

Using Patient-Reported Outcomes to Assess Continuing Medical Education Learner Performance in Improving Patient Health

The outcomes of a clinical intervention as reported by a patient are called patient-reported outcomes (PROs)¹.

PROs present the opportunity to collect an additional layer of information that can be used to inform more patient-centric care. These PROs provide valuable insight into patient care and have been increasingly used for regulatory purposes over the past few years. The US Food and Drug Administration has published guidance in support of using PROs in the medical product development process to substantiate labeling claims² as well as in the assessment of medical devices³.

Patient-reported outcomes exist on the premise that although many physical, physiological, or biochemical data can be collected through laboratory testing, the information may not provide the full picture of a patient's health, as some measures can be fully understood only by asking the patients themselves.

Although the benefits of PROs are numerous, the adoption of the tool's usage among clinical providers differs. Clinical populations vary among practices, making it challenging for providers to select appropriate measures, whereas others have difficulty creating a business case for PROs implementation⁷.

In addition, the use of PROs is a relatively new method of data collection; thus, clinical providers need training and education to successfully collect and use the data. Furthermore, while



PROs capture valuable insight into patient health by measuring items including¹:

- + Physical function
- + Symptoms
- + Global judgments of health
- + Psychological well-being
- + Social well-being
- + Cognitive functioning
- + Role activities
- + Personal constructs
- + Satisfaction with care
- + Health-related quality of life
- + Treatment adherence
- + Clinical trial outcomes

some providers may be aware of outcomes tools such as PROs, there is a potential for disconnect between the understanding and application of the tool, causing suboptimal implementation of the resultant interventions and a negative impact on the delivery of patient-centric care.

Web-based Continuing Medical Education Activities for the Use of PRO Measures

Vindico Medical Education conducted a study to analyze the data from a web-based continuing medical education (CME) activity that was designed to educate gastroenterologists and other health care providers who manage patients with irritable bowel disease on the use of PRO measures in clinical trials and patient care. To date, 109 gastroenterologists and 221 internal medicine providers have completed the education required to obtain CME credit. Of those who completed the education, pre-activity knowledge of PRO measures across specialty areas was relatively low—only 1 of 4 providers was able to identify the benefits of using PRO measures, and less than 1 of 5 (18%) was aware of the features of available PRO scales.

Examples of PROs

- + **Diabetes Distress Scale (DDS):** Measures the amount of distress caused by type 2 diabetes mellitus.
- + **MD Anderson Symptom Inventory (MDASI):** Assesses the severity of symptoms experienced by patients with cancer and how the symptoms interfere with daily living⁴.
- + **Routine Assessment of Patient Index Data 3 (RAPID3):** Routine assessment of patients with rheumatoid arthritis that measures function, pain, and patient global estimate of status⁵.
- + **Patient-Reported Outcomes Measurement Information System (PROMIS):** Used to measure and score physical and mental health.
- + **Patient Health Questionnaire-9 (PHQ-9):** A 9-item questionnaire used to measure potential for depression⁶.

Patient-Reported Outcomes Resources

Guidelines for inclusion of patient-reported outcomes in clinical trial protocols: the SPIRIT-PRO extension.

JAMA, February 2018⁸

“The SPIRIT-PRO guidelines provide recommendations for items that should be addressed and included in clinical trial protocols in which PROs are a primary or key secondary outcome.”

The effect of physician [CME] on patient-reported outcomes for identifying and optimally managing obstructive sleep apnea.

JCSM, March 2015⁹

“Patients’ reports demonstrate that participating physicians were 1.7 times more likely to initiate discussion of sleep problems than non-participating physicians and 2.25-2.86 times more likely to administer validated measures for OSA.”

COVID-19: Risk assessment and mitigation strategies for the collection of patient-reported outcome data through clinical sites.

Critical Path Institute, June 2020¹⁰

This presentation “[provides] a selection of risk assessment and mitigation strategies for consideration by sponsors and electronic clinical outcome assessment (eCOA) providers to facilitate the continued collection of PRO data in clinical trials.”

In addition, PRO usage was also considerably low compared with other measurement scales. Prior to participating in the learning activity, only 36% of gastroenterologists and 42% internal medicine providers reported always or frequently using PRO measures to achieve patient-centered care and informed decision-making.

However, after completing Vindico's course, the average relative increase in knowledge across all topics and specialties was 231%, which is indicative of both high posttest scores and low baseline knowledge. In addition, the adoption of PRO usage increased after learning, with 71% of gastroenterologists and 62% of internal medicine providers reporting frequently using PRO measures as a part of their measurement processes.

PROs to Enhance CME Impact Outcomes

There have been historical challenges regarding consistency around data collection in the field of CME, as well as the standardization of measuring how CME translates to the overall impact on patient and community health.

In a previous white paper¹¹, Vindico outlined the need to build on the historical guidelines for CME measurement and demonstrated a more meaningful approach to outcomes collection. The utilization of PROs in CME presents an option to align real-time learner practice with the intended application of knowledge presented in CME courses. Collecting metrics regarding provider implementation of information learned within CME, in tandem with PROs, adds a further dimension of understanding about the efficacy of CME and its impact on patient health.

Case Study with Pack Health

SCOPE

Vindico and Pack Health enrolled patients with lung cancer in a digital health coach program designed to assess and track PRO outcomes before, during, and after the program.

REFERRAL

Many patients were referred by their physicians who had recently participated in CME related to the value of PRO utilization in clinical care.

ANALYSIS

At program completion, there was insufficient data to draw conclusions. However, individual data suggested improvements in physical and mental health PROs.

UTILIZATION

This information can be sent back to providers to demonstrate where improvements in patient health and support can be made.

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