Excerpts of Previous NQF Submission

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Measure Type: Process; Level of Analysis: Health Plan, Population: State; Setting of Care: Other; Data Source: Administrative claims, Patient Reported Data/Survey

NQF #2850 assesses whether caregivers of CMC report that their child's primary care provider created a shared care plan for the child. The Committee noted this measure has a strong evidence base, with multiple RCTs, cohort studies, case series studies, and 2 consensus statements all supporting shared care plans. There were some concerns shared care plans may not be updated frequently enough, but the developer explained it had assessed this and, while overall performance on having a shared care plan was poor, performance on updating existing care plans within the last year was good.

The Committee agreed that a gap in care coordination for CMC exists and that this is an important topic to measure, but there are limited data and therefore a lack of consensus on the size of the gap. The Committee again noted that caregiver surveys are expensive and time consuming. As a plan-level measure, however, Committee members judged the measure to be feasible. Ultimately, the Committee agreed that the measure met the NQF criteria and recommended #2850 for endorsement.

2851 Family Experiences with Coordination of Care (FECC) -17: Child has emergency care plan (Seattle Children's Research Institute): Not Recommended

Description: The Family Experiences with Coordination of Care (FECC) Survey was developed to gather information about the quality of care coordination being received by children with medical complexity (CMC) over the previous 12 months. The FECC Survey is completed by English- and Spanish-speaking caregivers of CMC aged 0-17 years with at least 4 medical visits in the previous year. CMC are children identified by the Pediatric Medical Complexity Algorithm (PMCA) as having complex, chronic disease; **Measure Type**: Process; **Level of Analysis**: Health Plan, Population: State; **Setting of Care**: Other; **Data Source**: Administrative claims, Patient Reported Data/Survey

NQF #2851 assesses whether caregivers of CMC report that their child's main provider created an emergency care plan for the child. The Committee noted having an emergency care plan is important, but may not be technically possible at this time given the limitations of data portability that often exist across providers and care settings. The Committee also noted the lack of empirical evidence to support the measure; the evidence provided was based on expert consensus statements from the American Academy of Pediatrics. Because #2851 did not pass the must-pass criterion of Evidence, it was not recommended.

Imaging

2820 Pediatric Computed Tomography Radiation Dose (University of California, San Francisco): Endorsed

Description: The measure requires hospitals and output facilities that conduct Computed Tomography (CT) examinations in children to: 1. Review their CT radiation dose metrics, 2. calculate the distribution of the results, and 3.compare their results to benchmarks. This would then imply a fourth step to investigate instances where results exceed a trigger value for underlying cause, such as issues with protocol, tech, equipment, patient, etc.; **Measure Type**: Intermediate Clinical Outcome; **Level of Analysis**: Facility, Integrated Delivery System; **Setting of Care**: Ambulatory Care: Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Ambulatory Care: Outpatient Rehabilitation, Ambulatory Care: Urgent Care, Hospital/Acute Care Facility, Imaging Facility; **Data Source**: Electronic

Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Imaging/Diagnostic Study, Electronic Clinical Data: Registry

This intermediate outcome measure, #2820, requires facilities to review their CT radiation dose metrics, calculate the distribution of the results, and compare their results to benchmarks. A previous version of this measure was submitted to NQF's Patient Safety Project in 2014, but was not recommended. The developer provided additional information to address the issues raised during that project and submitted the measure for review in this project. The developer reported that, at current rates, 1 in 3 children will have at least one CT scan before his/her 18th birthday, and most hospitals currently do not tailor CT scans to the size of their patients, meaning children frequently receive the same radiation dose as an adult.

The Committee agreed that #2820 should drive organizations to examine radiation doses for pediatric scans and would give facilities a framework for setting their dose levels. In addition, the Committee noted that dose level, in and of itself, is an important outcome to patients. The Committee had questions about the specifications and the process of collecting the data for this measure, all of which were adequately addressed by the developer. The developer explained that consecutive exams should be used, and that the measure does not include certain procedures (such as radiological oncology). The developer also noted that while there is variability in dose depending on clinical indications, this variability is dwarfed by the variability resulting from institutional preference. For example, for some clinical questions, one facility will use a single-phase setting while another will use a multiple-phase setting, which results in twice as much radiation exposure. Further, the developer noted that this measure only requires that a facility meet the average benchmark, not that every patient be at or below the benchmark. Based on the developer's responses, the Committee agreed that NQF's criteria of Reliability and Validity were met. Of note, although the developer indicated that the health plan is an appropriate level of analysis, the Committee stated that the measure was not feasible because of a lack of access to the necessary data. It also was noted that the developer did not provide testing at the plan level. The developer agreed to remove this level of analysis. With this modification, the Committee agreed that #2820 met the NQF criteria and recommended it for endorsement.

