

COMMENTARY

Recruitment and Trial-Finding Apps—Time for Rules of the Road

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Abstract

The problem of insufficient recruitment to clinical oncology trials is well known. Some stakeholders view mobile apps as a solution with the potential to make recruitment more efficient, lower trial costs, support patient-centeredness, and accelerate treatment advances. Recruitment and trial-finding apps seek to disrupt the traditional approach to recruitment in several ways, including aggregating information about ongoing trials and presenting it in a user-friendly format, curating information to tailor search results to prospective participants' interests, facilitating direct contact between prospective participants and trial sites, and, in at least one case, analyzing individuals' tumor samples and medical records to provide tailored recommendations both for approved treatments and clinical trials. Although recruitment and trial-finding apps respond to a real need, they raise ethical concerns. Here, we outline six domains of ethical concern: review of recruitment materials, privacy and confidentiality, constrained choice and conflicts of interest, therapeutic misbranding, payment for accessing research-related information, and disruptions to care and research. We offer several suggestions and encourage additional dialogue to improve the ethical acceptability of these apps because, as third parties increasingly promise to revolutionize clinical trial recruitment by connecting patients and investigators via recruitment and trial-finding apps, we need some rules of the road.

The problem of insufficient recruitment to clinical oncology trials is well known. As a result of low accrual, as many as 40% of trials sponsored by the National Cancer Institute never reach completion and publication (1). Not even one in 20 adult cancer patients will enroll in a clinical trial. (1) Yet, an estimated 70% of Americans report being inclined to participate in clinical trials. This suggests the existence of a critical gap between willingness to participate in research and actual participation rates. Could mobile applications or “apps” help bridge that gap? Various stakeholders—including some digital health startups—argue that, yes, they can.

Recruitment and trial-finding apps respond to a real need. Investigators want to recruit research participants as efficiently as possible, and many oncology patients want to learn about opportunities to participate in clinical trials. Although investigators' and patients' interests are complementary, protocols are increasingly targeted to specific subpopulations and limited to a handful

of sites that—coupled with increases in the overall number of protocols—challenges investigators and prospective participants seeking to connect (2). Although clinicians are logical connectors between patients and investigators, the same factors that hamper investigator-patient connections can make it difficult for clinicians to maintain current knowledge of relevant clinical trials, and traditional recruitment methods fall short. Reducing friction within the system through widespread adoption of recruitment and trial-finding apps could advance the interests of investigators, sponsors, patients, and clinicians alike by making recruitment more efficient, lowering trial costs, supporting patient-centeredness, and speeding treatment advances.

Recruitment and trial-finding apps represent a promising means to disrupt the status quo. Nevertheless, apps that seek to connect cancer patients with clinical trials can raise ethical concerns. Here, we outline six such concerns and suggest strategies to address them.

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Recruitment and Trial-Finding Apps

Recruitment of appropriate participants is among the most consistent, challenging, and costly barriers to trial success (3,4). Traditionally, recruitment has relied on strategies such as clinician referrals, media advertising (ie, television, radio, and newspaper), and focused outreach to find prospective participants—strategies that may be limited both in their human and geographic reach. Insufficient recruitment gives rise to scientific, ethical, and practical concerns. Trials that do not reach target enrollment are more likely to go unpublished because of failure to meet the primary outcome measure; participants in underpowered trials are, therefore, participating in research that entails risks and burdens but is likely to be of limited social value (5,6). Even when trials ultimately reach target enrollment, difficulty recruiting participants prolongs their duration, increases costs, and delays medical progress for people with cancer (7). Given the persistence of poor recruitment and its attendant consequences, it is unsurprising that investigators and others have sought innovative means of improving recruitment such as the use of recruitment and trial-finding apps.

Apps are software programs designed and developed to run on smartphones, tablets, and other mobile devices and are typically available for download on Apple iOS and Android platforms. Apps differ from websites in that they are downloaded and installed on the user's mobile device rather than being loaded via a web browser. Apps offer a potentially powerful way to connect with prospective research participants, as more than three-quarters of Americans now own smartphones and spend many hours per day looking at their screens (8). Use of recruitment and trial-finding apps is consistent with both the broader trend toward increased patient control of information-seeking and a recognition that a majority of Americans go to the internet first for health information (9). Further, many people with cancer already actively look for clinical trials online.

