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Collection and Reporting of Patient-reported Outcome Measures in Arthroplasty Registries: A Multinational Survey and Recommendations

Running title: PROMs in Arthroplasty Registries

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patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

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Abstract

Background Patient-reported outcome measures (PROMs) are validated questionnaires that are completed by patients. Arthroplasty registries vary in PROM collection and use. Limited current information is available about registry collection and use of PROMs; this information is required to improve methods of PROMs data analysis, reporting, comparison, and use toward improving clinical practice.

Questions/purposes To characterize PROM collection and use by registries, we asked: (1) What is the current practice of PROM collection by arthroplasty registries that are current or former members of the International Society of Arthroplasty Registries, and are there sufficient similarities in PROM collection between registries to enable useful international comparisons that could inform the improvement of arthroplasty care? (2) How do registries differ in PROM administration and demographic, clinical, and comorbidity index variables collected for case-mix adjustment in data analysis and reporting? (3) What quality assurance methods are used for PROMs, and how are PROM results reported and used by registries? (4) What recommendations to arthroplasty registries may improve PROMs reporting and facilitate international comparisons?

Methods An electronic survey was developed with questions about registry structure and collection, analysis, reporting, and use of PROM data and distributed to directors or senior administrators of 39 arthroplasty registries that were current or former members of International Society of Arthroplasty Registries. There were 25 registries (64%) that responded and completed the survey. Missing responses from incomplete surveys were captured by contacting the registries, and up to 3 reminder emails were sent to nonresponding registries. Recommendations

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about PROMs collection were drafted, revised, and approved by the International Society of Arthroplasty Registries PROMs Working Group members.

Results In the 25 registries that completed the survey, 15 registries collected generic PROMs, most frequently the EuroQol 5 Dimension survey; 16 registries collected joint-specific PROMs, most frequently the Knee Injury and Osteoarthritis Outcome Score and Hip Disability and Osteoarthritis Outcome Score; and 11 registries collected a satisfaction item. Most registries administered PROM questionnaires within 3 months before and 1 year after surgery. All 16 registries that collected PROMs data collected patient age, sex or gender, body mass index, indication for the primary arthroplasty, reason for revision arthroplasty, and a comorbidity index, most often the American Society of Anesthesiologists classification. All 16 registries performed regular auditing and reporting of data quality, and most registries reported PROMs results to hospitals and linked PROMs data to other data sets such as hospital, medication, billing, and emergency care databases. Recommendations for transparent reporting of PROMs were grouped into four categories: demographic and clinical, survey administration, data analysis, and results.

Conclusion Although registries differed in PROM collection and use, there were sufficient similarities that may enable useful data comparisons. The provided recommendations may help guide registries and improve transparency in the collection, analysis, and reporting of PROMs.

Clinical Relevance By collecting PROMs, registries can provide patient-centered data to surgeons, hospitals, and national entities in order to improve arthroplasty care.

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Introduction

Patient-reported outcome measures (PROMs) are validated questionnaires that provide data about the impact of arthritis and arthroplasty. PROMs are completed by patients and complement existing clinical measures by providing standardized assessments of the perception of patients about their health, quality of life, and mental and social well-being [9, 20, 51]. Generic PROMs assess overall health-related quality of life, and joint-specific PROMs assess outcomes associated with the affected joint [39, 40]. Preoperative and postoperative PROMs are collected and reported by arthroplasty registries [39, 40, 52] and provide essential information for achieving patient-centered, value-based health care. Health systems may use PROMs to assess symptoms and quality of life before and after treatment, evaluate the efficacy of treatment options, monitor variability in indications and outcomes between providers, allocate finite healthcare resources, and identify areas for quality improvement [35].

International variation may occur in the use of PROMs scores by arthroplasty registries [34, 35]. Comparisons of results between registries and countries may be limited because varied PROMs questionnaires are used, limited validated algorithms are available to convert scores between different questionnaires, and there is limited ability to control for case-mix or comorbidity variations between registries [34, 35]. The International Society of Arthroplasty Registries PROMs Working Group was established to develop best practices for selecting, collecting, reporting, and advancing the use of PROMs. In a previous working group survey of registries, there was variation in the collection of joint-specific PROMs between registries [39, 40]. As registries evolve and use newer and varied PROMs, updated information about the registry

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collection and use of PROMs is needed to enable improved methods for PROM collection, analysis, reporting, and use, but there is limited current information available.