2802 Overuse of Imaging for the Evaluation of Children with Post-Traumatic Headache (Q-METRIC – The University of Michigan): Not Recommended

Description: Percentage of children, ages 2 through 17 years old, with post-traumatic headache who were evaluated in the emergency department (ED) within 24 hours after an injury, and imaging of the head (computed tomography [CT] or magnetic resonance imaging [MRI]) was obtained in the absence of documented neurologic signs or symptoms that suggest intracranial hemorrhage or basilar skull fracture; **Measure Type**: Process; **Level of Analysis**: Health Plan; **Setting of Care**: Hospital/Acute Care Facility; **Data Source**: Administrative claims, Electronic Clinical Data : Electronic Health Record, Paper Medical Records

This new process measure, #2802, focuses on overuse of imaging. Overall, the Committee was concerned that the developer had specified the patient population too narrowly. The Committee also raised other concerns, including: the level of analysis (health plan rather than hospital level); the exclusion of children without a documented neurological exam; the exclusion of children with suspected

7. Consensus Standards Approval Committee (CSAC) Vote (April 12, 2016): Y-16; N-0; A-0

• Decision: Approved for Endorsement

8. Board of Directors Vote (May 2, 2016)

• **Decision**: Ratified for Endorsement

9. Appeals

• No appeals were received.

2820 Pediatric Computed Tomography (CT) Radiation Dose

Submission | Specifications

Description: The measure requires hospitals and output facilities that conduct Computed Tomography (CT) examinations in children to: 1. Review their CT radiation dose metrics, 2. calculate the distribution of the results, and 3.compare their results to benchmarks. This would then imply a fourth step to investigate instances where results exceed a trigger value for underlying cause, such as issues with protocol, tech, equipment, patient, etc.

It is important to review doses of radiation used for CT, as the doses are far higher than conventional radiographs (x-rays), the doses are in the same range known to be carcinogenic (Pearce, Lancet, 2012; Ozasa, Radiation Research, 2012), and the higher the doses, the greater the risk of subsequent cancer (Miglioretti, JAMA Pediatrics, 2013) Thus the goal of the measure is to provide a framework where facilities can easily assess their doses, compare them to benchmarks, and take corrective action to lower their doses if they exceed threshold values, as per specifications in benchmarks.

The measure calls for assessment of doses for the most frequently conducted CT examination types, and compare these doses to published benchmarks. The measure calls for the assessment of radiation doses within four anatomic areas (CT's of the head, chest, abdomen/pelvis and combined chest/abdomen/pelvis.) The measure provides a simple framework for how facilities can assess their dose, compare their doses to published benchmarks (Smith-Bindman, Radiology, 2015) and identify opportunities to improve if their doses are higher than the benchmarks. For example, If a hospital finds their doses are higher than published benchmarks, they can review the processes and procedures they use for performance of CT in children and take corrective action, and follow published guidelines for how to lower doses (such as "child sizing" the doses, reducing multiple phase scans, and reducing scan lengths).

Published benchmarks for radiation dose in children exist (Smith-Bindman, Radiology, 2015) and additional benchmarks are under development and will be published within the year by us. (Kumar, 2015) Other groups have also published benchmarks (Goeske) or in the process of doing so.

Our work and that of others have shown that institutional review of dose metrics as outlined in this measure results in a significant lowering of average and outlier doses. (Demb, 2015; Greenwood, RadioGraphics, 2015; Miglioretti, JAMA Pediatrics, 2013; Keegan, JACR, 2104; Wilson, ARRS, 2015).

This measure is being proposed for diagnostic CT in children, but can also be used for CT in adults, and CT used in conjunction with radiation therapy for cancer. Whenever context the doses are used, the doses should be compared with appropriate benchmarks.

A similar measure (#0739) was previously endorsed by the NQF in 2011. The NQF did not provide ongoing endorsement when the measure was up for renewal in 2015, primarily because there was no evidence that assessing doses as called for in the measure would result in an improvement in outcomes (i.e. patient dose). Since that time, there has been additional research that has shown that assessing doses using the format outlined in the measure does indeed result in lower doses, and thus we are resubmitting a similar although updated measure.

Of note, the surrogate measure we are using for outcomes is radiation dose. The true outcome of interest is the number of cancers that result from imaging. Because of the lag time between exposure to radiation and cancer development (years to decades) it is not feasible to use cancer cases as the outcome of a quality improvement effort. Thus while there is ample evidence that radiation causes cancer (sited below), and evidenced that cancer risk is proportional to dose, there are no direct data that suggest that lowering doses lowers cancer risk. However, we have used mathematical modeling to try to understand the relationship between lowering doses and cancers and estimated that if the top quartile of doses were reduced in children (i.e. the very high doses are brought down the average doses), the number of cancer cases would be reduced by approximately 43%, the equivalent to preventing 4,350 cancer cases / year in the US among children (Miglioretti, JAMA Pediatrics 2013). Cited in this section:

Demb J, manuscript under preparation. CT Radiation Dose Standardization Across the University of

California Medical Centers Using Audits to Optimize Dose. 2015.

Following an in-person meeting regarding CT radiation dose, radiologists, technologists and medical physicists from University of California medical centers strategized how to best optimize dosing practices at their sites, which were then analyzed for effectiveness and success after implementation.

Greenwood T, Lopez-Costa R, Rhoades P, et al. CT Dose Optimization in Pediatric Radiology: A Multiyear Effort to Preserve the Benefits of Imaging While Reducing the Risks. RadioGraphics. Jan 2015;35(5):1539-1554

"This systematic approach involving education, streamlining access to magnetic resonance imaging and ultrasonography, auditing with comparison with benchmarks, applying modern CT technology, and revising CT protocols has led to a more than twofold reduction in CT radiation exposure between 2005 and 2012..." – Conclusion statement from Abstract

Keegan J, Miglioretti DL, Gould R, Donnelly LF, Wilson ND, Smith-Bindman R. Radiation Dose Metrics in CT: Assessing Dose Using the National Quality Forum CT Patient Safety Measure. Journal of the American College of Radiology: JACR; 11(3):309-315.

http://download.journals.elsevierhealth.com/pdfs/journals/1546-1440/PIIS1546144013006625.pdf. Mar 2014

Looking at dose metrics as per compliance with the previously endorsed #0739 NQF measure results in reasonably timed acquisition of CT doses, and seeing such doses resulted in 30-50% dose reduction.

