New approach to improving clinical trial enrollment and diversity

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NIAID clinical trial volunteer signs an informed consent form, acknowledging that he understands the study protocol as well as possible risks and benefits associated with his participation. Credit: National Institute of Allergy and Infectious Diseases

Before new therapies can reach patients, they must be tested in clinical trials in representative populations to show that they work and are safe. Failure to enroll enough participants in trials can delay the arrival of new therapies in the clinic and inflate their eventual price tags. Failure to recruit diverse patients could diminish the relevance and generalizability of trial findings. For example, a drug that proves effective for White patients might not work as well in people of other races or ethnicities.

Despite the urgency to increase both the volume and diversity of clinical trial participants, the stats are not good.

A 2018 study showed that 55% of terminated studies in a clinical trials database closed due to under-enrollment. In a 2020 U.S. survey, only 9% of respondents reported being invited to participate in a trial, and 41% acknowledged not knowing anything about clinical trials.

The numbers are no better when it comes to diversity. According to a 2011 Food and Drug Administration white paper, African Americans make up 12% of the U.S. population but only 5% of clinical trial participants. Hispanic people make up 16% of the population but only 1% of clinical trial participants.

The ultimate fix is, of course, to increase the number of clinical trial participants, especially diverse ones. However, community members can only choose to participate in clinical trials if they are aware of their existence. Some may hear about them from their doctors or see flyers or commercials. But many people remain unaware and therefore are unable to participate.

An innovative approach

The South Carolina Clinical & Translational Research (SCTR) Institute's patient outreach recruitment (POR) team and its partners are trying a

new approach at the Medical University of South Carolina (MUSC)—making patients eligible, by default, to learn of clinical trials in which they could participate. However, they are also offering them ways to opt out of being contacted about research opportunities. The team describes this new approach and its implementation in a recent article in the *Journal of Clinical and Translational Science* (*JCTS*). This is a departure from MUSC's previous opt-in model requiring patients to indicate in the patient portal that they want to receive research-related contact.

"We learned from many of our patients that they wanted to have greater opportunity to participate in research, but they had no knowledge of those opportunities," said SCTR co-director Patrick Flume, M.D., who is also the associate vice president of clinical research at MUSC and senior author of the *JCTS* article.

"We sought to address this request to learn about and participate in research opportunities, while being respectful of the wishes of those patients who would prefer not to be contacted," he said.

Once aware of a trial, patients can make an informed choice about whether to participate, said Tara Pittman, recruitment manager at SCTR's SUCCESS Center and lead author of the article.

"We believe that the opt-out approach really grants people the autonomy to choose whether they want to be engaged in research," said Pittman. "They can only have that choice if they know of that choice and that opportunity."

Since this new approach essentially put patients throughout the MUSC Health System into the pool of research participants, it dramatically increased the number of potential participants—from just over 51,000 to 1.7 million. The approach also ensured that the participant pool better

reflected the demographics of the community. The acquisition of new regional hospitals in rural, underserved regions of the state further diversified the clinical participant pool.

Doing their homework

Before launching the new initiative, the team reached out to other Clinical and Translational Science Award (CTSA) hubs to learn about their approaches to making more patients aware of clinical trials. Approaches varied widely. Some academic medical centers decided that all patients should be opted in by default with no subsequent opt-out option. Others went with a model like MUSC's previous opt-in approach, which meant that patients were not contacted unless they checked a box in the patient portal saying they wished to receive notifications.

In the end, MUSC chose a path between those two ends of the spectrum: notifying patients by default about research opportunities and allowing them to opt out if they desired.

To ensure that the approach achieved its end goal of raising awareness of clinical trials, the team gathered feedback from focus groups whose members reflected the demographics of the community. The POR team worked with the MUSC Biomedical Informatics Center (BMIC) to develop digital workflows that were efficient for researchers and also with enterprise communications to craft messaging that was respectful of patients.

"It took everybody coming together to agree on a path forward, and it's that same group that still serves as our steering committee as decisions about this process are made," said Stephanie Gentilin, SUCCESS Center director.

Researchers provide the eligibility criteria for their study and clinical

indicators of those criteria. A list of potentially eligible patients is then pulled from the research data warehouse, where patient information is securely stored. The patients who have opted out of research contact are filtered out, and the final patient list is delivered to the research teams via a secure application for managing databases.

Before gaining access to the list, researchers must attend a POR consultation, where they are provided with best practices for using this new approach effectively and training on how to document patient contact and any patient request to be removed from future research contact. Strategies for increasing the diversity of participants are also discussed.

Reception of the program

Initially, the POR team was concerned that patients might not like being contacted multiple times about studies and included safeguards to prevent that from happening. Those safeguards were dropped when it became clear that the new approach was well-received.

Dramatically increasing the pool of potential patients made it extremely unlikely that a patient would be contacted more than once or twice. If anything, patient burnout decreased, said Pittman, as the same few patients who were participating in trials before the transition to the new approach no longer received repeated requests from study teams.

While collecting data and researcher feedback on the process is still in its early stages, the initial reception by researchers has also been positive, both in terms of meeting their enrollment targets and increasing diversity.

Next steps

To determine whether the POR approach is indeed increasing patient enrollment and the diversity of enrollees, more data will be needed. That data will come from MUSC's recently implemented clinical trial management system, which study teams adopting POR are required to use. This data will also identify studies most likely to benefit from the POR approach, as some studies are more suited for this process than others.

Pittman said that it won't be a one-size-fits-all approach. "We're noticing definite trends and will be able to use those trends to consult with our research teams about the way to get the most success if they're going to use it."

The POR team will share the insights they glean from the data it collects with CTSA partners and other institutions nationwide. If participant volume and diversity increase, thanks to the POR approach, it could become an important new tool in research recruitment toolkits.

More information: Tara Pittman et al, Enhancing study recruitment through implementation of an opt-out, cold contact process with consideration for autonomy, beneficence and justice, *Journal of Clinical and Translational Science* (2023). DOI: 10.1017/cts.2023.21

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