The purpose of this study was to characterize current PROM data sources, collection, analysis, and reporting methods by registries, and to develop some general recommendations that could be used by registries to improve PROMs reporting and facilitate international comparisons. To satisfy these objectives, we asked: (1) What is the current practice of PROM collection by arthroplasty registries that are current or former members of the International Society of Arthroplasty Registries, and are there sufficient similarities in PROM collection between registries to enable useful international comparisons that could inform the improvement of arthroplasty care? (2) How do registries differ in PROM administration and demographic, clinical, and comorbidity index variables collected for case-mix adjustment in data analysis and reporting? (3) What quality assurance methods are used for PROMs, and how are PROM results reported and used by registries? (4) What recommendations to arthroplasty registries may improve PROMs reporting and facilitate international comparisons?

Materials and Methods

Survey Development

In this cross-sectional descriptive study, data were collected from an electronic survey that was developed using previously described methods [3, 12]. The survey was created from March 2018 to August 2018 with an iterative method. After we reviewed the findings from our previous studies about the use of PROMs in arthroplasty registries [39, 40], the survey was drafted by two coauthors (ERB and SK). The survey draft was reviewed and discussed by the entire International Society of Arthroplasty Registries PROMs Working Group in an online conference call and emails, and modified to the satisfaction of all group members who included orthopaedic surgeons and nonsurgeon scientists with expertise in PROMs and survey research.

The survey items were formatted on an internet-based survey platform (SurveyMonkey, www.surveymonkey.com, San Mateo, CA, USA) as closed-ended, structured multiple-choice questions, with a response option of "other" that included an open-ended free-text response comment field. Survey items were revised according to observations from preliminary testing of three registries. The final survey included 10 pages and 37 items (Supplementary Material 1; supplemental materials are available with the online version of *CORR*®). The survey opened with general questions about registry structure and continued with detailed questions about the collection, analysis, reporting, and use of PROM data. Adaptive questioning was used to reduce participant burden, and participants were able to change answers before survey completion by using a back button. No personal information was collected or stored.

Survey Administration

The survey was distributed in August 2018 by email to the senior medical leads and senior administrators of 39 arthroplasty registries that comprised all current or former members of the International Society of Arthroplasty Registries. The email included a description of the purpose of the study, request that 1 person from the registry complete the survey regardless of whether the registry routinely collected PROMs, and a hyperlink to the survey. In addition to the initial survey request, three reminder emails were sent, as required.

Survey responses were collated and reviewed by the lead author (ERB). When more than one response was received from different personnel of a registry, the responses were manually combined into a single response.

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Missing responses from incomplete surveys were captured by contacting the registries. Further clarifications that were required for a small number of items during manuscript preparation were requested from respondents by email.

Development of Recommendations

Based on the results of the survey, review of registry reports that include PROM methods and reporting [1, 10, 13, 21, 30, 32, 47], standardized reporting recommendations for observational studies from the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [50], published analyses about reporting issues [2, 6, 9, 11, 14, 16, 18, 24, 25, 29, 30, 38, 42, 43, 44, 49], and the experiences of International Society of Arthroplasty Registries PROMs Working Group members, we updated the previous recommendations of the International Society of Arthroplasty Registries PROMs Working Group to help guide registries about the selection and analysis of PROMs, transparency of reporting, and use of PROMs [39]. The updated recommendations were drafted by 2 coauthors (ERB, ET) as a tabulated list of recommendations and sent to all coauthors for comments, suggestions, revisions, and references. A revised draft was sent to all coauthors for additional review, revisions, comments, and approval.

Ethical Approval

Ethical approval for this study was not sought.

