NATIONAL QUALITY FORUM

Memo

TO: NQF Members

FR: NQF Staff

RE: Voting Draft Report: NQF-Endorsed Measures for Person- and Family-Centered Care Phase 2

DA: May 12, 2015

NQF Member Voting

Information for electronic voting has been sent to NQF Member organization primary contacts. Accompanying comments must be submitted via the online voting tool.

Please note that voting concludes on May 26, 2015 at 6:00 pm ET – no exceptions.

Background

Ensuring that every patient and family member is engaged as partners in their care is one of the core priorities of the National Quality Strategy (NQS). Despite recent and ongoing efforts to shift the healthcare paradigm from one in which patients are passive recipients of care to one in which they are empowered to actively participate in their own care, the current state of the system has a long way to go before this shift is realized. A recent definition of person- and family-centered care put forth by NQF emphasizes the inclusivity of recipients of healthcare services and their families and caregivers:

> Person- and family-centered care is an approach to the planning and delivery of care across settings and time that is centered on collaborative partnerships among individuals, their defined family, and providers of care. It supports health and well-being by being consistent with, respectful of, and responsive to an individual's priorities, goals, needs, and values.

Examples of person- and family-centered care include patient and family engagement in care, care based on patient needs and preferences, shared decision-making, and activation for self-care management. Assessments and treatment should acknowledge and address medical, behavioral, and social needs and should reflect the ability or willingness of the care recipient to be an active participant in making decisions and self-advocating. The process of goal setting should be a collaborative one driven by the patient in collaboration with a primary care provider and other team members.

Due to the large number of person and family centered care measures, maintenance review of endorsed measures and consideration of new measures is taking place over several phases in 2014 – 2015. The Phase 1 project focused on reviewing experience with care based measures. NQF endorsed one new measure and 10 measures undergoing maintenance review. The second phase of the project, detailed in the Phase 2 draft report, focused on reviewing 28 functional status measures. The 20 Standing Committee members recommended all 28 measures for endorsement. The Comment period for these measures was open from March 2, 2015 to March 31, 2015.

Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments prior to the evaluation of the measures via an online tool located on the project webpage. Third, NQF opens a 30-day comment period to both members and the public after measures have been evaluated by the full committee and once a report of the proceedings has been drafted.

Pre-evaluation comments

The pre-evaluation comment period was open from December 8-22, 2014 for all 28 measures under review. A total of six pre-evaluation comments were received. All of the comments pertained to the endorsement of measures derived from use of the Continuity Assessment Record and Evaluation (CARE) item set. The CARE tool is a CMS effort to promote standardized patient information used to examine the consistency of payment incentives for Medicare populations treated in various settings. The comments regarding measures 2612 and 2613 were mostly concerned about the measure descriptions and the use of terms, as well as comments regarding the CARE tool limitations of not assessing all components of self-care. One commenter provided comments on measures 2633, 2634, 2635, and 2636 indicating a series of concerns regarding the validity of measures, risk adjustment methodology, age of data, and burden and duplication of data collection and multiple assessments.

All of these pre-evaluation comments were provided to the Committee prior to their deliberations at the in-person meeting.

Post-evaluation comments

The Draft Report went out for Public and Member comment from March 2-31, 2015. During this commenting period, NQF received 94 comments from six member organizations and four members of the public:

Consumers – 0
Purchasers – 1
Providers – 1
Supplier and Industry – 0
Professional – 2
Health Plans – 2
QMRI – 0
Public & Community Health - 0

A complete table of comments submitted pre- and post-evaluation, along with the responses to each comment and the actions taken by the Standing Committee, is posted to the project page on the NQF website, along with the measure submission forms.

The Committee reviewed all comments received and considered the pre-meeting comments prior to making an endorsement recommendation. The Committee also reviewed and responded to all post-evaluation comments. Revisions to the draft report and the accompanying measure specifications are identified as red-lined changes. (Note: Typographical errors and grammatical changes have not been red-lined, to assist in reading.)

Comments and their Disposition

Six major themes were identified in the post-evaluation comments, as follows:

1. Requests for reconsideration/support for not recommended and consensus not reached measures
2. Measure gaps
3. Harmonization and creating composites
4. Concerns about unintended consequences and discrimination
5. Age exclusions
6. The IMPACT Act

Theme 1 – Requests for Reconsideration/Support for Not Recommended and Consensus Not Reached Measures

Many of the submitted comments requested reconsideration and recommendation of endorsement for the measures that were not recommended or where the committee did not achieve consensus for a recommendation. The rationale for support pointed to the major gaps in measures within a particular area or for measures that focus on patient centered outcomes. A sample of these comments is below; the full set is in the comment spreadsheet.

