Study of a Patient-reported Outcomes Registry for Musculoskeletal Conditions

by the Employees Retirement System of Texas and the Teacher Retirement System of Texas

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ERS
EMPLOYEES RETIREMENT SYSTEM OF TEXAS

TRS
TEACHER RETIREMENT SYSTEM OF TEXAS

INTRODUCTION

Senate Bill 55 (SB 55), 85th Legislative Session, by Senator Judith Zaffirini, requires the Employees Retirement System of Texas (ERS) and the Teacher Retirement System of Texas (TRS) to "jointly conduct a study of the benefits and disadvantages of establishing a patient-reported outcomes (PRO) registry for musculoskeletal care" provided under the plans of group coverage administered by the agencies.

The study conducted under SB 55 seeks to:

(1) "identify the musculoskeletal conditions and injuries that result in the highest cost for health care in the plans of group coverage;

(2) identify the percentage of the total cost for health care under the plans of group coverage that is spent for musculoskeletal conditions and injuries;

(3) estimate the cost for the systems, or for the entities administering the plans of group coverage on the systems' behalf, to establish and administer a patient-reported outcomes registry for musculoskeletal care;

(4) evaluate the potential benefits of a patient-reported outcomes registry for musculoskeletal care for the populations served by the plans of group coverage; and

(5) identify potential partners, such as a collaborative partnership between medical schools and chiropractic colleges located in this state, that could assist the systems in establishing and administering a patient-reported outcomes registry for musculoskeletal care."

The joint study found that there are nearly one million total participants combined in the ERS and TRS self-funded health plans, which cover Texas state, higher education and public school employees, retirees and their families (except for The University of Texas and Texas A&M University systems). One-third of current state employees and one-fourth of current public school employees have a diagnosed musculoskeletal condition.

According to medical claims data for Fiscal Year 2017, spending on musculoskeletal conditions and injuries is 13% of total health care spending in the ERS self-funded plans and 11% of total health care spending in the TRS self-funded plans. TRS and ERS work closely with third-party administrators to manage costs while ensuring that patients get the most appropriate treatment for their conditions. Cost-management strategies range from value-based payment arrangements with providers, to referral and prior-authorization protocols relevant to the process of diagnosing and guiding the patient to the most appropriate level of care.

PRO registries have been developed for various conditions and procedures as another tool that could be used for determining the best course of care for a patient. Patients report on their experience through a series of surveys, which are uploaded to a database (the registry) to enable data-sharing. According to the U.S. Food and Drug Administration (FDA), a patient-reported outcome (PRO) is defined as a measurement based on a report that comes directly from the patient about the status of a patient's health condition, without amendment or interpretation of the patient's response by a clinician or anyone else. PROs are a subgroup of patient outcomes.

As part of the background research for this study, ERS and TRS issued a Request for Information (RFI) in January 2018 to identify potential PRO registry solutions offered by community stakeholders, including models, costs, benefits and challenges for establishing and administering a registry for musculoskeletal conditions.

Information gathered from RFI responses was used to supplement the agencies' independent research. Responses were received from provider associations, academic health centers, private technology vendors and a health care specialty management company.

KEY FINDINGS

- State-sponsored benefit plans are not typically the sponsors or funders of registry projects in the United States.
- Without additional funds expressly appropriated for an expanded PRO registry, the expenditure of ERS and TRS health care trust funds is restricted to the exclusive benefit of its respective plan populations. Incentivizing providers to collect data only for ERS and TRS plan participants could pose a significant challenge.
- The cost to the state of establishing a PRO registry for ERS and TRS plan participants could range from $2 million to $7 million annually over five years, depending upon the specific solution selected and scope of reporting.
- Because PRO registries are relatively new in the U.S., it has not yet been established that savings would outweigh the costs of establishing and maintaining a registry.
- The primary stakeholder groups reporting interest in the development of a PRO registry are orthopedic surgeons, provider associations, academic institutions and private vendors, including technology and care-management companies.
- A registry could be used by providers and researchers to inform patient care and customize treatment to individuals through shared decision-making.
- Health plan participants could benefit from a registry if it resulted in appropriate, safer, cost-effective care by providers who use the registry to inform and improve their practices, and if it enhanced shared decision-making between the patient and provider in health care decisions.
- Health plans (or payors, including the State of Texas) might benefit from a registry if it resulted in more cost-effective care, cost savings and improved outcomes for patients. Registries could play a role in higher Medicare reimbursement rates for providers who participate.

