



## News and Stories - Fall 2020

### Clinical trials need to include more Black and other minority participants. Here's how

by Jocelyn Ashford

The Covid-19 pandemic and the disproportionate devastation it has wrought on Black, Hispanic, and poor Americans has (again) raised the call for creating inclusive clinical trials that are representative of patient populations. That's an important goal, but it's easier said than done.

I work as a patient advocate for Eidos Therapeutics, a biotech company focused on developing a treatment for transthyretin amyloidosis, an underrecognized cause of heart failure with a

disproportionate racial impact due to a disease-causing mutation found in 3% to 4% of Black

Americans. Part of my job is to help recruit Black and other underrepresented minority participants for clinical trials. I've seen the challenges of recruiting Black people to take part in clinical trials, but I've also seen how successful it can be.

It's necessary work. Unless clinical trial participants represent the people who will be using a new therapy, then we can't

know how it will work for those who need it the most.

Cardiovascular disease is a good example: Even though heart conditions disproportionately affect Black individuals, they accounted for only 2.5% of clinical trial participants in a global trials report by the Food and Drug Administration.

What's more, physicians may be reluctant to prescribe new medicines

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### \*SAVE THE DATE\* for #GivingTuesday

Every year we participate in #GivingTuesday. This year, it falls on December 1, 2020. We call it GivingTuesday - not fundraising Tuesday - for a reason. It's a day to inspire generosity in all forms, a day for people to generously share whatever they can, whether it is their time, skills, voice, or money.

GivingTuesday was created

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Education • Awareness • Support • Research

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## \*SAVE THE DATE\*

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in 2012 as a simple idea: a day that encourages people to do good. Over the past nine years, this idea has grown into a global movement that inspires hundreds of millions of people to give, collaborate, and celebrate generosity.

GivingTuesday is an opportunity for people around the world to stand together in unity—to use their individual power of generosity to remain connected and heal.

People can show their generosity in a variety of ways during GivingTuesday — whether it's helping a neighbor,

advocating for an issue, sharing a skill, or giving to causes, every act of generosity counts.

At a time when we are all experiencing the pandemic, generosity is what brings people of all races, faiths, and political views together across the globe. Generosity gives everyone the power to make a positive change in the lives of others and is a fundamental value anyone can act on.

We all have gifts to give, and with social media, online giving, delivery, mail, and phones, there are limitless ways to use your generosity to support others.

GivingTuesday emphasizes opportunities to give back to communities and causes in safe ways that allow for social connection and kindness even while practicing physical distancing.

In this time of uncertainty, there's a fundamental truth that gives us hope - that together we can do extraordinary things. Join us on #GivingTuesday and let's rally for a cure! **AF**



## Patient Resources

The foundation has several programs that benefit patients and their families. All of these are provided free of charge.

- Webinar recordings posted on our website
- Updated informational pamphlets
- Listing of experienced physicians that specialize in amyloidosis. Email us anytime with questions: [info@amyloidosis.org](mailto:info@amyloidosis.org)
- Treatment Centers (US / International)
- Support Groups
- Exercises
- Webinars and Videos
- Caregiver/Patient Binder
- Fundraising Toolkits

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## President's Corner



Hello All,

2020 has been an interesting year, to say the least. We were able to continue our work through the worst of the pandemic, working remotely, continuing to help patients and caregivers better understand their disease and to find qualified treatment facilities.

We had to curtail many activities, including any live fundraising, exhibiting at medical conferences and hosting medical Grand Rounds, but look forward to things getting back to normal in 2021.

We appreciate your support. Please stay safe!

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Our newsletter is published quarterly (Spring, Summer, Fall and Winter) by the **Amyloidosis Foundation**. We welcome letters, articles and suggestions.

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## Telehealth Boom Misses Older Adults

by Judy George, Senior Staff Writer, MedPage Today

Telemedicine is increasingly seen as a key component of healthcare in the future, but many older adults are being left behind, a pair of studies in *JAMA Internal Medicine* suggested.