Results

Current Practice of PROM Collection by Arthroplasty Registries

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In the 39 registries from which survey responses were requested, 25 registries (64%) responded to and completed the survey with no replies unanswered, including 16 registries that collected PROMs (Table 1). Most respondents were national registries that collected generic and joint-specific PROMs, and many registries also collected a patient satisfaction metric (Table 2). The 14 nonrepondents included 9 national, 2 regional, and 3 local registries. Most responding registries that used PROMs collected only one generic PROM, most frequently the EuroQol 5 Dimension health outcome survey, and multiple joint-specific PROMs, most frequently the Knee Injury and Osteoarthritis Outcome Score and Hip Disability and Osteoarthritis Outcome Score surveys. Most responding registries that collected a patient satisfaction metric used a single-item question about satisfaction.

PROM Administration and Variables Collected for Case-mix Adjustment

A census method (i.e., inclusion of all patients in the registry) was used by most of the registries for collecting preoperative and postoperative PROMs (Table 3). Most registries captured preoperative and postoperative PROMs for at least 40% of patients in the registry, and most registries reported that patient responses were provided by at least 40% of patients who were requested to provide PROMs, but many registries did not know the proportion of patients in the registry with PROMs captured or frequency of response for patients requested. Most registries administered PROM questionnaires to all patients in the registry coverage area within 3 months before surgery and by 1 year after surgery (Table 3). There was variation between registries in the timing of postoperative PROM collection; four of seven registries that collected 6-month postoperative PROMs did not collect 1-year postoperative PROMs, but no earlier postoperative PROMs were collected by six of 11 registries that collected 1-year postoperative PROMs and

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one of five registries that collected 2-year postoperative PROMs. All 16 registries collected patient age, sex or gender, body mass index (BMI), indication for the primary arthroplasty, reason for revision arthroplasty, and a comorbidity index, most often the American Society of Anesthesiologists classification (Table 4). Most registries collected demographic, clinical, and comorbidity index variables in the registry or by linking with other databases, but we did not ask registries to specify whether comorbidity information was obtained from self-report vs database linkage (Table 4).

Quality Assurance, Reporting, and Use of PROMs by Registries

For quality assurance, all 16 registries that collected PROMs data performed regular auditing and reporting of data quality (Table 5). Simultaneous bilateral procedures were analyzed by 11 of the 16 registries per joint and not per patient. Most registries reported and compared PROM results using mean or median scores, removed patients with missing questionnaires from analyses, and performed case-mix adjustment when reporting PROMs. Case-mix adjustment included potential confounders such as age, gender, diagnosis, and BMI. However, when a PROM questionnaire was missing several item responses, only seven registries completely excluded these PROMs from analysis, and other registries attempted to calculate the missing summary score with methods such as imputation. Most registries reported PROMs to hospitals and national-level entities and provided surgeons and administrators with access to reports (Table 6). PROM data were linked to diverse databases, most frequently hospital databases, using unique personal or personal health identification numbers, date of birth, or gender (Table 6).

Recommendations

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The Working Group recommendations for transparent reporting of PROMs were grouped into four categories: demographic and clinical, survey administration, data analysis, and results (Table 7). It was recommended that registries document the joint, date of surgery, arthroplasty details, comorbidity variables, PROMs surveys and one-item questions used, any modifications to original survey wording or structure, quality assurance methods for data entry, follow-up for unreturned survey responses, and PROMs scoring methods. It was recommended that registries document data analyses with clear definitions of variables in a data dictionary and detailed descriptions of statistical methods, linkage between data sets, and methods of addressing missing data. It also was recommended that reports of results include joint- and patient-specific outcomes and separate report categories for unilateral vs bilateral arthroplasty (Table 7).

Discussion

The 2 previous articles from this Working Group provided basic information about PROMs and suggestions about how arthroplasty registries may set up PROMs collection [39, 40], whereas the present study focused on developing recommendations about improving the quality of reporting and potential for comparison between registries. As limited current information is available about registry collection and use of PROMs, updating this knowledge may improve the feasibility of making comparisons between registries. Findings from the present survey, coupled with recommendations from the STROBE guidelines and other studies (Table 7), facilitated the development of recommendations specific to PROMs reporting by registries [50].