Interested stakeholders who responded to the RFI about a PRO registry were orthopedic surgeons, orthopedic associations, academic institutions and private vendors, including technology and care-management companies. The responses to the RFI represented a wide range of expertise and experience related to PRO registries.

Based on the responses, it could cost the state $2 million to $7 million annually over five years to establish a PRO registry, depending upon the specific model and scope selected.

ERS and TRS found the most engaged constituency for the establishment of a PRO registry to be orthopedic providers, orthopedic associations and researchers. A successful registry depends on the strong interest of the provider stakeholders, because provider investment of time and resources is essential for successful data collection and for applying data analysis to improve clinical practice.

A common vision articulated by the providers and associations “should be the routine and consistent collection of outcomes data for every patient that visits a musculoskeletal provider.” However, any TRS- and ERS-funded registry and data collection effort would be limited to ERS and TRS plan participants only.

The study also found the following information to suggest that ERS and TRS are not appropriate administrative homes for a health condition or health procedure registry:

- State-sponsored benefit plans are typically not payors or sponsors of a PRO registry.
- ERS and TRS health care trust funds are restricted to the exclusive benefit of the respective plan populations.
- Providers are not likely to assume the administrative burden of collecting PRO data only on a subset of patients, which may not yield meaningful results for their practice.
- ERS and TRS do not house the clinical expertise required to oversee a medical research project of this magnitude.

If the State of Texas seeks to implement a registry with an appropriate administering entity, potential partners could include private and non-profit entities with experience administering and successfully using a musculoskeletal registry, and academic research institutions. These partners would be responsible for all aspects of data collection, data warehousing and data analysis.

Feasibility of creating and administering a PRO registry

A registry administered by ERS and TRS must be limited to the plans' populations due to the requirement that health care trust funds be used for the exclusive benefit of the respective plan populations. Establishing a registry only for TRS and ERS patients poses a unique challenge for implementing a data-collection system that exists only for this subset of patients.

The collection of information about patients, their conditions, treatment and outcomes occurs at the provider and hospital level. For a registry limited to ERS and TRS plan participants, providers without a meaningful number of these patients would have little incentive to integrate this level of data collection into their clinical practice. One RFI respondent cited "institutional buy-in" as a true challenge to gaining meaningful results. The same respondent noted:

"Participating institutions in Texas may not have dedicated staff to implement a PRO program. It may take 10-20 minutes of administrative time to register and encourage patients to complete needed procedures to participate in a registry effort. Depending on the institutional buy-in, the follow-up response rate may be low."

If a registry met the goal of providing research analysis that would better inform providers about the most appropriate, cost-effective treatment for a patient, it could contribute to:

- improved patient experience of care (including quality and satisfaction);
- improved patient health outcomes; and
- lower treatment costs.

ERS and TRS would find value in a registry that would lead to improved health outcomes for their participants and potential cost savings to the plans. However, this study has found that while PRO registries in the United States so far have shown promise toward achieving these goals, it has not yet been established that savings would outweigh the costs of creating and maintaining a registry.

Musculoskeletal claims in the ERS and TRS plans

An analysis of medical claims shows that state spending on musculoskeletal conditions in this group was about $560 million in FY17 -- representing $300 million, or 13%, of total health care spending in the ERS self-funded plans and $259 million, or 11%, of total health care spending in the TRS self-funded plans. These costs include all treatments for these conditions, including, but not limited to, surgical procedures and pain management treatments.

Combined, ERS and TRS self-funded plans had 961,328 non-Medicare-primary participants enrolled in FY17, the large majority of whom reside in Texas. ERS has a higher percentage of participants with a musculoskeletal diagnosis, and subsequently has higher total spending on musculoskeletal claims. Participants enrolled in Medicare are not included in the analysis due to the difficulty in comparing total cost of treatment with Medicare as the primary payor.

The tables on the next page display demographic information, as well as information about cost and utilization for musculoskeletal conditions in both populations.