> **2653: Average change in functional status following total knee replacement surgery, MN Community Measurement:**
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> We strongly urge the Committee to reconsider and recommend this measure. The measure is deemed by consumers and purchasers to be important for assessing providers of knee replacement surgery. This is a high frequency and high cost procedure, and currently there is no information that enables patients to choose providers that can achieve better outcomes as assessed by patients themselves. Therefore, this measure is a high priority for these users.
>
> **2633: Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients, CMS**
>
> Support – While this measure may not be perfect, it is an important patient centered outcome. The measure can be analyzed and improved as additional data is collected.
>
> **2643: Average change in functional status following lumbar spine fusion surgery, MN Community Measurement**
>
> We believe this measure should be considered for endorsement once the reliability testing data is submitted by Minnesota Community Measurement because the measure focuses on an important patient-centered outcome and addressees an important gap area for quality improvement. We believe an explicit patient-centered focus on surgical outcomes is necessary and this measure begins to address this important quality issue.

Committee Response:

The Committee requested additional information to allow for more comprehensive evaluation of the consensus not reached and not recommended measures. This additional information was discussed on the post-comment committee call and the Committee had an opportunity to re-vote on the applicable measures.

Comments on the set of FOTO measures (0422 – 0428) noted that they are important patient centered outcomes, and while the measures are not perfect they could be improved as additional data is collected. A sample is below:

> We believe this measure should be considered for endorsement because it focuses on an important patient-centered outcome and addressees an important gap area for quality improvement.
>
> Support – While this measure may not be perfect, it is an important patient centered outcome. The measure can be analyzed and improved as additional data is collected**.**

> **Developer Response:**
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> "The PFCC committee has requested and FOTO has provided additional analysis of validity and reliability at the clinician and clinic level. FOTO is committed to the continual improvement of its measures as directed by further analysis of the data."

Theme 2 – Additional Gap Areas Identified

Many comments suggested additions to the measure gaps list. These suggestions included:

- Measures that determine how the provider improved the patient's life (mobility);
- Measures for inpatient rehabilitation facilities for outcomes based on functional improvement;
- Measures that apply to younger populations in hospital and ambulatory settings;
- Measures that take a more inclusive view of functional status and pair condition-specific or body part-specific functional status measures with global measures such as the PROMIS-10, PHQ-9, or SF-12. These tools can help provide a more comprehensive picture of an individual's functional status, the true outcome that matters;
- Measures that ensure the service system has captured personal goals: Individuals view success as the ability to live life at the highest functional level possible with the least intervention, whereas the system envisions success as providing a comprehensive range of services that meet total care needs;
- Measures that demonstrate whether a provider has collaborated with the individual to develop goals that reflect the needs, values, and preferences for daily living;
- Measures of function that measure against the individual's goals over time in relation to his/her environment as well as measuring preservation in function. Such measures document change and/or maintenance in the individual's function verses improvement allowing flexibility to align with his/her goals. Success could be defined as maintaining one's function;
- Measures that focus on meeting expected outcomes of the intervention, i.e., reducing further deterioration, rather than a focus on improvement, especially for populations in Home Health, SNF and Long-term Care Facilities; and,
- Patient-centered measures of maternity care.

Committee Response:

These suggestions have been added to the measurement gaps list in the report.

Theme 3 – Harmonization/creating composites

A number of comments focused on harmonization and creating composite measures.

Two sets of comments suggested that 2286, 2287, and 2321 be harmonized. As this decision is up to the developer, these comments were forwarded on for their response.

Developer Response:

"We agree that a composite measure is important. To that end, we have submitted a composite measure 2287: Functional Change: Change in Motor Score. This will allow for quality improvement in all levels of function being measured. However, we feel that leaving this as a separate measure offers greater refinement in assessing patient change relating to the construct measured. For instance, consider a patient admitted to a facility and upon admission is rated at the lowest functional levels for each item within a measure, upon discharge, the self-care items improved greatly however the mobility items did not change from the admission rating (perhaps the patient had not walked independently for many years prior to onset of recent condition under treatment), as a composite score, functional gain would be evident from admission to discharge, but it would not show the domain specific changes (exceptional progress in self-care, which was likely the focus of rehabilitation). We believe the option of serving as a 'stand-alone measure' may have interest and great utility to clinicians and since the motor measure is a combination of the self-care and mobility, the flexibility in options exist for clinical use."

Other comments suggested 0167, 0174, and 0175 be combined into a suite or composite measure. These comments were also forwarded on to the developer.

Developer Response:

"CMS is also exploring composite functional measures for future development."

A comment on the FOTO measures (0422 – 0428) noted that functional measures represent important outcomes or intermediate outcomes of interest for quality improvement and suggested considering combining all of the FOTO functional status measures into a composite that includes taking patient preference into account.

Theme 4 – Concerns about unintended consequences and discrimination

Several comments raised concerns about the unintended consequences of a particular measure or the possibility that the use of the measure may lead to discrimination in care or patient profiling, particularly for patients whom are unlikely to improve in various areas due to the nature of their disease, yet who still need therapy to prevent further losses in function. This concern was raised around several measures.

- 0176, 0177, and 0688 each received one comment raising this issue.
- 2612 and 2613 each received two comments raising this issue.
- 0167, 0174, and 0175 each received three comments raising this issue.

NQF is not able to monitor for unintended consequences directly, but we do encourage the submission of this information via the Quality Positioning System (QPS).

