Measure of Informed Consent Document Quality Prior to Elective, Hospital-Performed Procedures

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Importance

- Informed consent is part of standard clinical practice for elective procedures, with ~11 million/year performed among Medicare beneficiaries.[1,2]
- Yet, informed consent practices often fail to achieve the goals of transparency, autonomy, safety, beneficence, and respect.
- Current regulations holding hospitals accountable for informed consent (CMS COP; the joint commission; state laws), while well-intended, fail to ensure patients receive reliable written information about the procedure.
- A measure of informed consent document quality aligns with national strategies to promote patient-centered decision making and was supported by a national panel of patients and patient advocates.

[1] 2013 Medicare FFS data, Medicare Provider Analysis and Review (MEDPAR) File Data; [2] 2012 Medicare FFS data, Chronic Conditions Data Warehouse (CCW)

Purpose of Measure

- This measure assesses the quality of informed consent documents, which are:
  - A critical component of the informed consent process, necessary though not sufficient for high-quality decision making,
  - Feasible to measure, with demonstrated gaps and variation in quality, and
  - Important to patients and viewed as an important first step for improving the decision-making process.
- Hospitals will be held accountable for ensuring that patients undergoing elective procedures have the information they need in a readable document and with time to consider their options.
- Patients and TEP agree that: (1) the measure is necessary, though not sufficient to achieve high-quality decision making, and (2) the measure is an important first step to support future measures of shared decision making.

Measure Overview

- This measure assesses the quality of informed consent documents given to FFS beneficiaries ≥ 18 years undergoing elective inpatient procedures for which informed consent is standard practice.
- A sample of informed consent documents, representative of a hospital's procedure mix, are extracted from qualifying patients' medical records and evaluated using a standard, validated Abstraction Tool.
- The Abstraction Tool can be completed in under 3-4 minutes.
- Quality scores for each informed consent document (derived using the Abstraction Tool) are aggregated to determine hospital-level performance on the measure.
- The measure does not require or use risk adjustment.
- Patients were engaged in and provided input on all aspects of measure development, along with a formal Technical Expert Panel and public comment.

Measure Specifications

Hospitals Included

- Non-federal short-term acute care hospitals, including critical access hospitals.

Measure Cohort

- FFS beneficiaries ≥ 18 years undergoing elective inpatient procedures for which informed consent is standard practice.

Inclusion Criteria

- Enrolled in Medicare fee-for-service (FFS) Part A during the index admission,
- Aged 18 or older, and
- Having a qualifying (potentially) elective procedure during the index admission:
  - Cardiothoracic
  - Ear/Nose/Throat
  - General Surgery
  - Neurosurgery
  - Obstetrics/gynecology
  - Ophthalmology
  - Orthopedic
  - Plastic Surgery
  - Urology
  - Vascular Surgery
- Planned Readmission algorithm was applied to identify “planned” or “elective” admissions with one of the above procedures.

Exclusion Criteria

- Informed consent documents written in a language other than English.
- Informed consent documents for patients who are not the primary FFS Medicare beneficiary, as indicated by their health insurance claim (HIC) number.

Measure Outcome

- The measure outcome assesses the quality of a sample of informed consent documents.
- Individual informed consent documents are evaluated and scored using the Abstraction Tool.
- The results are then combined to produce a hospital-level score.

Measure Outcome: Abstraction Tool

- The Abstraction Tool assesses the quality of each consent document based on whether it meets the following criteria:

ABSTRACTION TOOL ITEM	POINTS
1) Is language describing "WHAT is the procedure" (beyond the medical name) provided for the patient?	2
1t) If provided, is it typed?	1
2) Is a description of HOW the procedure will be performed provided for the patient?	2
2t) If provided, is it typed?	1
3) Is the clinical rationale for WHY the procedure will be performed provided?	2
4) Is any patient-oriented benefit provided? (e.g., intended impact on patient's health, longevity, quality of life)	2
5) Is a QUANTITATIVE probability provided for any procedure-specific risk?	2
6) Is a QUALITATIVE probability provided for any procedure-specific risk?	1
7) Is any alternative provided for the patient?	2
8) Was the informed consent document shared with the patient at least one day before date of procedure, if the patient did not opt out of signing at least one day in advance?	5
Total	20

Risk Adjustment

- This measure is not risk adjusted as patient case mix does not influence the quality of informed consent documents.

Measure Calculation

Measure Calculation

- The hospital-level measure result is calculated as the percent of a hospital's documents exceeding a quality threshold.
  - The quality threshold will be a minimally acceptable document score (for example, 10 out of the possible 20 points on the Abstraction Tool).
- The quality threshold score will be set following broader measure testing during measure reevaluation.
- Technical Expert Panel and patient input supported raising the quality threshold over time to ensure continued improvement.
- We envision that once this measure achieves its goal of improving informed consent documents, then it could be phased out and/or replaced by measure(s) of shared decision making.

Measure Results

Results in Developmental Dataset

- The proportion of documents meeting or surpassing three possible quality thresholds: 5, 10, and 15 points (out of 20 points total)

Proportion of documents scoring equal to or above threshold (%) (N= 100 documents per site)

Hospital Site #	1	2	3	4	5	6	7	8
Threshold of 5 points	62	66	77	86	65	55	60	58
Threshold of 10 points*	0	0	3	29	0	2	8	10
Threshold of 15 points	0	0	0	6	0	0	1	0

* Proposed reporting threshold

Results in Testing Dataset

- The proportion of documents meeting or surpassing three possible quality thresholds: 5, 10, and 15 points (out of 20 points total)

Proportion of documents scoring equal to or above threshold (%) (N= 100 documents per site)

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

*Proposed threshold for reporting

Item and Measure Result Reliability

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

The Spearman correlation between document scores was 0.92. The ICC was 0.92.

CORE randomly selected 10 informed consent documents from each hospital for two abstractors to review (total of 250 documents). Two experienced external abstractors re-abstracted a subset of previously abstracted documents from the testing sample; none of the documents had been previously abstracted by either of these two abstractors.

Feasibility Testing

- Testing from a total of 33 hospitals and 6 abstractors supports that hospital coders can be trained to evaluate documents using standard Abstraction Tool training materials.
- After training, hospital coders can abstract documents in approximately 3 minutes per document, on average.
- Hospitals participating in the testing found the work to be meaningful.

Measure Status

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- The measure is ready for implementation.
- The measure was reviewed by the Measures Application partnership in December 2016 and signaled in the Inpatient Quality Reporting (IQR) program notice of proposed rulemaking.[3]
- NQF review is anticipated for 2018, pending confirmation of the NQF calendar.

[3] 42 CFR 412,42 CFR 413https://www.regulations.gov/docket?D=CMS-2017-0055