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Digitization of Patient-Reported Outcomes

Health care is a data-intensive industry. The methods for collecting, storing, and retrieving clinical data have been evolving within a global electronic ecosystem comprising computers, mobile devices, the Web, social media, and a more connected world. The digitization of health care is nearly complete. Imaging studies, laboratory assays, drug delivery systems, diagnostic devices, robot-assisted surgery, computer-assisted prosthetics, and biomonitors all rely on computers and electronic data systems. The biggest holdout for the digital health care transformation has been the routine clinical data derived from patients and recorded in health records. National policy such as the Health Information Technology for Economic and Clinical Care [1] and the Affordable Care Act of 2010 have led to a rapid acceleration in the amount of clinical information that is captured electronically and potentially usable in meaningful ways. The day when the business of health care is conducted without paper seems near at hand.

Digitization of health care will transform the research enterprise, because clinical data will be available on millions of patients and their encounters. Less clear is how patients' perspectives on their treatment preferences, health, well-being, and behavior, captured by patient-reported outcome (PRO) measures, will be obtained from electronic data systems, so-called ePRO systems. Progress implementing ePROs into clinical practice has been made in such fields as oncology [2], which benefits from standardized approaches to symptom assessment, but these efforts remain in their nascent stages of development.

PROs evolved from the tradition of questionnaire-based testing, and until recently, virtually all PRO data were obtained via paper-and-pencil methods. Today, there are a variety of electronic data capture systems for PROs, including interactive voice response systems, handheld and tablet devices, and Web-enabled technologies. These are available for clinical research and increasingly clinical practice.

In recognition of the need for demonstrating the validity of new electronic data collection systems, both for ensuring high-quality research and addressing regulatory requirements for using these technologies for labeling purposes, the Systems Validation Task Force of ISPOR has produced a set of recommendations for validating ePRO systems [3]. Zbrozek et al. [3] have provided producers and users of ePRO systems in clinical trials a comprehensive and thoughtful guide on design principles, documentation requirements, and evaluation of the data quality and validity of these tools. It is a unique contribution to the literature, and the Task Force should be applauded for its members' hard work to achieve these consensus-derived principles. Although the article is targeted at ePRO systems used in clinical trials, it is likely that anyone who develops or uses ePROs will find the guidance useful.

The adoption of ePRO systems is occurring so rapidly in clinical settings that the type of careful and rigorous validation suggested for clinical trials by Zbrozek et al. [3] will be challenging to accomplish in clinical practice settings. Electronic health record (EHR) vendors have already integrated PROs into their products. With its software release in fall 2012, Epic, a leading EHR developer, provided a new PRO application that enables patients to complete measures in waiting rooms (on tablets or kiosks) or on their home computers via a patient portal. Data are stored in the EHR and can be retrieved in tabular or graphical form just as laboratory and other forms of discrete clinical data are currently reported. New guidelines for PRO data collection in EHRs and other electronic clinical records, such as registries and patient health records, are urgently needed. The recommendations in the article by Zbrozek et al. [3] are a useful starting point.

There is little evidence to guide the effective integration of PROs into real-world patient care settings. In fact, published research to date is largely disappointing in that PRO administration has mostly yielded increases in chart notations of scores and associated diagnoses, but has had little or no impact on patient care and outcomes [4,5]. Although there have been attempts to define a common and practical set of PRO data for EHRs [6,7], national consensus on these standards has been elusive.

If the digitization of PROs in clinical settings is to enable longitudinal and multisite research, we will need terminology standards to facilitate interoperability. The latent traits and behaviors that PROs are intended to measure need to be defined and linked to common data elements and reference terminologies. For example, the Patient Reported Outcome Measurement Information System instruments (http://www.nihpromis.org) have incorporated common standards and definitions including Logical Observation Identifiers Names and Codes and Systematized Nomenclature of Medicine-Clinical Terms. Furthermore, the Patient Reported Outcome Measurement Information System instruments can use Health Level Seven messaging, the most widely used standard for exchanging health care data within and between health care organizations. This type of data standardization is needed for all PROs if we aspire to use them in comparative effectiveness, clinical research, and clinical trials.

Electronic data capture systems are creating novel and intriguing new ways to administer PROs. Computers can present PRO items as text, audio (for low-literacy populations, children, or blind individuals), or graphical (e.g., cartoon characters presented to children) formats. Videoconferencing can be used to enable interviewers to remotely administer PROs. Items may be presented as a fixed-format test or adaptively such that the selection of items is based on the sequential pattern of a response. Standards for these alternative, but rapidly emerging

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modes of administration will be needed to ensure data quality and the validity of PRO assessments. These types of evaluations need to be done as soon as possible, before ePROs are so embedded into clinical practice that the basic principles of ensuring high levels of data quality are ignored.

Electronic data capture and the digitization of PROs is rapidly replacing paper-and-pencil methods. These transformations are presenting new opportunities for clinical research and, as a result, offer tremendous promise for substantively improving the effectiveness and patient-centeredness of health care. The rapid advances in ePRO systems present a challenge to the research community, which will need to ensure that they are developed to produce high levels of data quality. Without such assurances, we run the risk of weakening the impact of significant investments made into the nation's digital infrastructure.

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