prior to the procedure is indeed applicable to all elective procedures (applicability is laid out as one of the principles for inclusion in the abstraction tool). For elective procedures for which a separate preoperative visit or detailed conversation is not routine, it is not clear to me that an expectation of a patient signing a consent form more than 24 hours before the procedure is appropriate. And if it is not appropriate (or a reasonable norm) to expect a signature more than 24 hours in advance because a formal interaction with a clinician has not occurred, it seems odd to ask a patient to document that they are opting out of doing so (note that it is ambiguous in the document whether it is opting out of signing or of receiving that counts). This is particularly an issue in the context of more minor procedures (cardiology examples include stress testing, imaging procedures involving contrast, and maybe transesophageal echocardiography, etc.), but these procedures do represent a relevant and important group.</p> <p>-Related to the above concern about variability in appropriateness of the timing criterion, it seems most appropriate to more clearly restrict the cohort of procedures to which this criterion is applied to those for which some form of pre-procedural contact is the norm.</p> <p>-Also related to the timing criterion, there is little evidence to support the role of advance signing or distribution in improving informed consent. The intuitive appeal of this approach is understandable, and it has become the norm in some cases. However, the impact of distributing a consent form in advance, particularly when a dedicated preprocedure visit is not the norm, should be studied more rigorously before being turned into a metric on which people are judged. This problem is magnified by the fact that this criterion is weighted very heavily (5 points out of 20). As proposed above, the most practical approach to this problem would seem to be to apply this criterion only to the set of procedures for which a preprocedure visit is known to be standard practice.</p> <p>-It is not clear that the process of validity testing as described adequately</p>	<p>Department of Medicine, Division of Cardiology, Emory University</p>		

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	<p>incorporates expert assessment. It seems highly possible that some elements could be considered complete by raters but highly inaccurate.</p> <p>-The purpose of the procedure and alternatives may vary appreciably across the appropriate patient populations for some tests. For example, a colonoscopy could be performed for workup of bleeding or for cancer screening. Both the alternatives and purpose differ for these indications. I suspect that this issue is one of the reasons why these elements often wind up being incomplete in forms (that is, they are hard to standardize). It would be problematic if this metric winds up encouraging more boilerplate language that satisfies raters but is not meaningfully informative to patients.</p> <p>These comments are submitted by me alone and are not on behalf of any organization or institution.</p>			
8/17/2016	<p>On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Yale New Haven Health Services Corporation’s Center for Outcomes Research and Evaluation (CORE) <i>Measure of Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures</i>. The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. The ACS believes informed consent serves as a communication tool for ensuring that patients understand the realities and ramifications of treatment, while also helping to reduce medical errors by outlining the details of scheduled procedures. ACS believes that obtaining informed consent is a critical step in the delivery of patient-centered care.</p> <p>The Centers for Medicare &amp; Medicaid Services (CMS) has contracted Yale CORE to develop a measure of informed consent document quality in order to “illuminate hospital-level quality, and to increase attention to informed consent processes in order to better support patients’ decisional needs, autonomy, and respect.” As stated in the draft report, the goal of this measure is to support national strategies to promote patient-centered decision making. Yale CORE notes that too often informed consent documents lack basic components such as information describing the procedure, associated risks and benefits, and alternative treatment options. In evaluating hospitals’ informed consent document quality, Yale CORE and CMS seek to increase the attention and effort that hospitals dedicate to providing high-quality</p>	<p>David B. Hoyt, MD, FACS, Executive Director, American College of Surgeons (ACS);  Jill Sage, MPH, Quality Affairs Manager, ACS Division of Advocacy and Health Policy</p>	Medical and Surgical Society	See Pages 3-8, 10, 11, and 16

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
	<p>informed consent, thereby supporting patient autonomy.</p> <p>ACS commends CMS and Yale CORE on the goal of this measure and notes that that obtaining informed consent is sometimes viewed as a document signing event, in particular when the signature form is either highly generic or simple fill-in-the-blank forms that either lack specific details or are at a level beyond the understanding of the average patient and their family. We have reviewed the Draft Measure Methodology Report and have the following recommendations and comments:</p> <p><b>1. Inclusion of the ACS Surgical Risk Calculator</b>  In order to facilitate the informed consent discussion and to enable patient-centered decision making, ACS developed the ACS National Surgical Quality Improvement Program (NSQIP) Surgical Risk Calculator. The ACS Surgical Risk Calculator is a patient-specific decision-support tool based on reliable multi-institutional clinical data, which can be used to estimate the patient’s risk for a specific operation (the calculator includes data on most operations). For more information on the ACS Risk Calculator, please visit <a href="http://riskcalculator.facs.org/RiskCalculator/">http://riskcalculator.facs.org/RiskCalculator/</a>.</p> <p><b>2. Alignment with the ACS Statement on Principles on the topic of Informed Consent</b>  Because the surgeon is responsible for obtaining informed consent, we strongly encourage Yale CORE to consider these principles in the development of the informed consent document quality measure to ensure that the measure aligns with the ACS principles:</p> <p><i>Informed consent is more than a legal requirement. It is a standard of ethical surgical practice that enhances the surgeon/patient relationship and that may improve the patient's care and the treatment outcome. Surgeons must fully inform every patient about his or her illness and the proposed treatment. The information must be presented fairly, clearly, accurately, and compassionately. The surgeon should listen carefully to understand the patient's feelings and wishes and should answer all questions as accurately as possible. The informed consent discussion conducted by the surgeon should include:</i></p> <ol style="list-style-type: none"> <li><i>1. The nature of the illness and the natural consequences of no treatment.</i></li> </ol>			

