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ISSUE BRIEF

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Empowering Patients to Participate in Clinical Trials

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KEY POINTS

- Increasing patient engagement in clinical trials offers opportunities to improve enrollment and retention in clinical trials, helping ensure interventions can be evaluated effectively and that clinical research dollars are used efficiently.
- Patient and provider awareness, trial exclusion criteria, proximity to trial sites, out-of-pocket medical expenses, and other factors all present as barriers to patient engagement in clinical trials.
- Congressional and Departmental action has made progress on reducing barriers to trial participation, but there are additional opportunities for future policy action to further empower patient participation.

INTRODUCTION

Randomized controlled trials are considered the gold standard of clinical research and provide critical evidence for new treatments, but financial and logistical barriers reduce opportunities to participate in trials for many Americans, particularly those living in remote or rural areas. Data show that patients are interested in participating in clinical trials, but very few adults ever do. There are many known barriers that reduce participation in clinical trials, including, but not limited to, distance to clinical trial sites, out-of-pocket medical expenses, missed work and lost wages, travel expenses, access to transportation, and childcare. These barriers may not only influence patient recruitment, but also retention – a critical factor in ensuring trials achieve the necessary enrollment to effectively evaluate the intervention. Removing such barriers may empower patients to participate in clinical trials, promote greater insights regarding how treatments/interventions work across the entirety of the U.S. population, and ensure clinical research dollars are used efficiently. This issue brief describes our current understanding of the facilitators and barriers to patient engagement in clinical research and provides an overview of previous policies and potential future opportunities to improve clinical trial efficiency and quality through enhanced patient engagement.

BACKGROUND AND CHALLENGES

Research has shown that most adults are familiar with the purpose and goals of clinical trials and consider them to be safe.[1,2] Many also report having seen or heard of trials that were recruiting and knowing of people in their communities who have participated in trials. However, one study of adults with chronic illnesses found that less than a quarter have ever discussed participating in a clinical trial with a healthcare provider,[1] and another national survey estimated that only 9% of Americans have ever been invited to participate in a trial.[3] Of those who were invited to participate, about half actually participated in a clinical trial, supporting often-

cited statistics that approximately 5% of Americans will ever participate in a clinical trial.[3] The lack of patient engagement in clinical trials has real consequences – an estimated 30% of clinical trials conducted between 2011 and 2021 were suspended or terminated after failing to reach enrollment targets.[4] Increasing patient engagement can reduce these types of failures and increase the efficiency of trials by reaching enrollment targets more quickly.

Patient and provider awareness represents the first potential barrier for clinical trial participation. Since clinical trials are traditionally conducted in academic medical centers, providers and patients in rural or under-resourced areas of the country may not be aware of opportunities to participate.[5] Research generally finds that rural healthcare providers are interested in participating in research, but may not be aware of trials that would be appropriate for their patients or be unsure of how to refer their patients in trials.[6,7] For example, one survey found that rural adults were 77% less likely to have been invited to participate in a trial than their urban counterparts.[3] However, willingness to participate in a clinical trial is generally high,[1,8,9] even in rural populations.[10,11]

Patients may also not be invited to participate in clinical trials because of restrictive exclusion criteria. Exclusions can be scientifically necessary and appropriate, but can also contribute to a lack of patient engagement.[12] For example, patients presenting with multiple comorbidities are commonly excluded from participating in clinical trials, which may result in the tested population being healthier than the actual target population for the medical product.[13] This can lead to a lack of clarity around the product's effectiveness in real-world populations. One study estimated that reducing these types of restrictions in oncology clinical trials could generate up to 6,317 additional patient trial registrations each year.[14] With more than half of American adults having one or more chronic conditions,[15] evaluating exclusion criteria for scientific necessity and with the lens of recruiting a representative patient population may significantly increase opportunities for patients to participate in clinical trials.

When deciding whether to participate in a trial, patients often cite cost and travel distance as two major factors influencing their decision.[1] These represent significant financial and logistical barriers to participation that may have potential to be addressed by policy action. Unsurprisingly, rural clinical trial participants are often required to travel much greater distances to participate in a clinical trial,[16] and this can result in both recruitment and retention challenges, particularly for trials requiring frequent in-person treatment.[17] Participating in a clinical trial often means missed work – either for the patient or for a caregiver – but the impact of lost wages can be reduced if trials are conducted closer to the patient's home or remotely.[18] Patients may also incur childcare or dependent care costs due to their clinical trial participation.[19]

