Operative Techniques in
Orthopaedics

Patient Reported Outcomes Measures and the Evolving Role of Predictive Analytics in Spine Care

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The field of predictive analytics in medicine is constantly expanding, in turn changing the paradigm in which providers and patients experience health care. Machine learning and neural networks are being utilized in diagnosis, individualizing care, and assisting in medical decision making in many fields, including orthopaedics. This technology's utility and accuracy are largely limited by providers' ability to communicate complex predictions to patients and the input which generates the predictive model including patient reported outcomes (PROs).

PROs, classically, are utilized in comparative and cost effectiveness research, but increasingly are being incorporated in patient-provider interactions. However, several limitations in PROs exist including a diverse number of legacy PROs, differing agendas amongst health care systems, providers, and patients, as well as providers' ability to translate these scores into meaningful information for patients. The Patient Reported Outcome Measurement Information System (PROMIS) is a tool developed by the National Institutes of Health (NIH) to combat some of these limitations. PROMIS is health domain rather than disease specific and therefore can be applied across many fields of medicine or subspecialties within a field. Shared decision making is a framework for patients and physicians to incorporate predictive analytics, PROs, and patient values to make complex medical decisions. Decision aides are utilized to reinforce information provided by physicians to patients. The overarching goal is to maximize patient education, manage expectations and deliver high value health care. As health care systems, providers, and patients generate more data points, the strength of predictive analytic models will improve. These advances will change the way providers deliver health care and present information to patients.
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Introduction

Patient reported outcomes (PROs) have increased in importance to medical practice and research over the past 20 years in parallel with the prioritization of evidence-based medicine (EBM). PROs are integral to comparative and cost effectiveness research. Outcomes tools can be separated into 2 general categories: general and disease specific. General assessments include tools to assess pain and function regardless of underlying condition. Examples include measures such as the Short Form 36 (SF-36), Sickness Impact Profile (SIP), and the Visual Analog Scale (VAS).[1,2]

Disease specific tools are developed for patients with a specific condition and include the Oswestry Disability Index (ODI) for lumbar spine pathology, Neck Disability Index (NDI) for cervical spine pathology, and Scoliosis Research Society-22 (SRS 22) assessment for patients with adolescent idiopathic scoliosis (AIS).[3-5] Early outcomes tools including those aforementioned were developed using classical test theory (CTT). These tools are known as "legacy measures." CTT involves the validation of a test in a specific population. Legacy measures developed using CTT must be revalidated if they are applied to new contexts or have alterations in content.

Item response theory (IRT) addresses many of the shortcomings of CTT. Two key tenants of IRT are (1) The properties of a question, such as its ability to estimate a trait, are not

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dependent on the specific group of patients taking the test and, (2) A patient's trait level, such as level of function or pain, is independent of the specific set of questions chosen out of a pool of validated questions.[6,7] PROs developed using IRT evaluate domains of health independent of specific disease, can be applied to multiple populations without validation, and can be administered with customized tests containing validated questions/items in variable order. Patient Reported Outcome Measurement Information System (PROMIS) is a tool developed by the National Institutes of Health (NIH) using IRT over the past 15 years. PROMIS contains a number of unidimensional domains such as pain interference and physical function. The scoring is simple for each domain as a score of 50 corresponds to a T-score of 0—population average—and a score of 10 points corresponds to 1 standard deviation away from the mean.

A number of studies have compared the psychometric properties of PROMIS compared to legacy measures in orthopaedic trauma, spine, hand, and foot and ankle populations. The studies to date overwhelmingly conclude that PROMIS outperforms legacy measures in terms of psychometric properties such as reliability, floor/ceiling effects, and unidimensionality.[8-15] Furthermore PROMIS can take substantially less time to administer due to the application of computer adaptive testing (CAT) technology. CAT utilizes item response theory which dynamically changes the amount, order, and number of questions in response to user input to minimize the amount of questions required to generate a reliable score.

While great effort has been placed in the development and assessment of PROs, a knowledge gap exists with regard their utility in direct patient care. One area within medicine incorporating PROs is predictive analytic modeling. This area or research is rapidly developing with the ultimate goals of projecting outcomes, individualizing care, and optimizing the allocation of resources. However, several barriers exist in communicating PROs and projected outcomes to patients.