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
	<ol style="list-style-type: none"> <li>2. <i>The nature of the proposed operation, including the estimated risks of mortality and morbidity.</i></li> <li>3. <i>The more common known complications, which should be described and discussed. The patient should understand the risks as well as the benefits of the proposed operation. The discussion should include a description of what to expect during the hospitalization and post hospital convalescence.</i></li> <li>4. <i>Alternative forms of treatment, including nonoperative techniques.</i></li> <li>5. <i>A discussion of the different types of qualified medical providers who will participate in their operation and their respective roles.</i></li> </ol> <p><i>The surgeon should not exaggerate the potential benefits of the proposed operation nor make promises or guarantees. For minors and incompetent adults, parents or legal guardians must participate in the informed consent discussion and provide the signature for elective operations. Any adequately informed, mentally competent adult patient can refuse any treatment including operation. When mentally incompetent patients or the parents (guardians) of minors refuse treatments jeopardizing the patient's best interest, the surgeon can request legal assistance.</i></p> <p><i>When patients agree to an operation conditionally or make demands that are unacceptable to the surgeon, the surgeon may elect to withdraw from the case.</i></p> <p><b>3. Measure at the Level of the Surgeon, Not the Hospital</b>  Informed consent is a critical aspect of a surgeon’s relationship with the patient and the surgeon is responsible for obtaining informed consent. Yet, the proposed methodology measures informed consent at level of the hospital. ACS believes that this is a missed opportunity to enhance the surgeon/patient relationship and promote patient-centered decision-making. The responsibility for informed consent should be measured by the party whom is responsible for working with the patient to ensure comprehensive informed consent.</p>			

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/ Action Take
	<p><b>4. The Measure Should Capture the Informed Consent Discussion, Not Simply the Timing of Signing the Legal Document</b></p> <p>As part of the Draft Measure Methodology Report, Yale CORE acknowledges that clinicians and patients have come to view the informed consent document as a transaction necessary for obtaining a signature of consent, rather than for information sharing or prompts for discussion. Yale CORE notes that these quality gaps are “conflicting with the ethical and legal principles of informed consent. They do not support patient autonomy and often undermine the decisional process of informed consent.”</p> <p>To address these gaps in quality, ACS believes that the measure should be inclusive of the <i>discussion</i> of informed consent—when the decision to operate is being made—not simply when the legal documents are signed. The proposed measure assumes that there is only one workflow for obtaining informed consent, when there are multiple workflows and scenarios. For example, the informed consent discussion often takes place during moments after the decision to operate, when the procedure is scheduled. Or, the surgeon and patient may have had the informed consent discussion a week prior to the procedure, and the office staff may have had the informed consent signature on file in the office. In fact, in addition to a signed legal document, some states or hospitals require a surgeon’s chart note covering the elements of informed consent. In this case, the legal document may be executed separately and reflect the patient’s consent as obtained by nursing or other ancillary staff. Patients and surgeons would have two separate opportunities to engage in an informed consent process. It is also common that a patient requires a procedure and the surgeon has an unexpected opening and can schedule the patient the following day. In conclusion, the proposed measure assumes incorrect timing for informed consent and does not recognize the diverse ways informed consent occurs.</p> <p><b>5. Streamline the Informed Consent Process with Interoperability</b></p> <p>ACS strongly encourages CMS to realize need for the creation of standards for informed consent to streamline the flow of data with electronic health records (EHRs) and other data sources. Much of the work outlined in the methodology document includes the abstraction of data by trained abstractors which introduces the possibility of bias and creates additional burden on the provider or the hospital/office staff. Instead of a specific tool for informed consent, ACS sees many opportunities to streamline this process with digital workflows using an application program interface (APIs) in an open platform around EHRs. For example, this process</p>			

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	<p>could be included in the toolkits identified as part of the Office of the National Coordinator for Health Information Technology (ONC) Patient Engagement Playbook and joined with the ACS Surgical Risk Calculator as a tool for a more comprehensive and complete informed consent discussion. For more information on the Patient Engagement Playbook visit <a href="https://www.healthit.gov/playbook/pe/">https://www.healthit.gov/playbook/pe/</a>.</p> <p><b>6. Simplify the Number of Elements in the Measure</b> The final taxonomy of the proposed measure includes three domains, 20 dimensions, and 53 elements. ACS believes that this is far too many elements. We strongly encourage further testing with patients in an effort to capture only the elements that are most important and understandable to the patient. We also note that if the informed consent process is automated, as suggested above, this will be less of an issue.</p> <p><b>7. Require Random Sampling to Reduce Bias</b> The proposed measure methodology allows for hospitals to select which procedures they would like to report. Allowing hospitals to select the sample to be reported will introduce bias, thereby compromising the validity and reliability of the measure.</p> <p>We appreciate the opportunity to comment on the proposed informed consent measure, as well as the chance to discuss the development of the measure with the Yale CORE staff during conference calls. ACS supports an informed consent measure that goes beyond the minimum standard for informed consent, and we look forward to continuing dialogue with Yale CORE and CMS on the important topic.</p>			
8/17/2016	<p>I appreciate the opportunity for comment on the reports, “Measure of Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures: Draft Measure Methodology Report for Public Comment” and the “Summary of Technical Expert Panel (TEP) Meetings as of March 30, 2016: Hospital-Level Measure of Informed Consent Document Quality Prior to Elective, Hospital-Based Procedures.” The attached file provides comments from the Veterans Health Administration, National Center for Ethics in Health Care.</p> <p>I greatly appreciate the desire of the Center for Medicare and Medicaid Services (CMS) to develop highly ethical, patient-centered informed consent requirements. Please let us know if the NCEHC can be of additional assistance.</p> <p><b>VHA National Center for Ethics in Health Care Comments</b></p>	<p>Lisa Soleymani Lehmann, MD, PhD; Executive Director, Department of Veterans Affairs: National Center for Ethics in Health Care (NCEHC)</p>	<p>Government organization</p>	<p>See Pages 3, 4, 10,11, and 14</p>