Kumar K, manuscript under preparation. Radiation Dose Benchmarks in Children.

This paper will describe dose metrics among 29,000 children within age strata <1, 1-4 years, 5-9 years, 10-14 years, and 15-19 years. 2015.

Miglioretti D, Johnson E, Vanneman N, Smith-Bindman R, al e. Use of Computed Tomography and Associated Radiation Exposure and Leukemia Risk in Children and Young Adults across Seven Integrated Healthcare Systems from 1994 – 2010. JAMA Pediatrics Published online June 10, 2013 joli:101001/jamapediatrics2013311, 2013.

Radiation-induced cancers in children could be dramatically reduced if the highest quartile of CT radiation doses were lowered.

Miglioretti, YX Zhang, E Johnson, N Vanneman, R Smith-Bindman. Personalized Technologist Dose Audit Feedback for Reducing Patient Radiation Exposure from Computed Tomography. Journal of the American College of Radiology: JACR 2014.

"Personalized audit feedback and education can change technologists' attitudes about, and awareness of, radiation and can lower patient radiation exposure from CT imaging." – Conclusion statement from Abstract

Ozasa K, Shimizu Y, Suyama A, et al. Studies of the mortality of atomic bomb survivors, Report 14, 1950-2003: an overview of cancer and noncancer diseases. Radiation Research; 177(3):229-243. Mar 2012

Fourteenth follow-up report on the lifetime health effects from radiation on atomic bomb survivor showing that: 58% of the 86,611 LSS cohort members with DS02 dose estimates have died, 17% more cancer deaths especially among those under age 10 at exposure (58% more deaths).

Pearce MS, Salotti JA, Little MP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. Lancet;380(9840):499-505. Aug 4 2012

"Use of CT scans in children to deliver cumulative doses of about 50 mGy might almost triple the risk of leukaemia and doses of about 60 mGy might triple the risk of brain cancer... although clinical benefits should outweigh the small absolute risks, radiation doses from CT scans ought to be kept as low as possible" – Conclusion statement from Abstract

Smith-Bindman R, Moghadassi M, Wilson N, et al. Radiation Doses in Consecutive CT Examinations from Five University of California Centers. Radiology 2015:277: 134–141

"These summary dose data provide a starting point for institutional evaluation of CT radiation doses." – Conclusion statement from Abstract

Wilson N. CT Radiation Dose Standardization Across the Five University of California Medical Centers. ARRS: Annual Toronto Meeting presentation. April 19-24, 2015

Understanding the reasons for variation in commonly performed CT procedures, and figuring out how to standardize them.

Numerator Statement: Radiation Dose metrics among consecutive patients, who have undergone CT of the head, chest, abdomen/pelvis, or chest/abdomen/pelvis. The metrics are 1) mean dose as measured using DLP, CTDIvol, and SSDE: within age strata. And 2) the proportion of exams with doses greater than the 75th percentile of the benchmark you are comparing with for the same anatomic area strata (Kumar, 2015; Smith-Bindman, Radiology, 2015; Goske, Radiology, 2013)

The CTDIvol and DLP are directly reported by the scanner using an "industry wide" standardized dose report (DICOM Radiation Dose Structured Report). The data should be assembled for the entire CT examination. If there are several series, the CTDIvol values should be averaged, and the DLP values should be added.

SSDE can be calculated using any dose monitoring software product, or using published multiplier coefficients which are highly valid.

These different metrics are highly correlated, but nonetheless reveal important differences regarding radiology practice and performance and are thus complimentary. However, if a practice only assesses data from a single metric, there is substantial opportunity for data-driven improvement.

CTDIvol reflects the average dose per small scan length. Modern CT scanners directly generate this. DLP reflects the CTDIvol x scan length, and is directly generated by modern CT scanners.

SSDE is a modified measure of CTDIvol that takes into account the size of the patient scanned and is useful for scaling dose to patient size. Several current radiation tracking software tools directly report SSDE.

Cited in this section

Goske MJ, Strauss KJ, Coombs LP, et al. Diagnostic reference ranges for pediatric abdominal CT. Radiology. Jul 2013;268(1):208-218.

"Calculation of reference doses as a function of BW (body weight) for an individual practice provides a tool to help develop site-specific CT protocols that help manage pediatric patient radiation doses." – Conclusion statement from Abstract

Kumar K, manuscript under preparation. Radiation Dose Benchmarks in Children.

This paper will describe dose metrics among 29,000 children within age strata <1, 1-4 years, 5-9 years, 10-14 years, and 15-19 years. 2015.