Predictive Analytics

Machine learning (ML) has been applied to healthcare for over 60 years. In the past decade the application of ML has increased substantially as technologic advances have provided numerous tools for physicians to analyze data and create frameworks for more data-driven patient care. Broadly defined, ML is the ability for computer algorithms to collect and interpret relationships and patterns within large empirical data sets, then produce models that can be used to predict outcomes or make decisions using a number of variables.[16] In theory, the computer ("machine") learns rules directly from data. ML has thus far been applied to medical imaging (radiographic imaging, EKGs, etc.) to diagnose and map pathology, medical diagnostic reasoning, exam values and risk assessments for prognostic evaluation, and determining outcomes for pre and postoperative monitoring.[17]

Neural Networks (NN) are a subset of ML, and describe computing systems that use multiple units or nodes to perform tasks and identify patterns. Each node performs a relatively simple function such as logistical regression, synthesis of multiple inputs, and communication with multiple other nodes.[18] Each connection between nodes or neurons has a weight associated with it. Data passes through multiple groups of nodes called layer before passing through a final layer to produce an output for the system. The system, as a whole, is iterative, and changes the weight of each connection between nodes as more data is processed and the predictive model gains accuracy. For example if a neural network is utilized in in spinal imaging to detect cervical stenosis, a node would be shown images that are consistent with stenosis and those which have no spinal narrowing. It would use these images to generate its own diagnostic criteria based on patterns it creates without any knowledge of concepts used by surgeons or radiologist such as space available for the cord or myelomalacia.

NN and deep learning have been applied to Orthopaedics in various capacities. Though still largely in phase 2 or smaller trials, there has been a significant increase in studies looking at the accuracy and applicability of these technologies in the past 20 years. The majority of these studies have specifically looked at spine pathology detection, osteoarthritis detection and prevention, and bone and cartilage image segmentation.[19-22] Medical imaging is one of the leading applications and data sources for deep learning, as data input in this domain has grown tremendously in recent years and corresponds with an increasing need for efficient and accurate assessment to help physicians diagnose and treat patients appropriately.[23] In 2 studies utilizing artificial NN, ultrasound images were used to "train" an algorithm to locate the ideal vertebral level and position for percutaneous spinal needle injections. The NN was able to locate optimal injection level with an accuracy of 95%, with a maximum sensitivity of 96% and specificity of 97%.[24,25] NN have also been used to predict surgical and non-surgical outcomes in the spine population. In one study, a NN was compared to a logistic regression (LR) model in the prediction of post-surgical satisfaction in patients with lumbar stenosis. Patient data was put into the NN to predict 2-year surgical satisfaction based on several input variables. The NN model produced higher accuracy predictions than the LR model in 96% of patients (N = 168).[26]

While predictive analytics and neural networks have improved markedly, challenges remain prior to widespread implementation. Specifically, any algorithm has the potential to exaggerate predictions and correlations in the large data sets that are required. This can lead to overly enthusiastic estimates of the accuracy of prediction(s), and give a false sense of security in using the algorithm(s) in direct patient care. Another important consideration is the quantity and quality of the data being fed into these NN. Because they rely so heavily on data, specific biases that affect data collection become amplified and negatively impact both performance and generalizability.[27] For example, while elevated inflammatory markers (ESR, CRP) are strong indicators of a septic joint, if only a small non-representative sample of patients undergoing arthrocentesis had inflammatory marker data in a given dataset, then the use of inflammatory markers within a predictive model can lead to poor accuracy. The application of predictive analytics as clinical decision aids risk assessment tools in orthopaedics has a number of issues.[28] Substantial clinical expertise cannot be replaced by statistical analysis, especially when the statistical models are based on poor data. The risk of applying an inaccurate model to clinical decisions such as surgical patient selection can lead to devastating complications. Ideally, predictive models will be used in conjunction with clinical expertise to improve patient care and minimize complications.

There is still a great deal to learn from ML and NN in the field of orthopaedics, but it is clear that the field is moving to implement these analytic tools in daily practice. As NNs move to phase 3 trial application and start to see similar applicability to fields like cardiology, orthopaedists will be equipped to provide improved patient care overall.[29] In the past 2 years, there have been 2 models published that can with reasonable accuracy determine the likelihood of achieving a satisfactory outcome—defined in one study as a decrease in ODI of 15 points—following lumbar surgical intervention.[54,55] Providers must translate this data into meaningful information for patients and can only utilize these models if the appropriate PROs and demographic information is collected. The power or predictive analytics is only as strong as our ability as providers to incorporate their outputs into point of care episodes.

