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Editorial: The Challenge of Electronically Captured Patient-Reported Outcomes

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By Barry Fortner, PhD

As illustrated by Matthew et al¹ in this issue of the *Journal of Oncology Practice*, it is exciting to witness the expanding array of electronic tools and platforms employed to capture patient-reported outcomes data. Although “patient report” is a mainstay of the clinical process, one of the primary factors limiting the routine, clinical use of tools for

collecting, standardizing, and facilitating patient reported information is assumed to be the practical limits of paper and pencil methods for capturing this type of data.

This and other recent work demonstrates the viability of collecting patient-reported outcomes through electronic methods, including personal digital assistants, personal computers, pen-based computers, Internet-based systems, and the phone (using interactive voice response or voice recognition systems). These electronic tools are stand-alone software programs or extensions of other electronic medical information systems, such as the electronic medical record. While significant progress has been made, serious challenges continue to plague the field, including those discussed below.

First, electronic capture of patient-reported outcomes does not necessarily translate directly from paper tools—clinical validity may be lost (or gained) in the translation. The practical usefulness of collecting patient-reported outcomes through electronic means has been well demonstrated. However, it should not be assumed that a given questionnaire, which may have proven reliability and validity in paper form, will have the same psychometric properties when reformatted for electronic administration, or that a scale administered in one electronic medium is reliable when deployed in a different electronic form. Alternate forms reliability and validity studies are required when scales are reformatted.

Moreover, a greater overarching challenge is to demonstrate that specific patient reported outcome measures are useful, or valid, in terms of everyday clinical practice. In contrast to the ubiquitous validation studies that compare a new measure with other established measures, studies are needed to explore the implications of patient reported outcome measures in relation to clinical screening, diagnosis, and treatment decision making. Only when these measures, electronic or not, are shown to be beneficial for the frontline clinician are they going to be adopted widely to the benefit of large numbers of patients.

The second challenge—quality control and scalability—may not be apparent to most scientists and end users who are unfamiliar with the mature software industry. Not only is the measure itself required to be reliable and valid, but the software supporting the measurement process must be reliable and valid. Extensive industry standards exist to guide and judge the programming required for this type of work. Extensive software validity testing must be completed and documented for a software program to withstand scrutiny and the inevitable external audits required when these measures find their way into the clinical charts of patients. Compounding this requirement is the fact that software may be valid when used in one context but not when used in another. For example, when moving from 10 to 1,000 users, the software may become unstable or may display unacceptable error rates. These extensive requirements directly affect the time and expense demanded to develop and validate the underlying software platform and ultimately to format and deploy a given measure.

Additionally, regulatory standards must be fulfilled. As electronic patient-reported outcomes become available in clinical settings, they face the challenge of being subject to federal and medical legal requirements. Perhaps the best known are the Health Information Portability and Accountability Act (HIPAA) and the Code of Federal Regulations (Part 11). HIPAA requires that software be constructed with demonstrated and documented characteristics ensuring the protection of personal health information and that policies and procedures surrounding the

use of the software ensure HIPAA compliance. When implemented in clinical settings, the data may serve as source documentation used directly or indirectly in clinical trials. Therefore, the software program used to generate this source data must be compliant with the electronic requirements laid out in Part 11 of the Federal Code of Regulations. Compliance with both sets of regulations is subject to pharmaceutical and US Food and Drug Administration audits of research study data.

Finally, electronic systems for capturing patient reported outcomes face the challenge of making such systems financially viable. The expense of developing, deploying, and supporting hardware and software platforms in the current regulatory and clinical environment is not feasible. Governmental and/or commercial mechanisms to sustain an industry offering this type of technology will be necessary for wide adoption. From a scientific and technologic standpoint, we are clearly entering a period when obtaining electronic patient-reported outcomes is clinically desirable and feasible. The financial model that will arise to ensure the widespread uptake of these advances is much less obvious.

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In summary, it is gratifying to see the availability of patient-reported outcomes through a growing variety of electronic delivery mechanisms. We also are witnessing a maturation of clinical research that may someday bring this area to a point where we consider patient-reported outcomes a required component of quality medicine. To this end, the above challenges must be met with increased focus and determination. The result will be a significantly empowered patient and a more efficient and effective clinical process that produces data worthy of external social and commercial verification and an ongoing, reciprocal process of scientific exploration.

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