Table 1: Demographic data for non-Medicare participants in self-funded plans, FY17

Demographic	ERS	TRS
Overview		
Total population	440,296	521,032
Average age	37	37
Participants residing in Texas	99%	99%
Participants with a musculoskeletal diagnosis	31.5%	23.8%
Total spending on musculoskeletal claims	$300 million	$259 million
Relationship Type		
Employee	48.0%	53.6%
Retiree	11.0%	10.6%
Spouse dependent	12.0%	7.1%
Child dependent	29.0%	28.5%

Table 2: Demographic data for participants with musculoskeletal conditions, FY17

Demographic	ERS	TRS
Relationship Type		
Employee	60.1%	56.6%
Retiree	9.7%	19.6%
Spouse dependent	15.5%	9.9%
Child dependent	14.7%	13.8%
Employment Status		
Active	83.9%	74.8%
COBRA	0.3%	0.3%
Retired	15.9%	24.9%
Gender		
Male	37.9%	27.8%
Female	62.1%	72.2%
Age		
Under 30	19.5%	17.8%
30 to 39	12.3%	11.1%
40 to 49	18.7%	16.9%
50 to 64	43.6%	50.6%
65+	5.9%	3.5%

The musculoskeletal conditions and injuries that result in the highest cost in the ERS and TRS self-funded plans are intervertebral disc disorders and osteoarthritis. For intervertebral disc disorders, the average cost is $2,130.57 per diagnosed ERS participant and $1,967.92 per diagnosed TRS participant. For osteoarthritis, the average cost is $3,383.44 per diagnosed ERS participant and $4,246.76 per diagnosed TRS participant.

Table 3: Musculoskeletal conditions by prevalence, FY17

Condition	ERS Prevalence (per 1,000 Participants)[1]	ERS Average Cost per Diagnosed Participant[2]	TRS Prevalence (per 1,000 Participants)[3]	TRS Average Cost per Diagnosed Participant[4]
Intervertebral disc disorders	120.4	$2,130.57	87.5	$1,967.92
Osteoarthritis	35.5	$3,383.44	31.5	$4,246.76
Other connective tissue disorder	117.1	$725.60	93.3	$665.59
Other non-traumatic joint disorder	105.6	$519.26	74.4	$443.29
Rheumatoid arthritis	9.0	$4,450.58	8.8	$2,063.78
Other acquired deformities	8.5	$3,766.34	7.0	$4,211.30
Bone disorder/musculoskeletal deformity	37.8	$602.35	37.1	$425.76
Inflammatory arthritis/osteomyelitis	1.2	$11,349.88	1.2	$8,991.66
Lupus/connective tissue disorder	4.7	$2,826.87	4.5	$1,623.21
Condition	**ERS Prevalence (per 1,000 Participants)[5]**	**ERS Average Cost per Diagnosed Participant[6]**	**TRS Prevalence (per 1,000 Participants)[7]**	**TRS Average Cost per Diagnosed Participant[8]**
Acquired foot deformities	6.1	$1,744.18	5.8	$1,902.06
Pathological fracture	0.5	$5,818.63	0.5	$5,822.38
Osteoporosis	6.9	$391.60	6.7	$224.84

[1] FY17 enrollment of 440,296 non-Medicare participants in ERS-sponsored self-funded plans.

[2] Average cost per ERS non-Medicare-primary participant includes paid (not allowed) medical costs, for those with musculoskeletal conditions only.

[3] FY17 average enrollment of 443,046 TRS-ActiveCare participants and 77,987 TRS-Care participants without Medicare, enrolled in TRS-sponsored self-funded plans.

[4] Paid (not allowed) medical costs for TRS participants with musculoskeletal conditions (no pharmacy costs included).

[5] FY17 enrollment of 440,296 non-Medicare participants in ERS-sponsored self-funded plans.

[6] Average cost per ERS non-Medicare-primary participant includes paid (not allowed) medical costs, for those with musculoskeletal conditions only.

[7] FY17 average enrollment of 443,046 TRS-ActiveCare participants and 77,987 TRS-Care participants without Medicare, enrolled in TRS-sponsored self-funded plans.

[8] Paid (not allowed) medical costs for TRS participants with musculoskeletal conditions. No pharmacy costs included.

