

# Open Enrollment: Rewriting the Rules of Access in Clinical Trials



## CMEO Podcast Transcript

### **Monica E. Peek, MD, MPH, MSc:**

Hello and welcome to a special program I'm moderating that is part of this series on health access by CME Outfitters. The CMEO webcast is titled Open Enrollment: Rewriting the Rules of Access in Clinical Trials. This program is supported by an independent medical educational grant from Johnson & Johnson. This activity may include discussions for products or devices that are not currently labeled for use by the FDA [U.S. Food and Drug Administration]. We, the faculty, are responsible to disclose any off-label or investigational uses.

So, my name is Dr. Monica Peek. I'm the Ellen H. Block Professor in the Department of Medicine at the University of Chicago, where I also serve as the Associate Director for the Chicago Center of Diabetes Translation Research. I'm thrilled to be joined today by two colleagues who are really experts in the field of clinical trials. So we're going to start with Dr. Lea Ann Chen. Lea Ann, would you mind introducing yourself to our audience today?

### **Lea Ann Chen, MD:**

So I'm Lea Ann Chen. I'm an adult gastroenterologist. I direct the Inflammatory Bowel Disease Translational Research Program at Rutgers Robert Wood Johnson Medical School in New Brunswick. And inflammatory bowel disease is one where we're seeing the incidence and the prevalence explode in all sorts of races and ethnicities worldwide, but we're not seeing that translate into our clinical trials. And so I'd love to discuss more about that today.

### **Monica E. Peek, MD, MPH, MSc:**

Thank you. Thank you for joining us. I'm also excited to have Dr. Priscilla Pemu with us today. Priscilla, would you mind introducing yourself to the crowd?

### **Priscilla Pemu, MD, MS, FACP:**

Thank you. Good evening, everyone. My name is Priscilla Pemu. I'm a professor of medicine, a general internist at Morehouse School of Medicine, where I also serve as interim chair for our Department of Medicine, Associate Director for our clinical research center and Associate Dean for clinical research. It's really great to be on here with you all.

### **Monica E. Peek, MD, MPH, MSc:**

Thank you both for joining us. You have a lot of expertise. I'm really looking forward to our conversation. And you've both been really leading voices in advancing equity in clinical trials and involving culturally responsive communication and specifically in the research that involves engaging communities. And so I'm really excited to really just dig into how we can expand fair access in clinical trials and how we can particularly build trust with both patients and communities. So welcome.

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## **Priscilla Pemu, MD, MS, FACP:**

Thank you.

## **Monica E. Peek, MD, MPH, MSc:**

Our first learning objective for today is to assess the socioeconomic, geographic, and systemic barriers that can contribute to disparities in clinical trial access, particularly in underserved or community-based settings. And then our second learning objective is to identify interprofessional strategies, including the use of culturally responsive communication, patient navigators, and advocacy partnerships to engage underrepresented patients in clinical trial discussions and enrollment. So let's begin first with the clinical rationale and context for what we would like to call inclusive research. And so to ground our discussion, we're going to start by hearing from a patient navigator and community health nurse Ms. Valarie Worthy, and she's going to talk about what she's learned over the years to help create optimal spaces for having conversations about clinical trials. Let's watch the video.

## **Valarie Worthy, MSN, RN:**

So I have been a nurse for 43 years, and the majority of my work was being either a community health nurse, public health nurse, or home infusion nurse. And so I got a wonderful opportunity to find out about the community. After I would provide care, I would talk to my patients and they would share their struggles, their barriers, and really begin to build relationships in the community. And so more importantly then I began to listen to patients and people in the community about the struggles that they had, anxiety about treatment, and fear of clinical trials. So that got me on my path and even my passion to engage the community even more and then to provide more education in our community – including our faith communities – about cancer and clinical trials.