Many trial participants will incur at least some medical costs, despite requirements for payers to cover "routine care costs," which have been implemented over the last several decades. This requirement was introduced first with Medicare in 2000,[20] expanded to include private payers in 2010,[21] and expanded to include all Medicaid beneficiaries in 2020.[22] However, it is not clear that these policy changes impacted clinical trial participation rates.[23] Researchers have noted that interpretation of "routine care" may vary, and patients may still be liable for out-of-pocket expenses due to copays, deductibles, or out-of-network expenses.[24,25] Uninsured individuals may face even greater costs, and thus, greater barriers to participation.[26] In combination, the costs outlined above can result in considerable financial stress for clinical trial participants and can be a barrier for participation and retention.[27,28]

PRIOR POLICY EFFORTS AND OPPORTUNITIES FOR FUTURE INTERVENTIONS

Researchers have examined the effectiveness of previously adopted policies intended to address barriers to clinical trial participation. This section describes three such efforts: clinical trial innovations, patient-focused drug development, and compensation in clinical trials.

Clinical Trial Innovations

Clinical trial strategies and innovations such as decentralized clinical trials (DCTs) and digital tools (e.g., mobile devices and apps, remote monitoring devices) may offer opportunities for patient empowerment in clinical trials. A DCT is a clinical trial in which some or all trial-related activities occur at locations other than traditional trial sites and has the potential to expand the reach of many clinical trials. DCTs may use digital tools, including those categorized by FDA as digital health technologies (DHTs) to facilitate real-time data collection and remote patient monitoring. According to IQVIA, 68% of patients expect flexibility and remote options in clinical trials, and 71% of investigators agree that DCTs reduce participant burden.[29]

Analyses from GlobalData's Clinical Trials Database found that the percentage of clinical trials using virtual elements increased from 1.3% in 2011 to 2.5% in 2020 and 3.5% in 2021.[4] As explained in a 2024 ASPE report, "DCTs and DHTs offer participant-centric approaches to clinical research that enable (more) remote participation, extending clinical research sites to community and even home settings. These approaches and tools can prove particularly impactful for enrolling underserved populations, including rural, socioeconomically disadvantaged, and mobility-limited people, as well as patients with rare or severe diseases."[30] Clinical trials with activities decentralized to community clinics can further reduce participant barriers during treatment and monitoring, potentially improving participant recruitment and retention. While DCTs and DHTs may not be appropriate or feasible for all trials (e.g., early-stage clinical investigations), and may require reforms regarding reimbursement and state-specific medical licensing regulations, they provide opportunities for participant-centric approaches to clinical trials and inclusion of participants that have historically been excluded from clinical trials.

HHS has taken various actions to support the implementation of DCTs and other trial innovations to help reach a broader population of patients. For example, FDA published final guidance on conducting clinical trials with decentralized elements[31] and created a framework for the use of DHTs.[32] In comments submitted on FDA's draft DCT guidance, the pharmaceutical industry expressed support for FDA's framework and provided additional recommendations for making clinical trials more accessible, such as FDA allowing for flexibility in DCT protocol design and implementation to incorporate patient input, as well as global harmonization of regulatory expectations around DCTs.[33]

In 2018, FDA held a workshop on evaluating inclusion and exclusion criteria in clinical trials. One proposed strategy for supporting better development of eligibility criteria and increasing patient enrollment is the use of innovative and alternative trial designs.[12] Such methods may allow for detection of relevant effects in populations who will be taking the drug but typically are excluded from studies (e.g., people with comorbidities) and may facilitate generation of dosing information for patient subgroups in which there may be differences in the systemic exposure of the drug, including those with certain chronic diseases (e.g., kidney disease) or older adults. Other strategies discussed in the workshop included using data from expanded access programs, which often enroll patients that are excluded from clinical trials because they do not meet study inclusion criteria. FDA has issued guidance documents on complex innovative trial designs and launched a complex innovative trial design pilot meeting program.[34]

The aforementioned 2024 ASPE report discusses additional opportunities for clinical trial innovations, such as integrating retail pharmacies into the clinical trial ecosystem, engaging patients who already use DHTs such as smartwatches to help streamline enrollment, and embedding trial-related information into contexts in which patients are already engaged (e.g., blood donation).[30] Engaging non-traditional trial sites and building on infrastructure such as community and rural health centers may also help address the geographical barriers to clinical trials discussed above and help broaden access to clinical trials.[8,35]

Patient-Focused Drug Development

Patient-focused drug development is a systematic approach intended to better incorporate patient input, experiences, and priorities in drug development, including in trial design and outcome measures. FDA is statutorily required to develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions.[36] Patient experience data can be collected through qualitative methods such as one-one-one interviews or focus groups, as well as quantitative methods such as survey instruments.[37] FDA has issued a series of guidance documents for "enhancing the incorporation of the patient's voice in medical product development and regulatory decision making."[38]