Table 4: Musculoskeletal procedures by cost, FY17

Condition	ERS Number of Procedures (per 1,000 Participants)	ERS Average Cost per Procedure[9]	TRS Number of Procedures (per 1,000 Participants)	TRS Median Cost per Procedure[10]
Spinal fusion	2.0	$49,247.54	1.7	$48,604.33
Hip replacement, total and partial	1.0	$25,104.56	1.2	$32,737.60
Arthroplasty, knee	2.2	$23,623.93	2.4	$32,712.19

[9] Average paid (not allowed) medical costs for ERS, inclusive of facility and professional fees due to inpatient stays associated with procedures. No pharmacy costs included.

[10] Median paid (not allowed) medical costs for TRS, inclusive of facility and professional fees due to inpatients stays associated with the procedures. No pharmacy costs included.

Current cost and quality care management practices around musculoskeletal care

ERS and TRS contract with third-party administrators (TPAs) with proven clinical and administrative expertise in working with providers and plan participants to ensure the most appropriate and cost-effective courses of treatment. What follows is not a comprehensive list of TRS and ERS practices, but rather illustrative examples of how the plans work to ensure that patients with musculoskeletal conditions are receiving the most appropriate, cost-effective care from their providers.

ERS

The ERS point-of-service plan, HealthSelect[SM] of Texas, requires referrals from a participant's primary care physician to see a specialist, including an orthopedic surgeon. Patients are not required to obtain a referral for certain "lower" levels of care for musculoskeletal issues, such as physical and occupational therapy or chiropractic visits.

In addition, ERS offers a reduced copay benefit to participants enrolled in HealthSelect of Texas and HealthSelect Out-of-State for visits to Airrosti Rehab Centers (Airrosti) in the network. Compared to a visit to a specialist, which requires a $40 copay, a visit to an Airrosti provider requires a $25 copay. Airrosti provides chiropractic treatment in conjunction with physical therapy exercises with the intent of reducing pain, by using "applied integration for the rapid recovery of soft tissue injuries."

The HealthSelect plan requires prior authorization for certain outpatient and inpatient surgical treatments, as well as high-tech radiology procedures for musculoskeletal issues. Prior authorization requests are reviewed by clinical staff at the TPA with condition-specific expertise to ensure that the services requested are medically necessary and the most appropriate course of treatment for the participant.

ERS' TPA also offers a care management program that aims to support participants by providing additional clinical support, education and care coordination for any health challenges a participant may be experiencing, including those related to musculoskeletal care. In hospitals that treat higher concentrations of HealthSelect patients, the TPA has these clinicians on site to support patients with care transitions and discharge instructions to ensure the best outcomes post-treatment and to avoid readmissions.

TRS

TRS employs various strategies to contain rising health care costs and deliver high-quality, efficient care for musculoskeletal conditions. Utilization management strategies help TRS ensure patients with these issues receive medically necessary care. TRS participants are required to get prior authorization before undergoing imaging and surgical procedures to diagnose and treat musculoskeletal conditions. Certain high-cost prescription drugs such as Humira and Enbrel are subject to prior authorization or step therapy. TRS has an advanced imaging steerage program in place to inform participants needing advanced imaging such as MRIs, CAT scans and PET scans about lower-cost providers. Participants also have access nutrition counseling, physical therapy and chiropractic benefits through TRS health plans.

TRS' health plan administrators all have comprehensive disease management programs that assist participants to manage complex and/or chronic conditions, including musculoskeletal conditions, and achieve health goals. In addition, TRS has invested in value-based purchasing arrangements in recent years, in which provider payments are tied to quality measures. For example, nearly 50,000 TRS-ActiveCare participants receive care through an accountable care organization (ACO) where a group of providers coordinates patient care. Patients with musculoskeletal conditions often have other health issues, and ACOs are particularly effective at providing care for patients with multiple chronic conditions.

Most recently, TRS has partnered with UT Health Austin, the clinical practice of Dell Medical School, to launch a pilot program effective December 2018 to treat TRS participants with low-back pain with the goal of avoiding surgery. As part of the program, participants receive team-based care coordinated around their specific needs. Physicians, physical therapists, behavioral therapy specialists and dieticians all work together with the patient to develop and carry out a treatment plan.