Some of this is related to Tuskegee, some of it is not. Some of them just have fear about being a Guinea pig. And so I tried to figure out how can I normalize this to make this sense to people. So I thought about what do people take commonly? Over the counter drugs. And of course most people say yes they have. And I said, "Did you know that they were on a clinical trial?" And the expressions that I see on people's faces are...I can't even describe it. They're like – "Yes, that was on a clinical trial. Absolutely. And do you know how they decide what doses we're going to take and how frequently we're going to take it?" They didn't know that either. I said, "It's by the majority of the people that participate in a clinical trial." And so what we do know when it comes to over-the-counter medications? The average person, the majority of the people, are 60-year-old White men. And our doses are measured by their height and weight. So we are not counted. So suppose the two tablets that we take every four hours, we need to take one every six hours, but we don't know that. And so we are not represented. So don't you want to be represented in this?

## **Monica E. Peek, MD, MPH, MSc:**

This video shows why speaking directly to patient's concern with evidence, using language that's very accessible is important. And also why inviting patients specifically, sort of saying, "Hey, this is really important. Don't you want to be involved?" Inviting them into the trial process really counts. Why that's important. And so you've just heard some of the common barriers in the front line. And so we're going to do our first of the night's audience

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response questions. And so the question is, how often do you discuss clinical trials? How often do you take this opportunity to discuss trial opportunities with patients from underserved communities?

All right. So we see that most people say sometimes, and only a small population – the very minority – says regularly that they're looking for opportunities. And so what we want to be able to do is have clinical trials be part and parcel of just the infrastructure and fabric that's part of our healthcare system apparatus so that it makes the easy choice, like we say with healthy food or healthy environment. And that it shouldn't be something that is challenging for physicians to do. It shouldn't be something that is hard for patients to enroll in. And so we're going to talk to you about some of the ways to help make that happen.

So we're going to start by talking about some of the disparities that we see in patient enrollment. And so if you look at these two graphics, these show the medians of our population demographics. And then the one on the right shows the median of the participation in trials. And so if you look, you'll see that there is some underrepresentation by every racial and ethnic group except for non-Hispanic Whites. And so I'm going to ask Lea Ann to talk a little bit more about what this means for evidence and care.

## **Lea Ann Chen, MD:**

So yes, you can see pretty clearly that there is underrepresentation of non-White groups. And this is important because we are missing important information about efficacy and safety when we have these skewed population distributions in our clinical trials. And so this is really a missed opportunity to get the key safety and efficacy data that we want from our studies. And furthermore, it means that access to the most novel therapy is gated for certain populations. And the baseline, the first step in the solution really is just measuring and reporting participation by race and ethnicity for every study. And in that way, we can really target our outreach where gaps are still persisting.

## **Monica E. Peek, MD, MPH, MSc:**

One thing I thought was really interesting is that when you actually zoom in on some of the numbers, they change a bit. And so if we actually go back and look at African Americans, we'll see that there are 13% of the population and 10% of the clinical trial representation. But if we dig in a little bit further, we'll see that some of these gaps widen. So if we look at certain specialties like oncology or cardiovascular disease, we see that Blacks and Hispanics show up far below what we would anticipate based on the disease burden. For some groups, there're like zero present in the clinical trials themselves. And then we know that some of the clinical trials actually don't report on race or ethnicity, which further exacerbates the problem of knowing exactly what's going on. And so Priscilla, can you talk a little bit what the impact – and it's sort of obvious – but can you walk us through what the implications of this could be?

## **Priscilla Pemu, MD, MS, FACP:**

Right. As you pointed out, cardiology does mirror this. Major diabetes studies show this as well: that Hispanic, Latino, non-Hispanic Blacks and Southeast Asian patients are underrepresented. But the reporting is also spotty. And what happens is when groups are missing, the evidence is skewed. You might miss safety signals and that then guarantees that when people then use these medications, you will have effects that were not accounted for. And for me what that does is first of all, it adds to the distress that we hear about related to medicines in

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the healthcare system and science. And on the other side, it just means there are gaps in people's health outcomes and who has access to a treatment. So it really matters.