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	<p><b>August 16, 2016</b></p> <p>The Veterans Health Administration (VHA) is the nation’s largest health care provider with nearly 9,000,000 veterans enrolled in 2015 and over 3,400,000 written informed consent forms completed in 2015. The National Center for Ethics in Health Care (NCEHC) is the VHA program office responsible for maintaining strong ethics practices through informed consent policy and management of our electronic iMedConsent™ software, used to document signature informed consent. We have two associated policy documents: VHA Handbook 1004.50, iMedConsent™ (<a href="http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3064">http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3064</a>) and VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures (<a href="http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2055">http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2055</a>).</p> <p>The goal of measuring informed consent document quality is appropriate if it promotes patient-centered communication and voluntary and informed decision making about elective treatments and procedures. However, a focus on documentation can also have the unintended effect of incentivizing documentation compliance (teaching to the test) over strong ethical practice and communication processes that are tailored to the needs of individual patients. The positive or negative effects of using the abstraction tool may depend on how CMS communicates about and implements the tool and how the data collected is used.</p> <p>Our comments below indicate support for proposed measures that we believe will promote strong patient-centered practices and flag measures that we are concerned may have the paradoxical effect of increasing the attention and effort of health care providers and institutions on complying with the measure rather than actually promoting high-quality informed consent discussions. The proposed Abstraction Tool’s focus on form legibility, describing the treatment/procedure, identifying risks, benefits and alternatives are important issues in the informed consent process. The proposed Abstraction Tool has many positive attributes, but also creates issues that may negatively impact patient care and the informed consent process.</p> <p><b>Specific Comments:</b></p> <p><b>Abstraction Tool Items #1 &amp; 2.</b> The proposed abstraction tool places a significant weight on having the “Description of the Procedure” typed (10% of possible score). The requirement for a typed</p>			

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	<p>description of the treatment/procedure supports legibility. However, requiring 100% typed input is problematic if it doesn't account for electronic systems being down. We would ask CMS to consider reducing the weight of this score due to the fact that electronic systems will be down from time to time. The goal of a "typed" document is legibility. This should not count heavily against a facility if legible, handwritten input is provided during system outage periods.</p> <p><b>Abstraction Tool Items #5 &amp; 6.</b>  The VHA National Center for Ethics in Health Care agrees that a requirement to document procedure risks is necessary. The additional requirement to document quantitative and qualitative risks is a positive step forward, when risk data is available. However, without an addition to the abstraction tool that demonstrates that the informed consent discussion was tailored to the risks of the individual patient, or the preference of the patient to have those risks specified, this requirement may have the paradoxical effect of standardizing and homogenizing communication that should be tailored to the individual patient. The requirement for a single quantitative and a single qualitative risk could be easily met by addressing a single, recurring minor risks associated with the majority of procedures (e.g., the risk of infection is 1:2,000). This "administrative" requirement could be easily met without documenting information that is truly relevant to the individual patient's situation.</p> <p>We also suggest that qualitative and quantitative risk documentation carry the same weight.</p> <p><b>Abstraction Tool Items #8.</b>  The timing requirement for the patient signing the form requires a specific patient interaction at least one day prior to the procedure, or documentation that the patient opted out of receiving the consent form at least one day prior to the procedure.</p> <p>The VHA National Center for Ethics in Health Care does not support a "prior day" signature requirement, with an "opt-out" option. This may have an unintended consequence that leads to the development of business practices that make the signing of the form a purely administrative act, separated from the informed consent conversation between the provider and the patient. This standard could be satisfied by the patient signing the form at a pre-admission, administrative appointment, with</p>			

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	<p>no discussion with a provider or opportunity to ask questions before signing the consent form. This is ethically problematic. Its possibility is heightened by the lack of a requirement for the provider to sign the form, attesting to the fact of an informed consent discussion and the patient’s voicing consent after an opportunity to ask questions. Also, providing an option for the patient to “opt-out” of the prior day signature requirement may place the same unspoken, negative pressure on patients that is present when the consent form is routinely offered on the day of the procedure. An “opt-out” option may communicate to the patient that if they don’t accept it, their procedure will be postponed and they will have wasted their own preparation time and efforts, as well as placing costs and/or inconvenience on the staff and facility. If this is still accepted going forward as proposed, “opting out” would be given the same score as signing the form the day before, making it equally acceptable and incentivizing hospitals to inappropriately induce patients into checking an “opt-out” selection.</p> <p>Additionally, placing ¼ of the achievable score on this single issue of “timing” elevates it to a level of importance significantly above documenting the risks of the procedure and other elements that hold greater ethical weight.</p> <p>The VHA National Center for Ethics in Health Care suggests that future data extraction include other strong ethical practices in informed consent documentation, such as:</p> <ul style="list-style-type: none"> <li>• The name(s) of all the practitioner(s) immediately responsible for the performance of the procedure, and if applicable, the supervision of the treatment or procedure, such as the resident physician and the attending physician.</li> <li>• An attestation statement with a written or valid electronic signature of the practitioner obtaining consent, stating that: <ul style="list-style-type: none"> <li>○ Relevant aspects of the treatment or procedure have been discussed with the patient in language that the patient can understand; and that the patient indicated comprehension of the discussion.</li> <li>○ The patient had an opportunity to ask questions.</li> <li>○ The patient consented to the treatment or procedure.</li> </ul> </li> </ul>			