Recruitment and trial-finding apps seek to disrupt the traditional approach to clinical trial recruitment in various ways. Most basically, apps aggregate information about ongoing clinical trials. Aggregation is of course not new. To choose but one example, ClinicalTrials.gov, the US federal trial registry and results database, has offered online information about many publicly and privately supported clinical trials since 2000 (10). The ClinicalTrials.gov interface has, however, been criticized as difficult to navigate, and the available information as difficult for laypersons to understand. Apps like Novartis's Clinical Trial Seek attempt to resolve these issues by aggregating information from ClinicalTrials.gov and presenting it via a user-friendly interface that helps individuals find open, enrolling clinical trials for a variety of conditions.

As a next step, many recruitment and trial-finding apps curate trial-related information. Whereas ClinicalTrials.gov is a general repository for trial-related information and encompasses numerous diseases and conditions, apps may selectively focus on a specific disease or on a collection of related diseases. For instance, ClinTrial Refer ANZMTG connects app users with a list of active and pending skin cancer trials worldwide (11). Other apps present only those trials offered within a particular hospital or health system. Examples of this model include Stanford's SCI Cancer Clinical Trials and Thomas Jefferson University's Clinical Trials—TJU apps, which allow users to search actively recruiting cancer clinical trials at the Stanford Cancer Institute and Sidney Kimmel Cancer Center, respectively (12,13).

Beyond aggregation and curation, app developers may take one or more additional steps to enhance the user experience for

prospective participants, such as including lay summaries of trials, allowing users to refine searches by inclusion and exclusion criteria or trial status, mapping trials using a global positioning system search function, detailing research-related time commitments and offers of payment made in exchange for research participation, allowing for easy sharing of study information (eg, with friends and family) by email or social media, enabling direct contact between prospective study participants and trial sites, facilitating online scheduling for study visits, and providing links to additional informational resources. The developers of the proposed PatientWing app liken their app to OpenTable, an app used by diners to discover restaurants and make reservations, in light of such features (14). Others have compared recruitment and trial-finding apps to Tinder, a popular dating app (15).

A handful of recruitment and trial-finding apps seek to go even further. For example, Driver—a startup that publicly launched and subsequently shuttered in 2018—marketed an app that provided tailored recommendations for approved treatments as well as cancer clinical trials based on an analysis of patients' tumor samples and medical records (16).

As the above examples show, recruitment and trial-finding apps have been developed by a range of stakeholders. Some of these stakeholders are familiar with clinical research, whereas others are new to this space and, presumably, less familiar with the norms of research. Additionally, it is worth noting that the minimum cost to develop an app easily runs into the thousands of dollars and can increase substantially from there depending on the app's aim and scope. Whereas most of the recruitment and trial-finding apps available today can be downloaded for free by prospective research participants, others are available for a nominal fee ranging from \$0.99 to \$24.99. While available, Driver was a notable outlier, charging patients \$3000 up front, plus a \$20 monthly fee, which had to be paid out of pocket, as insurers do not yet reimburse such costs (16).

Ethical Challenges

Although recruitment and trial-finding apps hold compelling potential for connecting prospective participants with clinical trials, they also raise ethical challenges. Here, we identify challenges in six domains. The extent to which any particular recruitment and trial-finding app raises these ethical issues will depend on app-specific features and characteristics.

Review of Recruitment Materials

Recruitment is widely considered to be the start of the informed consent process. Therefore, any methods and materials that investigators propose to use to recruit subjects are generally subject to institutional review board (IRB) review (17). Investigators planning to use recruitment and trial-finding apps should disclose this to the IRB and share information about the trial that will be presented to prospective participants within the app. Investigators can reasonably be expected to have some degree of control over how and what information is presented within an app, if, for example, it has been developed by their research institution, or if they are paying to promote their trial within a commercially developed app.

Yet, recruitment and trial-finding apps have the potential to upset the traditional logic of IRB review of recruitment materials. It is unclear that an IRB would have any meaningful oversight over any general information—for example, marketing materials for the app itself or background information provided

within the app about clinical research or the research-care distinction—that might affect participant recruitment. Moreover, depending on how an app functions, investigators may be entirely unaware that information about their trial is being shared via an app, leaving this information beyond investigator control and beyond IRB purview. We suggest that investigators have no affirmative obligation to surveil recruitment and trial-finding apps given the burdensomeness of this exercise; however, they should avoid willful ignorance by talking with participants recruited via apps and taking steps to correct misinformation or misrepresentations if they become aware of them (18).

Privacy and Confidentiality

Depending on their specific features, recruitment and trial-finding apps can facilitate the active sharing of information among prospective participants, investigators, and others. This is an asset, but also a potential threat to privacy and confidentiality. App users may, for example, share information about themselves and their diagnosis. Moreover, prospective participants may feel more comfortable sharing certain sensitive information through a screen than in person (19,20). App developers should take adequate precautions to protect personal information, and individuals should be informed of the risks associated with using an app's services as well as the possibility of a data breach. This is not solely an ethical concern: If an app collects, creates, or shares information, various state and federal laws may apply (21,22).