Smith-Bindman R, Moghadassi M, Wilson N, et al. Radiation Doses in Consecutive CT Examinations from Five University of California Centers. Radiology 2015:277: 134–141

"These summary dose data provide a starting point for institutional evaluation of CT radiation doses." – Conclusion statement from Abstract

Smith-Bindman R, Miglioretti DL. CTDIvol, DLP, and Effective Dose are excellent measures for use in CT quality improvement. Radiology. Dec 2011;261(3):999; author reply 999-1000.

An explanation as to why these radiation dose metrics are useful in calculating a patient's absorbed doses.

Huda W, Ogden KM, Khorasani MR. Converting dose-length product to effective dose at CT. Radiology. Sep 2008;248(3):995-1003.

"This article describes a method of providing CT users with a practical and reliable estimate of adult patient EDs by using the DLP displayed on the CT console at the end of any given examination." – Conclusion statement from Abstract

Denominator Statement: Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis and chest/abdomen/pelvis. No examinations should be excluded

Exclusions: CT examinations conducted in anatomic areas not included above (such as CTs of the extremities or lumbar spine) or that combine several areas (head and chest) should not be included. In children, these four included categories will reflect approximately 80% of CT scans.

Examinations performed as part of diagnostic procedures – such as biopsy procedures – should not be included. CT examinations performed as part of surgical planning or radiation therapy should not be included.

Examinations that are considered "limited abdomen" or "limited pelvis" studies should be included in the abdomen and pelvis category. Any examinations that include any parts of the abdomen and or pelvis should count in the abdomen/pelvis category.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Integrated Delivery System

Setting of Care: Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Ambulatory Care : Outpatient Rehabilitation, Ambulatory Care : Urgent Care

Type of Measure: Intermediate Clinical Outcome

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Registry

Measure Steward: University of California, San Francisco

STEERING COMMITTEE MEETING [12/01/2015-12/02/2015]

1. Importance to Measure and Report: The measure meets the Importance criterion

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: H-7; M-16; L-1; I-2; 1b. Performance Gap: H-11; M-14; L-0; I-1

Rationale:

- The Committee agreed this is an intermediate outcome: while it is not possible to show a direct outcome on a particular patient, on a population level the general evidence linking radiation dose to cancer is strong.
- The Committee also noted patients care about radiation dose as an outcome on its own.
- The developer stated most hospitals do not currently tailor their scans to the age of their patients, so children receive the same doses as adults at non-pediatric hospitals—yet a lower dose in a child still produces the same quality of scan. The Committee questioned whether non-pediatric radiologists could properly read lower dose scans, which are "noisier," but radiologists on the Committee explained a lower dose for children would produce an image of the same quality that occurs for an adult at the higher dose. In other words, using the higher dose in children yields much clearer images for children than radiologists are used to seeing for adults.
- The submission materials noted an earlier version of this measure was not endorsed due to concerns that simply assessing doses was not enough to change them. The developer presented new data, however, demonstrating merely tracking doses alters behavior and lowers an institution's dose profile for children. According to the developer, dose metrics collected from 2010-2012 showed a 30-50% decrease in variability of doses after an earlier version of this measure was implemented. Five University of California hospitals reported 0-18% reduction after being given strategies to optimize CT doses. Doses have declined 10-30% across all published studies, with the greater reduction shown among sites with higher doses. Additionally, the Committee noted the gap between doses in county hospitals as compared to academic hospitals.
- The Committee agreed the new data demonstrate the measure should lead organizations to address the issue of high doses for children if their doses are higher than national benchmarks, and it should give facilities a framework for setting their dose levels. Committee members also noted the measure can be useful internally for a facility to examine its own dose profile over time.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability</u> <u>criterion</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity) 2a. Reliability: **H-5**; **M-17**; **L-1**; **I-3** 2b. Validity: **H-6**; **M-16**; **L-0**; **I-4** Rationale:

• The Committee raised a number of questions about the specifications and the process of collecting the data, all of which were adequately addressed. The developer explained

consecutive exams should be used, and the measure does not include certain procedures (such as radiological oncology). Further, the developer noted this measure only requires that facilities meet the average benchmarks, not that every patient be at or below the benchmark. It also was explained that while there is variability in dose depending on clinical indications, this variability dwarfs the variability from institutional preference. For example, in some situations 1 facility will use a single-phase setting while another will use a multiple-phase setting, which results in twice as much radiation exposure.

- The developer performed empirical testing at the data element level and the performance measure score at 7 integrated health systems and 5 hospitals, from 2012-2014. Overall, more than 115,000 scans were included.
- Reliability testing was done at the level of data elements using several metrics reflecting CT dose indices, including DLP, CTDIvol, and SSDE.
- DLP and CTDI are calculated automatically by all current CT scanners, without variability. Reliability of CT radiation dose metric abstraction (DLP and CTDIvol) was tested through both manual and automated data abstraction, both yielding identical results, perfect Kappa statistics.
- SSDE is a calculated variable that is automatically calculated by dose monitoring programs. Errors from manual calculation were not tested.
- The developer noted nearly 99% of facilities should be able to report on this measure automatically, since any scanner built in the last 10 years reports on the data needed.
- The Kappas for the reliability testing were high (greater than 95%), but on a limited number of sites.
- Empirical testing was performed at the performance measure score. The developer indicated a study was conducted comparing each of the dose metrics with measures of absorbed dose among a sample of 10,000 CT examinations showed a "high correlation," >90%.
- After the developer clarified the questions about the specifications and data collection, the Committee agreed the measure met the Reliability and Validity criteria.