> **Committee response**: The issues of unintended consequences, "cherry-picking" patients for inclusion in measures, and assessing "improvement" for payment or penalty use in quality programs were discussed during the in-person meeting. The Committee continues to encourage measure developers and implementers to consider implications of measurement, including potential unintended consequences.
>
> **Developer response:**
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> 0176 and 0177-"We recognize that there are some home health patients for whom improvement in management of oral medications and in pain interfering with activity is not a reasonable expectation. Risk adjustment, while not perfect, helps to mitigate the effect of the patient's clinical condition at admission and other patient characteristics on the home health agency's measure value. Notwithstanding recent changes in the types of patients accepted for home health care, it remains primarily a post-acute benefit. The measure steward will continue to explore options for refining the measure based on committee input and comments received, and will explore potential alternative measures that address management of oral medications outcomes for patients with limited likelihood of improvement."
>
> 0688- "NQF #0688 tracks potential decline in function by measuring "the percent of residents whose need for help with activities of daily living (ADL) has increased." Accordingly, the purpose of this measure is to assess decline in ADL function among long-stay nursing home residents. This change in ADL function is documented during the period of nursing home stay by comparing ADL function from one nursing home assessment to the next. We agree that the goal of many long-stay residents is to maintain their existing ADLs and may not be focused on ADL improvement; we believe that NQF #0688 is aligned with this perspective, as it is not focused on improvement. A higher score for this measure indicates lower quality. Patients maintaining their level of functional ability for the 4 late-loss ADLs would NOT be counted in the numerator for this measure and would be considered as experiencing good quality. We also believe that NQF #0688 is not at odds with other potential measures described by the commenter that would focus on improving ADLs in other settings prior to nursing home admission. However, the measure proposed by the commenter might be more appropriate for short-stay nursing home residents who are generally admitted for goals different from long-stay residents."
>
> 2612 and 2613- "Any effective patient outcome quality measure has the potential to be utilized for patient profiling and this risk is minimized through the use of risk adjusters and exclusions."
>
> 0167, 0174, 0175- "We recognize that there are some home health patients for whom improvement is not a reasonable expectation. Risk adjustment, while not perfect, helps to mitigate the effect of the patient's clinical condition at admission and other patient characteristics on the home health agency's measure value. Notwithstanding recent changes in the types of patients accepted for home health care, it remains primarily a post-acute benefit. The measure steward will continue to explore options for refining the measure based on committee input and comments received, and will explore

potential alternative measures that address these outcomes for patients with limited likelihood of improvement."

Theme 5 – Age exclusions

The recommended measures in this project all focused on older populations. Several commenters noted this and there were comments requesting that measures focusing on pediatric populations, maternal health/women of reproductive age, and younger patients in hospitals and ambulatory settings be included.

NQF Response:

"This particular phase of PFCC focused on acute care settings and functional status, as stated in the report. We do have pediatric measures in the PFCC portfolio; this list is in Appendix B of the report. In addition, NQF has a number of other maternal and child health measures in our full portfolio. We have added measures that apply to younger populations as a gap area in the report."

One commenter requested information on whether measures 0688 and 2632 had been tested in populations under age 18. They also noted that they agreed with the Committee that the set of FOTO measures should be restricted to the tested population of over age 18.

Developer response:

0688- "NQF #0688, the percent of residents whose need for help with activities of daily living (ADL) has increased (long stay), has not been tested for patients under the age of 18. However, we would argue that the objective of this measure, to monitor nursing home performance with regard to preventing ADL decline for long-stay nursing home residents, is appropriate for both nursing home residents under and over the age of 18. Because this measure is focused on maintenance of function and prevention of decline, rather than improvement, it is well suited for monitoring quality of care for residents of nursing homes with long-term services and support needs across age ranges. Additionally, according to a 2013 report from The Centers for Medicare and Medicaid Services, only 0.2% of all U.S. nursing home residents are age 21 years or younger (1). Within this 0.2%, even fewer would be under age 18, and not all would meet the criteria for inclusion in the ADL measure (i.e., not currently comatose, prognosis of life expectancy less than 6 months, receiving hospice care, or total dependence for all four ADL items on prior assessment). (1) http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/downloads/nursinghomedatacompendium_508.pdf"

2632-"Our testing data included patients in long-term care hospitals who were 20 to 99 years old. It did not include patients who were 18 or younger. However, we would like to note that this is a process measure focused on whether a functional assessment is completed and whether a functional goal is reported. It is not an outcome measure, and does not include comparing patient scores. The objective of this measure is to promote standardized functional assessment of basic daily activities for all patients. Therefore, we believe it applies to all patients, regardless of age."

Theme 6 – IMPACT Act

The IMPACT Act passed by the Congress in September 2014 requires post-acute care (PAC) providers to report standardized patient assessment data as well as data on quality, resource use, and other measures. According to the IMPACT Act, the data is required to be interoperable to allow for its exchange among PAC and other providers to facilitate care coordination and improve Medicare beneficiary outcomes. The IMPACT Act affects PAC programs including: 1) HHA Quality Reporting Program; 2) newly required Skilled Nursing Facility Quality Reporting Program; 3) IRF Quality Reporting Program; and 4) LTCH Quality Reporting Program. The new quality measures will address several domains including functional status and changes in function, skin integrity and changes in skin integrity, medication reconciliation, incidence of major falls, and the accurate communication of health information and care preferences when a patient is transferred. The IMPACT Act also requires the implementation of measures to address resource use and efficiency such as total Medicare spending per beneficiary, discharge to community, and risk-adjusted hospitalization rates of potentially preventable admissions and readmissions.

