AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

Position Statement

Principles for Musculoskeletal Based Patient Reported Outcome-Performance Measurement Development

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

The AAOS is committed to leading musculoskeletal-based performance measures development, and musculoskeletal healthcare reform. The AAOS specifically supports the development of patient- centered, patient reported outcome performance measurement and believes there is an urgent need within this evolving field, to lead and guide its ongoing development which results in a uniform, and logical development process that culminates with superior patient engagement and limits provider/patient burden.

Introduction

Beginning with the pivotal 2001 report from the Institute of Medicine (IOM), *Crossing the Quality Chasm*[1], the question to define and measure healthcare quality and value has been center stage in the healthcare reform debate. Healthcare reformists and visionaries strive to measure value by defining successful outcomes from the patient's perspective. The National Quality Forum (NQF), Centers for Medicare & Medicaid Services (CMS), and other national stakeholders are seeking to assess provider performance, provide accountability for care provided, and ultimately compare patient, payer and provider outcomes across the nation. One example is the CMS developed *Physician Compare* website, found here: https://www.medicare.gov/physiciancompare/).

Multiple legitimate stakeholders are developing musculoskeletal-based patient reported outcome performance measures (PRO-PM)[2-6]. This has often been a disjointed development with each group defining the patient cohort differently (i.e. inclusion and exclusion criteria), choosing different instruments for their Patient Reported Outcome Measure (PROM), choosing different time points for assessment, as well as different thresholds for success. This lack of harmonization holds back the field and the speed at which valuable effective measures can be tested, rationally validated, and optimized before implementation.

Promoters and developers recognize other limitations related to implementing PRO-PMs. For example, most PROM instruments were developed primarily for research. The instruments lack an infrastructure that enables efficient data collection. The instruments are often long and burdensome to administer. Furthermore, these instruments generally lack data from diverse populations with various co-morbidities, leaving their utility unconfirmed in settings where risk stratification or other adjustment approaches are needed (e.g. for comparison of clinicians or practices).

Given these limitations, and the importance of this effort, the AAOS believes PRO-PM development must be steered in a logical and step-wise direction with the goal of assessing each patient's outcome

perspective with aligned PRO-PMs that are focused on readily defined populations, are cross cutting (i.e. are relevant and generalizable across multiple diagnoses or procedures), have low random variation (i.e. high repeatability), high sensitivity and range of responsiveness, the lowest possible cost to patients and providers. Moreover, the threshold for success must be clearly achievable and validated for risk adjustment. The AAOS does not support the production of measures that do not clearly meet this intent.

Background

The National Quality Forum Perspective

The National Quality Forum (NQF) represents a major stakeholder and valuable resource for the development and consensus-based implementation of performance measures. In January of 2013, the NQF released its "Patient Reported Outcomes (PROs) in Performance Measurement" report.[7] The NQF defines a Patient Reported Outcome (PRO) as "any report of the status of a patient's (or person's) health condition, health behavior, or experience with healthcare that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."[8] Patient Reported Outcome Measures (PROM) are defined as "various tools (e.g., instruments, scales, single-item measures) that enables researchers, administrators, and others to assess patient-reported health status for physical, mental, and social well-being."[7] A PRO-based performance measure (PRO-PM) is "based on PRO data aggregated for an entity deemed as accountable for the quality of care or services delivered. Such entities can include (but would not be limited to) long-term support services providers, hospitals, physician practices, or accountable care organizations (ACOs)."[7] Each of these are distinctly different and require different levels of validation that requires robust data collection and analysis.

NQF acknowledges "two critical steps are to engage patients by building capacity and infrastructure to capture patient-reported outcomes routinely and then to use these data to develop performance measures to allow for accurate appraisals of quality and efficiency."[7] This is an acknowledgement that recognizes the existing limitations and barriers to PRO-PM implementation and supports a stepwise and logical development plan for PRO-PMs.

NQF seeks to guide the direction of NQF-endorsed performance measures in general toward the goal of improving quality and reducing costs by:

- encouraging higher performance reflected in actual outcome rather than just compliance with basic processes that are thought to positively correlate with preferred outcomes;
- measuring disparities;
- using composite measures that summarize multiple aspects of care; and
- harmonizing measures across sites and providers.

Although "interest and appreciation of the value of using PRO-PMs in performance measurement as part of the broader accountability and performance improvement landscape are mounting," NQF recognizes "PROMs have not been widely adopted for clinical use outside research settings in the United States…and second, there are several method-related challenges such as aggregating patient data on PROMs to measure performance at multiple levels (e.g., individual, group practice, organization).

In an effort to address these complex issues, the NQF has identified critical goals:

- Identify key characteristics for selecting PROMs to be used in PRO-PMs;
- Identify any unique considerations for evaluating PRO-PMs for NQF endorsement
- Identify unique considerations for PRO-PMs and use in accountability or performance improvement applications; and
- Lay out the pathway to move from PROs to NQF-endorsed PRO-PMs.