## **Monica E. Peek, MD, MPH, MSc:**

Absolutely. The other thing that it underscores for me is why data quality is important, because if we don't have the data, we can't understand what's happening. And right now in the current environment that we're in, there's a big push to say that we don't really need data, we don't really need to collect it by race and ethnicity. That just shuts the lights out. We're just stumbling around in the dark. We have to be able to understand where there are gaps and understand what those gaps mean before we can begin addressing them. And so we can only do this when we have complete data, when we have accurate data, and when we have that comprehensively over time.

And so I'm going to move to our next slide where we can...and so I consider that a myth that's circulating in the public domain right now. I'm going to bust another myth, which is that underserved patients are never interested in clinical trials. And this is one that has been with us for a long time. And I do know that there are many that are not for legitimate reasons. However, we do know that that's not always the case. And many do say yes. There was one cancer study that surveyed patients and found that only 32% of patients had ever even been asked. And of those who were asked, 84% said yes. And so what we do know is that if we can again normalize the asking process, if we can make it eligible to everyone, do warm handoffs in the navigation, if we can make the system structure easy for everyone, for clinicians and patients alike, then we're going to increase that patient enrollment for everyone, including those who we may not think are going to be interested in this.

And so what we know is that these gaps, like I was mentioning earlier, can change care. And so we know that evidence varies by populations for lots of different reasons. And so when trials lack the diversity that we have historically seen or that they have historically lacked diversity, then where our ability to generalize them to wide populations where we know there's genetic variation across the globe, then it's difficult to say that this medication is going to work the same for everyone. And so Lea Ann, can you walk us through this slide that talks a little bit more about that?

## **Lea Ann Chen, MD:**

Yeah. So I was just going to mention a great example of this would be the angioedema risk that comes with ACE [angiotensin-converting enzyme] inhibitors. So that risk is higher in Black patients, and treatment response can differ as much as 40%. And so if we have dosing guidance that's built on a very narrow population, then that has huge implications for approvals and appropriate dosing for the real patients that we're treating. And I think what we need to do is to acknowledge this. Not to hide it, but to say this is a known limitation and that's why your representation, your participation really matters. We just need to be transparent about the history of research to build that trust or rebuild that trust sometimes.

## **Monica E. Peek, MD, MPH, MSc:**

Absolutely. Rebuilding trust is really important and that word implies that trust has been lost. And we're in a moment right now where I have worked my entire life to rebuild trust in our governmental institutions and we're seeing the erosion of that currently. So we're going to have to go through another wave of rebuilding that. But right now for certain marginalized populations, that historical legacy around unconsented sterilizations, the

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Tuskegee study, prison experiments, and so many other things that launched the whole movement around IRBs [Institutional Review Boards] and ethics, the whole field of ethics led us to where we are today, where we can pretty confidently say that we know that these studies are going to be safe for our patients. That is something that helps strengthen our ability to enroll patients in studies and that's something that we should be proud of when we're having these conversations. And so Priscilla, can you talk a bit about this slide and how we should be using these as anchors for conversations with patients?

## **Priscilla Pemu, MD, MS, FACP:**

Thank you. I think this is key. If we look at the responses from the poll questions, there was about 50-something percent that said "I don't," and I can only guess as to why that is the case. So if you would just focus in on this fact that it's going to be a question that comes up, and like Ms. Worthy said, you have to normalize participation in trials. If the question is how do we approach this in a conversation, that's what this slide is sharing with us. One, name the past. Acknowledge the past. We have to be transparent about people's experiences and what it means. At the same time, let's talk about what is now available. What are the guardrails that are in place to make sure that when a person chooses to participate in a trial that their interests are safeguarded? What is the role of IRB oversight? What is the role of independent safety boards? What is the ongoing monitoring that happens in a study? What does informed consent look like? What should people be looking for when they choose or decide that they want to examine the possibility of taking part in the study? How should they think about what is listed about the study? What kind of questions should they ask?