A few articles have described how patient-focused drug development has been used in clinical trials generally and with respect to specific diseases or conditions.[39,40] For example, patient experience data has been used to identity disease symptoms that are most burdensome for patient populations of interest, inform development of patient reported outcomes, modify study elements (e.g., procedures, visits, eligibility criteria, study duration, and endpoint selection to improve patient access to treatment options), as well as to determine interest in clinical trial participation, identify barriers to trial involvement, and discover factors associated with willingness to participate in trials. Although these efforts suggest that patient-focused drug development programs can be used to meaningfully engage patients in the drug development process, more research is needed to assess the effectiveness of such programs on clinical outcomes.

Further, questions remain regarding how FDA uses patient experience data in application approval decisions. A 2021 FDA report assessing the use of patient experience data in regulatory decision-making generally found that whether and how FDA uses patient experience data in application approval decisions varies widely.[41] In the report, stakeholders (i.e., patients, caregivers, clinicians, advocacy/research organizations) recommended that patient experience data be collected to determine how to facilitate patient participation in clinical trials and to identify what endpoints and other measures are meaningful to patients. These stakeholders further recommended that results of patient experience data collections be shared with study participants and patient advocacy groups. Such information sharing may help maintain positive relationships with patients, and thus improve participant retention, and allow investigators to obtain additional, ongoing insights during trials. Congress also has introduced legislation to more explicitly instruct FDA to consider patient-focused drug development data in the risk-benefit assessment framework used in the process for approving new drugs.[42]

Compensation for Clinical Trial Participation

As described above, financial barriers associated with clinical trial participation continue to affect recruitment and retention efforts. Some studies have suggested that compensating participants for their time may be one way to offset these costs and improve recruitment and retention.[43,44] However, participant compensation must be balanced with ethical considerations to avoid creating undue influence or coercion.[45] Further, participant

compensation in clinical trials may have other unintended consequences, for example, creating tax liability for participants or potentially resulting in loss of eligibility for government benefits.[46,47]

Across studies, use of compensation varies and may depend on factors such as research type (e.g., biomedical versus behavioral), study setting, risk or burden to participants, and the conditions or interventions being studied. For example, a study of Phase 1 trials, which require healthy volunteers and do not offer any benefit to the participant, found the median compensation per trial to be $3,070.[48] However, studies of compensation offered to participants in later-phase trials generally find more nominal amounts.[49-51]

A few studies have evaluated the effectiveness of financial incentives for improving enrollment in clinical trials. For example, one meta-analysis evaluated the effectiveness of incentives for research participation across six randomized controlled trials and found statistically significant increases in the rate of consent and responses from participants when offered even small monetary value incentives.[52] However, the size of the incentive needed to offset the costs of the clinical trial may vary significantly depending on the type of trial. One survey found that participants of a cancer clinical trial would need $200-$1,000 per month to offset trial-related expenses.[53]

In 2022, the HHS Office for Human Research Protections (OHRP) held an exploratory workshop on payment for research participation.[54] During the workshop, several potential solutions were presented that could address concerns related to participant compensation, for example, specific and empirically informed payment guidance and transparency (e.g., for certain types of studies with certain levels of participation or risk, a clear range of reimbursement would be expected) and recognizing research participation as a charitable contribution that is rewarded with a tax exemption or credit.[54]

Congress also has taken steps to address financial barriers associated with clinical trial participation, for example, by passing legislation to exclude under the Supplemental Security Income and Medicaid programs certain compensation provided to individuals who participate in clinical trials for rare diseases or conditions,[55] as well as introducing legislation to exclude from gross income certain compensation to clinical trial participants.[56] However, given variation in the use of compensation across clinical trials, as described above, additional research is needed to further understand how participant compensation may reduce financial barriers to clinical trial participation.

CONCLUSIONS

Barriers such as patient and provider awareness, proximity and access to trial sites, trial exclusion criteria, and financial stress can all reduce clinical trial participation. Understanding the facilitators and barriers to clinical trial participation has the potential to improve trial recruitment, trial efficiency, and promote access to the highest quality healthcare for all Americans. This paper summarizes a few of the ways Congress and HHS have tried to reduce barriers to trial participation and increase patient involvement. Additional research—for example, examining the effects of patient-focused drug development programs or different approaches to clinical trial compensation on patient recruitment and retention in clinical trials—may help elucidate the effectiveness of these strategies and guide future policy development.

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