One commenter appreciated NQF's awareness and consideration of the goals of the IMPACT Act around cross-setting measures and avoiding burdensome and duplicative measures and would appreciate continued transparency as well as publicly available information regarding next steps with respect to cross-setting measures. This comment was repeated on 4 measures.

Measure Specific Comments

0167 Improvement In Ambulation/Locomotion, CMS

0174 Improvement In Bathing, CMS

0175 Improvement In Bed Transferring, CMS

These three measures received two sets of comments suggesting that they be combined to be a composite that would "collectively address daily living activities". In addition, it was suggested that the measure specifications be revised to "measure patients upon meeting expected outcomes of interventions versus the achievement of patient goals".

Three comments were received regarding the exclusions, one in favor, and two raising concerns: that this measure may discriminate against patients who require therapy to maintain abilities, but who may not improve due to their condition, and that not enough rare/unpredictable diseases could be included, therefore leading to potential unintended consequences.

Committee response:

The Committee had discussed this issue during the in-person meeting, especially raising concerns around the Jimmo v. Sebelius settlement, but felt that the developer had adequately addressed it using the exclusion criteria. Additionally, the developer (CMS) noted that they are working to balance incentives to ensure patients who will not improve are still receiving high quality care and are not being discriminated against.

Developer Response:

"The current OASIS does not allow for the inclusion of patient goals in the calculation of a measure. In the context of implementing cross-setting measures, some items related to goals for patient functioning may be added to the assessment and could be the basis for additional quality measures. CMS is also exploring composite functional measures for future development."

> “We recognize that there are some home health patients for whom improvement in ambulation/locomotion is not a reasonable expectation. Risk adjustment, while not perfect, helps to mitigate the effect of the patient's clinical condition at admission and other patient characteristics on the home health agency's measure value. Notwithstanding recent changes in the types of patients accepted for home health care, it remains primarily a post-acute benefit. The measure steward will continue to explore options for refining the measure based on committee input and comments received, and will explore potential alternative measures that address ambulation/locomotion outcomes for patients with limited likelihood of improvement.”

0176 Improvement In Management Of Oral Medications, CMS

0177 Improvement In Pain Interfering With Activity, CMS

These two measures received two comments indicating a lack of support. Commenters stated that the methodology used to show improvement is subjective and that the measure does not add value to the portfolio.

Another commenter raised two concerns with this pair of measures, first the potential disincentives for maintenance therapy, and second, the related concern that the list of exclusions is not broad enough.

Committee response

During the in-person meeting, the Committee specifically requested more information on the usability of the two additional concepts (ability to take medicines correctly and frequency of pain) and noted these might be better operationalized via patient reported outcomes due to their subjectivity. However, the Committee voted to recommend these measures for endorsement.

Developer response:

“Centers for Medicare & Medicaid Services (CMS) will review your comment and address your concerns shortly.”

“We recognize that there are some home health patients for whom improvement in management of oral medications is not a reasonable expectation. Risk adjustment, while not perfect, helps to mitigate the effect of the patient's clinical condition at admission and other patient characteristics on the home health agency's measure value. Notwithstanding recent changes in the types of patients accepted for home health care, it remains primarily a post-acute benefit. The measure steward will continue to explore options for refining the measure based on committee input and comments received, and will explore potential alternative measures that address management of oral medications outcomes for patients with limited likelihood of improvement.”

0688 Percent of Residents Whose Need for Help with Activities of Daily Living Has Increased (long stay), CMS

This measure received two comments indicating a lack of support for endorsement. The rationale focused on the fact that many SNF patients are working on maintaining function, not improvement, and that improvement should be happening before patients are moved to SNFs.

Another commenter did not specify support or lack of support, but raised two concerns with this measure, first, the potential disincentives for maintenance therapy, and second, the related concern that the list of exclusions is not broad enough.

Committee response

During the in-person meeting, the Committee raised similar concerns about this measure, but ultimately agreed that the therapeutic goal to delay decline in the selected ADLs is very important for this population. While the Committee raised concerns about the exclusions in the denominator, the discussion was mainly about the reliability of identifying people with less than six months expected survival. The measure developers explained that there are multiple intentions with regard to this exclusion. One is that if people are at end of life, they are going to be at much higher risk for ADL decline. On the other hand, if they are included in the measure there may be an unintended consequence where facilities may not be willing to set aside some interventions that they need to do in order to maintain function and thus not respecting preferences at end of life.

