Defense Health Agency (DHA) Clinical Communities Speaker Series

OCT 2022 CCSS: Military Health Care: Innovative Health Care Delivery for a Ready Medical Force

S06: The Adoption of Patient-Reported Outcomes Across the MHS with Lessons Learned from the Musculoskeletal Community

Resource List

The National Institutes of Health (NIH) National Institute on Aging has a dedicated webpage on Patient-Reported Outcomes Measurement Information System (PROMIS) (2020), an NIH-funded initiative to develop and validate patient reported outcomes (PROs) for clinical research and practice. PROs is a set of person-centered measures that evaluates and monitors physical, mental, and social health in adults and children. It can be used with the general population and with individuals living with chronic conditions. PROMIS is developed and validated to be psychometrically sound and to transform how life domains are measured. This program was created to be relevant across all conditions for the assessment of symptoms and functions. It is available in multiple formats and is easily integrated into diverse administration platforms.

The Journal of the American College of Medical Quality published the article, Barriers and Benefits to the Use of Patient-Reported Outcome Measures in Routine Clinical Care: A Qualitative Study (2018) that details the benefits of using patient-reported outcomes (PROs). PROs provide information on how health care affects patient health and well-being and represent a patient-centered approach. Despite this potential, PROs are not widely used in clinical settings. Semi-structured focus groups were conducted with three stakeholder groups (patients, providers, and health care administrators) to determine the top 5 perceived barriers and benefits of PRO implementation. This study found that the greatest perceived benefits were the ability to track changes in clinical symptoms over time, improved quality of care, and better disease control among patients, providers, and administrators, respectively. These results may guide the development of novel frameworks for PRO implementation by addressing perceived barriers and building on the perceived benefits to encourage the adoption of utilizing PROs in clinical care.

The U.S. Food and Drug Administration (FDA) increasingly looks to patients to understand how patients describe their health status, because patients are the experts in living with their disease or condition. The article, Focus Area: Patient-Reported Outcomes and other Clinical Outcome Assessments (2022), details how input from patients or their caregivers can be used to select or develop tools to measure what matters most to patients. Clinical outcome assessments (COAs) may capture outcomes that are important to patients, such as how they feel or function or how long they survive. They play a central role in ensuring that what matters to patients is factored into regulatory decision-making. Strengthening FDA's ability to use patient-focused methodology to inform regulatory decision-making is specified in FDA user fee agreements for medical product development and the Cures Act. FDA increased knowledge and experience by performing research that informs the development and refinement of COA measures to support regulatory decision-making.

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References

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U.S. Food and Drug Administration (FDA). (2022). Focus Area: Patient-Reported Outcomes and other Clinical Outcome Assessments. *FDA*. https://cacmap.fda.gov/science-research/focus-areas-regulatory-science-report/focus-area-patient-reported-outcomes-and-other-clinical-outcome-assessments