Implementing PRO collection into Clinical Practice

Why should I buy into collecting Patient Reported Outcomes?

Patient-reported outcomes (PROs) are a hot topic right now, but is this trend here to stay? There is ample reason to believe it is. As state and federal governments and private payers continue to emphasize value and quality of healthcare, they are recognizing PROs as a critical element of assessing whether a treatment provides a tangible benefit at the individual patient level. In line with these payer interests, there have been federally funded agencies and initiatives focused on PROs, including the National Institutes of Health's Patient Reported Outcomes Measurement Information System (PROMIS), and the Patient-Centered Outcomes Research Institute (PCORI). Other facets of PRO collection are also being addressed at the federal level, including the technical aspects of collection into the electronic health record. The final report of their pilot, Advancing the Collection and Use of Patient-Reported Outcomes through Health Information Technology, included an implementation guide for Information Technology departments. Many of these initiatives began over two decades ago; the duration and levels of funding of these multiple aspects of PRO collection are strong evidence that they are here to stay.

It is important to note that many specialties have already embraced PRO collection and incorporation into clinical care. There are many lessons we can learn from their experiences. The clinical disciplines and scales of these implementations are broad, including the system-wide implementation at Cincinnati Childrens' Hospital Medical Center, the multi-specialty, systemwide implementation at the University of Utah Health, and the adoption by the Centers for Medicare and Medicaid Services of a Comprehensive Care for Joint Replacement Model for bundled payment. This provides ample evidence of the feasibility of PRO collection outside research studies, across inpatient and outpatient settings, geographic locations, pediatric and adult patients, and even medical and surgical populations.

Can PROs be used to penalize providers?

Whenever outcomes are measured, it is a reasonable question if they will be scrutinized by payers, with potential penalties enacted for "poor" outcomes. While there is certainly no guarantee that *couldn't* happen with PRO collection, that isn't a practical reason not to collect this data. Instead, a better strategy is to embrace this movement, collect the most robust data we can, and trust that it will show what we know to be true: that our interventions provide benefit. The optimist would even propose that PROs may show *more* benefit to our interventions than other endpoints, such as major adverse limb events and major adverse cardiac events. PROs promise to capture the value of the care we provide in terms of other domains of health-related quality of life.

Addressing challenges to PRO collection

It is widely recognized that PRO collection can be challenging. There are valid reasons why it has not become the norm in routine clinical practice in most specialties. Several aspects of these challenges

have been studied, to facilitate overcoming them. Specific considerations must be addressed and tailored to one's specific practice environment, including:

- o **Identifying the proper patient and PRO instrument for completion:** This process involves selecting appropriate PRO instruments based on the patient's health condition and the outcomes that healthcare providers aim to measure. Tailoring the choice of instrument ensures accuracy and relevancy in capturing patient-reported outcomes.
- o **Ensuring the PRO instrument is completed in the manner in which it was validated:** It is crucial to ensure that patients accurately complete the PRO instruments. This involves providing clear instructions and providing a reasonable amount of time to complete the questions. Most importantly, it must be clear that the *patient* must answer the questions, without the external influence of providers or family members.
- o **Ensuring there is a user-friendly method of survey completion**: Encouraging patient participation with PRO surveys is made easier with accessible and user-friendly digital platforms, paper forms, or mobile applications.
- o **Addressing survey fatigue – motivating patients to complete the PRO instruments:** It is vital to keep patients engaged and motivated when completing PRO instruments. This can be achieved by explaining the value of their input and choosing surveys that aren't overly burdensome.
- o **Creating a system for troubleshooting real-time problems that may arise:** A support system is required that can address any issues patients may encounter while completing the Patient-Reported Outcome (PRO) instruments. This support system should include technical assistance for online surveys or a helpline for questions, ensuring a seamless process for patients and healthcare providers.

Patient-Reported Outcomes (PROs) can be used to inform the clinical care. Integrating PRO technology into healthcare requires consideration of system factors.
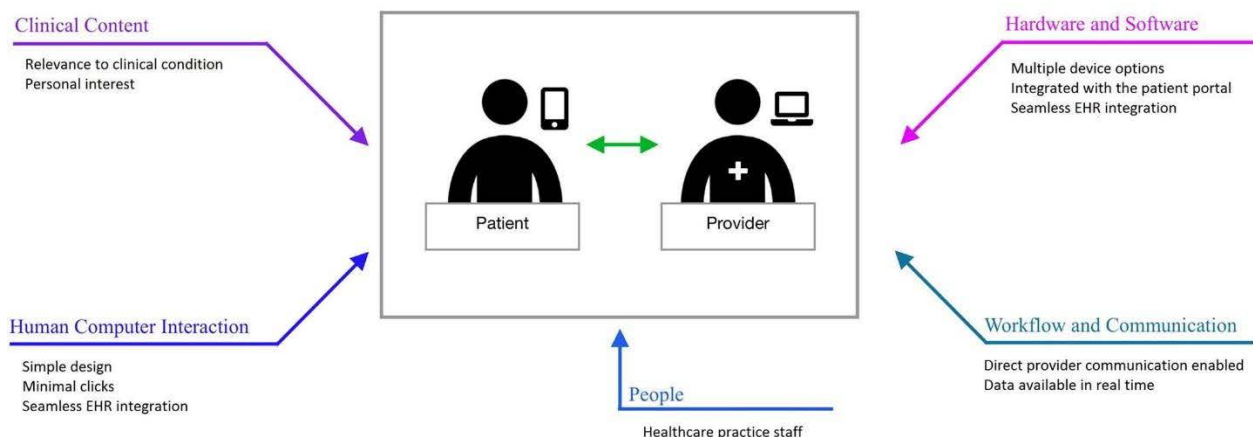
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Addressing challenges to PRO interpretation