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8/17/2016	<p>Thank you for the opportunity to provide comments on the Informed Consent Document Quality measure. The Pacific Business Group on Health (PBGH) is a non-profit organization that leverages the strength of its 65 members—who collectively spend \$40 billion a year purchasing health care services for more than 10 million Americans—to drive improvements in quality and affordability across the U.S. health system.</p> <p>PBGH concurs with the CORE views on informed consent as a process in which patients decide whether to proceed with a procedure or intervention, and its relationship to patient autonomy. As noted in the Summary of TEP meetings, this process entails “bidirectional communication between the clinician and patient and, importantly, the exchange of written materials that describe the procedure, alternatives to the procedure, and the associated risks and benefits.” Furthermore, the Summary states that high-quality informed consent can uphold patient autonomy by:</p> <ul style="list-style-type: none"> <li>• Providing information to patients that is relevant, accurate, and understandable;</li> <li>• Providing opportunities for patients to consider their decisions in the context of their preferences, values, and goals; and</li> <li>• Supporting patients to choose what is best for them.</li> </ul> <p>PBGH offers these recommendations in the context of its experience building and administering one of the first and most comprehensive joint replacement data registries in the country. Founded in 2009 and now incorporated into the nationwide American Joint Replacement Registry, the California Joint Replacement Registry (CJRR) serves as an important public resource for comparative effectiveness research and evidence-based decision-making. CJRR is a “Level 3” registry that includes patient-reported outcome data as well as payer, provider, clinical, surgical, laboratory, pharmacy, and device information. The CJRR implementation was also accompanied by robust shared decision making that has been well documented. (Bozic KJ1, Chenok KE, Schindel J, et al. “Patient, surgeon, and healthcare purchaser views on the use of decision and communication aids in orthopaedic surgery: a mixed methods study,” BMC Health Serv Res. 2014 Aug 31;14:366. doi: 10.1186/1472-6963-14-366.)</p> <p>Based on this experience, PBGH and its members offer the following feedback:</p>	David Lansky, PhD; President and CEO; Pacific Business Group on Health	Quality improvement organization	See Pages 3-5, 13, and 16

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	<ul style="list-style-type: none"> <li>• Include the 3-question CollaboRATE measure of decision quality as part of the informed consent protocol. This would embed a set of well-tested and standardized questions on shared decision-making.</li> <li>• Support the goal of capturing structured data at the hospital level to facilitate benchmarking and comparison. Similarly, include documentation of the rendering provider NPI so that decision quality information can be aggregated for identification of feedback and quality improvement opportunities.</li> <li>• Initiate Patient-Reported Outcomes (PRO) data collection at the time of informed consent. One of the major challenges for PRO adoption is engaging patients and encouraging them to complete surveys, and encouraging clinicians to use the results of PRO responses as part of a shared decision-making or informed consent process. <ul style="list-style-type: none"> <li>○ We recommend aligning efforts with CMS innovation pilots and alternative payment models, such as the Comprehensive Care for Joint Replacement (CJR) bundled payment program. Building a repository of benchmark information on patient-reported outcome and functional status measures through established tools such as the hip disability and osteoarthritis outcome score (HOOS Jr.) and knee injury and osteoarthritis outcome score (KOOS Jr.), as well as general health status surveys, such as PROMIS 10, can inform the refinement and design of such pilots.</li> </ul> </li> </ul> <p>We also note that similar practices have been implemented. For example, Blue Shield of California has embedded CollaboRATE and PRO data collection as part of its authorization review process. This is an important demonstration of how such information can be integrated into routine workflows. In the long-term, PBGH believes that provider-level data collection is the optimal nexus for hospital and physician feedback and improvement.</p> <p>We are also cognizant of the length of the informed consent document. However, we believe that the mandatory collection of this document creates a more streamlined process for the patient insofar as it manages the issue of multiple touchpoints and surveys (with low to modest response rates at best) being requested of the patient. Furthermore, the integrated administration of PROs helps to address the issue of costs being a prohibitive barrier to data collection.</p>			