ERS and TRS are not appropriate administrative homes for a registry, given the following:

- State-sponsored benefit plans are typically not payors or sponsors of a PRO registry.
- ERS and TRS do not house the clinical expertise required to oversee a medical research contract.
- ERS and TRS health care trust funds are restricted to the exclusive benefit of the respective plan populations.
- Providers may not be willing to assume the administrative burden of collecting PRO data on only a subset of patients, which may not yield meaningful results for their practice.
- Orthopedic provider respondents to the RFI reported that ideally, PROs would be collected for all musculoskeletal patients, meaning they believe a statewide registry would be preferable.

If the State of Texas seeks to implement a registry with an appropriate administering entity, there are key considerations that apply to its implementation. In developing this report, the agencies leveraged journal articles, personal interviews and web sources from other PRO registry initiatives, plus information submitted through a Request for Information to develop a list of variables and best practices that should be considered in any potential PRO registry.

Purpose is important

A PRO registry could be structured in any number of ways, depending on the defined objectives. For example, if the state's focus is to foster shared decision-making between patients and clinicians, then the program would be scaled and targeted to that outcome. However, if the State of Texas seeks to gather and leverage PRO measures to facilitate value-based payment arrangements, a PRO registry might have other characteristics.

Experts suggest there are four primary ways to use PRO measures. Each use-case creates a unique value proposition for key stakeholders:

- Individual patient care decisions (patients and clinicians)
- Quality improvement (hospital leaders and clinicians)
- Value-based payment (insurers, payors and hospital leaders)
- Population health and research (researchers, policy makers and funders)[11]

An immediate challenge, as indicated by the National Quality Forum (NQF), is that standard PRO measures have not been widely adopted for clinical use outside research or pilot settings in the United States. Therefore, Texas has few templates from which to draw best practices.[12] Nonetheless, there are several prominent orthopedic registries that could provide informative models and at least two national registries that providers and hospitals in Texas may participate in today, in addition to other models: the Comparative Effectiveness Translational Network (CERTAIN) at the University of Washington; Michigan Arthroplasty Registry at University of Michigan; The Kaiser Permanente National Total Joint Replacement Registry (TJRR); and the California Joint Replacement Registry.[13]

[11] Patricia Franklin, Kate Chenok, Danielle Lavalee, "Framework to Guide The Collection and Use of Patient-Reported Outcome Measures in the Learning Healthcare System," eGEMs Volume 5, Issue 1 (2017).

[12] National Quality Forum, Patient Reported Outcomes (PROs) in Performance Measurement.

[13] Franklin, *eGEMs*.

Costs, funding and privacy concerns

In a survey of the literature and existing programs, we found that neither state governments nor government benefit programs typically serve as the sponsors or funders of registry projects. A few examples of registries and their sponsors are:

- The Kaiser Permanente National Total Joint Replacement Registry, run by Kaiser Permanente, a health maintenance organization (HMO);
- Comparative Effectiveness Translational Network (CERTAIN) at the University of Washington, run by an academic institution;
- FORCE-TJR at the University of Massachusetts Medical School, operated by the medical school and federally-funded by the Agency for Healthcare Research and Quality (AHRQ);
- The Michigan Arthroplasty Registry at University of Michigan, financially supported by Blue Cross and Blue Shield of Michigan as part of the BCBSM Value Partnerships program; and
- California Joint Replacement Registry (CJRR), formerly funded by grants through a non-profit philanthropic organization.

Apart from Kaiser Permanente, which, as an HMO is both a payor and a provider of health care, the study was unable to identify any model that directly engages payors in implementation or downstream activities. In other words, there does not appear to be any health plan sponsor or insurance company that is actively involved in collecting PRO data or using the information to inform incentive or value-based payment models.

It is challenging to estimate the cost to develop and implement a PRO registry because of the number of variables and dependencies (inputs) that would influence the design and the relative availability of data. RFI respondents supplied a wide variety of cost estimates, based on various design assumptions that differed greatly from one another. Those cost estimates ranged between $2 million and $7 million annually, depending on the solution. Start-up costs could be reduced by partnering with an existing platform.

To establish and administer the CJRR, the Pacific Business Group on Health spent approximately $9 million over five years, awarded by the California HealthCare Foundation. Although this registry collects information about plan participants in the California Public Employees' Retirement System (CalPERS), CalPERS does not access or use the data, even though it does promote hospitals that participate in the registry to its participants seeking musculoskeletal care.

