Most CVD-related PROMs fall short of quality standards needed to guide clinical research and practice

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A systematic review of patient-reported outcome measures (PROMs) used in cardiovascular disease (CVD) populations has found that most fall short of quality standards required to guide clinical research and practice. Few measurements reported on the validation of all Food and Drug Administration (FDA)-recommended psychometric properties, had psychometric properties rated as sufficient by Consensus-based Standards for the selection of health Measurement Instruments (COSMIN), or had minimally important differences established. The review is published in *Annals of Internal Medicine.*

Patient-reported outcomes are important measures of treatment effect and can be used to inform the approval of cardiovascular drugs and devices by the FDA. Health status PROMs assess symptom burden, functional status, and health-related quality of life and are more reproducible than clinician-elicited measures, which can be limited by reporting variability. Despite recognition of the stated importance of PROMs in clinical and research settings, they remain underused in CVD trials.

Cardiovascular researchers from McMaster University and University of Calgary created a comprehensive evidence map of 50 health status PROMs from 83 studies. They identified 45 disease-specific and five generic PROMs. The disease-specific PROMs had been testing in specific CVD conditions such as heart failure, ischemic heart disease, and arrhythmias. The investigators report that 22% of the 50 PROMs validated in CVDs had minimally important differences (MIDs) established, and 16% reported on the validation of all psychometric

properties recommended by the FDA.

By COSMIN standards, only two PROMs had all of their psychometric properties rated as sufficient in quality, and 64% of PROMs had less than 50% of psychometric properties rated as sufficient. The authors found that no generic PROM and only 1 in 6 disease-specific PROMs fulfilled all the FDA requirements for product approval. They also report that no generic PROMs and only two disease specific PROMs had all nine COSMIN-defined properties classified as sufficient.

According to the authors, their work highlights the need for careful adherence to standardized methodological criteria for PROM development and validation and clear reporting of the psychometric properties of existing instruments. They add that given the use of PROMs to guide FDA approvals of drugs and devices in CVDs, there is a need for better adherence to quality standards in PROM validation studies.

More information: Derek S. Chew et al, Patient-Reported Outcomes Measures in Cardiovascular Disease: An Evidence Map of the Psychometric Properties of Health Status Instruments, *Annals of Internal Medicine* (2022). DOI: 10.7326/M22-2234

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