The present results showed that joint registries varied substantially in whether generic and joint-specific PROMs were collected and used. However, there were sufficient similarities between responding registries that may enable useful PROMs data comparisons, evidenced by the high

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frequency (≥ 69%) of multiple variables including similar administration method, variables collected for case-mix adjustment, method of collecting case-mix adjustment variables, quality assurance methods, and report use variables. Although most survey respondents collected and used PROMs, nine of the 25 responding registries did not collect PROMs. The absence of a response to the survey request from 14 of the 39 registries (36%), despite sending three reminder emails, may be indirect evidence that some of these registries may not have been collecting PROMs. Of the 14 nonresponders, 10 were national registries with no on-line evidence of comprehensive national PROMs collection and reporting, 3 were university-based local registries (including 2 registries that had a long publication track record that included PROMs), and 1 was a regional registry with incomplete coverage.

Limitations

The limitations of the present study include those inherent with survey research, including selection bias due to the inclusion of motivated participants and the high percentage of registries that did not participate. The low frequency of responses is in the range typical of surveys of health professionals, and surveys with a 60% or higher frequency of responses may have acceptable face validity [4], but the results should be interpreted with caution because of the high frequency of nonrepondents. As most respondents were national registries, the interpretation of results cannot be generalized to regional, local, or multicenter registries (Table 1). Survey terms may have been misinterpreted because of varied use internationally, such as the term “provider,” which was intended to be synonymous with surgeon but in the United Kingdom may refer to a hospital unit, and future surveys should include unambiguous terms with clear definitions to minimize potential misinterpretation by respondents. The present survey did not include a question to follow up our previous recommendation to include a one-item pain question [39] because we aimed to limit the survey length, but information about pain was provided from pain assessments that were included in PROMs used by respondents such as the Hip Disability and Osteoarthritis Outcome Score, Knee Injury and Osteoarthritis Outcome Score, Oxford Hip Score, and Oxford Knee Score [31, 41, 48, 53]. Furthermore, we did not ask registries about preoperative and postoperative sampling methods such as queries in person or by telephone or postal mail. Documenting sampling methods may be important for improving sampling and comparing data between different registries.

Transparency of reporting PROM results was recommended previously [39] but not assessed in the present survey. A recent example of excellent transparency in reporting PROMs after primary shoulder arthroplasty showed that the frequency of responses may be low, and failure to collect a preoperative PROM survey prospectively may introduce recall bias when it is collected after surgery [30]. A detailed comparison of annual reports of participating registries was beyond the scope of the present study but may provide a useful evaluation of the transparency of current PROM reporting that may enable the assessment of potential sources of bias.

Current Practice of PROM Collection by Arthroplasty Registries

In our survey in 2014, 15 registries routinely collected PROMs, including one registry that was planning to begin PROM collection [40]. In these 15 registries, the present survey showed that 11 registries were still collecting PROMs, two registries (Italian Register of Orthopedic Prosthetic Implants and Lithuanian Arthroplasty Register) had stopped collecting PROMs (reasons for termination unknown), and two registries did not respond. The present survey showed that registries varied in the PROMs instruments that were collected, with ongoing use of

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the EuroQol 5 Dimension health outcome survey, 12-item SF Health Survey, Hip Disability and Osteoarthritis Outcome Score, Knee Injury and Osteoarthritis Outcome Score, Oxford Hip Score, Oxford Knee Score, and Western Ontario and McMaster Universities Osteoarthritis Index, and an increase in the use of Patient-Reported Outcomes Measurement Information System 10 (PROMIS-10) that was not represented in the previous survey [7, 17, 26, 28, 40, 41, 45]. The previous International Society of Arthroplasty Registries PROMs Working Group recommendation to include a one-item measure of satisfaction was not followed by most registries, even though patient satisfaction is an important indicator treatment outcome, possibly because satisfaction may be difficult to standardize and may vary with patient age, sex, comorbidities, expectations, perioperative pain, and duration of hospital stay [33, 39]. Although we reaffirmed the previous recommendation that registries consider using a one-item question for satisfaction, this may be superseded with the development and testing of validated satisfaction instruments [15].

