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In 2016, The People's Republic of China (PRC) formally passed the blueprint of Healthy China 2030, working toward the national goal of reaching a health standard on par with high-income countries by 2030.[1] In 2021, the Chinese government approved its 14th Five-Year Plan for National Economic and Social Development of the PRC, which includes a comprehensive strategy for advancing the quality of health care delivered by its national health system.[2] Yet, achieving this goal for China's diverse population of 1.4 billion people is often complex, depending on employment, insurance type, geodemographic location, socioeconomic status, health care workforce supply, and many other variables.[3] In addition, PRC overall health care expenditures as a percentage of gross domestic product have increased by more than 42% since 2010, with the most currently available data showing 7.1% in 2020.[4]

Over the past several years, patient-reported outcomes (PROs) and derivative standardized patient-reported outcome measures (PROMs) have come into widespread use in other countries, including use, for example, as part of industry-sponsored clinical trials, population outcomes and comparative effectiveness research, health care delivery system program evaluation, and health insurance coverage determinations.[5] PROs are intended to provide objective and subjective assessments of a variety of dimensions, for example, health-related quality of life (eg, I do not socialize with friends much anymore), physical capacity (eg, I have difficulty walking 3 city blocks), mental and cognitive changes (eg, I sometimes have trouble concentrating), functional status (eg, I am unable to lift more than 5 pounds on the job), symptoms (eg, I experience moderate pain on most days), and overall well-being (eg, I am in poor health). Data on PROs are usually collected via standardized, psychometrically developed, and validated survey-type instruments that are often used by clinicians and researchers to evaluate health care delivery from the perspectives of individual patients. A PROM is often then generated, which is most typically a summary composite score of the individual PRO item response scores captured by the survey instrument.

Using a cross-sectional survey of interventional clinical trials using data from the Chinese Clinical Trial Registry and the ClinicalTrials.gov databases, Chinese researchers have evaluated the current applications of PROMs in clinical trials in the PRC.[6] As the authors note, this study documents the major increase from 2010 to 2020 in the number of clinical trials originating in the PRC that include the application and characteristics of PRO instruments and PROMs as primary and secondary outcomes in clinical trials across China. Only 29.7% of the selected 10 093 eligible PRO-related trials were categorized according to those that precisely listed PRO tools as outcomes, and 70.3% did not incorporate PROMs into the analyses. Also documented was a striking use imbalance by regional provincial locations, sponsors, clinical phases, and a relative lack of diversity of PROMs deployed. Most trials were in phase 4, performed in hospitals, and located in the most populous eastern Chinese provinces. The authors accurately conclude that there is a need for more widespread, robust, and correctly targeted use of standardized PROMs in clinical trials across the PRC.

In the important context of achieving its goals outlined in Healthy China 2030, the PRC has been aggressively evaluating the new improvements to the Chinese health care delivery system. Much is required to generate better quality of evidence and measurement of cost-effectiveness for guideline-directed medical therapies indicated for major chronic conditions and other, less common diseases. As such, the discovery of new insights reported by Zhou et al[6] requires more widespread and consistent deployment of well-constructed PROMs that provide the best understanding of which

PROs matter most to patients and other subsequent relevant stakeholders interested in the resultant data.

The benefit of this well-done study by Zhou et al[6] is that it exposes both challenges and opportunities for the all-important future of PROM development and implementation—not just for the PRC, but for the entire international field. Fortunately, several reliable and publicly available resources and repositories for PROMs now exist widely, such as Patient-Reported Outcomes Measurement Information System, Patient-Reported Outcomes and Quality-of-Life Instrument database, and Online Guide to Quality-of-Life Assessment.[5,6] The joint initiative between the Consensus-Based Standards for the Selection of Health Measurement Instruments initiative and the Core Outcome Measures in Effectiveness Trials initiative helps facilitate agreement among PROMs-focused stakeholders with regard to the selection of outcomes (eg, constructs or domains) and outcome measurement instruments for clinical trials.[7]

Measure development and evaluation standards are also in use by consensus-driven groups (eg, the National Quality Forum) for the various and complex design domains of true PROMs, including content validity (including face validity), structural validity, internal consistency, reliability, measurement error, hypotheses testing, cross-cultural validity, criterion validity, and responsiveness. Initial PROM development and subsequent evaluation should include a formal evidence review and standardized quality of evidence grading process for each PROM item property, taking into account the number of studies, the methodologic quality of the studies, and the consistency of the results of the measurement properties.[5] Several sophisticated statistical-based methods are also often required, such as systematic review, meta-analysis, interrater reliability, internal consistency, factor analysis, analysis of variance, bayesian estimation, risk adjustment, and exclusion and missing data analysis. From empirical data generated through PROMs, it is now also becoming important to determine causal relationships between changes in PROs to generalizable improvements in at least 1 health care delivery system structure, process, intervention, or service.

Data for PROMs generated through traditional methods, such as self-reported questionnaires, structured interviews, and clinical assessments during patient encounters, is rapidly moving toward electronic data capture and storage in patient records. PROM data are now often collected through digital health interfaces that automate accurate and complete response capture and interoperable data transmission to electronic health records, clinical registries, and data analytic platforms. Translations of country- and language-specific PRO instruments may require additional psychometric testing that is appropriately sensitive to racial, ethnic, and cultural nuances of different target populations. As such, the generation of PROMs is becoming more resource intensive in terms of development, field testing, and ongoing evaluation, such as detection of changes consistent with improvement or worsening in specific and aggregate patient health outcomes.

Most recently, for-profit digital health firms have aggressively entered this market, touting sophisticated and parsimonious measure development and field-testing capability; robust interoperable data science-driven storage and access platforms; advanced data analytical expertise (eg, supervised machine learning and artificial intelligence); patient-centered interfaces for meaningful, team-based shared decision-making; and cost-effectiveness evaluation methods for assessing precision and multifactorial health outcomes. Hence, the standards generated today by more traditional stakeholders, such as regulators, policy-makers, health technology assessment authorities, and researchers may become less relevant and outdated for future PROM developments.

All of these diverse groups are necessary for the emergence of new tenets for a global learning health system necessary to achieve the worldwide goal of improving personalized population health. Building on and expanding these extensive advances should not, therefore, require the invention of a new wheel.

ARTICLE INFORMATION

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