Further, NQF has established the following guiding principles for selecting PROMs:

- Psychometric soundness: Is the PROM valid and reliable?

- Person-Centered: Does the PROM engage patients and healthcare providers? Does it facilitate shared decision-making?
- Meaningful: Does the PROM have relevance and importance to patients, their families, and health professionals?
- Amenable to change: Is there evidence the outcome of interest is responsive to the intervention?
- Implementable: Does the infrastructure exist to support the PROM?

NQF recognizes that ongoing development will require further examination of the best practices for utilizing proxy respondents, exploring means of conversion of data obtained using different PROMs or means of calibrating multiple PROMs to a standard scale, using computer adaptive testing (CAT), and utilizing convenient secure web portals to reduce respondent burden and improve response rates. Incorporation of PROMs into EMRs needs to be standardized.

The Musculoskeletal Community perspective

The orthopaedic community is embracing patient reported outcomes. Musculoskeletal care has many unique attributes, requiring collaboration and consensus across multiple domains of anatomy and function, and multiple allied subspecialties. The AAOS is engaged with many multidisciplinary stakeholders, is broadly aligned in goals, and is in agreement with NQF as outlined above.

In 2015, the AAOS released information statement 1044 *Principles of Patient Reported Outcome Measures (PROM) Reporting*,[9] which stated: "There has been much written in recent years on the need to improve value in health care, where value is defined as outcomes achieved per dollar spent.[1] In health care, *outcomes* include both the *quality* of care delivered as well as the *service* as experienced by the patient. This has led to great debate over how *quality* should be defined in healthcare. As Teisberg and Porter[10] have noted in their work, value in any field is defined by the customer, not the supplier. Therefore, it is important to measure outcomes from the patient's perspective using patient reported outcomes measures (PROMs). Although PROMs have long been used in clinical outcomes research in orthopaedic surgery, efforts to incorporate PRO measurement into routine clinical practice have been more challenging.[11] However, significant progress has been made in developing and validating PROMs for specific musculoskeletal disorders or treatments and those that give a broader picture of general health status. Furthermore, technological advances have made PRO measurement less burdensome for patients and providers."

This document summarized the following recommendations related to PRO implementation from the Fall 2014 AAOS Council on Research and Quality (CORQ):

1. Patient Reported Outcomes are important to patients and providers.
2. This is not a research effort, but one aimed at practice improvement.
3. Patients and orthopaedic surgeons should work together to make patient-reported outcomes data as complete and accurate as possible.
4. The orthopedic community, through the AAOS, should work to develop agreement on a common set of metrics.
5. Both generic and condition-specific measures of health-related quality of life should be used.
6. Members selecting survey tools for PROM acquisition should be sure that those instruments are easily administered, validated, and free to use.
7. Every effort should be made to make the gathering of PROM data as easy and reliable as possible for patients and providers.

In August of 2015, a summit for PRO development related to total joint arthroplasty was convened. Participants included representatives from AAHKS, AAOS, The Hip Society, The Knee Society, American Joint Replacement Registry, CMS, Yale New Haven Health Services Center (YNHHSC)/Center for Outcomes Research & Evaluation (CORE), National Committee for Quality Assurance (NCQA), Mathematica, CECity (now Premier Analytics), and Blue Cross/Blue Shield. This summit made the following recommendations[12]:

1. Utilize a hybrid approach to PROM use (#5 above), by using a general health instrument PROM combined with a disease specific PROM. Specifically:
    a. General health instrument:
        i. PROMIS-10
        ii. VR-12
    b. Disease specific:
        i. HOOS-jr (for hips)
        ii. KOOS-jr (for knees)
2. CMS should use a staged approach in selecting the candidate variables for risk adjustment…It is essential that risk adjusted data be collected or access to care for certain patients will be limited in the future.

In 2015, the AAOS formed the Quality Outcomes Data (QOD) work group, which reviewed existing patient reported outcome tools (i.e. PROMs). In February 2016, the Board of Directors approved the recommendations of the QOD workgroup and recommended a list of PROMs to consider for PRO-PM development[13]. The work group acknowledges; "This list is not comprehensive, rather it is intended to steer data collection and reporting. We anticipate this list could change over time". Additionally, the criteria used for PROM selection by the work group included:

- Open access to the PROM (i.e. no cost for the instrument itself)
- Patient reported outcomes only (no surgeon entered data)
- Multiple entry platforms (digital, paper, web)
- Approximately 20 questions or less
- Clinically meaningful (responsiveness)
- One generic quality of life PROM
- No more than 3 joint or disease specific PROMs
- Computer Adaptive Testing (CAT) version available (preferable)

The current state of musculoskeletal based PRO-PM development

Stakeholders such as the NQF, CMS, and others are moving aggressively to promote the development and implementation of PRO-PMs. This rush, occurring in parallel across different organizations, risks confusion from varying and often competing structural components. There is danger that a disjointed approach will significantly increase the burden on patients and providers. More worrisome, a disjoined approach risks the commitment of resources that do nothing to improve quality in care.