PROM Administration and Variables Collected for Case-mix Adjustment

Registries that collected PROMs had some uniformity of methods such as census method of administration and similar variables collected for case-mix adjustment. The high frequency of registries that reported unknown proportions of patients in the registries with PROMs captured and unknown patient response frequency suggested that registries may not be tracking these important measures of data completeness, and these observations formed the basis for our recommendations that registries should collect and report these data (Table 7). The collection of case-mix variables may enable an adjustment of PROM data for comparisons between registries (Table 4) [39]. All registries that collected PROMs captured age, sex or gender, and diagnosis, as recommended previously [35, 39], but the collection of general health status variables was inconsistent between registries, evidenced by the registries that did not collect information about smoking status, medical comorbidities, alcohol use, activity level, and socioeconomic variables (Table 4).

Quality Assurance, Reporting, and Use of PROMs by Registries

Registries typically audited PROM results and reported data quality but varied in the handling of missing data (Table 5), PROM use, and methods of dataset linkage (Table 6). Comparisons of outcomes between registries may be facilitated by harmonization of methods, language translation, cross-cultural adaptation, and validation of PROMs for diverse languages and cultures [9, 26, 36]. However, variation between registries may occur because of variation in local resources, disease profiles, and purposes of PROM collection [35], and the lack of standardized methods between registries may confound comparative analyses of outcomes between different countries.

Recommendations

In the present recommendations about PROMs quality assurance, reporting, and use, we attempted to highlight issues common to diverse registries and health systems and provide guidance about methods to optimize data quality and comparisons between registries, while avoiding recommendations that may be unrealistic for registries with limited resources or scope. With the previous and present recommendations, we avoided recommending a specific PROMs instrument to incorporate into registries because of variation in PROM instruments in use and potential challenges to registries associated with a change in PROMs instruments [39]. However, PROMs selected for use by registries should have been developed with good measurement

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properties in a relevant population, which are characteristics of most or all of the PROMs currently in use. It is important to recognize and address the limitations of specific PROMs, but these limitations may be unknown upon implementation. When the limitations of a PROM instrument are identified, such as during application of the instrument to a different cultural setting or surgical procedure, a modification of the instrument may be considered [8, 27], and we recommended that the modifications be specified and reported. Future work may include the development of a procedure that may enable instrument modification or updating that would facilitate validation and adoption of the updated version by registries and maintain the potential for evaluation of longitudinal trends. Flexibility in updates of PROMs instruments with structured elements may prevent obsolescence of the instruments caused by rapid advances in technology and may improve learning from the data [23, 37].

When PROMs have floor and ceiling effects that may have implications for analysis and reporting, it is advisable to report the proportion of patients who have scores at the floor or ceiling levels [8, 42]. A critical evaluation of PROM use in other fields such as the foot and ankle shows that widely used but unvalidated scores may continue to be used for several decades despite the lack of validation [19, 22]. The use of recently released guidelines [35] may be considered toward the development of a prescriptive checklist of recommended items for inclusion by registries that may facilitate standardization, analogous to the successful development and application of guidelines to improve the conduct and reporting of observational clinical research studies [46, 50].

Conclusion

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In summary, arthroplasty registries may vary in PROMs collection and use because of variation in resources and goals in different health systems, but the surveyed registries had sufficient similarities in the use of PROMs that may provide a foundation toward harmonizing methods that may enable data integration and comparisons between countries and varied cultures. Variation between registries including PROMs selection, collection methods, and timing of surveys may be dictated by variation between health systems covered, resources available, and local use of survey data. The International Society of Arthroplasty Registries PROMs Working Group recommendations primarily serve to identify issues that may be important to most registries such as the need to make decisions about survey times and collection methods, select generic and joint-specific surveys, handle missing data and attrition, report data, and ensure representativeness of the sample. Transparent and detailed reporting of these issues by registries may enable the performance of high-quality studies using registry data and comparative analyses of data between different registries toward improving arthroplasty care globally.

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References

1. American Academy of Orthopaedic Surgeons (AAOS), American Joint Replacement Registry (AJRR). *Sixth AJRR Annual Report on Hip and Knee Arthroplasty Data, 2019*. Rosemont IL: AAOS; 2019.