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	<p>PBGH has been a strong advocate for informed patient choices through shared decision-making and treatment decision support aids, as well as measures of patient-reported outcomes. Standardization of informed consent processes presents a unique opportunity to incorporate these concepts into the clinical workflow for elective procedures. Thank you again for the opportunity to provide feedback to the TEP on this important issue. We look forward to continuing to engage public and private purchasers in the CORE's activities.</p> <p>Please contact me should you require any additional information or clarification.</p>			
8/17/2016	<p>Submitted on behalf of myself:</p> <p>Yale CORE and the group developing the informed consent measure should be congratulated on excellent work. They have created a measure which will improve the quality of the informed consent document. This is to be commended and my surgical colleagues have been working on developing electronic consent documents in large part for risk reduction if there is a dispute regarding consent. My major concerns are whether this acknowledged first step will achieve the goals. Shared decision making is clearly a goal in many patients but many others desire to defer to the physician as the perfect agent. A large part of the conceptual framework assumes the goal of shared-decision making with regard to the patient preferences when an alternative goal is that patients were offered a choice of how they would like to obtain the information. Making legibility of equal value as stating the risk is a value judgement which may not be accurate. Also, the tool measures both quantitative and qualitative statements of risk. It is unclear if this is patient specific, surgeon specific, setting specific or an overall assessment of all three. If all of the consents are presented using the same data, then you are not achieving a patient-centered assessment of risk. For example, a very sick patient may have a very different risk than a healthy one. Therefore, a key element is a patient-specific assessment of risk as opposed to simply stating generic risk both quantitatively and qualitatively. Given that patients (and physicians) have poor numeracy understanding, it is unclear why the qualitative assessment of risk is valued lower than the quantitative.</p> <p>In an attempt to meet the measure, the "form" and the transactional nature may</p>	<p>Lee Fleisher, MD;  Robert D. Dripps  Professor and Chair of Anesthesiology and Critical Care;  Professor of Medicine  Perelman School of Medicine;  Senior Fellow, Leonard Davis Institute of Healthcare Economics,  University of Pennsylvania</p>	Individual	See Pages 3-5, 10, 11, 13, and 14

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	<p>obviate an important issue- the discussion in the room. The team also mentions the understanding of risk, which is not assessed in any manner.</p> <p>While I believe that the measure will improve the transactional consent form and could serve as a basis for the conversation, I think it is important to assess whether it will achieve a higher quality conversation that addresses the patient desires for information to make a decision- including the option of using the physician as a perfect agent.</p>			
8/18/2016	<p>Thank you for the opportunity to comment on the measure of Quality of Informed Consent Documents for hospital elective procedures. Probably the most important factor in providing truly patient-centered care in surgical procedures is rigorous informed consent interactions between surgeons and patients. Given that there is substantial variability among the hospitals tested in developing this measure -- with most informed consent documents not even meeting these minimal standards -- it is evident that some measure of these communication documents is warranted and needed. However, the subjective part of this process - it is all in the delivery, which is different with each provider and patient – creates an inherent challenge to such evaluations. A hospital could have all of the right tools but poor communication that fails to adequately informed the patient. Still, starting with the right tools is the first step. We recognized the attempt here to create an objective measure to use for comparison of hospitals but this limitation regarding delivery should be noted. This is important work but as proposed, this tool is missing some important basic details. We encourage the group to continue refining it.</p> <p>It also must be recognized that truly informing patients is most critical – but most unlikely – where it may conflict with a hospital’s or surgeon’s ability to conduct their business as they please. For example, a surgeon who uses an off-label device that he has modified in a way he believes is an improvement but that has not been tested in an evidence based manner might not be totally forthcoming to his patients about the safety record of the device. Hospitals using heating/cooling devices in operating rooms that have recently been connected with deadly infections in cardiac patients should inform their patients of this danger, but will they? For years, procedures were conducted using duodenoscopes, even though hospitals and surgeons knew or should have known that they were connected with the spread of infections. It wasn’t until these scopes were spreading deadly CRE superbugs that appropriate attention was given to the fact that the devices were not being thoroughly cleaned. Even after</p>	Lisa McGiffert, Consumers Union, Safe Patient Project	Patient/ Consumer Advocacy Organization	See Pages 3, 4, 6-8, 10, 11, 13, and 15

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	<p>problems with cleaning these devices were clear, the procedures continued and one wonders if those patients were informed about the risk. Where information can be clearly required, then, it could drive helpful changes in practice.</p> <p><b>General comments:</b></p> <ul style="list-style-type: none"> <li>• The missing link to this measure is the patient – did the patient understand? What was the patient’s assessment of the informed consent? Ideally, this measure would include several survey questions from patients following the informed consent exchange.</li> <li>• 4.2.1: “Allowing hospitals to select patient cases from the cohort list acknowledges that claims data are imperfect; for example, some patient encounters may not easily be identified in the medical record.” This could also allow hospitals to game the system – picking the patients who may have received the best informed consent. While I may not completely understand why this is in the methodology, it might be better to simply allow hospitals to throw out patients who were not correctly identified through the administrative data extraction. This allowance might also foil the process to ensure that a diversity of sampling of procedures will be submitted for review.</li> <li>• We support NOT risk adjusting this measure.</li> <li>• 5.3.2: Regarding the proposed hospital-level scoring approaches. Option 2 seems to be preferable because it will be less likely to mask the poor performers. Also, a stated strength of Option 1 is that it will be more sensitive to incremental improvements. We don't really want incremental improvements, we want hospitals to do informed consent correctly on all points in the measure, which frankly establish some fairly basic thresholds.</li> <li>• Patients should be offered information from studies, best practices and any existing guidelines relating to their procedure. The proposed measure doesn’t address provision of this critical information.</li> <li>• The proposed measure should add a score for advising the patient who will be involved in the surgical procedure and each person’s specific role. This is especially important in teaching hospitals where poorly supervised residents may be doing a procedure for the first time.</li> </ul>			