If claims information were to be used in conjunction with PRO measures (for example, in measuring cost-effectiveness), another cost to the state comes with the potential risks in sharing an individual's health information with a third party. Regardless of what entity is administering a registry, as the insurance payor, the state has an obligation to protect the health information of ERS and TRS plan participants in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Any failure of this obligation results in steep federal fines. With HIPAA concerns in mind, third-party entities working with claims data would need to adhere to federally required agreements and be subject to a high level of due diligence.

Structural variables

Research revealed a wide range of variables to consider in defining the operating structure of a PRO registry. Those variables include, but are not limited to:

- quality measurement;
- patient population (inclusion/exclusion);
- survey instrument;
- technology and interoperability;
- support systems;
- security; and
- legal considerations.

In the following sections, we explore each of these variables. It should be noted that these variables could be combined in a variety of possible iterations, depending on the desired outcomes of a program and the realities of implementation.

PRO measures

The FDA defines "patient-reported outcome" as a measurement based on a report that comes directly from the patient about the status of a patient's health condition, without amendment or interpretation of the patient's response by a clinician or anyone else.[14] PROs are a subgroup of patient outcomes.[15] Unlike process measures, which capture provider productivity and adherence to the standards of recommended care – or patient experience measures, which focus on aspects of care delivery such as communication – PRO measures attempt to capture whether rendered services actually improved patients' health and sense of well-being. For example, patients might be asked to assess their general health, ability to complete various activities, mood, level of fatigue and pain.[16]

Selected measures for a PRO registry (also called inclusion criteria) could depend (a) on the types of data sought by project sponsors and (b) how that data will be used. One RFI respondent recommended initially focusing on prevalent conditions, like osteoarthritis, that require high-cost procedures or treatments.

For example, The Center for Medicare and Medicaid Innovation (CMMI) uses validated PRO measures on knee or hip arthritic pain, joint-related functional limitations, and physical health status before and after total joint replacement for their national bundled payment program.[17]

Some constraints in selecting PRO measures are:

- the limited existence of validated measures for musculoskeletal conditions;[18]
- the need to translate PRO measures into multiple languages for use among diverse patients;
- the cost of fees and licenses for some validated measurements and measurement instruments; and
- varied requirements to meet certain literacy levels.

In summary, the selection of specific, validated measures should guarantee research-quality data with a high level of reliability.

Registry participants

The specific goals of a registry would help determine the patient population and the providers that should be asked to participate. Some examples of population registries include:

- product registries for persons with medical devices or other products;
- health registries for persons who have a defined procedure, episode or clinical experience (such as hip and knee replacement); and
- condition registries for persons identified by a specific diagnosis.

Additionally, other inclusion criteria could include: (1) specific conditions that are either high risk, high cost or subject to potential over-treatment; and (2) specific procedures such as surgeries that are high risk, high cost or subject to potential over-utilization or wide variance in outcomes.

Criteria for inclusion or exclusion should be based on the desired strategies for the program, such as shared decision-making, clinical research and/or pursuit of additional value-based purchasing.

Patient recruitment and tracking

After consideration of an appropriate administrative home for the registry, that entity or collaborating partners would recruit providers and hospitals for participation. Providers and hospitals would then need support for integrating a data collection system into the clinical practice. A partner with clinical and analytical expertise would need to determine the level of patient participation that would be meaningful, and strategically begin recruitment with the providers and hospitals with the highest volumes of state-sponsored plan participants. Potential partners could include private and non-profit entities with experience administering and successfully using a musculoskeletal registry, as well as academic research institutions.

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[14] U.S. Food and Drug Administration, Guidance for Industry: Patient Reported Outcome Measures: Use in Medical Product Development and Labeling Claims. (2009)

[15] Gliklich RE, Dreyer NA, Leavy MB, editors. Registries for Evaluating Patient Outcomes: A User's Guide [Internet]. 3rd edition. Rockville (MD): Agency for Healthcare Research and Quality (US); 2014 Apr. 5, Use of Patient-Reported Outcomes in Registries.

[16] Hostetter, M. and Klein, S. "Using Patient Reported Outcomes to Improve Health Care Quality," Washington (DC): The Commonwealth Fund.

