Standardized Library of Lumbar Spondylolisthesis Outcome Measures

Research White Paper

Standardized Library of Lumbar Spondylolisthesis Outcome Measures

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This report is based on research conducted by the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers' Methods Workgroup. The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help EPCs and AHRQ understand health-systems need and use of evidence to inform their decisionmaking. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States.

The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To improve the scientific rigor of these evidence reports, AHRQ supports empiric research by the EPCs to help understand or improve complex methodologic issues in systematic reviews. These methods research projects are intended to contribute to the research base in and be used to improve the science of systematic reviews. They are not intended to be guidance to the EPC program, although may be considered by EPCs along with other scientific research when determining EPC program methods guidance.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The reports undergo peer review prior to their release as a final report.

If you have comments on this Methods Research Project they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Introduction

Significant variation exists in both the types and definitions of outcome measures used in patient registries, even within the same clinical area. This variation reduces the utility of registries, making it difficult to compare, link, and aggregate data across the spectrum of clinical care and reporting. To address these limitations, the Agency for Healthcare Research and Quality (AHRQ) developed the Outcome Measures Framework (OMF), a conceptual model for classifying outcomes that are relevant to patients and providers across most conditions; it is intended to serve as a content model for developing harmonized outcome measures for specific clinical areas.[a]

AHRQ is assessing the feasibility of using the OMF to develop standardized libraries of outcome measures in five clinical areas, including (1) Atrial fibrillation, (2) Asthma, (3) Depression, (4) Lung cancer, and (5) Lumbar spondylolisthesis.[b] These clinical areas represent diverse populations and care settings, different treatment modalities, and varying levels of harmonization. For each clinical area, the relevant registries and observational studies are identified, and registry sponsors, informaticists, and clinical subject matter experts are invited to participate in a registry group that focuses on harmonizing outcome measures through a series of in-person and web-based meetings. A stakeholder group, including payers, patient representatives, Federal partners and health system leaders, is also assembled to discuss challenges and provide feedback on the harmonization effort.

A key goal of this effort is to standardize the definitions of the components that make up the outcome measures, so users can understand the level of comparability between measures across different systems and studies. As a final step in the harmonization process, clinical informaticists map the narrative definitions (generated by the workgroups) to standardized terminologies to produce a library of common data definitions.

This document describes the technical approach used to prepare the Standardized Library of Lumbar Spondylolisthesis Outcome Measures workbook. For reference, the narrative definitions for the minimum set of outcome measures produced by the Lumbar Spondylolisthesis Workgroup are included in Appendix A.

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[a] Gliklich RE, Leavy MB, Karl J, et al. A framework for creating standardized outcome measures for patient registries. Journal of Comparative Effectiveness Research. 2014;3(5):473-80.
[b] This work was supported by the Office of the Secretary Patient-Centered Outcomes Research Trust Fund under Interagency Agreement #16-566R-16.

Approach to Representing an Outcome Definition

For each measure, the accompanying workbook (Appendix B) contains the narrative definition and recommended reporting period (timeframe), the initial population for measurement (e.g., all lumbar spondylolisthesis patients), the outcome focused population (patients who experienced the outcome of interest), and the data criteria and value sets.

Electronic Health Record (EHR) data often will not contain all the requisite components of an outcome definition that would allow for the computational confirmation of that outcome. The approach used for this project is to gather the clinician's assertion of an outcome condition and as much supporting evidence as possible, so that even where the expression logic cannot computationally confirm an outcome, some structured evidence might still be available.

Relationships between events raise a challenge because relationships are often not directly asserted in an EHR. Thus, where possible, relationships have been inferred based on time stamps and intervals. Where this is not possible (e.g., cause of death), the logic requires an asserted relationship.

For each outcome, the following have been defined:

- *An object representing the outcome condition itself:* In many cases, the only structured data will be an assertion of an outcome, with all the supporting evidence being present in the narrative.

- Fast Healthcare Interoperability Resources (FHIR) resources for evidence for the outcome: These include labs, diagnostic imaging, etc.

- *FHIR resources for additional relevant events:* These might include procedures, encounters, etc.

- *Temporal aspects for all events:* These allow for inferred relationships.

Approach to Identifying Overlaps

A key goal of this project is to leverage existing resources and build connections across initiatives, where possible. To support that goal, the following sources were searched for overlap:

- https://ecqi.healthit.gov/: Primarily looking for overlapping criteria
- https://vsac.nlm.nih.gov/: Primarily looking for overlapping value sets
- C-CDA: Primarily looking for overlapping data representations
- https://www.nlm.nih.gov/cde/: Primarily looking for overlapping data element definitions

Each website has a specific, unique purpose, and data representations vary, so while there are some direct comparisons with similar use cases, there are also important differences both in terms of data structures and use cases. Results of the comparisons are provided below.