So in clinic, we can enhance the trust with four actions. So you acknowledge, you explain protections, you demonstrate transparency, give people time to ask you questions and answer them in all honesty, and then follow up on commitments. I think transparency is the biggest first thing that we need to do, but you are already in a relationship with these patients. They trust you as their provider. Take it to the next level.

## **Monica E. Peek, MD, MPH, MSc:**

Excellent. I'm just going to note that I see some questions coming in about what can we do, what are the interprofessional practices? All of that is going to be coming in our second learning objective, so stay tuned. We are going to get to that shortly. So I just want to make sure that people are aware that we are going to be addressing that. One of the things that I do want to make sure that we cover is some of the ways that barriers can show up. They're not just patient barriers. I was mentioning earlier that we need to have systems where it's easy for physicians and for patients alike. And there are many system barriers that can block the whole process for clinical trials before the conversation can even start. And so we have to ask ourselves – is our healthcare system optimally set up to enroll patients? Not just enroll them, but enroll them in a welcoming and supportive way? I'm from the south, and so I always like to hug people and imagine myself wrapping my loving arms around patients. Can we say that we're doing the same when we're trying to enroll them in clinical trials?

And so there are a lot of common barriers that really stem from a lack of infrastructure, a lot of research infrastructure, or the distance to the mothership, the academic medical center that's conducting – the home base is really far away. There may be other barriers around payments or stipends or insurance limitations, language accessibility. Are we giving the materials at a reading level that's appropriate? Are we translating them into all the languages that are appropriate? Are we doing all that we can as an institution to make entry into this

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trial as easy as possible for patients so that when we as providers are trying to introduce that, we're not encountering stumbling blocks ourselves?

## **Lea Ann Chen, MD:**

Yeah. Exactly. I think in addition to all of the system barriers that you had mentioned, there's a number of potential provider barriers that can really play an issue as well. So people may feel like, "Oh, I don't know what the trials are or I'm not comfortable discussing them." And as you mentioned before, there's this myth – not true, but there's this myth that patients are disinterested, and so a provider may never even bring up the topic. And then there's also sometimes this provider concerned that, oh, I don't have the training to do this. This is outside of my wheelhouse. Maybe somebody else will do it. But hopefully everybody who's here today is interested in learning ways to overcome some of these barriers and take a little bit of individual responsibility for improving the situation.

## **Priscilla Pemu, MD, MS, FACP:**

Absolutely, Lea Ann. And sometimes even when the interest is there, everyday realities can stand in the way of a yes to participation. So if there are language barriers – or you may both be speaking English, we're using the same words, but the meaning does not come across – it can be a problem that prevents the door to participation from ever opening. Sometimes it's just the reality of life. The person has a work schedule and the clinic or the research center is only open while they're at work. That can be an issue. Or they've had prior negative experiences, they may have caregiving responsibility, and people because of prior negative experiences may feel like "you're experimenting on me, I don't want to be experimented on." Or some people might have worries about immigration, about people losing their privacy. People are very worried about that. What does this mean? I've had people say, "If I get compensated for the study, will it change my tax situation?" Those can all be things that come up.

And so there can also be paperwork hurdles, issues with translation, notarization, requiring an ID from participants. Basically knowing all of these issues is our opportunity to then create a pathway. So depending on what the issue is, if we engage with our patients, we'll learn what those issues are and we can solve for a lot of them. So this is my pitch to say when people share, understand what the issue is and create a path to yes.

## **Monica E. Peek, MD, MPH, MSc:**

So now, we're going to try and translate some of what we've learned into practical methods to communicate, navigate, and enroll patients, which is what a lot of people were asking for. But before we do, we have another audience response question. And so the question is, you just heard a lot about some of the barriers, what is the biggest barrier that you personally have experienced to discussing clinical trials?