Challenges in Implementing Patient Reported Outcome Measures

The challenges in implementing PRO's are numerous as the patient, providers, and health care system must align their efforts in the face of divergent agendas. Furthermore, there exist numerous logistical challenges in implementing and collecting PRO data from patients.[30] First, the selection of appropriate PRO for individual patients must be carefully considered which has proven difficult. For example, a systematic review identified 36 PRO instruments for measuring back-specific functional status in patients with low back pain.[31] Second, the workflow of presenting the patient with the PRO instrument via online portal, mail, or email prior to the clinical encounter or by the front desk staff immediately prior to the visit can be met with reluctance due to perceived disruptions in clinical workflow.[32,33] This is exacerbated if electronic devices are relied upon as problems with internet connectivity and complex login procedures designed for security can stifle patient acceptance.[32] Finally, concerns regarding patient information, HIPAA compliance, and data storage must be reconciled prior to any PRO collection.

Aside from the logistical difficulties of implementing PRO's, there exist obstacles from the patient perspective. To the patient, PRO's may represent an onerous and seemingly irrelevant task within the context of a potentially stressful doctor's visit.[32,33] Furthermore, PRO length can lead to survey fatigue and there exists a certain point in which the patient will either cease to participate or give poor input when participating.[34] When PRO's are presented to patients with multiple percentages or numeric scales, especially when queried sequentially, survey fatigue may be exacerbated. As such, it is critical for the provider or healthcare system to communicate the utility of PRO instruments to patients as well as the short and long-term benefits of participation.[35] Presently, PRO's are becoming more prevalent, and in turn, the medical community would benefit from a public that understood, accepted, and readily participated in PRO measures. For better or worse, the onus falls on the healthcare community to ensure the message is communicated.

Providers and health care systems would benefit most from a concerted effort to establish PRO's.[32,33,35] However, one significant hurdle to overcome in this effort is one of divergent agendas – providers seek to sophisticate their understanding of outcomes following interventions without disrupting workflow, and health care systems, to some degree, seek to tie these outcomes to the value of provider interventions all while placing the burden of implementation on the provider. The difference in these 2 agendas can undermine PRO implementation. This particular challenge in PRO implementation requires coordination and the alignment of goals. At the Mayo Clinic, providers sought to document their outcomes through PRO's for research and optimization of outcomes, and the health care system obliged their providers with the necessary infrastructure, resources, and personnel.[32]

Nordan et al chronicled their experience in implementing electronic PRO measures at their institution and the lessons learnt from salient challenges.[32] Among the challenges identified were provider reluctance to utilizing a standardized PRO as opposed to specialty-specific, workflow disruption, reduced PRO completion rate with remote capture outside the clinical encounter, security concerns, and electronic medical record data management. Each of these challenges was confronted by a concerted effort by the providers and institution, the process of which took place over multiple years. In their publication, they concluded that following implementation, the PRO system provided essential information in optimizing the quality of their care, and that the key to implementation was dedicated personnel overseeing the design and implementation of the PRO instruments. Likewise, other institutions seeking to implement PRO's in their health care delivery must endow the effort with the appropriate resources, personnel, and "buy-in" from all involved parties in order to overcome the significant challenges of implementation.

Lastly, patients and physicians face a communication barrier with PROs. Physicians are tasked with the responsibility to present complex PROs to patients with potentially low health and numerical literacy without a common language with which to interact. Patients, on average, read at an 8th grade level and have challenges understanding percentages, odds ratios, and standard deviations—all things providers use in discussing PROs.[36,37] At the University of Utah, for example, providers have tried to overcome these barriers by understanding how patients prefer PRO data to be presented. A common language was established by converting numerical PROMIS physical functions scores into plain language terms. For example a score of 38-42 equates to a patient being able to do chores and yardwork with some difficulty, walk greater than 1 mile with some difficulty, and able to climb a flight of stairs with some difficulty. One hundred patients were surveyed as to whether they preferred graphical, numerical, or plain language presentation of PROMIS scores. Of 92% of patients could understand a graphical representation and the vast majority preferred plain language or graphical over numerical scores (Table 1/Fig. 1).[38] Other techniques shown to minimize this last barrier are utilization of shared decision-making techniques as well as decision aids.