- https://ecqi.healthit.gov/; https://vsac.nlm.nih.gov/:
    - We identified the following overlapping value sets in VSAC:
        - C2SOpioids
        - PROMIS29DepressionScore
        - PROMIS29PainInterferenceScore
        - PROMIS10GlobalPhysicalHealthScore
        - PROMIS29FatigueScore
        - PROMIS29PhysicalfunctionScore
        - PROMIS29AnxietyScore
    - Minor differences were resolved. Reasons for differences may include:
        - Different use cases
        - +/- inclusion of retired codes
        - Different groups find different codes
        - Drug class ambiguities
        - +/- inclusion on non-billable ICD codes
        - Lack of intensional rules makes comparison difficult
    - eCQMs are based on the National Quality Forum's Quality Data Model, as expressed as HL7 QRDA templates, whereas this project is based on FHIR version

1.8.0 objects. The HL7 Clinical Quality Improvement committee is actively harmonizing QDM and FHIR resources, and a FHIR-based quality reporting format is expected to be balloted soon.

- o VSAC does not at this time provide intensionally-defined value sets. Therefore, comparisons are done based on enumerated lists.

- C-CDA:

  - o There are no lumbar spondylolisthesis specific templates or value sets in C-CDA.

- https://www.nlm.nih.gov/cde/:

- We were unable to identify any data elements that laid out specific criteria for any of the lumbar spondylolisthesis outcomes. CDEs generally look for presence/absence of a condition, and may associate a condition with a code system or value set. As a result, there was minimal overlap between any lumbar spondylolisthesis outcome and existing CDEs.

Challenges and Lessons Learned

Some challenges were encountered in translating the text definitions produced by the workgroup into standardized definitions and value sets. Of note, a directly asserted association between adverse event and medical intervention may not be present in the EHR (e.g., reason for hospitalization is simply stated as "hypoglycemia"). The association may need to be inferred (e.g. if a patient was recently started on an oral hypoglycemic, one can infer that the hypoglycemia is a medication-related adverse event). For medication-related adverse events, three possible representations that could potentially be seen in EHR-extracted data are provided: 1) association is based on the adverse reaction being similar to the stated reason for the intervention (e.g., adverse reaction to opioid is apnea; reason for intervention is apnea); 2) association is based on the stated reason for the intervention having a dueTo relationship to a drug (e.g., reason for hospitalization = GI Bleed; GI Bleed is due to adverse reaction to NSAID); and 3) association is based on the stated reason for the intervention having a dueTo relationship to an "Adverse Reaction Caused by Drug" code (e.g., reason for hospitalization is 'oral hypoglycemic adverse reaction').

In addition, the concept of complications related to a procedure or treatment may be challenging to capture when using retrospective data, such as data collected from an EHR or billing system. It is often not feasible to attribute causality; events may or may not be recorded as procedure or treatment-related complications, and it can be difficult to verify. In defining treatment-related complications, the relationship between the complication and the presumed inciting procedure/therapy is inferred by date/time stamps (as opposed to a directly asserted causal relationship).

Appendix A. Harmonized Definitions for Lumbar Spondylolisthesis Outcome Measures

OMF CATEGORY	OUTCOME MEASURE	DEFINITION
Survival	All-cause death at 30 days	All-cause death within 30 days of treatment. Collect cause of death when possible.
Clinical Response	Pain intensity, pain interference, physical function & mobility, and psychological well-being	The domains of pain intensity, pain interference, physical function & mobility, and psychological well-being are critical to measuring clinical response. Recommendations for measuring these domains are included in the *Patient Reported* category.
Clinical Response	Use of morphine-equivalent pain medication	Use of morphine-equivalent pain medication (collect type, duration, dosage). Measurement Intervals: • Pre-treatment • 1 month post-treatment for specific purposes (e.g., use of morphine-equivalent pain medications, non-surgical treatments) • 3 months post-treatment • 1 year post-treatment *Annual follow-up beyond 1 year is recommended as a supplemental measure to support patient management and increase understanding of long-term patient outcomes.*
Patient Reported	Pain intensity	Pain intensity, measured separately for Back Pain and Leg Pain with Numeric Rating Scale using anchors from PROMIS. Measurement Intervals: • Pre-treatment • 1 month post-treatment for specific purposes (e.g., use of morphine-equivalent pain medications, non-surgical treatments) • 3 months post-treatment • 1 year post-treatment *Annual follow-up beyond 1 year is recommended as a supplemental measure to support patient management and increase understanding of long-term patient outcomes.*

