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Cancer clinical trial enrollment has plummeted. Will patients come back amid Covid-19?

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BRENDAN SMIALOWSKI/AFP/GettyImages

Cancer clinical trials have seen a drastic drop in patient enrollment since the onset of the Covid-19 pandemic, driven in part by some institutions pausing recruitment in order to prevent the spread of the virus.

Bringing enrollment numbers back up safely will prove crucial for researchers running clinical trials and the drug companies that sponsor them. In a [new paper](#)⁶ published Thursday in JAMA Oncology, researchers surveyed cancer patients to gauge their willingness to participate in clinical trials once enrollment restrictions lifted, even if Covid-19 was still spreading in their community.

The nationwide survey of 933 patients, conducted between May and June 2020, revealed that nearly 1 in 5 patients were hesitant to participate, mostly from the fear of being exposed to Covid-19, although the majority of the responders felt undeterred when it came to the idea of participating in future trials.

STAT spoke with Mark Fleury, a co-author of the study who also oversees policy development and emerging science at the American Cancer Society Cancer Action Network, to learn more about the survey outcomes and its implications for future patient recruitment.

Tell me about the motivation for the study and the participants you surveyed.

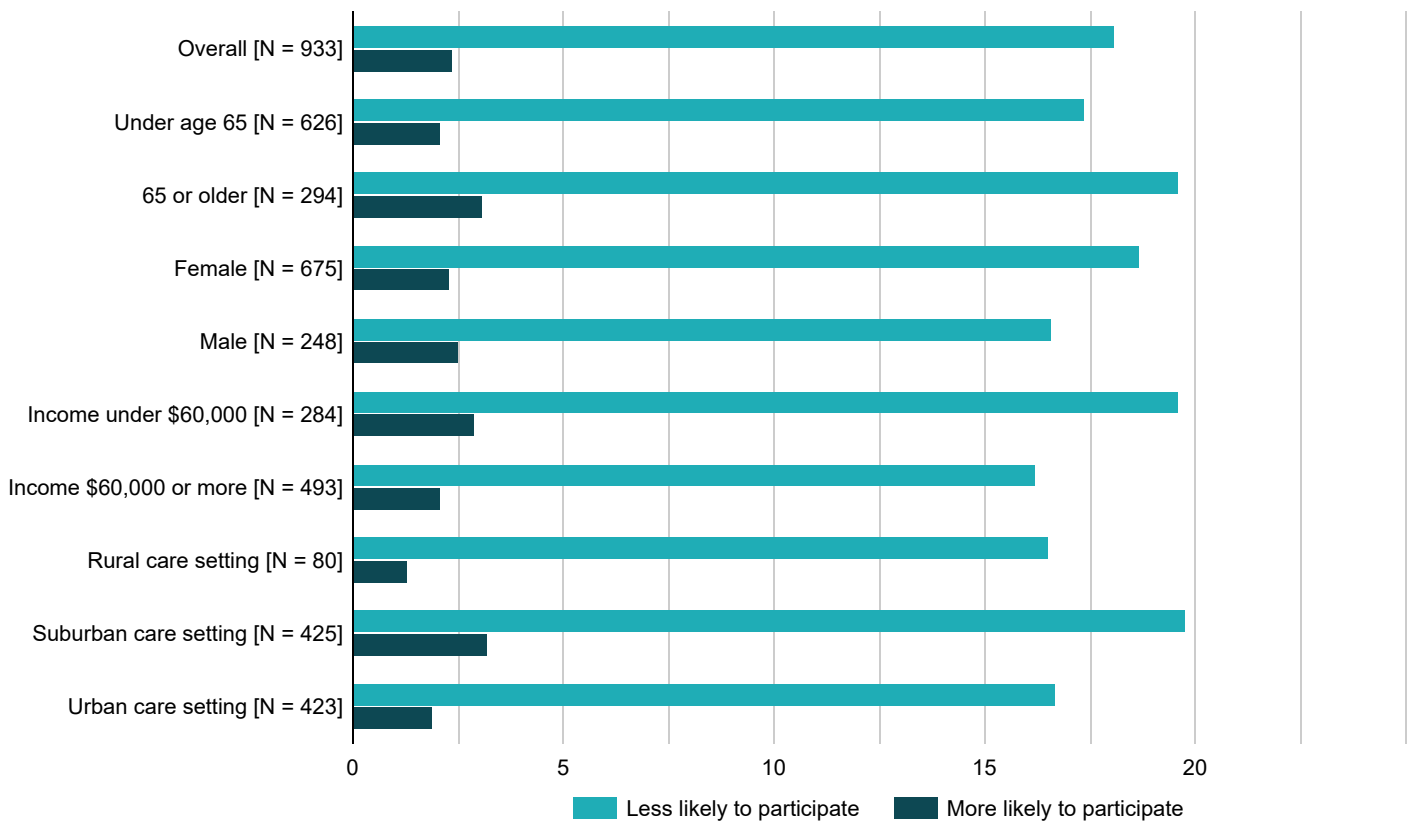
We observed that clinical trial enrollment had dropped precipitously during the pandemic. The hope was that at some point these sites would be able to reopen and begin recruiting patients to these clinical trials again. But it wasn't clear whether the patients would have an equal willingness as they did prior to the pandemic. What we set out to do is really to answer that question ...