More than 41% of Medicare beneficiaries lacked access to a computer with high-speed Internet access at home, reported Eric Roberts, PhD, of University of Pittsburgh, and Ateev Mehrotra, MD, MPH, of Harvard Medical School. Nearly as many didn't have a smartphone with a wireless data plan, and one out of four didn't have either option.

And more than one-third of those older than 65 may have trouble with video telehealth visits, because they're inexperienced with technology and/or have disabilities that interfere with it, according to Kenneth Lam, MD, of the University of California San Francisco, and co-authors.

"I'm very concerned we are overlooking issues of virtual access for older adults," Lam told MedPage Today. "As long as clinics remain virtual, older people can't get in."

"It's like having a clinic up a flight of stairs with no ramp

or elevator," he continued. "We need to realize that providing telecommunications devices -- like smart phones and tablets, and preferably geriatric-friendly ones -- in the current

during a personal visit, they added.

In their analysis, Lam and colleagues looked at 2018 data on 4,525 older adults from the National Health



environment is like building a ramp to get to a virtual clinic."

Older adults account for 25% of physician office visits and often have multiple morbidities and disabilities, Lam and co-authors noted. While HHS and other organizations have promoted video visits to reach patients at home especially during the COVID-19 pandemic, these consults require patients to be able to get online, operate and troubleshoot audiovisual equipment, and communicate without the cues available

and Aging Trends Study of Medicare beneficiaries. The average patient in the study was 79.6 years old; 69% were white, 21% were Black, and 6% were Hispanic.

The researchers defined "telemedicine unreadiness" as meeting any of the following criteria:

- Difficulty hearing well enough to use a telephone, even with hearing aids
- Problems speaking or being understood

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- Possible or probable dementia
- Difficulty seeing well enough to watch television or read a newspaper, even with glasses
- Owning no Internet-enabled devices or being unaware of how to use them
- Not using email, texting, or the Internet in the past month

Overall, 38% of Medicare beneficiaries -- representing 13 million older adults -- were unready for video visits. Even if people who provided social support could set up a video visit, 32% of older adults still were unready. An estimated 20% of older patients were unready for either telephone or video visits because they had difficulty hearing, difficulty communicating, or dementia.

In the other JAMA Internal Medicine study, Roberts and Mehrotra looked at 638,830 community-dwelling Medicare beneficiaries in the 2018 American Community Survey. They found that 41.4% had no access to a desktop or laptop computer with a high-

speed Internet connection at home, 40.9% did not have a smartphone with a wireless data plan, and 26.3% lacked either form of digital access.

The proportion of Medicare beneficiaries with digital access was even lower among people who were 85 or older, widowed, had a high school education or less, were Black or Hispanic, received Medicaid, or had a disability.

"Whether this disparity in access to technology has



led to a disparity in care remains to be seen," Roberts told MedPage Today. "We're still observing the effects of COVID and disruption in care patterns. But our study highlights a reason to be concerned that the rapid conversion of paid visits to telemedicine could widen disparities for certain populations."

While telephone visits remain an option, "the inability to see a patient

diagnosis may limit the level of care a provider can deliver," Roberts added.

"If it's a simple visit like a cholesterol medication refill, you can do that over the phone. Medically, that's pretty safe," Lam noted. But phone consults aren't always the best option.

"Older patients are more likely to face a Catch-22," Lam pointed out. "I'm more worried about a frail 90-year-old person with abdominal pain compared to a 24-year-old -- can they get groceries? can they get out of bed? -- so I want to see them more. Yet, the 90-year-old person is less likely to be able to get online with a video visit to get a better assessment. They are also at greater risk if they seek care in person because if they contract COVID, they're more likely to die."

Older people are online more than ever before and "I do not want to paint an ageist picture of our elders as Luddites because it's not true," he added. "But it's also not true that virtual care is 'virtually perfect,' as an early editorial about telemedicine claimed." **AF**



## Amyloidosis Symposium

to Black people if investigational trials did not include them, even for diseases such as sickle cell disease or hereditary transthyretin amyloidosis that affect Black people more than others.

I've found that one of the first and most important steps to creating an inclusive clinical trial is to engage the target community in discussions around the recruitment plan. By bringing these communities to the table early, we can hear their input instead of making assumptions about how to best reach them.