This variability is highlighted by reviewing the current state of joint replacement PRO-PMs.[3-6] These hip/knee assessment PRO-PMs are being developed by competing organizations. They contain basic structural differences with respect to the recommended PROM tool and the time frames for PROM administration. A commitment to consensus is essential to avoid dizzying variability in recommendations for implementation.

Recommendations and guidance related to PRO-PM development

Recognizing NQF's desire for harmonization, the PMC believes PRO-PM development should take place along uniform structural recommendations. The following recommendations are intended to be utilized by workgroups developing PRO-PMs and provide guidance to facilitate patient centeredness and engagement, eventual uniform implementation of PRO-PMs across diagnoses and treatments, and guide future research efforts and development needs.

- **Recommendation #1: Staged PRO-PM development & implementation**
    - The AAOS recognizes and acknowledges that the infrastructure and clinical processes currently do not exist in such a manner to facilitate widespread adoption of PRO-PMs. Additionally, the impact on clinical care from widespread use is unknown due to lack of data on their use. As a result, the AAOS believes PRO-PM development should progress in a logical, staged fashion, which will allow the necessary infrastructure and

clinical process development to support widespread adoption of PRO-PMs and allow the generation/collection of data related to PRO and PROM use. This staged implementation would prepare the healthcare system to implement PRO-PMs for practice outcome comparison with sound data-based recommendations. The AAOS envisions this recommendation to result in a given PRO-PM to evolve over the maintenance cycle of the measure and could take several years to complete. The decision to move to the next stage would be at the discretion of the developing organization and based on feedback/data from the previous stage. To facilitate this staged development, the following is recommended:

- ***Stage 1: Routine PRO use in clinical based practice—a process measure.*** Outcome based PRO-PM development should begin as a process measure, answering the question: *"Are providers collecting PRO data on their patients?"* This process measure would reflect the percentage of practices collecting PRO data on their patients and would be reported as a percent of total patients treated for a given condition.
- ***Stage 2: Pre- and post- treatment comparison—a process measure.*** Once stage 1 has been successfully implemented, the PRO-PM is redesigned through its routine maintenance cycle, with the goal to assess that individual practices are comparing the results of their pre- and post- PROM findings with their patients. This performance measure would report a change score for an individual patient and document that the change score was shared with the patient. Although the change score is reported as part of the measure, at this stage the change score is not averaged or published for practice comparison. Instead it is used at the individual patient/provider level for real time care assessment and at a national level for data analysis and assessing impact on clinical care.
- ***Stage 3: Outcome based PRO-PM assessment*** Following completion of Stage 2, and again utilizing the routine maintenance cycle of the PRO-PM process, the measure is redesigned to focus on reporting the PRO-PM comparison outcome data with the appropriate risk stratification and presented to the public in a manner to allow practice comparison.

- **Recommendation #2: Timeframes for administering PROMs in performance measurement**
  - Measurement development groups creating PRO-PMs are encouraged to utilize standardized time periods for PROM collection (see attached Table 1). Standardizing time periods allows all collected data to be included in clinical registries that are being developed by AAOS. Workgroups do not need to recommend all time frames. PRO-PMs should have a pre-intervention collection period and a single post-intervention collection period. The post-intervention time period depends on the intervention being measured. For example, total joint arthroplasty post-intervention PROM collection is at one year.
    - ***Pre-Intervention****: PROM's are administered 90 days prior to the planned intervention (a time frame which coincides with current requirements for H&P and operative consent completion needs)*
    - ***Early****: Post-intervention 4 months +/- 30 days (ensures a data point 3 months post procedure)*
    - ***Mid****: Post-intervention 13 months +/- 30 days (ensures a data point 12 months post procedure)*
    - ***Late****: Post-intervention 25 months +/- 30 days (ensures a data point 24 months post procedure)*
- **Recommendation #3: Utilization of Consistent PROM tools**
  - Following the work of the AAOS, AAHKS, NQF and other organizations and striving to utilize PROMs across various diagnoses in a consistent and logical manner, it is recommended work groups:
    - Develop PRO-PMs which recommend use of both a general health instrument and a disease specific health instrument.