2. Bachrach-Lindström M, Karlsson S, Pettersson LG, Johansson T. Patients on the waiting list for total hip replacement: a 1-year follow-up study. *Scand J Caring Sci*. 2008;22(4):536-542.

3. Burns KE, Duffett M, Kho ME, et al. A guide for the design and conduct of self-administered surveys of clinicians. *CMAJ*. 2008;179:245-252.

4. Burns KEA, Kho ME. How to assess a survey report: a guide for readers and peer reviewers. *CMAJ*. 2015;187(6):E198-E205.

5. Canadian Institute for Health Information (CIHI). *Patient-Reported Outcome Measures Data Collection Manual – Hip and Knee Arthroplasty 2019*. Ottawa: CIHI; 2019. https://www.cihi.ca/sites/default/files/document/proms-data-collection-manual-may2019-en-web.pdf. Accessed March 31, 2021.

6. Canfield M, Savoy L, Cote MP, Halawi MJ. Patient-reported outcome measures in total joint arthroplasty: defining the optimal collection window. *Arthroplast Today*. 2020;6(1):62-67.

7. Cella D, Yount S, Rothrock N, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH Roadmap cooperative group during its first two years. *Med Care*. 2007;45(5 suppl 1):S3-S11.

AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.

8. Cobb J, Collins R, Manning V, Zannotto M, Moore E, Jones G. Avoiding the ceiling effect of PROMs: a patient-centred outcome measure correlates with objective differences in gait that are undetectable using the Oxford Hip Score. *Orthop Proc*. 2018:98B(suppl 1). https://online.boneandjoint.org.uk/doi/abs/10.1302/1358-992X.98BSUPP_1.ISTA2014-089. Accessed September 27, 2020.

9. Collins NJ, Roos EM. Patient-reported outcomes for total hip and knee arthroplasty: commonly used instruments and attributes of a "good" measure. *Clin Geriatr Med*. 2012;28(3):367-394.

10. Dutch Arthroplasty Register (LROI). Online LROI annual report 2019. LROI Web site. https://www.lroi-report.nl/previous-reports/online-lroi-report-2019/. Accessed November 10, 2020.

11. Ekegren CL, de Steiger R, Edwards ER, et al. Using patient-reported outcomes to predict revision arthroplasty following femoral neck fracture: enhancing the value of clinical registries through data linkage. *Int J Environ Res Public Health*. 2019;16(8):1325.

12. Eysenbach G. Improving the quality of web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). *J Med Internet Res*. 2004;6:e34. doi:10.2196/jmir.6.3.e34 [published correction in doi:10.2196/jmir.2042].

13. Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE–TJR). FORCE–TJR 2015 Annual Report. FORCE–TJR Web site. https://force-tjr.org/wp-content/uploads/2017/04/FORCE-2015-AR.pdf. Accessed November 10, 2020.

AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.

14. Glymour MM, Weuve J, Berkman LF, Kawachi I, Robins JM. When is baseline adjustment useful in analyses of change? An example with education and cognitive change. *Am J Epidemiol*. 2005;162(3):267-278.

15. Goodman SM, Mehta BY, Kahlenberg CA, et al. Assessment of a satisfaction measure for use after primary total joint arthroplasty. *J Arthroplasty*. 2020;35(7):1792-1799.e4.

16. Hamilton DF, Lane JV, Gaston P, et al. What determines patient satisfaction with surgery? A prospective cohort study of 4709 patients following total joint replacement. *BMJ Open*. 2013;3(4):e002525.

17. Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Qual Life Res*. 2009;18:873-880.

18. Hinman AD, Chan PH, Prentice HA, Paxton EW, Okike KM, Navarro RA. The association of race/ethnicity and total knee arthroplasty outcomes in a universally insured population. *J Arthroplasty*. 2020;35(6):1474-1479.

19. Hunt KJ, Hurwit D. Use of patient-reported outcome measures in foot and ankle research. *J Bone Joint Surg Am*. 2013;95(16):e118(1-9).