Decision Aids, Shared Decision Making, and Patient Reported Outcomes

In 1982, the President's Commission for the Study of Ethical Problems in Medicine urged the medical community to move away from paternalistic medicine (physician-controlled decision making) and empower the patient with agency in their medical care.[39] Furthermore, in seminal articles published in the 1990s, Braddock et al documented the marked deficiencies in patient involvement during medical encounters through the analysis of thousands of recorded clinical interactions.[40,41] Over the last four decades, progress has been slow-moving with recent publications revealing more of the same with regard to poorly informed care decisions.[42,43] However, the call for patient involvement, increased patient agency, and the utilization of patient reported outcomes has become louder in recent years with an exponential increased in "PRO" related publications in the last decade.[44]

Shared decision making (SDM) is defined as patients and providers mutually engaging to align clinical decisions with patient values and preferences.[45] The first step in shared decision making is reducing the asymmetries of information between provider and patient. There exists a growing body of evidence that patient outcomes are improved and health care utilization/costs are reduced with SDM.[46] One such instrument to bridge the gap between patient and provider

Table 1 Example of PROMIS-PF (Physical Function) Clinical Tool

PROMIS-PF GROUP	Descriptive Summary Statement
<18	Unable to walk about the house. Unable to wash and dry their body. Unable to transfer to a bed and chair and back.
20 ± 2	Unable to carry a shopping bag or briefcase. Wash and dry their body with much difficulty. Transfer to a bed and chair and back with much difficulty.
25 ± 2	Unable to do chores such as vacuuming or yard work. Run errands and shop with much difficulty. Walk about the house with much difficulty.
30 ± 2	Unable to do 2 hours of physical labor. Do chores such as vacuuming or yard work with much difficulty. Unable to walk at a normal speed.
35 ± 2	Carry a laundry basket up a flight of stairs with much difficulty. Walk at a normal speed with some difficulty. Unable to walk more than a mile (1.6 km).
40 ± 2	Do 2 hours of physical labor with much difficulty. Walk more than a mile (1.6 km) with some difficulty. Do yard work like raking leaves, weeding, or pushing a lawn mower with some difficulty.
45 ± 2	Walk more than a mile (1.6 km) with little difficulty. Do heavy work around the house like scrubbing floors, or lifting or moving heavy furniture with some difficulty. Do chores such as vacuuming or yard work with little difficulty.
50 ± 2	Do 2 hours of physical labor with little difficulty. Hike a couple of miles (3 km) on uneven surfaces, including hills with little difficulty. Walk more than a mile (1.6 km) with no difficulty.
55 ± 2	Do strenuous activities such as backpacking, skiing, playing tennis, bicycling or jogging with no difficulty. Hike a couple of miles (3 km) on uneven surfaces, including hills with no difficulty. Do heavy work around the house like scrubbing floors, or lifting or moving heavy furniture with no difficulty.
60 ± 2	Do vigorous activities, such as running, lifting heavy objects, participating in strenuous sports with no difficulty. Do 2 hours of physical labor with no difficulty. Run at a fast pace for 2 miles (3 km) with little difficulty.
>62	Exercise hard for half an hour with no difficulty. Do 8 hours of physical labor with no difficulty. Run ten miles (16 km) with some difficulty.

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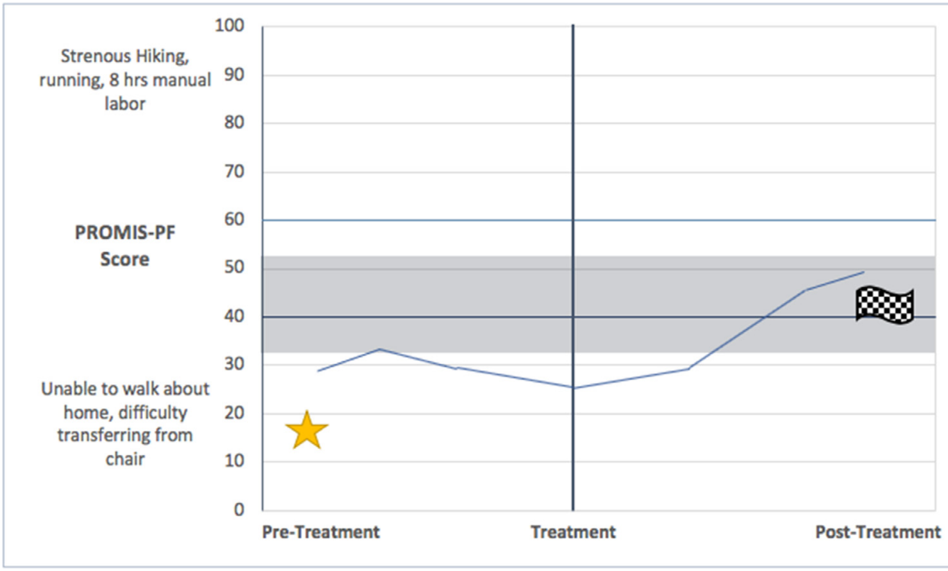