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	<ul style="list-style-type: none"> <li>While the report indicates that the Working Group consistently emphasized that the informed consent should “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)” it is unclear where this kind of information is to be covered. We may have missed it, but it is important to include this information in the scoring.</li> <li>It is unclear where informed consent regarding anesthesiology services that occur during surgery. Is the information to be completely separate? Requiring a meeting with an anesthesiologist to discuss the type of drugs to be used and expected reactions to the drugs and lingering effects of the drugs. Too often patients meet this physician in the OR and have no conversations about the drugs being used. Since this is a hospital measure, we recommend adding an item for all of these components being covered by the anesthesiologist involved. This was also mentioned in the report as an element consistently emphasized by the Working group.</li> <li>The issue of who delivers the informed consent should be addressed somewhere to ensure that the conversation is actually happening between the patient and the surgeon.</li> </ul> <p><b>Comments regarding Abstraction Tool Scoring and Instructions.</b>  These are comments regarding the specific components of the measure included in Table 5.1 and Figure D2:  <b>Description of procedure</b>  Item 1: Is language describing "WHAT is the procedure" (beyond the medical name) provided for the patient?</p> <ul style="list-style-type: none"> <li>Seems like a more important scoring point than whether the information is typed would be whether it is legible or understandable and to operationalize that more broadly than “is it typed.” For example, use of the plain language and use of graphics or pictures that would make the procedure clearer to the patient.</li> <li>Many of these procedures will include implants, such as knee and hip implants. If devices are involved, the description of “what” should include information about the type of device used (e.g. staples, surgical mesh) and for knee implants, the model number, company that makes the device, how long the device is expected to last and the material the device is made of</li> </ul>			

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	<p>should be included. The latter could be extremely important for patients allergic to certain materials. Patients generally have no idea that surgical mesh is being put into their bodies and the risk associated with these devices should also be included.</p> <ul style="list-style-type: none"> <li>• Similarly, any device used during the procedure, such as a morcellator, should be described.</li> </ul> <p>Item 2: Is a description of HOW the procedure will be performed provided for the patient?</p> <ul style="list-style-type: none"> <li>• The best informed consent can be enhanced with pictures. Use of pictures and videos should garner extra points as long as they meet the criteria (e.g. describe how the procedure will be done)</li> </ul> <p><b><u>Rationale for Procedure</u></b></p> <p>Item 3: Is the clinical rationale (condition-specific justification) for WHY the procedure will be performed provided?</p> <p><b><u>Patient oriented benefits</u></b></p> <p>Item 4: Is any patient-oriented benefit provided (intended impact on patient's health, longevity, and/or quality of life)?</p> <ul style="list-style-type: none"> <li>• We suggest changing this question to “Is relevant patient oriented benefit information provided?” <ul style="list-style-type: none"> <li>○ The measure appears to only require ONE (“any”) patient oriented benefit, which could lead to hospitals only including one, when many may exist, because that is all they must include to get a good score. This might create a low standard.</li> <li>○ We also suggest adding the concept that this information needs to be relevant to the specific patient – for example, information would be different for a 20 year old than an 80 year old; or for a diabetic patient v. non-diabetic.</li> </ul> </li> </ul> <p><b><u>Probability of procedure specific risks</u></b></p> <p>Item 5: Is a QUANTITATIVE probability provided for any procedure-specific risk?</p>			

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	<ul style="list-style-type: none"> <li>• This standard appears to only require ONE risk, which, in our opinion, is not a strong enough standard. We recommend removing the word “any.”</li> <li>• Risk discussions should include the specific risk of infection for the procedure being performed. Ideally risk of infection would also be tied to that surgeon. If the hospital is not tracking a surgeon's infection rate, shame on them. And this information should be shared with the patients. Just stating “there is a risk of infection” is not appropriate and I think would not pass according to the instruction manual for the measure.</li> <li>• Scoring should include an extra point for the use of graphics to explain these concepts that might be difficult for patients to understand.</li> <li>• Informed consent should always include a discussion is off-label use of devices is involved. In these cases, the specific risks associated with the off-label use should be explained - not the evidence connected to FDA approval or clearance of the device, but based on the evidence gathered on the off-label use.</li> <li>• Risk should be expressed in a way that is relevant to the patient. For example, what is he risk to 80 year olds? This is especially important for elder Medicare patients who are undergoing procedures without much information on success rate or estimates of survival relative to their age.</li> </ul> <p>Item 6: Is a QUALITATIVE probability provided for any procedure-specific risk?</p> <ul style="list-style-type: none"> <li>• Again, we recommend removing the word “any” from this component for the reasons described above.</li> </ul> <p><b><u>Alternatives to the Procedures:</u></b></p> <p>Item 7: Is any alternative provided for the patient?</p> <ul style="list-style-type: none"> <li>• Determining if this component is scored positively should also include discussion of what would happen if nothing is done. The Choosing Wisely initiative includes in its questions for patients to ask regarding surgery, “what happens if I do nothing?”</li> </ul> <p><b><u>Timing</u></b></p> <p>Item 8: [collection of date of consent and date of surgery]</p>			