[17] CMMI measured 30-day post-Total Joint Replacement survey (TJR) readmission and 90-day complication rates, as well as PROMs collected before and after TJR.

[18] National resources, including the National Institutes of Health's Patient-Reported Outcomes Measurement Information System (PROMIS) are working toward development of PROMs in standardized and consistent ways.

An interview with the former executive director of the California Joint Replacement Registry (CJRR), revealed some potential implementation concerns related to patient recruitment and tracking. In the CJRR program, patient recruitment and tracking was critically important and challenging.[19] CJRR conducted all patient recruitment through their participating hospitals and orthopedic clinics. The executive director who oversaw implementation reported that it likely would be difficult to recruit participants to a PRO registry program in any other way. Even with the cooperation of the hospitals, patient recruitment required high-effort marketing strategies such as producing patient information sheets and brochures. CJRR also sent staff to orthopedic clinics to provide coaching on patient engagement. Such marketing activities carry direct costs.

Patients communicated concerns to CJRR about privacy and were hesitant to release their Social Security numbers on the surveys. Therefore CJRR developed unique patient identifiers to track patient information and survey data over time and across facilities. For the State of Texas, this raises further questions and concerns relating to connecting patient identifiers with electronic health records (EHRs) and individual clinician patient tracking systems.

Physician participation

Former CJRR staff identified a number of challenges associated with recruiting and maintaining provider and hospital participation. First, at the outset of the pilot project, hospitals had significant privacy concerns. This was a barrier to participation because hospitals typically have their own unique approaches to oversight of HIPAA and privacy regulations. As a result of security and liability concerns, most large hospitals persuaded patients to sign individual approval documents per their institutional review boards (IRBs). These types of administrative and legal barriers may prove to be a concern for provider participation in any PRO registry.

Second, the level of effort involved in a PRO registry program may be a concern for hospitals and physicians. A CJRR survey of hospital participants indicated that staff spent an average of 10 to 20 minutes per patient to initially register and encourage patients to take the survey. CJRR saw 34.4% of patients complete surveys upon receipt. After a pilot in which a medical assistant called to follow-up and offer assistance, the response rate rose to 51.3%. Some hospital and physician practices may be unwilling or unable to provide the intense engagement efforts necessary to ensure patient participation throughout the continuum of care, affecting overall success of the program.

Survey instrument and collection

The specific goals of a registry would help determine the validated survey instrument, or tool, to use, as well as:

- the method(s) of capture (the device);
- timing, or when participants should take the survey;
- location of collection;
- accessibility – both functional limitations and web access, if internet-based; and
- costs.

The selection of the best survey tool can be completed only after the program sponsor identifies inclusion criteria. In other words, you have to know what it is you want to measure and then choose the yardstick. One RFI respondent recommended the SF-12, a peer reviewed outcomes assessment tool used to measure an individual's health status: physical function, mental health status, and pain severity. They report that the SF-12 is applicable across all disease categories and comorbid conditions, allowing for statistically powerful benchmarking and comparative analysis.

Another respondent argued that "PRO measures [should] include Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR.) and Knee injury and Osteoarthritis Outcomes Score for Joint Replacement (KOOS, JR.) as joint-specific measures; while the Patient-Reported Outcomes Measurement Information System (PROMIS) 10-Item Global Health and Veterans Rand 12-Item Health Survey are options for health-related quality of life measures."

Study research indicates that any PRO registry program should include a survey instrument that has been validated for specificity and interrater-reliability,[20] being mindful of data interoperability (the ability of one system to work with another system) with national and other registries. In addition, licensing costs are a key consideration with many survey instruments; therefore, another option would be to use surveys available in the public domain.

[19] In March 2015, CJRR was subsumed by a national registry.

[20] Inter-rater reliability is the statistical measurement of how similar or different are the data collected by different raters.

Survey device

There are a number of options that could be selected for the survey device. One example might be an online survey instrument (or web-based capture) using a tablet or kiosk at the hospital. For example, in one registry model, providers assign surveys to their patients through a PRO platform, in which a patient either completes the survey directly at the clinic or hospital (via a kiosk or tablet) or via an email link. The surveys are automatically scored and data entered into the platform.