        - Identify appropriate PROMs within each category for utilization and to not be restrictive or prescriptive with their use/selection within each category.
        - Strive to include within recommended PROMs, ones that engage patients to identify outcomes important to individual patients, such as the Single Assessment Numeric Evaluation (SANE) or the Patient Generated Index (PGI), Health Quality of Life (HQOL).
        - Standardized PROMs for activity level or pain can be used to pre-intervention activity level and pain, as well as post-intervention expectations. Measurement of patient expectations assist in the shared decision making process.
- **Recommendation #4: Guidelines for future PROM development**
    - The majority of musculoskeletal-based PROMs were developed primarily as research-based tools and do not necessarily meet the characteristics put forth by the NQF and AAOS for PROM implementation. The ideal PROM should be:
        - Non-proprietary (public domain, no licensing fees)
        - Usable across different diagnoses (cross-cutting)
        - Responsive to the measured intervention
        - Patient centered (includes function/activities/domains important to patients, engages patients with their care)
    - Historical development of PROMs has centered around developing a unique PROM for a unique diagnosis/treatment and are typically developed by a panel of experts who determine the appropriate questions to ask related to the intervention. This potentially leads to questions being asked which do not have the same priorities across patients within the treatment group. Additionally, the current method of PROM development is necessitating use of a large number of PROMs across different diagnoses.
    - Moving forward, the AAOS believes future PROM development should focus on creating a foundation for uniform scoring of patient selected outcome traits. One example of this type of PROM is the Patient Generated Index, Health Quality of Life (PGI, HQOL). This 'future' PROM could guide patients on selecting appropriate traits related to musculoskeletal care (such as pain, activity, sensation, etc.) and general health traits. By empowering patients to select the outcomes important to them as individuals, the AAOS believes this approach to PROM development could result in simplifying the burden associated with PRO-PM development and implementation by having one cross-cutting PROM that is usable across multiple musculoskeletal diagnosis

The AAOS believes PRO-PM development should occur with the goal of simplifying end-user participation needs by finding opportunities to align PRO-PM across varying diagnosis and guide future PROM development with a similar goal.

References:

1. Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Washington DC: National Academies Press; 2001.
2. Functional Status Assessment for Hip Replacement, Steward: Center for Medicare & Medicaid Services, PQRS #376, CMS Measure ID #CMS56v3. Available at https://ecqi.healthit.gov/ep/ecqms-2016-reporting-period/functional-status-assessment-hip-replacement. Last Accessed June 24, 2017.
3. Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairment, Steward: Focus on Therapeutic Outcomes, PQRS #218. Available at https://pqrsregistry.clinicspectrum.com/2016/individual_measures/218.pdf. Last Accessed June 24, 2017.
4. Hip Arthroplasty: Health and Functional Improvement, Steward: American Association of Hip and Knee Surgeons, Measure #2. Available at http://www.aahks.org/wp-content/uploads/2014/07/hip-arthroplasty-measures.pdf. Last Accessed June 24, 2017.
5. Preoperative Functional/Health Status Assessment as Reported by Patient, Joint Commission, Draft Measure: THKR-06. Available at

https://www.jointcommission.org/assets/1/6/Draft_THTK_Candidate_Perf_Measure_Profiles.pdf. Last Accessed June 24, 2017.
6. Average change in functional status following total knee replacement surgery, Steward: MN community measurement, NQF #2653. Available at https://www.qualitymeasures.ahrq.gov/summaries/summary/49547. Last Accessed June 24, 2017.
7. Patient Reported Outcomes (PROs) in Performance Measurement, Developed by the National Quality Forum, January 10, 2013. Available at https://www.qualityforum.org/Publications/2012/12/Patient-Reported_Outcomes_in_Performance_Measurement.aspx. Last Accessed June 24, 2017.
8. U.S. Food and Drug Administration, Guidance for Industry, Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, *Fed Resist*. 2009;74(35): 65132-133. Available at https://www.fda.gov/downloads/drugs/guidances/ucm193282.pdf. Last Accessed June 24, 2017.
9. Principles of Patient Reported Outcome Measures (PROMs) Reporting, AAOS Information Statement 1044, June 2015. Available at https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/advistmt/1044%20Principles%20of%20Patient%20Reported%20Outcome%20Measures%20(PROMs)%20Reporting.pdf. Last Accessed June 24, 2017.
10. Porter ME, Teisberg EO: *Redefining Health Care: Creating Value-Based Competition on Results*. Boston, MA: Harvard Business School Press, 2006.
11. Saleh KJ, Goldberg MJ: Joint registries and the lessons learned from MODEMS. *AAOS Bulletin,* February 2004.
12. Patient Reported Outcomes Summit for Total Joint Arthroplasty Report, American Association of Hip and Knee Surgeons, August 31, 2015, Available at http://www.aahks.org/wp-content/uploads/2016/08/AAHKS-2015-Outcomes-Summit-Report.pdf. Last Accessed June 24, 2017.
13. Patient Reported Outcome Measures, American Academy of Orthopedic Surgeons, February 29, 2016. Available at https://www.aaos.org/quality/performance_measures/patient_reported_outcome_measures/. Last Accessed June 24, 2017.

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