3. Feasibility: H-9; M-12; L-3; I-2

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented) Rationale:

- Two of the specified metrics (CTDIvol and DLP) are generated as part of clinical CT examinations. Two additional metrics can be calculated from these 2 primary metrics, and these calculations are done within existing software products or can be done manually, or by using various additional approaches. Nearly all facilities (~99%) that perform CT examinations can collect all the measure elements (3 dose metrics: DLP, CTDI and SSDE). Facilities that do not automatically report can use a free software program to compile the data. The Committee agreed this measure is feasible.
- The Committee noted the measure submission states it can be analyzed at the health plan level, but testing data were not provided. Concern also was expressed that plans do not have access to this data and would have to go through providers or get direct access to EMRs. The developer stated testing has been completed at the HMO level, and that certain types of plans, such as those run by integrated health systems, can report this measure. The developer acknowledged other plans, such as commercial or Medicaid plans, may not be able to report the measure. After discussion, the developer agreed to remove the health plan level of analysis.

4. Usability and Use: H-10; M-14; L-1; I-1

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

- The Committee inquired about potential unintended consequences of some patients receiving repeat scans due to the dose being too low. The developer explained this should not be an ongoing problem because, if the dose is set too low and facilities start having to repeat most scans, they will raise the dose. The radiologist on the Committee agreed lowering the dose until it is too hard to read and then increasing it incrementally is a common approach to setting dosage. It was agreed the potential risk for an individual was far lower than the population benefit.
- The developer seeks to use the measure for public reporting through the Joint Commission and a University of California San Francisco patient safety project.

5. Related and Competing Measures

• No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-24; N-2

6. Public and Member Comment: January 14, 2016 - February 12, 2016

Comments received:

 This measure received comments from two organizations. One comment noted the importance of education and accountability for following Pediatric Emergency Care Applied Research Network (PECARN) rules; it also noted the importance of clear terms for the measure to assist in implementation. One commenter supported the Committee's recommendation for endorsement.

Developer response:

• The point made here is a valid and important next step. But first, the adoption of a measure that asks facilities for the standardized collection of data on pediatric CT doses must occur, to help lead to standardizing radiation doses. Physicians who send patients to a facility can then ask that the doses that are used fall within certain accepted standards.

Committee response:

• Thank you for your comment.

7. Consensus Standards Approval Committee (CSAC) Vote (April 12, 2016): Y-16; N-0; A-0

• **Decision**: Approved for Endorsement

8. Board of Directors Vote (May 2, 2016)

• Decision: Ratified for Endorsement

9. Appeals

• No appeals were received.

2842 Family Experiences with Coordination of Care (FECC)-1 Has Care Coordinator

Submission | Specifications

Description: The Family Experiences with Coordination of Care (FECC) Survey was developed to gather information about the quality of care coordination being received by children with medical complexity (CMC) over the previous 12 months. The FECC Survey is completed by English- and Spanish-speaking caregivers of CMC aged 0-17 years with at least 4 medical visits in the previous year, and it includes all of the information needed to score 20 separate and independent quality measures, a sub-set of 10 of which are included in this submitted measure set. CMC are identified from administrative data using the Pediatric Medical Complexity Algorithm (PMCA), which uses up to 3 years' worth of International Classification of Diseases—9th Revision (ICD-9) codes to classify a child's illness with regard to chronicity and complexity. CMC are children identified by the PMCA as having complex, chronic disease.

The full NQF submission includes a set of 10 of the FECC quality measures; this submission relates to FECC 1, described below. The short descriptions of each quality measure follows:

- FECC-1: Has care coordinator
- FECC-3: Care coordinator helped to obtain community services
- FECC-5: Care coordinator asked about concerns and health changes
- FECC-7: Care coordinator assisted with specialist service referrals
- FECC-8: Care coordinator was knowledgeable, supportive and advocated for child's needs
- FECC-9: Appropriate written visit summary content
- FECC-14: Health care provider communicated with school staff about child's condition
- FECC-15: Caregiver has access to medical interpreter when needed
- FECC-16: Child has shared care plan
- FECC-17: Child has emergency care plan

Each of the quality measures is scored on a 0-100 scale, with higher scores indicating better care. For dichotomous measures, a score of 100 indicates the child received the recommended care; a score of 0 indicates that they did not.

Numerator Statement:

FECC-1: Caregivers of CMC should report that their child has a designated care coordinator.

Denominator Statement: The eligible population of caregivers for the FECC Survey overall is composed of those who meet the following criteria:

1. Parents or legal guardians of children 0-17 years of age

2. Child classified as having a complex, chronic condition using the Pediatric Medical Complexity Algorithm (PMCA) (see Simon TD, Cawthon ML et al. 2014)

3. Child had at least 4 visits to a healthcare provider over the previous year

While some of the FECC measures only apply to a subset of the overall eligible population for the survey (e.g., measures related to the quality of care coordination services provided are only scored for those

adolescent, the CG CAHPS survey is intended to be completed by parents of an adolescent as opposed to the adolescents themselves. However, both surveys target the outpatient care setting experience. The ADAPT survey complements the CG CAHPS survey well and has the potential to be administered concurrently, with both surveys mailed to the patient residence so that parents can complete the CG CAHPS survey and adolescents can complete the ADAPT survey.