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	<ul style="list-style-type: none"> <li>The Working Group emphasized the issue of timing – the patient needs sufficient time to digest the information to make an informed decision. We are aware that this is a significant problem, with many hospital patients getting this information the day of their procedure.</li> <li>We believe this standard of doing the informed consent within one day of the procedure is extremely weak, specially since this is scored with 5 points. One day prior is too close to the procedure for a patient to thoroughly digest the information and make a final decision. Most patients would be reluctant to cancel a procedure one day prior to the procedure, when the surgery is already scheduled and decided. Ideally, the patient would have this information at least one week before the procedure.</li> </ul>			
8/20/2016	<p>My name is John Spertus and I am a cardiologist and health services researcher who has been very interesting in developing the infrastructure to improve patient engagement in medical decision-making.</p> <ul style="list-style-type: none"> <li>I am very pleased to see CMS develop a structural measure for the quality of informed consents – a clear gap in current practice.</li> <li>I, personally, believe that such a regulatory demand is necessary, as hospitals do not have an incentive to improve the consent forms. For example, even the home institution from which this measure was developed has the capacity to use personalized informed consents in the conduct of PCI, but does not use them. This highlights the need for external forces to mandate the use of improved consent documents.</li> <li>In the Exploratory Study of Medical Records (2.1.3), I do not understand why only a single institution was used. Wouldn't it have been far more useful to examine a range of institutions, perhaps for the same procedure, to see the diversity of approaches to obtaining informed consent?</li> <li>I was a bit disappointed that the environmental scan did not identify some of the work that our group has conducted to demonstrate that an improved, personalized, lower-literacy consent supplemented with procedure specific information has been documented to improve patients' experiences with care. It would seem to me that these experiences could highlight the</li> </ul>	<p>John Spertus, MD, MPH, FACC, FAHA; Daniel Lauer/Missouri Endowed Chair and Professor University of Missouri – Kansas City; Clinical Director of Outcomes Research Saint Luke's Mid America Heart Institute</p>	Individual	See Pages 3, 5-7, and 15

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	<p>importance of this proposed measure. References showing improved patient experiences include the following:</p> <ul style="list-style-type: none"> <li>○ Spertus JA, Bach R, Bethea C, Chhatrwalla A, Curtis JP, Gialde E, Guerrero M, Gosch K, Jones PG, Kugelmass A, Leonard BM, McNulty EJ, Shelton M, Ting HH, Decker C: Improving the process of informed consent for percutaneous coronary intervention: Patient Outcomes from the Patient Risk Information Services Manager (ePRISM) study. Am Heart J. 2015; 169(2):234-241 e231. PMCID: 4315511</li> <li>○ Decker C, Arnold SV, Olabiyi O, Ahmad H, Gialde E, Luark J, Riggs L, Dejaynes T, Soto GE, Spertus JA. Implementing an innovative consent form: the PREDICT experience. Implement Sci. 2008;3:58. PMCID: 2621244.</li> <li>○ Arnold SV, Decker C, Ahmad H, Olabiyi O, Mundluru S, Reid KJ, Soto GE, Gansert S, Spertus JA. Converting the Informed Consent From a Perfunctory Process to an Evidence-Based Foundation for Patient Decision Making. Circ Cardiovasc Qual Outcomes. 2008;1(1):21-28.</li> </ul> <ul style="list-style-type: none"> <li>● Similarly, there is evidence that creating personalized consents can improve the safety and outcomes of treatment. Some articles documenting that include: <ul style="list-style-type: none"> <li>○ Rao SC, Chhatrwalla AK, Kennedy KF, Decker CJ, Gialde E, Spertus JA, Marso SP. Pre-procedural estimate of individualized bleeding risk impacts physicians' utilization of bivalirudin during percutaneous coronary intervention. J Am Coll Cardiol. 2013;61(18):1847-52</li> <li>○ Spertus JA, Decker C, Gialde E, Jones PG, McNulty EJ, Bach R, Chhatrwalla AK. Precision medicine to improve use of bleeding avoidance strategies and reduce bleeding in patients undergoing percutaneous coronary intervention: prospective cohort study before and after implementation of personalized bleeding risks. BMJ. 2015;350:h1302. PMCID: 4462518.</li> </ul> </li> </ul>			

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	<ul style="list-style-type: none"> <li>• Among the elements to comprise an informed consent document, the proponents have suggested that the costs of the procedure be disclosed. This has several critical problems, including...               <ul style="list-style-type: none"> <li>○ The costs are often not knowable. The variations in insurance types, supplemental insurance, copays, and whether or not an individual patient’s deductibles have been met makes this information impossible for the providers to share.</li> <li>○ Only the costs of the procedure, and not the alternatives (e.g. Not doing the procedure), can reasonably be shared.</li> <li>○ The costs over time are often offset by the benefits from the procedure in improving health or functioning.</li> <li>○ At the extreme, nothing is cheaper than dying immediately without any life support. Thus, cost minimization is not a clear goal, but conveying these nuances is very tough.</li> <li>○ Thus, despite the appeal to share with patients the costs of a procedure, I believe that this will be inaccurate and misleading and this element should be struck from the measure.</li> </ul> </li> <li>• A critical challenge in designing a consent form to meet the ideal metrics is its length. It is detrimental to patients and providers to have 20 page consent forms (as an example) because too much information can preclude the patient paying attention to any information. There is a robust literature on this point in the use of informed consent documents for clinical trials. Thus, I think that there needs to be a hierarchy, or that a ‘perfect score’ on the abstraction document could reflect excellence in several, but not all areas, with a focus on those areas deemed most important by the hospital (or CMS should prioritize the elements they articulated).</li> <li>• I agree that a structural measure like this should not be risk-adjusted (4.1)</li> <li>• It is not possible to comment on the inclusion criteria until more details are provided. I do think it is important to insure that if consents are sought for a limited number of conditions that all hospitals are asked to provide the same number of consents within each condition to insure fairness. For example, if a hospital has a very good consent form for PCI, but a generic</li> </ul>			