Even if app users are not deliberately sharing personal information, they will passively share it. Mere use of an app can be a rich source of data. Mobile analytics—the practice of collecting information about user behavior—could provide information about user demographics, engagement (ie, how often they are using the app), tracking (ie, how they are interacting with features within the app), and more. Some uses for these data may be relatively benign, such as using usage data and app performance analytics to improve user experience or to determine where to locate future trial sites. More concerning, user data may be of monetary value to app developers, given the value of analytics and aggregation to commercial actors.

Prospective participants who use apps should at a minimum be notified if data will be collected, and if so, what data and how they might be used. Presently, many apps disclose information about data use in clickwrap agreements—digital prompts for individuals to accept an app's terms and conditions of use before accessing the app. For example, Clinical Trial Seek provides information about its data collection practices—including information related to the device, app use, and real-time location information—and provides a physical address to which individuals can write if they have further questions about the privacy policy. Users must accept these terms prior to accessing the app. Concerns have, however, been raised about the ethical value of these clickwrap agreements. Namely, by clicking “I agree,” app users evince an affirmative choice, but they spend so little time reviewing information that this is unlikely to constitute an informed choice (23). There is a question as to whether recruitment and trial-finding apps can or should be held to a higher standard than other apps. Additionally, further conversations are needed around what app developers can and cannot do with prospective participants' information.

Constrained Choice and Conflicts of Interest

Recruitment and trial-finding apps constrain user choice in a variety of ways, some of which are beneficial to users (eg, showing only skin cancer trials to people with skin cancer) and others that are more likely to be beneficial to the app developer than the user. For example, a developer might choose to prioritize its own trials over others in search results. On Clinical Trial Seek, the default search option is set to “Novartis trials,” and users must actively select “All trials” as an alternative; the field of behavioral economics has shown that defaults like this can powerfully shape behavior. Apps developed by hospitals or health systems often explicitly limit search results to trials offered by that hospital or health system. Alternatively, an app developer may give trial sponsors and sites the opportunity to increase visibility by promoting their trials—that is, by paying for more advantageous placement to reach a wider group of users. This is, for instance, a proposed feature of PatientWing.

Constrained choices such as these are understandable in light of developers' reasonable motives to accrue financial or other benefits, including reputational benefits from enhanced recruitment rates. Yet, they also raise several concerns. First, prospective participants may not be matched to the trial best suited to them, recognizing that “best” is the result of a complex interplay between personal and trial-related factors. Second, recruitment might be driven by study budgets rather than by relative social value. Third, constrained choices may constitute conflicts of interest if an app developer's primary interest, such as a health care system's interest in patient care, is at risk of being biased by a secondary interest, such as research prestige (24). It is essential to acknowledge, of course, that these problems are not unique to recruitment and trial-finding apps. Nevertheless, we suggest that promoted trials should be clearly labeled, just as promoted tweets are labeled on Twitter. Further, prospective participants should be able to easily discern designs and defaults that might constrain their choice of trials and, ideally, have a relatively easy way of opting out of the default.

Therapeutic Misbranding

Some recruitment and trial-finding apps appeal to the altruism of potential users. PatientWing, for example, suggests that “[y]ou can help save lives in the near future by participating in a clinical trial” (25). Or, they offer a relatively straightforward value proposition. Clinical Trial Seek explains that the app “makes it easy for patients and health care professionals to find, navigate, and share in-depth clinical trial information” (26). Such language is ethically unproblematic. Yet, marketing materials may inappropriately conflate clinical research and clinical care. For example, Driver described its service as “the cure for cancer treatment,” falsely equating clinical trial participation with treatment (27). Elsewhere, it described clinical trials as offering “new medicines or therapies that aren't yet available to the general public but may have significant benefits.” The quoted language problematically overemphasized the potential benefits of trial participation and may have led users to believe that research participation offered a high likelihood of securing access to a drug that will go on to receive FDA approval. The real probability of receiving such a drug through a prelicense, early-phase trial is, however, much less than 10% (28).