So the most common reason is that we just don't know what trials are available. And that I think is a real concern. And then a lot of the other things that just happen in the clinic setting. We're busy. We may not have the staff. We're concerned about our patients, both about the safety of the trial itself and that they may not understand what's happening, what they're getting into. And so all of those I think are realistic concerns, but how do we as providers know all the trials that are happening at our hospital? And so that is something that is an important area to address as well. Lea Ann, Priscilla, any immediate reactions to this?

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## **Lea Ann Chen, MD:**

Almost a little relieved to hear this because I feel like the lack of knowledge about which trials are available might be...I don't want to say, perhaps the easiest to fix. Wanting that knowledge and going out and getting it or as a researcher providing that information to colleagues is something that we can just do out of our own will.

## **Priscilla Pemu, MD, MS, FACP:**

Absolutely. What I'd like to share to both providers and to patients is [clinicaltrials.gov](https://clinicaltrials.gov). People can search by their disease condition. They can search by their zip codes. It'll tell you the studies that are enrolling close to where you are. I feel like empowering your patients to look, they have an interest for those who do have an interest. That way they know what to bring up to you. And in your case, depending on what institution you're in, besides [clinicaltrials.gov](https://clinicaltrials.gov), look for those resources. I'm aware that there's some electronic health record systems that will match patients to appropriate clinical trials that they could potentially participate in. So all of those are opportunities, but I think a key thing is to empower your patients with the knowledge that if you have a health condition, you're wondering if there's a clinical trial that's going on close to you or whatever, you can search on [clinicaltrials.gov](https://clinicaltrials.gov).

## **Monica E. Peek, MD, MPH, MSc:**

Right. That's important because many people are looking for... "I'm at the end of the road as far as treatment options. Is there something new around the corner that I can have access to?" And so patients are often motivated to find something else. And so it's not just us trying to expand the science. It may be patients looking for another answer for themselves.

And so let's move to thinking about how we may talk to patients and make some of the conversations easier by addressing some of the patient's concerns. And so we may think about comprehension at the system level. We have things that are embedded in our computers to assess literacy. We usually have teams in our hospitals that can help us to make sure that our flyers and visual aids and all that stuff are using plain language. As physicians, we learn a second language as providers, and so making sure that we're translating things back into normal regular English, or that English needs to be translated into another language. Making sure that we're using visual aids. Someone asked about teach-back in the questions. Absolutely. Using teach-back just like we would in clinical practice. Doing that as part of enrollment. Using cultural brokers. We've heard from our patient navigator, we're going to hear from her again, having multiple touch points and really using what we call transcreation. And I've talked a lot about that in some of the other podcasts that I've done. But using community-based organizations and people from the community to help create the materials themselves, not just take our materials and translate them, but to co-create materials for patients.

All of these are important. And then Priscilla, I know that you're an expert in health literacy and thinking about how that is relevant to the clinical trial context. And so do you want to talk a little bit about that?

## **Priscilla Pemu, MD, MS, FACP:**

Not an expert, just someone with an opinion about this. So it just always gets me when we talk about health literacy, like it is a patient doesn't have a high health literacy level. I don't think that that's the frame. I want us to reframe that entire conversation and see health literacy as a system attribute. Now, regular literacy can be a

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person's attribute, but health literacy is a system attribute. So for us as health care providers in our practices, in our clinics, just to think about how we are communicating things to our patients and making sure that they understand. I love this list of strategies or tactics to use in making sure that that happens. I think cultural brokers, community health workers, promoters, whatever we choose to call them, are amazing. And depending on your practice, actually having people in your practice be that for you, I think creates an engagement and a connection with your community that goes beyond, "Hey, I have a health issue and I'm here for this transaction." I think it's great. It'll help your patients really trust you in your practice. But yes.

