Engage with research participants about social media

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A growing number of participants in clinical trials are sharing information about their health online. It's time that the drug development community starts to examine how this social media use might compromise the integrity of research studies and how it might also offer new opportunities.

Not long ago, the likelihood of clinical trial participants socializing and sharing information was limited to the clinic waiting room. As such, the risk of conversations among patients leading to the unblinding of experimental treatments in research studies was generally viewed as minimal. Over time, this has changed. During the HIV/AIDS crisis of the 1980s and 1990s, activist patient communities with unmet medical needs attempted to navigate blinded clinical trials to gain access to investigational medicines. At that time, social networks were geographically isolated and did not have the technology to enable rapid dissemination of information on a global scale. But today, patients around the world use the internet and social media to find and share health information and use it in their interactions with healthcare providers. This sharing of information has its benefits, but it can also undermine the scientific integrity of medical research.

It is time for the clinical research community to recognize the impact of these conversations on the conduct and interpretation of blinded clinical trials. Patients must be made aware of the potential implications of social media use on the scientific integrity of the study in which they are participating, and researchers must be trained on the risk in maintaining blinding through their own use of online networks. Perhaps most important, clinical trial sponsors must work with regulators to define pathways to monitor social media use by trial participants to understand if conversations on the internet will affect their interpretation of study results.

Looking forward, clinical trial designs may be enhanced by leveraging the insights from research participant conversations on social media. Organizations are already beginning to take advantage of online communities and other social media channels to improve study recruitment and certain aspects of study design. In late 2012, the US Food and Drug Administration (FDA) approved an Investigational New Drug Application with a crowdsourced protocol developed with an online community of patients, physicians and researchers.

What many have failed to appreciate, however, is that the patient who is online before a trial begins will probably continue to use information via the internet during the trial. A 2013 survey by the Pew Internet Project reported 59% of adults in the US search on the web for health information, a rate that continues to trend upward. The rise of the internet has led to the rise of the 'eParticipant', a term used to describe individuals who engage in social media during their participation in a clinical trial.

One format through which information is shared is blogs. During the initial trials of the Novartis drug Gilenya (fingolimod) for multiple sclerosis, one trial participant maintained an active blog documenting and sharing her experience from her initial screening visit in 2007 through drug approval in 2010 and beyond. Her website (fty720.blogspot.com) even referenced the drug's investigational name, FTY720.

Discussion forums, meanwhile, serve as an active area of online interaction among study participants. For example, during the clinical trials for Incivek (telaprevir), a drug from Vertex Pharmaceuticals for hepatitis C, trial participants maintained online discussions at community sites such as MedHelp.org. These conversations extended into robust conversations on potentially sensitive topics, such as suggesting how to identify to which treatment arm of the trial one had been assigned.

Pioneering platforms such as that hosted by PatientsLikeMe enable patients to share health data to support their ability to select treatment options for optimal outcomes. In addition to sharing perceptions of efficacy and safety for approved products, patients can also track and share data for investigational medicines during clinical trials. PatientsLikeMe used data posted by patients with amyotrophic lateral sclerosis who participated in several ongoing clinical trials in an effort to determine whether the investigational products (lithium carbonate, NP001, KNS-760704 and sodium chlorite) may have therapeutic benefit—and this paper was published while the trials were ongoing[1].

Organizations such as the Society for Participatory Medicine, of which I am a founding member, are committed to ensuring the patient is an active participant in health decision making. But with this empowerment come risks, such as the potential for misinformation or inappropriate self-diagnosis and treatment[2]. Unfortunately, there has been little research on the implications of the eParticipant on the scientific integrity of clinical trials[3]. The eParticipants in these various forums are motivated by the desire to support one another as well as by innate curiosity. They may not appreciate how their activities may undermine the scientific integrity of the study by touching on topics such as eligibility (patients sometimes coach one another on how to meet eligibility criteria), blinding (participants share advice on how to determine treatment assignment) and safety (patients sharing safety events may stimulate other patients to perceive the same symptom, affecting data integrity through a false spike in safety reports).

Just as patients conversing among themselves may put the scientific integrity of a blinded clinical trial at risk, researchers who monitor participant conversations on treatment assignment may jeopardize their ability to maintain their own blinding. If a researcher spots an adverse event conversation on social networks, what should she do? Not only is there a lack of FDA guidance specific to social media in the research setting, but also research sponsors in these situations may struggle to confirm that the patient is truly in the trial and may face difficulty in determining whether the online report is one already captured in the study database. In most cases it is unrealistic to match a posting in a web forum to a randomized patient in a study to confirm the finding.

It is likely that in the near future participants may be counseled by the study investigator at the time of informed consent on limiting social media use during their involvement with a clinical trial, or that research investigators and sponsors themselves may receive training to ensure that their blind is maintained. As one trial participant counseled me—"we are human beings and we will talk; patients are not going to change, so the researchers must." As use of online networks continues to rise, research sponsors and regulators must begin studying the implications of social media on the integrity of current blinded and randomized clinical trials.

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