This survey was one among several others conducted as part of a program called Survivor Views. We recruited around 3,000 cancer patients in 2019. The only requirements were that they be treated or diagnosed in the last five years, they be over the age of 18 years, and live in the U.S. We tried to recruit a population that was as reflective of the U.S. cancer population as possible, but in this survey of 933 respondents we ended up with more women [675 of 933] than were representative. Also, it tended to be more white [866 of 933] than the cancer population. So, it wasn't exactly a representative population, but it was a pretty broad sampling of folks.

The majority of the patients said they'd be willing to participate in the future trials, even as the pandemic continues. Was that surprising?

We expected some reduced willingness, but we weren't predicting what the scale of that would be. Seeing that almost 80% of the patients' willingness remained unchanged was a really positive sign. What really jumps out is that proportion that said they're less willing. But there is a little bit of silver lining in that the majority would still be willing to enroll in the clinical trial.

Patient willingness to participate in cancer clinical trials during Covid-19



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Priyanka Runwal / STAT Source: "Association of the COVID-19 Outbreak With Patient Willingness to Enroll in Cancer Clinical Trials," JAMA Oncology.

What do we know about the 18% who were less willing to participate?

With just under a 1,000 respondents, the number of people who fit into particular subgroups, race for instance, were too small to analyze. But for all other subgroups based on age (older or younger than 65), male or female, annual income above or below \$60,000, rural urban or suburban, we didn't see a statistical difference in their willingness or unwillingness to participate.

Essentially, we could not discriminate [whether] a certain group that was much less willing to participate than another. But the number one answer from those less willing was the fear of being exposed to Covid-19.

A small percentage of patients indicated that they were more likely to participate. Why might that be?

That number was relatively small and we really couldn't discern any major trends. I would say that there has been a lot of conversation during this pandemic, with the rapid development of the vaccines, there's certainly a heightened awareness of the role that clinical trials play in developing new treatments and therapeutics for any kind of disease. So, there was an assumption that we may perhaps see even more people willing to enroll in clinical trials because of this enhanced awareness. But again, it was a relatively small number.

How might things change if the survey were repeated now, given the geographic shift in Covid-19 hot spots?

I'm not sure that they would change significantly. We asked these questions hypothetically to cancer patients who have experience with the medical system. We've done surveys on patient worries not related to clinical trials, and we've conducted those all the way from May to as recent as August this year. There is really a steady level of concern for health when it comes to those in-person visits and a sense of heightened vulnerability as a cancer patient ...

Certainly, your point is well-taken in the level of the pandemic and infection rates. Any individual response is colored by the situation they see around them. It would be a good experiment to run to see if the willingness stays as high or perhaps is even higher.

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Going forward, what are the implications of this survey for those recruiting patients?

Remember, folks are nervous about coming into health centers but also Covid-testing sites or those places where Covid patients are seen. The U.S. FDA along with the National Cancer Institute – two government agencies that have a lot of authority over cancer clinical trials in the U.S.— have both issued recommendations and allowances during this public health emergency that allow some of these practices to be changed. You can now send study drugs directly to patients' homes so that they don't have to come in to pick up a prescription. They have now allowed some telemedicine visits. For example, if you're just checking in to see how you feel, you may not have to actually come into the facility but you can do so via Zoom.

There's also flexibility to allow patients to see providers who are more local or in smaller care settings as opposed to coming to a large academic center to get some of their treatments. Previously, every provider had to be registered as part of the clinical trial. Those requirements have been loosened. We're seeing a number of practices now being allowed with clinical trials that weren't before.

I spend a lot of my time trying to understand both the barriers that prevent patients from enrolling in clinical trials and trying to enact policy changes to overcome those barriers. There are so many barriers already that adding another in the form of the pandemic is really challenging. I see this as a fairly major finding that is going to impede clinical trial enrollment. Here at American Cancer Society, as well as in the broader community, there is a recognition that once the pandemic is over, many of these same flexibilities should remain in place.

There are a lot of underserved populations that have a hard time traveling to cancer centers, whether it's a rural setting or folks don't have their own vehicles, or they're frail and have limited mobility. The same things that are helping people not have to go into a medical center today could be used to enhance clinical trial enrollment even after the pandemic is over. We're looking really hard in trying to understand the patient experience with some of these new modalities and how we can continue these practices.

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