We can hear their concerns and attempt to address them, while educating the communities about the importance of clinical trials, all that's involved, and the potential to bring high-quality care to their community.

One way to accomplish this is by engaging with community education programs, such as those sponsored by church groups. Eidos partners with the Association of Black Cardiologists to help us understand where our target audiences spend their time and who they trust.

With this information, educational opportunities can be established for people to learn in safe places.

Approaching trial outreach through tight-knit community groups gives potential participants and their family members an opportunity to learn about information they would have never been exposed to, all from the people they trust.

One of the successful tactics I've used to help recruit older Black participants for clinical trials is to engage the younger generation. The family unit is important in the Black community.



One obvious place to start is reaching out to historically Black fraternities and sororities. These organized groups of educated, social-minded individuals are looking to give back to their communities and can act as bridges to their parents, grandparents, and the Black community more.

In the Black community, elders often trust younger family members on matters of health, and the younger generation is protective of their elders, so these types of initiatives recognize the dynamics of Black culture and work within those cultural dynamics.

Beyond reaching out to Black people in the U.S., looking overseas to engage individuals of African descent is another option. That can open the door to countries in Africa, as well as in Brazil and elsewhere in Latin America, where Black populations may welcome the opportunity to participate in trials, which can then be more inclusive thanks to their participation.

Engaging investigators is another important strategy. Even simple tactics, like giving physician-investigators a goal for the number of Black participants they recruit, can help fill a clinical trial with a representative population. That's what the National Institute of Health does — It says it wants a representative population, and that's what it gets. Data that represents the

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racial breakdown in NIH-funded clinical research since 2015 show that there has been a significant increase in the number of Black participants over the last five years. While these trials are still not fully representative (notably of other minority groups), it is an improvement. Another piece of the puzzle is physician representation at trial sites. Black patients like to see Black doctors, so they should be among the investigators. At trial sites where this is not an option, it's helpful to include other Black staff members who can meet with patients in addition to the investigator.

While it's important to recruit Black participants for clinical trials, it's also important to understand and overcome the barriers to keeping them enrolled. Once enrolled, Black participants tend to drop out of trials at a higher rate than other groups. Based on my work with Black participants, I feel that one reason for this is that some may not be used to people trying to accommodate them, even around basic items like scheduling. Clinical trial sponsors are keenly interested in ensuring their participants stay on protocol, and so are very accommodating to individuals' needs. But that

message can get lost. If trial participants don't know to speak up and say they need accommodations around, for example, child care, transportation, or scheduling issues, they're more likely to drop out. To run a successful inclusive trial, investigators need to encourage participants to be vocal about what they need and then explain how investigators and clinical trial sponsors can help.

Another reason typical clinical trial recruitment strategies often don't extend to Black participants is the repeated use of certain trial criteria and sites. When planning trials, companies tend to use similar guidelines and work with the same clinical sites time and time again. Establishing trial sites at clinics and medical centers with significant minority populations is a good place to start.

Even when creating criteria for a study, something as simple as carrying over the commonly used target blood pressure level can exclude large portions of racial groups from participation. On average, Black people tend to have higher blood pressure compared to those of European descent. Not adjusting for that difference can lead to inadvertently excluding Black patients

from many studies. We must do a better job of looking outside the typical clinical trial site repertoire or reading over exclusion criteria with fresh sets of eyes.

Unconscious bias within the medical community can also hinder trial recruitment. Physicians may not even think to suggest to their patients of color that a clinical trial is an option if they assume their patients are not interested or have a negative perception of clinical trials. Training works to help physicians and investigators think past their biases, proactively encourage their Black patients who might qualify for clinical trials to participate, help educate them about the process and the clinical studies, and make it clear that patients should never be afraid to ask questions.

As many of us in biotech and pharma push for more equal representation across our industry, we need to ensure that it's a priority in our clinical trials as well. With the right focus and commitment, clinical trials can and should be inclusive, leading to improved studies and access to experimental medicines for more Black patients. **AF**



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