technical challenges with apps, parental involvement in weighing, being told by clinicians to weigh, and intervention impact. Most parents desired more directions and help with setting up the app connection to the EHR. Most parents did not ask their child daily about their weight status as they did not want to cause stress. Some adolescents found it stressful when parents asked about daily weight status; others found it helpful or at least not stressful. Most participants had never been advised by their clinician to regularly self-weigh. Most found it helpful to monitor their weight regularly. Most asked for reminders from clinic to weight and for feedback on weight between visits. DISCUSSION/SIGNIFICANCE OF FINDINGS: Overall, adolescents with obesity reported self-weighing as being helpful and most wanted some, but not daily, involvement from parents. Most parents wanted additional technological support to create the scale set-up. Nearly all parents and adolescents wanted the weights to be connected to clinic, and for there to be feedback from clinic on weight.

Commercialization/Entrepreneurship

92090

Novel use of REDCap to develop a Crisis Management Decision-Support Portal at an Academic Medical Center

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ABSTRACT IMPACT: Implementation of digital and mobile applications in clinical research crisis response protocols can mitigate their impact on clinical research. OBJECTIVES/GOALS: Crisis management is fundamental to ensuring the protection of human subjects during a clinical trial. Mobile apps have the capacity to allow for quick access to crisis response plans and can serve to mitigate their impact on clinical research. Electronic data capture tools can be used to create digital applications for such a response. METHODS/STUDY POPULATION: The Clinical Research Center at Rutgers University transferred a paper-based crisis management response plan to a digital mobile application format using Vanderbuilt's Research Electronic Data Capture Tool (REDCap). REDCap's branching logic allowed for programming a decision support functionality to guide users through 3 specific crises. (1) threatening or aggressive study subject behavior; (2) clinical research center break in or theft; and (3) adverse event observed for ongoing or closed clinical research study. Applicable U.S. Code of Federal Regulations, IRB guidelines, institutional policies and procedures were also used as a component of the mobile development. RESULTS/ANTICIPATED RESULTS: The Crisis Management Decision-Support Portal within the Clinical Research Center has an interactive structure. The use of branching logic demonstrates the ability for users to answer each question and be guided to appropriate responses specific to selected criteria related to each event. The tool contains a self-correct function by providing a reset option after answering each section. The portal itself can be accessed using any computer or cellphone with an internet connection. It provides the users with appropriate criteria to determine to exact communication and management protocols for reporting for the crisis event they are witnessing. As users access the portal, usage data can be collected, tracked, and stored. DISCUSSION/SIGNIFICANCE OF FINDINGS: The REDCap platform offers the opportunity to digitize crisis management protocols that ensure professionals have easy access to appropriate responses to crises at the center. The use a digital application rather than paper allows for a CTSA sponsored hub to mitigate damage, simply build new protocols, modify existing protocols, and track usage.

Evaluation

62610

Effects of electronic verses paper based data capture in large multinational trials on time to complete, time to publication, participation and collaboration.

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ABSTRACT IMPACT: My work evaluates the impact of electronic data capture/eSource on several aspects of clinical trial efficiency and scale, aiming to demonstrate how eSource can be used to improve the way we run clinical trials. OBJECTIVES/GOALS: Using eSource may increase the efficiency of data collection in clinical trials. However, adoption of eSource has been slow. We reviewed over 100 large multinational clinical trials to analyze how eSource use correlated with trial size, sponsor collaborations, time to complete, and time to publication. METHODS/STUDY POPULATION: We searched ClinicalTrials.gov for completed, interventional, Stage II-IV clinical trials with posted results and an uploaded study protocol document. This produced 3,962 trials. We identified all studies with over 1,200 participants and sites in multiple countries (or at least 100 sites in one country). After eliminating ten studies with duplicate protocols, we had a database of 123 trials. From the ClinicalTrials.gov listing, the study protocol, and any published papers, we determined the start, end, and publication dates, data collection protocol, sponsors and collaborators, and any reasons given for delays for each trial. We performed statistical tests comparing trial delay, participant and country count, and collaboration status (yes or no) between the two groups (eSource users and non-eSource users). RESULTS/ANTICIPATED RESULTS: Of our 123 trials, 60 (48.7%) used eSource, 48 (39.1%) used paper source documentation, and 15 (12.2%) used some combination. We found no statistically significant difference between eSource and non-eSource trials in terms of trial delay ($p=0.43$), time to publish ($p=0.33$), collaboration status ($p=0.54$), number of participants ($p=0.36$), or number of countries ($p=0.12$). However, our analysis was limited by what data was publically available. To investigate the effects of eSource on site efficiency, data accuracy, and data security, which are three major factors behind the FDA's 2013 eSource recommendation, we would need access to proprietary information from trial sponsors. DISCUSSION/SIGNIFICANCE OF FINDINGS: The use of eSource in large multinational clinical trials is not correlated with a change in time to completion or publication nor a higher number of participants or countries. We aim to acquire proprietary data to further analyze the impacts of eSource on trial efficiency, data accuracy, and data security.

https://doi.org/10.1017/cts.2021.492 Published online by Cambridge University Press