Even if a web-based device is used, the program may also need to offer paper surveys. For one registry, participating hospitals may distribute surveys either via paper or using a computer/web-based tool, and submit survey responses to the registry either by manual entry into the platform or as a file upload to the secure server for inclusion in the reporting and dashboard system. In another example, CJRR primarily used an electronic survey by email and, in the beginning, the emailed surveys were initiated by CJRR rather than the physician. As a result, up to 40% of emailed surveys were caught in SPAM filters. As a course-correction, physicians' offices administered the surveys directly on iPads or on paper, which increased open rates.

Other variations could include sending a patient survey via text, web app or mail.

Point of collection

As previously noted, data is typically collected at the provider or hospital level. For example, one registry features PRO collection as a hospital- or practice-based effort in which the doctor's staff assigns, disseminates and monitors survey instruments. After unsuccessfully attempting to collect data as the registry administrator, CJRR determined that patients were more likely to open and complete surveys when their surgeon's office issued the surveys.

According to one journal article, "In general, leaders who successfully implemented PRO measures to date concur that PRO measures collection is most likely to be complete if collection is embedded in the standard clinic workflow, serves patient and clinician decisions, and is supported by electronic means."[21]

Alternately, one RFI respondent recommended employing a case-management/disease-management vendor that would be responsible for direct patient contact, distinct from a data service that would be responsible for data collection, data enhancement, data integration, data analysis and data reporting.

Data storage and use

After the data is collected via the patient surveys, the data must be stored for future analysis. Key storage concerns include privacy, security and interoperability.

Unless a unique data storage solution is created, third-party data warehouses are available.

The data and storage software platform should be able to "talk" to other systems, including integration with EHRs and claims information at the clinics, and maintain interoperability with ERS/TRS infrastructure over time. The Office of the National Coordinator for Health Information Technology issues useful guidelines for setting up a system that meets standards for data-sharing across electronic health system platforms.[22]

Performance reporting and risk adjustment

In order to put PRO data to use, the data must be risk-adjusted for variances in hospital and patient populations.

To analyze PRO data for TRS and ERS populations and report against a benchmark, a registry program should include the ability to perform risk-adjusted analysis. Therefore, a potential partner could be an entity that holds Texas private-market claims data for benchmarking, is compliant with HIPAA privacy concerns and has the ability to adjust for risk using ERS- and TRS-specific claims data.

A second option could be to have analysis performed by a data-analysis vendor that provides performance reporting and interactive dashboards for comparing utilization, spending and quality measures for the hospitals. However, it is not clear how many vendors would hold Texas private-market claims data and could provide customized Texas benchmarking for ERS and TRS populations.

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[21] Kate Chenok, Stephanie Teleki, Nelson SooHoo, et al. "Collecting Patient-Reported Outcomes: Lessons from the California Joint Replacement Registry," eGEMS Vol. 3, Iss. 1 (2015), Art. 20.

[22] Chenok, *eGEMS*.

Conclusions

To build an independent PRO registry for ERS and TRS plan participants that collects and stores PRO data for analysis, ERS and TRS conservatively estimate a cost of $10 million over five years. After initial start-up costs, maintenance costs could be lower. However, the feasibility of implementing a registry only for ERS and TRS participants is questionable if providers see little value in collecting PRO measures only for a subset of their patient populations. Additionally, ERS and TRS are not appropriate administrative homes for a health condition or health procedure registry for the following reasons:

- State-sponsored benefit plans are typically not payors or sponsors of a PRO registry.
- ERS and TRS health care trust funds are restricted to the exclusive benefit of the respective plan populations.
- Providers may not be willing to assume the administrative burden of collecting PRO data only on a subset of patients, which may not yield meaningful results for their practice.
- Orthopedic provider respondents to the RFI suggested that ideally, PROs would be collected for all musculoskeletal patients in the state.
- ERS and TRS do not house the clinical expertise required to oversee a medical research contract.

Finally, PRO registries and associated quality activities for musculoskeletal conditions are relatively new. There is a shortage of evidence that payors are using patient-reported outcomes data to inform value-based purchasing or other innovative payment models. ERS and TRS would value a registry that would lead to improved health outcomes for their participants and additional cost savings to the plans in the form of avoiding unnecessary imaging and ineffective care. However, this study has found that, while PRO registries so far have shown promise toward achieving these goals, it has not yet been established that savings would outweigh the costs of creating and maintaining a registry.

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