5b.1 If competing, why superior or rationale for additive value:

2820 Pediatric Computed Tomography (CT) Radiation Dose

STATUS

Endorsed

STEWARD

University of California, San Francisco

DESCRIPTION

The measure requires hospitals and output facilities that conduct Computed Tomography (CT) examinations in children to: 1. Review their CT radiation dose metrics, 2. calculate the distribution of the results, and 3.compare their results to benchmarks. This would then imply a fourth step to investigate instances where results exceed a trigger value for underlying cause, such as issues with protocol, tech, equipment, patient, etc.

It is important to review doses of radiation used for CT, as the doses are far higher than conventional radiographs (x-rays), the doses are in the same range known to be carcinogenic (Pearce, Lancet, 2012; Ozasa, Radiation Research, 2012), and the higher the doses, the greater the risk of subsequent cancer (Miglioretti, JAMA Pediatrics, 2013) Thus the goal of the measure is to provide a framework where facilities can easily assess their doses, compare them to benchmarks, and take corrective action to lower their doses if they exceed threshold values, as per specifications in benchmarks.

The measure calls for assessment of doses for the most frequently conducted CT examination types, and compare these doses to published benchmarks. The measure calls for the assessment of radiation doses within four anatomic areas (CT's of the head, chest, abdomen/pelvis and combined chest/abdomen/pelvis.) The measure provides a simple framework for how facilities can assess their dose, compare their doses to published benchmarks (Smith-Bindman, Radiology, 2015) and identify opportunities to improve if their doses are higher than the benchmarks. For example, If a hospital finds their doses are higher than published benchmarks, they can review the processes and procedures they use for performance of CT in children and take corrective action, and follow published guidelines for how to lower doses (such as "child sizing" the doses, reducing multiple phase scans, and reducing scan lengths).

Published benchmarks for radiation dose in children exist (Smith-Bindman, Radiology, 2015) and additional benchmarks are under development and will be published within the year by us. (Kumar, 2015) Other groups have also published benchmarks (Goeske) or in the process of doing so.

Our work and that of others have shown that institutional review of dose metrics as outlined in this measure results in a significant lowering of average and outlier doses. (Demb, 2015;

Greenwood, RadioGraphics, 2015; Miglioretti, JAMA Pediatrics, 2013; Keegan, JACR, 2104; Wilson, ARRS, 2015).

This measure is being proposed for diagnostic CT in children, but can also be used for CT in adults, and CT used in conjunction with radiation therapy for cancer. Whenever context the doses are used, the doses should be compared with appropriate benchmarks.

A similar measure (#0739) was previously endorsed by the NQF in 2011. The NQF did not provide ongoing endorsement when the measure was up for renewal in 2015, primarily because there was no evidence that assessing doses as called for in the measure would result in an improvement in outcomes (i.e. patient dose). Since that time, there has been additional research that has shown that assessing doses using the format outlined in the measure does indeed result in lower doses, and thus we are re-submitting a similar although updated measure.

Of note, the surrogate measure we are using for outcomes is radiation dose. The true outcome of interest is the number of cancers that result from imaging. Because of the lag time between exposure to radiation and cancer development (years to decades) it is not feasible to use cancer cases as the outcome of a quality improvement effort. Thus while there is ample evidence that radiation causes cancer (sited below), and evidenced that cancer risk is proportional to dose, there are no direct data that suggest that lowering doses lowers cancer risk. However, we have used mathematical modeling to try to understand the relationship between lowering doses and cancers and estimated that if the top quartile of doses were reduced in children (i.e. the very high doses are brought down the average doses), the number of cancer cases would be reduced by approximately 43%, the equivalent to preventing 4,350 cancer cases / year in the US among children (Miglioretti, JAMA Pediatrics 2013).

Cited in this section:

Demb J, manuscript under preparation. CT Radiation Dose Standardization Across the University of California Medical Centers Using Audits to Optimize Dose. 2015.

Following an in-person meeting regarding CT radiation dose, radiologists, technologists and medical physicists from University of California medical centers strategized how to best optimize dosing practices at their sites, which were then analyzed for effectiveness and success after implementation.

Greenwood T, Lopez-Costa R, Rhoades P, et al. CT Dose Optimization in Pediatric Radiology: A Multiyear Effort to Preserve the Benefits of Imaging While Reducing the Risks. RadioGraphics. Jan 2015;35(5):1539-1554

"This systematic approach involving education, streamlining access to magnetic resonance imaging and ultrasonography, auditing with comparison with benchmarks, applying modern CT technology, and revising CT protocols has led to a more than twofold reduction in CT radiation exposure between 2005 and 2012..." – Conclusion statement from Abstract

Keegan J, Miglioretti DL, Gould R, Donnelly LF, Wilson ND, Smith-Bindman R. Radiation Dose Metrics in CT: Assessing Dose Using the National Quality Forum CT Patient Safety Measure. Journal of the American College of Radiology: JACR; 11(3):309-315.

http://download.journals.elsevierhealth.com/pdfs/journals/1546-1440/PIIS1546144013006625.pdf. Mar 2014

Looking at dose metrics as per compliance with the previously endorsed #0739 NQF measure results in reasonably timed acquisition of CT doses, and seeing such doses resulted in 30-50% dose reduction.

Kumar K, manuscript under preparation. Radiation Dose Benchmarks in Children.