Developer response:

“NQF #0688 tracks potential decline in function by measuring “the percent of residents whose need for help with activities of daily living (ADL) has increased.” Accordingly, the purpose of this measure is to assess decline in ADL function among long-stay nursing home residents. This change in ADL function is documented during the period of nursing home stay by comparing ADL function from one nursing home assessment to the next. We agree that the goal of many long-stay residents is to maintain their existing ADLs and may not be focused on ADL improvement; we believe that NQF #0688 is aligned with this perspective, as it is not focused on improvement. A higher score for this measure indicates lower quality. Patients maintaining their level of functional ability for the 4 late-loss ADLs would NOT be counted in the numerator for this measure and would be considered as experiencing good quality. We also believe that NQF #0688 is not at odds with other potential measures described by the commenter that would focus on improving ADLs in other settings prior to nursing home admission. However, the measure proposed by the commenter might be more appropriate for short-stay nursing home residents who are generally admitted for goals different from long-stay residents.”

“NQF #0688 is an outcome measure defined as “the percent of residents whose need for help with activities of daily living (ADL) has increased.” Accordingly, the purpose of this measure is to assess decline in ADL function among long-stay nursing home residents, rather than improvement. We agree that the goal for many long-stay residents is trying to maintain their level of activity, thus focusing on maintenance, not improvement. We believe that the focus of NQF #0688 is aligned with this perspective by quantifying the proportion of long-stay residents who have experienced a loss in function. Residents are counted in the numerator of this measure if they experience an increase in need for assistance with late-loss ADLs in a given assessment period, as compared to a prior assessment. A higher score for this measure indicates lower quality. Thus patients maintaining functional ability for the 4 late-loss ADLs would NOT be counted in the numerator for this measure and would be considered as experiencing good quality.”

“This measure (NQF #0688), the percent of residents whose need for help with activities of daily living (ADL) has increased (long stay), is designed to track decline in ADL function among long-stay nursing home residents from one assessment period to the next. CMS understands that improvement and recovery are not always feasible among long-stay nursing home resident populations, hence the appropriateness of using this measure to monitor increased needs for assistance (i.e., functional decline), rather than improvement for the long-stay nursing home resident population. The measure is designed so that each instance of a resident maintaining functional status is counted as an indicator of good facility quality. This comment references the Steering Committee recommendation to add exclusions to this measure, but these recommended exclusions noted in the Draft Report for Comment apply to measures of ADL improvement, whereas NQF #0688 measures ADL decline. As it stands, this measure has four exclusion groups: currently comatose, prognosis of life expectancy less than 6 months, receiving hospice care, or total dependence for all four ADL items on prior assessment. The Steering Committee suggested that there may be a potential for gaming, particularly with the six month prognosis item. We suggest that the item used to identify residents who have a prognosis of less than six months to live has relatively little risk for gaming because it is based on physician documentation in the medical record, rather than the clinical judgment of facility staff completing the assessment. In addition this exclusion applies to only a small number of residents, and the proportion of residents excluded from the measure for this reason has declined over time, which does not support the suggestion that it is an exclusion that is being gamed (1). While there is concern regarding physicians' ability to identify end of life prognosis, analyses of residents included in this measure (i.e., greater than six month prognosis) show that very few (3.3%) expired. In addition, item level reliabilities were very high when tested during the RAND development of the MDS 3.0 (gold standard to gold standard nurse kappa: 0.872; gold standard nurse to facility nurse kappa: 0.964) (2). Lastly, we reiterate that including end of life residents in the measure could not only put them at risk for reduced access, but also at risk for care at odds with end-of-life goals and patient preferences. With regard to the commenter's concerns that other high risk populations should be added to the exclusions, we will continue to analyze and monitor this measure for conditions that should be excluded.

(1) RTI analyses of MDS 3.0 data show that in Quarter 1 of 2011, 0.4% of long-stay residents were excluded due to less than six-month prognosis. This proportion declined to 0.08% in quarter 2 of 2012, rebounded slightly to 0.13% in Quarter 4 of 2012, and declined again to 0.11% in Quarter 2 of 2013 where it has held steady at 0.11% through Quarter 2 of 2014. (RTI programming reference: nh_22_10, all quarters through 13_14).

(2)Saliba D., Buchanan D., Development and Validation of a Revised Nursing Home Assessment Tool: MDS 3.0 Appendices. Prepared for the Centers for Medicare & Medicaid Services. April 2008. Available at: http://www.geronet.med.ucla.edu/centers/borun/Appendix_A-G.pdf"

0701: Functional Capacity in COPD patients before and after Pulmonary Rehabilitation, American Association of Cardiovascular and Pulmonary Rehabilitation

One commenter requested a clarification in the specifications regarding ages.

Developer response:

"The age range is greater than or equal to 18 years old, with no upper limit."

2612 CARE: Improvement in Mobility, American Health Care Association

This measure received two comments in support for the measure, one of which mentioned the need for monitoring to ensure there would be no unintended consequences of the measure. An additional comment did not support the measure and raised concerns regarding unintended consequences around patient profiling.

