CHEST

Smart Technology in Lung Disease Clinical Trials

Nancy L. Geller, PhD; Dong-Yun Kim, PhD; and Xin Tian, PhD

This article describes the use of smart technology by investigators and patients to facilitate lung disease clinical trials and make them less costly and more efficient. By "smart technology" we include various electronic media, such as computer databases, the Internet, and mobile devices. We first describe the use of electronic health records for identifying potential subjects and then discuss electronic informed consent. We give several examples of using the Internet and mobile technology in clinical trials. Interventions have been delivered via the World Wide Web or via mobile devices, and both have been used to collect outcome data. We discuss examples of new electronic devices that recently have been introduced to collect health data. While use of smart technology in clinical trials is an exciting development, comparison with similar interventions applied in a conventional manner is still in its infancy. We discuss advantages and disadvantages of using this omnipresent, powerful tool in clinical trials, as well as directions for future research.

CHEST 2016; 149(1):22-26

KEY WORDS: clinical trials; lung disease; mobile health; personal electronic devices; smart technology

Contemporary randomized controlled trials have become prohibitively expensive, thus limiting the number of conventional clinical trials that can be undertaken. One way to make clinical trials less expensive is through the use of computer technology. Over time, the use of computers has become increasingly a part of everyday life, and, consequently, their use in clinical trials has become more commonplace. We focus on use of smart technology: electronic health records (EHRs), web interventions, and mobile devices. These can now be used in clinical trials to enhance accrual and compliance, to collect health data, and to provide more accurate outcome measures.

Use of EHRs

The Health Information Technology for Economic and Clinical Health Act of 2009 brought the rapid and broad adoption of EHRs to hospitals in the United States. As of 2014, more than three-quarters of the non-federal acute care hospitals adopted at least a basic EHR system, and almost all of the surveyed hospitals have certified EHR technology.[1] Increased efficiency in handling patient information and care coordination are significant benefits of EHRs.[2] The use of EHRs can also facilitate patient identification and recruitment for clinical trials.[3]

Traditionally, patient screening was done manually by clinical trial personnel. Manual

ABBREVIATIONS: EHR = electronic health record; eIC = electronic informed consent; LASST = Long-acting β Agonist Step Down Study; MICT = Mobile Devices and the Internet to Streamline an Asthma Clinical Trial

AFFILIATIONS: From the Office of Biostatistics Research, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD.

CORRESPONDENCE TO: Nancy L. Geller, PhD, Office of Biostatistics Research, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Dr, MSC 7913, Bethesda, MD 20892-7913; e-mail: gellern@nhlbi.nih.gov

DOI: http://dx.doi.org/10.1378/chest.15-1314

review of patient records is labor-intensive and likely to be error-prone. Studies show that automating such searches leads to a dramatic increase in efficiency and accuracy. Beauharnais et al[4] reported a 50% reduction in total screening time per patient. Ni et al[5] found that an eligibility matching algorithm resulted in 85% workload reductions in patient chart review.

While electronic patient screening has been used in the past,[6] clinical trial recruitment support systems that specifically use EHRs have emerged in previous years.[7,8] There are several feasibility trials that recruited patients with asthma or COPD using EHRs and clinical trial recruitment support systems, such as the Salford Lung Study[9] and eLung.[10]

The broad adoption of EHRs offers great opportunities in clinical trials. However, for EHRs to be fully used, there are substantial issues to address. There is a lack of common terminology in different EHRs and lack of ability to connect electronic data capture and EHRs.[11] There are other major obstacles such as nonuniform local regulations governing the use of EHRs and language barriers in multinational trials. Commercial EHR packages are expensive, especially for small clinics. Furthermore, clinicians may not adapt easily to a system they did not help design.

Electronic Informed Consent

Use of electronic informed consent (eIC) is another technological innovation that benefits both the patient and the clinical trial investigator. An eIC can facilitate the enrollment process by allowing patients to sign up for a clinical trial from a remote location using smartphone applications, a web interface, a touch-screen terminal, or a combination of these. It also allows the investigator to use various interactive electronic formats such as text, clickable URLs, videos, and diagrams, all of which enhance the patients' understanding of the content.[12] For the investigator, eIC provides searchable data, such as the date and time that a subject signed the consent, unlike the scanned copy of the paper form. The design of the user interface and the choice of consent models are important issues to consider to ensure the success of this new consent medium.[13,14] To address the privacy and security issues of eIC, the US Food and Drug Administration has issued a draft guidance.[15]

Web-Based and Short Message Service-Based Interventions

Web-based interventions provide the opportunity to intervene in symptomatic subjects in a cost-effective manner.[16] In the Puff City clinical trial, Joseph et al[17] tested a multimedia web-based intervention in students with asthma at six Detroit high schools, randomizing them to an individually tailored program or to access generic asthma websites over a 180-day intervention period. The program was available on the high school's computers, and students were allowed to access the material during the school day. The trial found that asthma outcomes were significantly improved in the intervention group in this traditionally hard-to-reach population.[17]

Some previous clinical trials use smartphones as a delivery mechanism via short message service (text messaging). Use of text messaging has certain advantages.[18] A text message is immediate so it can be an effective tool for quick reminders. Also, it may be better suited to younger subjects. Text messages can reach patients in remote areas at low cost, which could be especially useful in bringing health care and clinical trials to an underserved population.[19] They also help improve retention, as found in studies involving patients with HIV and TB.[20]

Interventions using text messages have been shown to be effective in several areas, including smoking cessation.[21] Text message-based interventions have been found to be more effective when the messaging interval is not too frequent and the messages have personalized content.[22]

In a meta-analysis of pooled randomized or quasi-randomized trials, Whittaker et al[23] showed that a mobile phone-based intervention for smoking cessation was effective in increasing the 6-month cessation rate. The Nicotine Exit (NEXit) is a new randomized trial that will examine the effectiveness of a stand-alone text-based intervention to help university students in Sweden stop smoking.[24] The 12-week intervention will occur simultaneously through Swedish universities served by 25 health-care centers.

This trial has certain features worth noting, namely access to a large number of potential subjects, simple eligibility criteria, and a simple intervention. The health-care system in Sweden includes everyone and therefore facilitates wide publicity for volunteers. The trial had few eligibility criteria other than being a daily or weekly smoker, but participants are required to be willing to set a date within the next 4 weeks to stop smoking. This should help to decrease noncompliance and dropout. The intervention itself is straightforward, in the sense that successful delivery is assured (once a telephone number is confirmed), and the timing and number of the messages can be automated. The large number of eligible subjects should enable rapid completion of this trial.