The medical community recognizes that interpreting Patient-Reported Outcomes (PRO) is complex. However, it is clear that there is little benefit to collecting this information if it will not be used. The first step towards ensuring that PRO data is useful is gaining a clear understanding of the purpose and content of the PRO instrument that is being used. This helps the clinician interpret the results and present the information back to the patient. PRO data should be thought of as any other test result – for example, clinicians learn about a complete blood count, which, in turn, facilitates how they describe the results and trends to a patient. Therefore, the biggest challenges for PRO "test results" are determining (1) how we can quickly retrieve the result from a survey, (2) present it in context with the results at other time points, and (3) present this information to a patient during a bedside encounter. Specific considerations must be addressed and tailored to one's specific practice environment, including:

- o **Ensuring the ability to collect PRO instrument responses at several time points along a patient's treatment course:** It is essential to establish a system that can collect PRO responses at various intervals throughout a patient's care continuum. This enables monitoring changes over time and facilitating necessary adjustments to care plans. Following a delta-change, rather than an absolute value, also helps account for between-patient differences in baseline scores.
- o **Adjusting for confounding when comparing results between patients, providers, etc.:** To ensure the validity and reliability of comparisons across patient groups or healthcare providers, it can be useful to apply statistical techniques that adjust for confounding variables. Collection of both a *general* health-related quality of life measure as well as a *disease-specific* health-related quality of life measure can facilitate this.
- o **Developing systems for accessing the data in real-time for patient counseling:** Ideally, technology can be leveraged to facilitate swift access to PRO data, including graphical displays of the results and trends that can enable prompt patient counseling and intervention using the latest available data.
- o **Understanding limitations of the data when PRO instruments are completed imperfectly:** It is important to acknowledge the inherent limitations of PRO data, particularly when responses are incomplete or influenced by someone other than the patient. Strategies should be devised and implemented to address these challenges in the data analysis and decision-making processes.

Key Elements for PRO Integration	
Leadership Engagement:	
O	Consensus on PRO importance
O	Designated PRO leader
PRO Selection Process:	
O	Defined outcome for improvement with patient input
O	Chosen PRO tools targeting specific outcomes
O	Brief, feasible PRO tools for patient completion
Evaluation Metrics:	
O	Criteria for clinical intervention from PRO scores
O	Published alongside PRO tool
Intervention Strategies:	
O	Identified evidence-based practices
O	Informed clinicians on intervention protocols
Educational Initiatives:	
O	Comprehensive PRO training for healthcare teams
O	Emphasis on the clinical value of PRO data
Consistency and Application:	
O	Regular PRO completion within a set timeframe post-implementation
O	Real-time discussion of PRO results with patients

Quality Assurance:	
O	Ongoing review of patient data for consistent reliability
O	Adjustment of protocols based on data review outcomes

Some examples of PRO collection in vascular surgery

PRO collection has been integrated into clinical practice in some settings in vascular surgery. For example, PRO collection has been a routine part of the evaluation of patients with neurogenic thoracic outlet syndrome for many years for many of the leading experts in TOS care. Balderman and colleagues described the use of PRO scores to assist with identifying patients' likelihood of response to surgical treatment. This is a clear demonstration of how PROs can directly impact patient counseling and clinical decision making.

For vascular specialists performing vein procedures for axial reflux, PRO collection has become increasingly common. In 2015, the American Venous Forum and Vascular Quality Initiative introduced their varicose vein module which facilitates recording of seven different subjective components scored from 0 to 5 (heaviness, achiness, throbbing, swelling, itching, appearance, and impact on work) at both a preoperative and postoperative timepoint. Obi and colleagues described the initial 10-month experience with the registry, including details of the PRO collection.

More recently, the VQI conducted a pilot study of PRO collection for patients undergoing peripheral vascular intervention. The goals for participating sites included demonstration of feasibility of collecting these at three separate timepoints. The logistical aspects of survey administration were left to the individual sites. Rates of data capture have not yet been published; however, the lead investigators did solicit input from experts in the field, specifically from the Swedvasc Registry and the NORKAR Registry.

While PRO collection is far from the norm in most busy vascular practices at the present time, these initiatives demonstrate important proof of concept and value to PRO collection. They likely represent the early adoption phase, with more widespread use across vascular practices expected in the coming decades.

ADDITIONAL REFERENCES:

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