> **Committee Response:**
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> The Committee requested additional information to allow for more comprehensive evaluation of the consensus not reached and not recommended measures. This additional information was discussed on the post-comment committee call and the Committee had an opportunity to re-vote on the applicable measures.
>
> **Developer response:**
>
> "Any effective patient outcome quality measure has the potential to be utilized for patient profiling and this risk is minimized through the use of risk adjustors and exclusions."
>
> "We provided basic information on the measure inclusions within the measure specifications; however, we wanted to make sure that all of the detail information regarding the exclusions could be accessible for those interesting in replicating this measure. Therefore, we chose to place this more detailed information in the appendix."

2613 CARE: Improvement in Self Care, American Health Care Association

This measure received two comments in support and two critical comments that raised concerns, one which explicitly did not support the measure and one of which did not explicitly state whether or not the commenter supported the measure. The focus of the concerns centers around the risk of unintended consequences around patient profiling. In addition, one of the critical comments raised additional concerns with the measure:

> We continue to be concerned that the Improvement in Self-Care measures appears to consider self-care related movement alone and does not consider performance and cognitive elements of self-care such as sequencing, problem solving, temporal appropriateness (e.g., whether to dress for day or bed), memory, and activity planning. Further, it is notable that the Improvement in Self-Care measure does not consider or measure performance of activities of daily living, including the broader instrumental activities of daily living (IADLs) which significantly impact a patient's ability to function and live independently in the community.

> **Committee Response:**
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> The Committee requested additional information to allow for more comprehensive evaluation of the consensus not reached and not recommended measures. This additional information was discussed on the post-comment committee call and the Committee had an opportunity to re-vote on the applicable measures.
>
> **Developer response:**
>
> "Any effective patient outcome quality measure has the potential to be utilized for patient profiling and this risk is minimized through the use of risk adjusters and exclusions."

“The CARE: Improvement in Self-Care measure is not intended to make a statement on the overall value of occupational therapy, physical therapy, or nursing services. The measure simply reflects the self-care items present in the CARE Tool that was developed and validated by CMS.

We agree that occupational therapy and other functional outcomes include additional domains than those present in this self-care measure, such as cognition (e.g. sequencing, problem solving, temporal appropriateness, memory, and action planning), and would support any other measure(s) that addresses these domains. However, we believe the CARE: Improvement in Self-Care measure is reliable and valid for its intended purpose.

We would be happy to modify the description of the measure to more clearly state that this is a change measure that seeks to identify the effectiveness of therapy and is only intended for those patients who are receiving therapy.”

“We provided basic information on the measure inclusions within the measure specifications; however, we wanted to make sure that all of the detail information regarding the exclusions could be accessible for those interesting in replicating this measure. Therefore, we chose to place this more detailed information in the appendix.”

2643 Average Change In Functional Status Following Lumbar Spine Fusion Surgery, MN Community Measurement

2653 Average change in functional status following total knee replacement surgery, MN Community Measurement

Measure 2643 was not recommended and 2653 did not achieve consensus. Both measures received three comments each supporting the endorsement of the measures. Commenters noted that the measures focus on an important topic area, patient-centered surgical outcomes, and that while the measures were not perfect, they could be improved over time as additional data is collected.

Committee response:

The Committee requested additional information to allow for more comprehensive evaluation of the consensus not reached and not recommended measures. This additional information was discussed on the post-comment committee call and the Committee had an opportunity to re-vote on the applicable measures.

Developer response:

2643: “We agree that these types of measures focused on patient reported outcomes and change over time, which represent newer cutting-edge measures, are more difficult to evaluate as compared to traditional measures that are expressed as a binary Yes/No. We have provided additional testing in response to the steering committee’s concerns and look forward to continued conversation and working with NQF staff to determine the best statistical methods and tests for determining the reliability and validity performance scores. A new published study supports the use of the Oswestry Disability Index as a PROM tool appropriate for outcome measurement. “A proposed set of metrics for standardized outcome reporting in the management of low back pain.” Clement, RC et al Acta Orthopaedica 2015; 86 (4)”

> 2653: “We agree that these types of measures focused on patient reported outcomes and change over time, which represent newer cutting-edge measures, are more difficult to evaluate as compared to traditional measures that are expressed as a binary Yes/No. We have provided additional testing in response to the steering committee’s concerns and look forward to continued conversation and working with NQF staff to determine the best statistical methods and tests for determining the reliability and validity performance scores. Thanks for your suggestion to determine modes that address survey burden. In addition to obtaining survey information from the patient during an in-person visit, we do allow mailed survey and when permitted by the tool developer/ copyright holder, electronic administration of the tool to the patient by patient portal. Additionally, although not yet submitted for endorsement, MN Community Measurement is also measuring the change in quality of life for this patient population, initially using the EQ5D and now transitioning to PROMIS Global Health-10.”