Figure 1 Example of graphical description for patient PROMIS-PF (Physical Function). Reproduced with permission from Shaw et al. (Color version of figure is available online.)

to engage in SDM are decision aids which are instruments created to inform the patient of his or her condition, treatment options, and potential outcomes of differing treatment modalities.[47] They ought not to replace any element of the face-to-face encounter, but instead, decision aids can be utilized to facilitate SDM with efficiency.

Decision aids can take the form of written pamphlets, graphics, or flowcharts on a printed or electronic medium. In a Cochrane meta-analysis, decision aids seemingly reduced the difficulty in decision making and improved satisfaction.[48] Within the orthopedic literature pertaining to hip and knee osteoarthritis, decision aids led increased rates of an informed decision at the initial visit and greater confidence of the patient in asking appropriate questions without increasing encounter duration.[49] Decision aids are gaining acceptance within the surgical community and the systematic implementation of such aids may represent a substantial step forward in reducing the asymmetries of information between provider and patient.[50,51]

Within the SDM paradigm, PRO's can be utilized as powerful decision aids. First, they can be utilized to inform the indications for and timing of surgery.[44] If armed with extensive PRO data prior to and following intervention in high numbers of patients, a patient and physician can better understand the individual patient's condition and ramifications of treatment. In Sweden, the Swedish Rheumatology Quality Registry contains PRO data collected from nearly 66,000 patients over an extended timeline, and the data has been utilized to help guide treatment resulting in sustained improvements in objective and patient reported outcomes.[52,53] Second, large amounts of PRO data can be compiled and analyzed to guide health care policy. As the acceptance of PRO data as a primary outcome in medicine has exponentially increased in the past decade, the systematic and comprehensive collection of PRO data can qualify and quantify the patient specific benefits of medical encounters and treatments. Of course, this is predicated on the challenging task of implementing PRO measures on a large scale as described in the preceding section. Nonetheless, PRO data in guiding treatment and policy may represent the next watershed moment in medicine that could drastically improve patient satisfaction, outcomes, and health care system efficiency.

Future Directions

The future of healthcare delivery may heavily rely on predictive analytics and PROs data. With that data, physicians can be more precise with diagnosis, better manage patient expectations, and be well-equipped to optimize treatment plans based on individual characteristics. Neural networks, while in their infancy of clinical implementation, have shown great promise in medicine including the field of orthopedic surgery. Machine learning and neural networks are largely limited by the input from which they are created highlighting the need for standardization of PROs and medical records.

PROs have their own unique set of challenges: collection can be burdensome to patients and providers, the scores can be challenging to communicate, and legacy measures are often disease specific limiting their utility. PROMIS, a relatively new outcome measure gaining popularity, addresses many of these issues. It utilizes item response theory to decrease survey burden, is domain rather than disease specific, and several groups are working on the standardization and simplification of these instruments. PROs and predictive analytics should serve as adjunct tools in provider-patient interaction and decision making.

Since the Precision Medicine Initiative was announced at the State of the Union address in 2015, healthcare has moved swiftly to implement more patient-focused, individualized care. As we continue collecting more organized data, utilize increasingly sophisticated analytics to interpret them, and develop more precise outcome measurement tools, we will deliver more personalized and data-driven care. For example, prior to investing in a company, individuals are presented with expected outcomes, past performance reports, and competitive analyses based on data. Medicine in coming years will mirror industry and finance in this regard. With PROs and use of predicted analytics, patient with spinal pathology would know their projected outcomes with surgery vs nonsurgical management, risk of complications, the performance of the provider and how they compared to their peers prior to making a treatment decision. Spine care professionals have made great strides to improve medical decision making, health care delivery and value but we are only in the beginning of a changing patient-physician paradigm with PROS and predictive analytics.

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