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	<p>one for surgery, selecting more PCI vs. CABG patients to score the consent could markedly alter their overall rating. Since there is no risk-adjustment, it does seem to me that within each procedure, a similar number of consents should be required from each center.</p> <ul style="list-style-type: none"> <li>• The weighting of items in Table 5.1 seems very arbitrary. In particular, I do not understand why 5 points was assigned to the consent being signed &gt;1 day prior to the procedure was decided upon. Often there is education provided prior to a procedure, but the consent form is signed just before the procedure because that is the most efficient process to insure that it is signed before treatment. If the consent was the ONLY means to communicate the reasons and risks of treatment, I would agree with aggressively weighting this item. However, since there are alternative ways to engage patients in SDM, I do not think this arbitrary assignment of 5 points is justifiable. Is there any data that patients in whom the consent is signed &gt;1d before the procedure have less decision conflict, more SDM or some other way of defining better quality consent??</li> <li>• In section 5.3.1, I would propose that the scores (assuming a fair collection of instruments across hospitals) be used, rather than the threshold percentage. Depending on the threshold, a well-written consent may be available for all patients that meets/exceeds the threshold but if it is not given prior to the procedure (the process part of this measure) then they will still score 100% for all of their forms. I think having a continuous score is the most accurate way to quantify the consents across sampled patients. You can then provide an interpretative framework for these scores. However, given the very poor performance of the 8 hospitals in your test set, it is unlikely that your choice makes much of a difference at this time. Once performance improves, I think the mean scores will be more useful.</li> <li>• It is not clear to me how the elements listed in Table F.1 relate to the dimension scores. However, I am troubled that there are a number of elements for which there is absolutely NO evidence that they are important to patients – thereby running the risk of introducing extraneous information that distracts, rather than supports, the goals of informed consents. Examples that concern me include:</li> </ul>			

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	<ul style="list-style-type: none"> <li>○ what the patient hopes to get out of the procedure, (not feasible to systematically integrate into consents.</li> <li>○ Outcomes associated (quantitative estimates) of alternatives. While possible, this is very hard to individualize</li> <li>○ Procedure volume by physician and hospital – I would like to see some evidence that patients would know how to interpret this and that it is important to them.</li> <li>○ Procedure success rates by physicians – same as above</li> <li>○ Physician (or hospital) specific complication rates – almost impossible to accurately estimate for patients of a given risk, as opposed to patients’ individual risks across ‘average’ physicians/hospitals, as estimated from risk models.</li> <li>○ Patient safety check list (all 4 items) is clearly important, but should not be part of the consent form, as opposed to a procedural checklist for safety</li> <li>○ In Additional Resources – it is not clear that much of these elements (specifically invitation to others to participate, additional medical specialists, phone numbers/referral to patient support groups) are appropriate for an informed consent document. Again, you can make the document too long to be usable or relevant (consider the disclosure statements by banks, credit cards or informed consents for RCTs, as examples)</li> <li>○ I don’t have a strong opinion, but I don’t know why it is relevant to separate the risks of anesthesia from the overall procedure.</li> <li>○ In Accessibility, noting in each consent that a patient was offered a braille version or an alternative language is only relevant for blind and non-English speaking patients. I do not think this should be calculated on a per-consent form basis, but perhaps at a hospital level, although I would completely omit this for practical reasons. There is already a compelling legal reason for hospitals to be sure that they have the means to elicit consent from all patients.</li> </ul>			

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8/22/2016	<p>I am writing to submit public comments for the “Measure of Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures.” My name is Brandon Wojcik and I am a general surgery resident at the Massachusetts General Hospital.</p> <p>I realize that the submission period closed on August 17<sup>th</sup>. I understand if they will not be considered. I delayed the submission as I recently submitted an editorial to the Annals of Surgery which discusses the issue of full disclosure of trainee involvement and proper documentation in the informed consent process. I was hoping to have a copy of the approved PDF to submit, however, this has not been sent to me yet and did not want to further delay. A summary of my thoughts are below. If you include my comments, I would be happy to submit the PDF of the editorial along with this once I receive the proof.</p> <p>The disclosure of trainee involvement in an operation during the informed consent process should be a quality metric or concept measure included in this project. This is an often undiscussed, but ethically imperative aspect of the informed consent process. Prior studies have found that surgeons often avoid disclosing the extent to which residents will participate in a given patient’s care for a variety of reasons, including fear of provoking anxiety on the part of the patient. Furthermore, patients may (and have a right to) decline the participation of trainees in their care. This is a reality which directly conflicts with our obligation as surgical educators to train the next generation of surgeons. However, studies have shown that patients are more willing to consent to procedures with trainees when they have a personal conversation about the topic with the attending. Moving forward, we must be transparent and clear to the patient in our disclosure of the trainee’s role in the operation. This conversation should be properly documented in the patient’s medical record with a statement regarding the exact role of the resident in the operative procedure and, if known pre-operatively, the name of the resident that will be assisting in the operation. This will accomplish three important goals, including demonstrating respect for patient autonomy, initiating a discussion about the appropriate degree of resident autonomy for that case, and strengthening her/his medicolegal position.</p> <p>References:  1. Nguyen TN, Silver D, Arthurs B. Consent to cataract surgery performed by residents. Can J Ophthalmol 2005; 40(1):34-7.</p>	Brandon Wojcik, MD, General Surgery Resident, Massachusetts General Hospital	Individual	See Page 13

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	<p>2. Counihan TC, Nye D, Wu JJ. Surgeons' Experiences With Patients' Concerns Regarding Trainees. J Surg Educ 2015; 72(5):974-8.</p> <p>3. Sharda RK, Sher JH, Chan BJ, et al. A comparison of techniques: informed consent for resident involvement in cataract surgery. Can J Ophthalmol 2012; 47(2):113-7.</p> <p>4. Council on E, Judicial Affairs of the American Medical A. Medical students' involvement in patient care. J Clin Ethics 2001; 12(2):111-5.</p>			