20. Johnston BC, Patrick DL, Devji T, et al. Chapter 18: Patient-reported outcomes. In: Higgins J, Thomas J, Chandler J, et al. (eds). *Cochrane Handbook for Systematic Reviews of Interventions. Version 6, 2019*. https://training.cochrane.org/handbook/current/chapter-18. Accessed July 22, 2020.

AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.

21. Kärrholm J, Rogmark C, Nauclér E, Vinblad J, Mohaddes M, Rolfson O. *Swedish Hip Arthroplasty Register: Annual Report 2018*. Göteborg, Sweden: Svenska Höftprotesregistret Registercentrum Västra Götaland; 2019.

22. Kearney RS, Achten J, Lamb SE, Plant C, Costa ML. A systematic review of patient-reported outcome measures used to assess Achilles tendon rupture management: what's being used and should we be using it? *Br J Sports Med*. 2012;46(16):1102-1109.

23. Keszei AP, Berkels B, Deserno TM. Survey of non-rigid registration tools in medicine. *J Digit Imaging*. 2017;30(1):102-116.

24. Keurentjes JC, Van Tol FR, Fiocco M, et al. Patient acceptable symptom states after totalhip or knee replacement at mid-term follow-up: Thresholds of the Oxford hip and knee scores. *Bone Joint Res*. 2014;3(1):7-13.

25. King MT. A point of minimal important difference (MID): a critique of terminology and methods. *Expert Rev Pharmacoecon Outcomes Res*. 2011;11(2):171-184.

26. KOOS translations. KOOS Web site. http://www.koos.nu/koosfaq.html#koostranslations. Accessed November 20, 2020.

27. Lyman S, Omori G, Nakamura N, et al. Development and validation of a culturally relevant Japanese KOOS. *J Orthop Sci*. 2019;24(3):514-520.

28. Murray DW, Fitzpatrick R, Rogers K, et al. The use of the Oxford hip and knee scores. *J Bone Joint Surg Br*. 2007;89(8):1010-1014.

AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.

29. Naal FD, Impellizzeri FM, Lenze U, Wellauer V, von Eisenhart-Rothe R, Leunig M. Clinical improvement and satisfaction after total joint replacement: a prospective 12-month evaluation on the patients' perspective. *Qual Life Res*. 2015;24(12):2917-2925.

30. National Joint Registry. *17th Annual Report 2020*. Hemel Hempstead, Hertfordshire: NJR Service Centre; 2020:34-36, 254-263. https://reports.njrcentre.org.uk/Portals/0/PDFdownloads/NJR%2017th%20Annual%20Report%202020.pdf. Accessed September 27, 2020.

31. Nilsdotter AK, Lohmander LS, Klässbo M, Roos EM. Hip disability and osteoarthritis outcome score (HOOS) – validity and responsiveness in total hip replacement. *BMC Musculoskelet Disord*. 2003;4:10.

32. Norwegian National Advisory Unit on Arthroplasty and Hip Fractures. Report June 2020. Nasjonalt Register for Leddproteser Web site. http://nrlweb.ihelse.net/eng/Rapporter/Report2020_english.pdf. Accessed November 10, 2020.

33. Okafor L, Chen A. Patient satisfaction and total hip arthroplasty: a review. Arthroplasty. 2019;1:6.

34. Organisation for Economic Cooperation and Development (OECD). *Health at a Glance 2019: OECD Indicators*. Paris: OECD Publishing; 2019. OECD iLibrary Web site. https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2019_4dd50c09-en. Accessed July 22, 2020.

AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.

35. Organisation for Economic Cooperation and Development, Patient-Reported Indicator Surveys (PaRIS) Initiative. *Patient-Reported Outcome Measures (PROMs) for Hip and Knee Replacement Surgery: International Data Collection Guidelines*. Ottawa: Canadian Institute for Health Information and Organisation for Economic Co-operation and Development; 2019. http://www.oecd.org/health/health-systems/OECD-PaRIS-hip-knee-data-collection-guidelines-en-web.pdf. Accessed July 22, 2020.

36. Paulsen A, Odgaard A, Overgaard S. Translation, cross-cultural adaptation and validation of the Danish version of the Oxford hip score: Assessed against generic and disease-specific questionnaires. *Bone Joint Res*. 2012;1(9):225-233.