This paper will describe dose metrics among 29,000 children within age strata <1, 1-4 years, 5-9 years, 10-14 years, and 15-19 years. 2015.

Miglioretti D, Johnson E, Vanneman N, Smith-Bindman R, al e. Use of Computed Tomography and Associated Radiation Exposure and Leukemia Risk in Children and Young Adults across Seven Integrated Healthcare Systems from 1994 – 2010. JAMA Pediatrics Published online June 10, 2013 joli:101001/jamapediatrics2013311, 2013.

Radiation-induced cancers in children could be dramatically reduced if the highest quartile of CT radiation doses were lowered.

Miglioretti, YX Zhang, E Johnson, N Vanneman, R Smith-Bindman. Personalized Technologist Dose Audit Feedback for Reducing Patient Radiation Exposure from Computed Tomography. Journal of the American College of Radiology: JACR 2014.

"Personalized audit feedback and education can change technologists' attitudes about, and awareness of, radiation and can lower patient radiation exposure from CT imaging." – Conclusion statement from Abstract

Ozasa K, Shimizu Y, Suyama A, et al. Studies of the mortality of atomic bomb survivors, Report 14, 1950-2003: an overview of cancer and noncancer diseases. Radiation Research; 177(3):229-243. Mar 2012

Fourteenth follow-up report on the lifetime health effects from radiation on atomic bomb survivor showing that: 58% of the 86,611 LSS cohort members with DS02 dose estimates have died, 17% more cancer deaths especially among those under age 10 at exposure (58% more deaths).

Pearce MS, Salotti JA, Little MP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. Lancet;380(9840):499-505. Aug 4 2012

"Use of CT scans in children to deliver cumulative doses of about 50 mGy might almost triple the risk of leukaemia and doses of about 60 mGy might triple the risk of brain cancer... although clinical benefits should outweigh the small absolute risks, radiation doses from CT scans ought to be kept as low as possible" – Conclusion statement from Abstract

Smith-Bindman R, Moghadassi M, Wilson N, et al. Radiation Doses in Consecutive CT Examinations from Five University of California Centers. Radiology 2015:277: 134–141

"These summary dose data provide a starting point for institutional evaluation of CT radiation doses." – Conclusion statement from Abstract

Wilson N. CT Radiation Dose Standardization Across the Five University of California Medical Centers. ARRS: Annual Toronto Meeting presentation. April 19-24, 2015

Understanding the reasons for variation in commonly performed CT procedures, and figuring out how to standardize them.

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Intermediate Clinical Outcome

DATA SOURCE

Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Registry The data sources will include electronic CT images [captured from the CT console at the time of scanning or harvested from

the PACS (Picture Archiving Communication System) - the computerized systems for reviewing and storing imaging data], Radiology Information System, EPIC, printed CT images, or information stored in the medical record. Numerous other software products are now available for capturing these data (Bayer, GE, etc.) and several free ware programs are also available. Of note, the 2012 California law now requires the reporting of several of the dose metrics outlined in this measure in the patient medical record, and as a results, many software companies have provided techniques for collating these data.

No data collection instrument provided No data dictionary

LEVEL

Facility, Integrated Delivery System

SETTING

Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility, Ambulatory Care : Outpatient Rehabilitation, Ambulatory Care : Urgent Care

NUMERATOR STATEMENT

Radiation Dose metrics among consecutive patients, who have undergone CT of the head, chest, abdomen/pelvis, or chest/abdomen/pelvis. The metrics are 1) mean dose as measured using DLP, CTDIvol, and SSDE: within age strata. And 2) the proportion of exams with doses greater than the 75th percentile of the benchmark you are comparing with for the same anatomic area strata (Kumar, 2015; Smith-Bindman, Radiology, 2015; Goske, Radiology, 2013)

The CTDIvol and DLP are directly reported by the scanner using an "industry wide" standardized dose report (DICOM Radiation Dose Structured Report). The data should be assembled for the entire CT examination. If there are several series, the CTDIvol values should be averaged, and the DLP values should be added.

SSDE can be calculated using any dose monitoring software product, or using published multiplier coefficients which are highly valid.

These different metrics are highly correlated, but nonetheless reveal important differences regarding radiology practice and performance and are thus complimentary. However, if a practice only assesses data from a single metric, there is substantial opportunity for data-driven improvement.

CTDIvol reflects the average dose per small scan length. Modern CT scanners directly generate this.

DLP reflects the CTDIvol x scan length, and is directly generated by modern CT scanners.

SSDE is a modified measure of CTDIvol that takes into account the size of the patient scanned and is useful for scaling dose to patient size. Several current radiation tracking software tools directly report SSDE.

Cited in this section

Goske MJ, Strauss KJ, Coombs LP, et al. Diagnostic reference ranges for pediatric abdominal CT. Radiology. Jul 2013;268(1):208-218.

"Calculation of reference doses as a function of BW (body weight) for an individual practice provides a tool to help develop site-specific CT protocols that help manage pediatric patient radiation doses." – Conclusion statement from Abstract

Kumar K, manuscript under preparation. Radiation Dose Benchmarks in Children.

This paper will describe dose metrics among 29,000 children within age strata <1, 1-4 years, 5-9 years, 10-14 years, and 15-19 years. 2015.