0422 Functional Status Change For Patients With Knee Impairments, Focus On Therapeutic Outcomes, Inc

0423 Functional Status Change For Patients With Hip Impairments, Focus On Therapeutic Outcomes, Inc

0424 Functional Status Change For Patients With Foot And Ankle Impairments, Focus On Therapeutic Outcomes, Inc

0425 Functional Status Change For Patients With Lumbar Impairments, Focus On Therapeutic Outcomes, Inc

0426 Functional Status Change For Patients With Shoulder Impairments, Focus On Therapeutic Outcomes, Inc

0427 Functional Status Change For Patients With Elbow, Wrist And Hand Impairments, Focus On Therapeutic Outcomes, Inc

0428 Functional Status Change For Patients With General Orthopaedic Impairments, Focus On Therapeutic Outcomes, Inc

The FOTO Functional Status Change Measures (0422-0428) were not recommended due to the lack of sufficient information. A total of 28 comments from four different organizations were received on these measures, of which 21 comments were in favor of the measures and urged the Committee to reconsider their votes. The Commenters noted that these measures focus on an important patient-centered outcome and address an important gap area for quality improvement. One commenter called out the fact that these measures are specific to patients with a certain kind of disability as its strength and encouraged FOTO to consider pairing their specific functional status tools with a global measure. Another commenter suggested considering combining all functional status measures into a composite that takes patient preferences into account. One commenter made the same comment on all seven measures that supported the Committee’s discussion and request for evidence that the measures are understandable and appropriate for patients under the age of 18, as the measures were initially developed for patients 18 and over.

Committee response:

The Committee requested additional information to allow for more comprehensive evaluation of the consensus not reached and not recommended measures. This additional information was discussed on the post-comment committee call and the Committee had an opportunity to re-vote on the applicable measures.

Developer response:

"The PFCC committee has requested and FOTO has provided additional analysis of validity and reliability at the clinician and clinic level. FOTO is committed to improvement of its measures and is involved in research to examine the relationship of its measures to other measures, including global ratings. In FOTO's survey development it has progressed from global measures to more body part specific measures because of the improved measure sensitivity realized with a specific vs. global measure, which FOTO believes is an important psychometric advantage. For example effect size was more than doubled comparing the FOTO Lumbar CAT (1.05) and AM PAC CAT Daily Activity Scale (.42) when applied to patients with spine impairments. This increased sensitivity has been noted in all of the body part data. There are also clinical advantages with the patient being presented with more pertinent (to their impairment) body part functional items to answer."

"The PFCC committee has requested and FOTO has provided additional analysis of reliability and validity. Reliability was assessed at the provider level (clinic and clinician) using the signal to noise approach as advised by the committee (see section 5 within the FOTO full comments document submitted on March 19th 2015). Additional information on validity has also been presented at the provider level (clinic and clinician) assessing whether clinics and clinicians classified as higher performing using FOTO's methodology of risk-adjusted aggregated scores also have a greater proportion of patients who had improved during treatment by at least minimal clinically important improvement (MCII). Finally, also at the request of the committee, FOTO has provided analysis of the validity and reliability for three additional impairment groups; Thoracic Spine, Ribs and Trunk and Craniofacial. These combined with the cervical spine, which was previously reported composes 100% of the impairments measured by this measure."

"The committee requested evidence that the instrument, which was originally developed for ages 18 and over, has been tested for understandability and appropriateness for youth down to age 14, as included in the measure. FOTO justified their initial request to change the inclusion criteria for its measures from 18 to 14 years old using the results of sensitivity analyses examining the impact of changing the age exclusion criteria on the risk adjustment models. However, in light of the discussions in committee, we recognize that additional testing is necessary. Therefore, we have requested permission to withdraw this change and return to the 18 years and older inclusion criteria. FOTO plans to perform studies on the understandability and appropriateness for youth 14-18 in the future. We have also recalculated the marginal means estimates by age-groups 18 and older."

2624 Functional Outcome Assessment, CMS (new)

The Committee did not reach consensus on this measure. There was only one comment received on this measure which supported its endorsement.

Committee response:

The Committee requested additional information to allow for more comprehensive evaluation of the consensus not reached and not recommended measures. This additional information was discussed on the post-comment committee call and the Committee had an opportunity to re-vote on the applicable measures.

2631 Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function, CMS (new)

The Committee did not recommend this measure at the Committee in-person meeting and requested additional information from the measure developers. The Committee reevaluated the measure based on the new information received from the developers on a post-meeting call. The Committee did not reach consensus on this measure after a revote. Two comments were received on this measure of which one supported the endorsement of this measure. The second commenter noted that this measure is an important topic within the PAC industry and has been subject to contentious discussions across NQF committees and raised concern about the NQF processes for re-consideration and re-voting. The commenter further noted that the MAP Committees have “Conditionally Supported” this measure for use within all PAC venues and recommended that the Committee take all PAC settings into consideration when reviewing this measure to identify whether it meets all of the criteria previously reviewed not just for LTCHs, but also for SNFs, IRFs, and Home Health agencies.

NQF response:

This measure was re-discussed during the follow up call after the in-person meeting. During the meeting, the Committee requested additional information regarding the measure. The developers had already submitted this information; however, due to timing of receipt being just prior to the in-person meeting; the Committee did not have time to review it. Due to the fact the information was already available, NQF agreed to have the Committee re-discuss the measure during the post-meeting call rather than waiting until after the public comment period.