37. Pinto Dos Santos D, Brodehl S, Baeßler B, et al. Structured report data can be used to develop deep learning algorithms: a proof of concept in ankle radiographs. *Insights Imaging*. 2019;10(1):93.

38. Prentice HA, Chan PH, Dillon MT, Reddy NC, Navarro RA, Paxton EW. Lower-extremity total joint arthroplasty in shoulder arthroplasty patients: does the order of the lower-extremity total joint arthroplasty matter? *J Shoulder Elbow Surg*. 2020;29(2):e45-e51. doi:10.1016/j.jse.2019.07.002.

39. Rolfson O, Bohm E, Franklin P, et al. Patient-reported outcome measures in arthroplasty registries. Report of the Patient-Reported Outcome Measures Working Group of the International Society of Arthroplasty Registries Part II. Recommendations for selection, administration, and analysis. *Acta Orthop*. 2016;87(suppl 1):9-23.

AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.

40. Rolfson O, Eresian Chenok K, Bohm E, et al. Patient-reported outcome measures in arthroplasty registries. Report of the Patient-Reported Outcome Measures Working Group of the International Society of Arthroplasty Registries. Part I. Overview and rationale for patient-reported outcome measures. *Acta Orthop*. 2016;87(suppl 1):3-8.

41. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes*. 2003;1:64.

42. Sayers A, Whitehouse MR, Judge A, MacGregor AJ, Blom AW, Ben-Shlomo Y. Analysis of change in patient-reported outcome measures with floor and ceiling effects using the multilevel Tobit model: a simulation study and an example from a National Joint Register using body mass index and the Oxford Hip Score. *BMJ Open*. 2020;10:e033646.

43. Sayers A, Wylde V, Lenguerrand E, et al. A unified multi-level model approach to assessing patient responsiveness including; return to normal, minimally important differences and minimal clinically important improvement for patient reported outcome measures. *BMJ Open*. 2017;7(7):e014041.

44. Schamber EM, Takemoto SK, Chenok KE, Bozic KJ. Barriers to completion of patient reported outcome measures. *J Arthroplasty*. 2013;28(9):1449-1453.

45. Shim J, Hamilton DF. Comparative responsiveness of the PROMIS-10 Global Health and EQ-5D questionnaires in patients undergoing total knee arthroplasty. *Bone Joint J*. 2019;101-B(7):832-837.

AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.

46. Sorensen AA, Wojahn RD, Manske MC, Calfee RP. Using the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement to assess reporting of observational trials in hand surgery. *J Hand Surg Am*. 2013;38(8):1584-1589.e2.

47. Swedish Knee Arthroplasty Register. *Annual Report 2020.* Lund, Sweden: Swedish Knee Arthroplasty Register; 2020. http://myknee.se/pdf/SVK_2020_Eng_1.0.pdf. Accessed November 10, 2020.

48. van Hove RP, Brohet RM, van Royen BJ, Nolte PA. High correlation of the Oxford Knee Score with postoperative pain, but not with performance-based functioning. *Knee Surg Sports Traumatol Arthrosc*. 2016;24(10):3369-3375.

49. van Reenen M, Janssen B, Stolk E, et al. EQ-5D-5L User Guide, 2019. Rotterdam: EuroQol Research Foundation; 2019. https://euroqol.org/publications/user-guides/. Accessed November 18, 2020.

50. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. *PLoS Med*. 2007;4(10):1623-1627.e296.

51. Weldring T, Smith SM. Patient-reported outcomes (PROs) and patient-reported outcome measures (PROMs). *Health Serv Insights*. 2013;6:61-68.

52. Wilson I, Bohm E, Lübbeke A, et al. Orthopaedic registries with patient-reported outcome measures. *EFORT Open Rev*. 2019;4:357-367. doi:10.1302/2058-5241.4.180080.

AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.

53. Wylde V, Learmonth ID, Cavendish VJ. The Oxford hip score: the patient's perspective. *Health Qual Life Outcomes*. 2005;3:66.

AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.