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COMMENTARY

Can We Use Social Media to Support Content Validity of Patient-Reported Outcome Instruments in Medical Product Development?

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ABSTRACT

We report a panel designed to open a dialog between pharmaceutical sponsors, regulatory reviewers, and other stakeholders regarding the use of social media to collect data to support the content validity of patient-reported outcome instruments in the context of medical product labeling. Multiple stakeholder perspectives were brought together to better understand the issues encountered in pursuing social media as a form of data collection to support content validity. Presenters represented a pharmaceutical sponsor of clinical trials, a regulatory reviewer from the Food and Drug Administration, and an online data platform provider. Each presenter shared its perspective on the advantages and disadvantages of using social media to collect this type of information. There was consensus that there is great potential for using social media for this purpose. There remain, however, unanswered questions that need to be addressed such as identifying which type of social media is most appropriate for data collection and ensuring that participants are representative of the target population while maintaining the advantages of anonymity provided by online platforms. The use of social media to collect evidence of content validity holds much promise. Clarification of issues that need to be addressed and accumulation of empirical evidence to address these questions are essential to moving forward.

Keywords: clinical trials, online communities, patient-reported outcomes, social media.

Introduction

Patient-reported outcomes (PROs) are increasingly recognized as important tools in adding value to the drug review and evaluation process [1] because they provide unique perspectives on medical conditions or their therapies that are known only to the patient [2]. "Content validity" describes the extent to which a PRO intended to assess such subjective outcomes actually measures the concept of interest [3] and is an ongoing process that relies on the generation of qualitative and quantitative evidence. Crucially, PRO measures must reflect patient concerns relative to the concept being assessed and, therefore, documentation of content validity relies on patient input from the target population of patients [4]. Qualitative studies are used to generate appropriate items and domains; to ensure the instrument is comprehensive relative to its intended measurement concept, population, and context of use; and to ensure patient understanding of the instrument, that is, instructions, items, and response options through cognitive debriefing [5]. Best practices usually include either individual interviews or focus groups with participants who are experiencing the target condition or have recent experience with it. These traditional methods of collecting qualitative data to support the content validity of a new or existing PRO instrument, however, are labor intensive, time consuming, and relatively expensive. Although detailed figures are not available for specific parts of the instrument, development estimates from the New England Research Institutes suggest that developing a PRO from beginning to end takes at least 24 months and costs between $1 million and $5 million [6], whereas estimates shared at the 2011 C-Path meeting suggest up to 4 years for development and costs between $725,000 and $2.1 million [7]. Furthermore, there are potential limitations in the diversity of the sample and the amount of data that may be collected to support both comprehensiveness of concepts and understanding of the PRO instrument using these methodologies [5].

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Social Media

A new tool that may offer a technological boost to these efforts is "social media," a group of Internet-based applications (such as Facebook, Twitter, forums, or blogs) that allow the creation and exchange of user-generated content. The Pew Internet & American Life Project noted in 2011 that the Internet has "changed people's relationships with information" in many areas that affect our lives including health. For example, "online resources, including advice from peers, are a significant source of heath information in the US" [8]. In a large and nationally representative survey of US adults in 2013, Pew found that 26% of the Internet users had read or watched someone else's experience about health or medical issues in the past year and 16% had tried to find others with the same health concerns, typically through social media [9].

The reach of such online communities is their greatest strength. For example, it is estimated that in 2013 the number of total users for the four largest social media platforms was 1.15 billion for Facebook, 500 million for Twitter, 500 million for Google+, and 238 million for LinkedIn (http://visual.ly/social-media-2013). Given that a proportion of the cost of PRO development lies in contacting and recruiting people with specific medical conditions and gathering data from them, social media presents an intriguing new route to accelerating research.

This new form of technology is relatively untested in terms of the adequacy of the information collected to support current definitions of best practices for data generation and analysis. This is particularly true of research to support content validity for the development of PROs for use in clinical trials to support labeling claims in the United States. To capitalize on the advantages of this new technology, stakeholders need to agree on what is appropriate methodology and focus research on resolving these issues. Currently, there is limited knowledge in the public domain on this topic.

To address this question, the authors organized a panel at a recent ISPOR meeting (2013, New Orleans) to discuss the application of social media for this type of data collection. We identified four stakeholders to share their perspective although there are certainly others who may be able to contribute knowledge, expertise, and experience to understanding the topic. Panelists who contributed to this article included representatives from a pharmaceutical sponsor of clinical trials (M.R. and A.G.), a US regulatory reviewer (E.J.P.), and a provider of a patient-powered research network for data collection through social media (P.W.). Presenters were asked to share their knowledge and experience, particularly with respect to their perception of the advantages and disadvantages of using social media to generate data to support the content validity of PRO measures in the context of drug development (Table 1). The focus of this panel was on concept elicitation.

Table 1 – Comparison of traditional methods and potential for social media in PRO development.

	Traditional methods	Social media
Participant identification	Clinicians, hospital referral, advertising	Patient self-identification and membership of online communities
Diagnostic validation	Primarily physician or medical records, sometimes self-reported	Primarily self-reported, sometimes electronic medical records of physician
Data collection setting	Face-to-face individual or group interviews	Asynchronous message boards, instant message chat, video chat
Data collection format	Semi-structured interview, in-person cognitive debriefing	Interactive surveys, questionnaires, rating scales, video cognitive debriefing
Advantages	Criterion standard widely accepted by researchers and regulators as producing high-quality outputs	Rapid, cheap, participatory, large-scale, new methods iterate rapidly. Typed data do not require transcription
Limitations	Time and labor intensive tasks such as transcription and recruitment	New, untested in the regulatory approval process

Benefits of Social Media for PRO Concept Elicitation

All the speakers indicated their belief that there are potential benefits to using social media for collecting concept elicitation data. The potential to access larger numbers of persons in the target population and thus obtain a greater amount of information in a shorter period of time is an advantage over traditional methods. Each social network has its own strengths and weaknesses (which should be tailored to each study); however, it is important to recognize that networks go through life cycles far more rapidly than do traditional social establishments [10]. Although a full review of each network's strengths and limitations was outside the scope of the panel, a recent review by Grajales et al. [11] provides a comprehensive overview of the scientific literature describing research with blogs (e.g., Wordpress), microblogs (e.g., Twitter), social networks (e.g., Facebook), professional sites (e.g., LinkedIn), wikis (e.g., Wikipedia), mashups (e.g., HealthMap), collaborative filtering sites (e.g., Reddit), media sharing sites (e.g., YouTube), and multiuser virtual environments (e.g., Second Life).

In a comparison of semi-structured interviews with blogs for purposes of PRO development, Acaster and Wild [12] reported a high degree of convergence about symptoms experienced by women with menopausal hot flashes, with no major discrepancies in themes elicited between the two methods. In a study eliciting concepts among children from ulcerative colitis, Yen et al. [13] used blogs to substantiate concepts identified through traditional interviews and found these data to be supportive. This area is still developing, however, and the most recent ISPOR PRO Good Practices Task Force guidance makes no mention of data gathered online [14]. It is worth acknowledging, however, that different forms of social media might have differing potential to offer useful data. For example, the patient-powered research network PatientsLikeMe was recently described in the "tapestry of big data" as differing from blogs and tweets in that it not only captures structured data including demographic characteristics, medication, and diagnoses but also has aspects of a social network [15].

Although the authors are unaware of examples of the use of social media to develop PRO instruments for regulatory use to support labeling claims, it is often informative to draw from examples of uses of social media in instrument development outside this specific regulatory context. For instance, among the potentially broader online population there may be more