Smith-Bindman R, Moghadassi M, Wilson N, et al. Radiation Doses in Consecutive CT Examinations from Five University of California Centers. Radiology 2015:277: 134–141

"These summary dose data provide a starting point for institutional evaluation of CT radiation doses." – Conclusion statement from Abstract

Smith-Bindman R, Miglioretti DL. CTDIvol, DLP, and Effective Dose are excellent measures for use in CT quality improvement. Radiology. Dec 2011;261(3):999; author reply 999-1000.

An explanation as to why these radiation dose metrics are useful in calculating a patient's absorbed doses.

Huda W, Ogden KM, Khorasani MR. Converting dose-length product to effective dose at CT. Radiology. Sep 2008;248(3):995-1003.

"This article describes a method of providing CT users with a practical and reliable estimate of adult patient EDs by using the DLP displayed on the CT console at the end of any given examination." – Conclusion statement from Abstract

NUMERATOR DETAILS

Radiation dose distribution for the three metrics (CTDIvol, DLP, and SSDE) need to be recorded for a consecutive sample of CT examinations within anatomic area and age stratum. The mean, median, and the percent of examinations above the published 75% percentile needs to be generated.

These data can be extracted from the CT examinations in several ways. These numbers can written down directly from the CT scanner itself at the time of the examination; they can be written down from the PACS (computer terminal where images are reviewed and stored); or can be written down from the medical record if the facility stores these data as part of the medical record (all facilities in California due this based on statutory requirements.) The CT manufacturers have agreed (through MITA, Medical Imaging and Technology Alliance, the professional trade association of imaging manufacturers) to make these data electronically available through export from the CT machines to a local server), and these data can also be collected electronically. A growing number of companies are leveraging the standardized data format to systematically collect dose metrics directly from a facilities imaging infrastructure. This not only improves the accuracy of the data but also markedly reduces the costs of data collection. From the PACS, Radiology Information System, EPIC program if the data are exported there, or using any number of dose monitoring software programs allowing the collection and reporting of these dose data. The easiest way to collect these data is through one of the 6 or so commercial software programs developed for dose tracking, and several free-ware programs that enable directly extracting CT dose information from the PACS. We have published (Keegan, JACR 2014) several examples of techniques for dose extraction that can be completed even by a small facility.

The strata for this measure include:

Anatomic area strata: head, chest, abdomen/pelvis, Chest/abdomen/pelvis

Age strata: infant (<1); small child (1-5); medium child (>5 - 10); large child (>10-15) and adult (>15)

NOTE: The SSDE was developed as a metric for adjusting for size. However, it does not completely adjust for size and analysis within age strata are still needed among children to account for the different doses that are used and should be used for infants to obese children.

Cited in this section:

Keegan J, Miglioretti DL, Gould R, Donnelly LF, Wilson ND, Smith-Bindman R. Radiation Dose Metrics in CT: Assessing Dose Using the National Quality Forum CT Patient Safety Measure. Journal of the American College of Radiology: JACR; 11(3):309-315.

http://download.journals.elsevierhealth.com/pdfs/journals/1546-1440/PIIS1546144013006625.pdf. Mar 2014

Looking at dose metrics as per compliance with the previously endorsed #0739 NQF measure results in reasonably timed acquisition of CT doses, and seeing such doses resulted in 30-50% dose reduction.

DENOMINATOR STATEMENT

Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis and chest/abdomen/pelvis. No examinations should be excluded

DENOMINATOR DETAILS

Consecutive sample of CTs conducted in the head, chest, abdomen/pelvis, chest/abdomen/pelvis

EXCLUSIONS

CT examinations conducted in anatomic areas not included above (such as CTs of the extremities or lumbar spine) or that combine several areas (head and chest) should not be included. In children, these four included categories will reflect approximately 80% of CT scans.

Examinations performed as part of diagnostic procedures – such as biopsy procedures – should not be included. CT examinations performed as part of surgical planning or radiation therapy should not be included.

Examinations that are considered "limited abdomen" or "limited pelvis" studies should be included in the abdomen and pelvis category. Any examinations that include any parts of the abdomen and or pelvis should count in the abdomen/pelvis category.

EXCLUSION DETAILS

Most abdominal/pelvis CT scans in adult patients include scanning of the abdomen and pelvis as one contiguous area. If examinations are conducted limited to one region, these should also be included, as it is difficult/impossible to define what areas would be considered limited.

RISK ADJUSTMENT

No risk adjustment or risk stratification

N/A

Available in attached Excel or csv file at S.2b

STRATIFICATION

Anatomic area strata: head, chest, abdomen/pelvis, chest/abdomen/pelvis

These were chosen based on being the most common CT examination types conducted in the US, comprising >80% of all CT scans, and because dose varies by these groups.

Age strata: infant (<1); small child (1-5); medium child (>5 - 10); large child (>10-15) and adult (>15)

These patient age groups were chosen based on the variation of CT settings and resulting radiation dose based on patient size (and age is frequently used as a surrogate for size.) The ICRU (International Commission on Radiation Units and Measurements) uses these child size categories, they correspond to available phantoms, and they are the ones found to be most reliable

Geographic location where studies were done (zip code or state), to facilitate using the data to create geographically specific benchmarks

TYPE SCORE

ALGORITHM

N/A No diagram provided

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5.1 Identified measures:

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: N/A