Committee response:

This comment was completed after the post-comment call. Consensus was not reached on some of the required criteria, and additional information was requested. While the comments on expanding the settings for the measure’s use are appreciated, the Committee is charged with evaluating measures based on the information submitted and for the level of analysis and care setting as submitted by the developer. This additional information was discussed on the post-comment committee call and the Committee had an opportunity to re-vote on the applicable measures.

Developer response:

“The Improving Medicare Post-Acute Care Transformation (IMPACT) Act directs the Secretary to specify quality measures on which PAC providers are required to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to five quality domains, one of which is functional status, cognitive function, and changes in function and cognitive function.

Following the enactment of the IMPACT Act, a technical expert panel (TEP) was convened by the Centers for Medicare and Medicare Services’ measure development contractor and provided input on implementing an application of this measure across four post-acute care settings, including IRFs, LTCHs, SNFs and HHAs. The TEP supported the implementation of this measure as specified across PAC providers and also supported our efforts to standardize this measure for cross-setting use.

> The Measures Application Partnership (MAP) met on February 9, 2015 and conditionally supported the specification of an application of Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; under review) for use as a cross-setting measure. MAP conditionally supported this measure pending NQF-endorsement and resolution of the use of two different functional status scales for quality reporting and payment purposes. MAP reiterated its support for adding measures addressing function, noting the group's special interest in this PAC/LTC core concept. More information about the MAPs recommendations for this measure is available at: http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx."

2632 Long-Term Care Hospital (LTCH) Functional Outcome Measure: Change in Mobility Among Patients Requiring Ventilator Support, CMS (new)

This measure was recommended by the Committee. One commenter stated that there does not appear to be a specific age exclusion for this measure and inquired whether the measure has been tested in patients under the age of 18.

> **Developer response:**
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> "Our testing data included patients in long-term care hospitals who were 20 to 99 years old. It did not include patients who were 18 or younger. However, we would like to note that this is a process measure focused on whether a functional assessment is completed and whether a functional goal is reported. It is not an outcome measure, and does not include comparing patient scores. The objective of this measure is to promote standardized functional assessment of basic daily activities for all patients. Therefore, we believe it applies to all patients, regardless of age."

2633 Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients, CMS (new)

2635 Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients, CMS (new)

The Committee did not reach consensus on these two measures, which received two similar comments. One commenter noted that these are important measures but they need to be analyzed and improved as additional data is collected. Another commenter concurred with the Committee's concern with the validity and reliability of measures developed using a cross-sectional study design from a demonstration project, which did not follow the same patients across venues of care and thus limiting applicability across sites.

> **Committee response:**
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> The Committee requested additional information to allow for more comprehensive evaluation of the consensus not reached and not recommended measures. This additional information was discussed on the post-comment committee call and the Committee had an opportunity to re-vote on the applicable measures.

Developer response:

"As discussed during the measure review on January 22, 2015 and documented in the Person- and Family-Centered Care Phase 2 Draft Report on page 11, the Post-Acute Care Payment Reform demonstration was a prospective cohort study, not a cross-sectional study. In addition to collecting admission and discharge data using the CARE Tool during the post-acute care stay, inpatient claims data for acute care stays prior to and following the post-acute care stay were linked to the CARE admission and discharge data.

The reliability and validity of the CARE function items were presented and discussed during the January 21-22, 2015 meeting, and several committee members referred to our analysis as very good. We have also submitted provider-level reliability data to the committee for review, as requested during the January 21-22, 2015 meeting.

The Improving Medicare Post-Acute Care Transformation (IMPACT) Act directs the Secretary to specify quality measures on which PAC providers are required to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to five quality domains, one of which is functional status, cognitive function, and changes in function and cognitive function."

2634 Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients, CMS (new)

2636 Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients, CMS (new)

These two measures were recommended by the Committee and received two similar comments. The first commenter supported the underlying concept of the measures, stating that inpatient rehabilitation facilities need to be measured on outcomes based on functional improvement. However, the commenter suggested that an alternative measure that determines how the provider improved the patient's life (mobility) would better incentivize a change in clinical practice and associated patient-level outcomes as opposed to measure 2634 and measure 2636. Another commenter concurred with the Committee's concern with the validity and reliability of measures developed using a cross-sectional study design from a demonstration project, which did not follow the same patients across venues of care and thus limiting applicability across sites.

Committee response:

While the Committee did indicate a level of discomfort in evaluating these measures without testing provided at the measure (or facility level), they did not raise a concern on the study design as suggested by the commenter. The developer clarified the study design during the in-person Committee meeting.

Developer response:

"As discussed during the measure review on January 22, 2015 and documented in the Person- and Family-Centered Care Phase 2 Draft Report on page 11, the Post-Acute Care Payment Reform demonstration was a prospective cohort study, not a cross-sectional study. In addition to collecting admission and discharge data using the CARE Tool during the post-acute care stay, inpatient claims data for acute care stays prior to and following the post-acute care stay were linked to the CARE admission and discharge data.

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The Improving Medicare Post-Acute Care Transformation (IMPACT) Act directs the Secretary to specify quality measures on which PAC providers are required to submit standardized patient assessment data and other necessary data specified by the Secretary with respect to five quality domains, one of which is functional status, cognitive function, and changes in function and cognitive function."