OMF CATEGORY	OUTCOME MEASURE	DEFINITION
Patient Reported	Pain interference	Pain interference, using PROMIS domain. Measurement Intervals: • Pre-treatment • 1 month post-treatment for specific purposes (e.g., use of morphine-equivalent pain medications, non-surgical treatments) • 3 months post-treatment • 1 year post-treatment *Annual follow-up beyond 1 year is recommended as a supplemental measure to support patient management and increase understanding of long-term patient outcomes.*
Patient Reported	Physical function & mobility	Physical function & mobility, using PROMIS domain or Oswestry Disability Index (ODI). Measurement Intervals: • Pre-treatment • 1 month post-treatment for specific purposes (e.g., use of morphine-equivalent pain medications, non-surgical treatments) • 3 months post-treatment • 1 year post-treatment *Annual follow-up beyond 1 year is recommended as a supplemental measure to support patient management and increase understanding of long-term patient outcomes.*
Patient Reported	Psychological well-being (depression/anxiety)	Psychological well-being (depression/anxiety), using PROMIS domain or PHQ-4. Measurement Intervals: • Pre-treatment • 1 month post-treatment for specific purposes (e.g., use of morphine-equivalent pain medications, non-surgical treatments) • 3 months post-treatment • 1 year post-treatment *Annual follow-up beyond 1 year is recommended as a supplemental measure to support patient management and increase understanding of long-term patient outcomes.*

Events of Interest	Adverse events associated with surgical and non-surgical treatment	Defined as treatment-related and systemic adverse events occurring ≤ 30 days after a surgical procedure or non-surgical treatment (injections, chiropractic care, physical therapy, acupuncture, and complementary care):
		Treatment-related: • CSF leak not requiring a new hospitalization or invasive treatment • CSF leak requiring a new hospitalization or invasive treatment • Infection (wound or injection site) requiring oral antibiotics • Infection (wound or injection site) requiring IV antibiotics or a new hospitalization or new operation • Instability requiring non-surgical management • Instability requiring a new operation • Instrumentation failure requiring re-operation • Recurrent disc herniation requiring non-surgical management • Recurrent disc herniation requiring a new operation • New neurological deficit (unresolved at 30 days) • Disc injury (e.g., annular tear or disc herniation) not requiring a new hospitalization • Disc injury (e.g., annular tear or disc herniation) requiring a new hospitalization • Cauda equina syndrome not requiring a new hospitalization • Cauda equina syndrome requiring a new hospitalization • Fracture not requiring hospitalization • Fracture requiring a new hospitalization • Organ injury not requiring a new hospitalization • Organ injury requiring a new hospitalization Systemic events: • Central neurological deficit not requiring a new hospitalization • Central neurological deficit requiring a new hospitalization • Urinary complications not requiring a new hospitalization • Urinary complications requiring a new hospitalization • Pulmonary embolism not requiring a new hospitalization • Pulmonary embolism requiring a new hospitalization • Deep vein thrombosis • Myocardial infarction not requiring a new hospitalization • Myocardial infarction requiring a new hospitalization • Any other event that results in an emergency room visit, new hospitalization, or new operation

OMF CATEGORY	OUTCOME MEASURE	DEFINITION
		Post-treatment adverse events, defined as any treatment-related adverse event (see list above) that occurs > 30 days post-treatment.
Events of Interest	Adverse events associated with medications	Medication-related adverse events, defined as: • Adverse events related to use of medications, including NSAIDs, opioids, and other medications, that result in medical intervention (such as hospitalization or surgical intervention) within 30 days of treatment *Use of opioids 30 days post-treatment is considered an adverse event and is captured under Clinical Response.*
Events of Interest	Adverse events associated with disease progression	Adverse events associated with natural progression of disease, reported at 12-month intervals for the duration of the study. • Development of new neurological deficit • New onset urinary retention • Worsening back and/or leg pain symptoms. Recommendations for measuring Pain Intensity and Pain Interference are included in the *Patient Reported* category
Resource Utilization	Treatment-related resource utilization	Any treatment-related resource utilization, including elevation of care (e.g., outpatient to inpatient) and further treatment after initial treatment

Appendix B. Standardized Library of Lumbar Spondylolisthesis Outcome Measures

See associated Excel file.