Presentation of clinical trials as cutting-edge treatments within apps, as in other contexts, constitutes problematic therapeutic misbranding that perpetuates known misunderstandings

about participation in clinical trials. Although it may be reasonable to hypothesize that therapeutic misbranding concerns will be heightened when recruitment and trial-finding apps charge for access to trial-related information, cost is not the only correlate to therapeutic misbranding. Academic medical centers have, for example, been criticized for problematic invocation of their therapeutic mission to bolster participation in clinical trials and for using the prestige of research to elevate their institutional reputation (28). Marketing materials for the app—as well as for individual trials—should clearly distinguish clinical care from research. In particular, app developers must be mindful to describe clinical trials as primarily directed at advancing scientific knowledge for the benefit of future patients, rather than promising direct benefit to individual participants.

Payment for Accessing Research-Related Information

Although most recruitment and trial-finding apps are presently available to prospective participants for free or for a nominal fee, we note that more expensive pay-to-play apps raise distinct concerns. Here, we identify two: therapeutic misconception and exacerbation of financial barriers to trial participation.

First, therapeutic misconception—that is, the mistaken idea that trial participation constitutes treatment—is an ethical challenge in clinical research generally, but may be exacerbated when access to information about clinical trials is monetized. Our concerns about pay-to-play recruitment and trial-finding apps are roughly analogous to concerns raised by others about patient-funded trials. In these trials, participants pay for their participation; it has been noted in that context that, “[a]lthough willingness to pay might indicate understanding and voluntariness by participants, it might also reveal unrealistic expectations” (29). Particularly if combined with language that problematically elides the research-care distinction—such as that highlighted in the prior subsection—the demand for payment may make therapeutic misconception inevitable (30). A prospective participant’s use of a paid recruitment and trial-finding app to explore clinical trials is not, however, the same as giving informed consent for a particular clinical trial. Trial-specific factors will greatly influence the ultimate outcome, and study staff will continue to serve as a bulwark against therapeutic misconception.

Second, requiring patients to pay to access recruitment and trial-finding apps risks exacerbating known financial barriers to participation in cancer research. Economically disadvantaged patients and those experiencing the financial toxicity of cancer already encounter extensive barriers to their participation. Investigators have consistently found that patients with lower socioeconomic status are statistically significantly less likely to participate in clinical trials (31). Socioeconomic disparities in research participation undermine the generalizability of research findings. Additionally, disparities raise ethical concerns because justice demands the fair distribution of not only research risks but also potential benefits. Ongoing efforts to address financial barriers to participation in cancer clinical trials include the launch of philanthropic efforts to reimburse trial-related expenses, the amendment of state laws to allow for reimbursement, and the revision of FDA guidelines to state explicitly that reimbursements are not unduly influential (32). Moreover, the American Society of Clinical Oncology recently issued a policy statement highlighting financial barriers to trial participation (31). Pay-to-play apps are in tension both with these efforts and with the growing consensus that people

should not have to pay to contribute, or have access, to socially valuable research. Offering recruitment and trial-finding apps that are free to prospective participants will not solve the problem of financial barriers; however, it is preferable to avoid exacerbating inequalities. Thus, the economic model of recruitment and trial-finding apps should be structured so costs are borne by the research institutions, trial sponsors, or clinical trial recruiters rather than by patients themselves.

Disruptions to Care and Research

Because 98% of health care startups fail, it is reasonable to expect that many recruitment and trial-finding apps will also fold, despite the clear need they aspire to address. Driver closed its doors within 2 months of its public launch (33). Previously, Cure Forward, which used cancer patients’ uploaded genetic sequencing to connect them to clinical trials, closed after failing to generate sufficient revenue to attract new investors (34).

If a recruitment and trial-finding app shutters, its failure has the potential to disrupt patient care, research, or both. Apps that are purely informational—say, simply sharing information from ClinicalTrials.gov via a user-friendly interface—pose little risk in this regard. However, apps that offer additional features like subject monitoring or entry of patient-reported outcomes could be problematic. The cautionary examples of Driver and Cure Forward raise questions about how, if at all, to protect patients and other key stakeholders who are early adopters of new recruitment and trial-finding apps. Protections will need to be tailored in light of the services offered by the app and might include ensuring that clinical care and research-related records remain secure and available to relevant parties.

Conclusion

Systemic change is needed to increase participation in oncology trials, and innovation is occurring as a result. Recruitment and trial-finding apps offer one promising means to disrupt the status quo. These apps should be evaluated in substantially the same way as more traditional modes of recruitment while also striving to be sensitive and responsive to their potentially novel aspects (35). Safeguarding patient interests and the integrity of the cancer trial research enterprise will require that app developers, research institutions, IRBs, clinicians, and prospective research participants all be aware of these ethical challenges—and input from all these stakeholders will be needed to clarify much-needed “rules of the road.”

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