## **Monica E. Peek, MD, MPH, MSc:**

Great. One person asked specifically, going back to the teach-back. When I use teach-back with patients in clinical trials or about clinical trials, are there any particular key points I should confirm that they understand? Are any frameworks or anything like that? Lea Ann or Priscilla, anything that you want to talk about when you're specifically using teach-back?

## **Priscilla Pemu, MD, MS, FACP:**

Do you want to take that Lea Ann?

## **Lea Ann Chen, MD:**

No. I think the key things, especially at enrollment, that you want patients or potential subjects to understand is one, the benefit – whether it's a benefit to them or someone else – and then the risks, and that it's voluntary. So those are the things that I'm wanting to hear back from patients that they understand about the informed consent process.

## **Priscilla Pemu, MD, MS, FACP:**

Right. So what is going to be expected of them? What can they expect to experience? Who should they go to if they have any questions, all of those things. And more importantly, whatever they discuss in the clinic, that is not the end of it: that they can take that document with them to their family, to their trusted people and take another look at it before they get to a decision. That it is not rushed.

## **Monica E. Peek, MD, MPH, MSc:**

I hope that the person who put this question in got a sense of the answer, but I'm just going to quickly go over it just in case. And they said that you're touching on this already, but one of my more mature Black patients, I think they mean in age, mentioned the Tuskegee study when I brought up a trial. How can I acknowledge the history appropriately while still encouraging participation? And so I think that as we're talking about acknowledging that and building trust, I think honesty and transparency is so important to that.

And so I'm like, yes. Anytime that you may feel mistrustful, that is something that has been on our government. All of that happened and more. And so what I'm here to say now is that a lot of that has changed. That those horrific things that happened in our country, that happened in Nazi Germany, all of those were things that motivated the world to make sure that studies were going to be safe for people who were vulnerable. That people who didn't have all of their rights, who didn't have decisional capacity, who may have been imprisoned,

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who we knew were being structurally oppressed, had safeguards put in place so that they wouldn't be involuntarily experimented on because we'd already seen what had happened in this country, across the globe, and in other specific countries. And so we'd already just experienced all those horrors that led to safeties for people like us. And that I'm a researcher, I'm here seeing you in clinical practice, but I do 80% of my time doing research. And so I know, having to put all of my studies through the IRB, how diligent they are in making sure that their primary concern is patient safety.

And so I think part of what I do is talk about my lived experience as a Black person, acknowledging what they may be feeling is real, and that my role in health care is that of a clinician as well as that of a researcher and how I interface with the IRB. And so I think all of these things are part of how we build trust with patients, and the transparency and the accountability I think are all part of that.

I'm going to have Lea Ann and ask you to walk through this conversational map, which gets to some of our other patients, other audience members, questions about some of the conversations that we have. And I'm in a busy clinic and how do I do these things? And so some of the logistics of how to make this happen in a clinical setting.

## **Lea Ann Chen, MD:**

So, I like to think of three time periods. One is before the visit, before you ever see the patient. Second is during the visit, and then afterwards. So going into a visit, it's important to do your pre-charting. If you're seeing a patient the next day, look and see: is this a patient who could potentially go into a trial that I know about? Or this patient looks like they're running out of medical options, maybe I should be looking into trials that they can go into. And then have the flyer, have the materials ready to go. Have it ready to go in that patient's language. So that will facilitate enrollment and approaching patients during your very busy clinic schedule.

During the visit, I think it's really important that we're talking to patients about the benefit, who's benefiting. Sometimes it's the patient. It could be an interventional trial, this is a therapy if they've run out of other therapies, but sometimes it's not. Sometimes the benefit is to future generations, future patients. And I think that that's really important for patients to understand. One, whether they have a personal benefit to participating. But also there's been these studies that have been done looking at best ways to cope with stress, for example. And they show that it's not taking a long walk or a bubble bath or whatever, but it's volunteering. It's the ability to get out of your own situation and think about serving others or helping others. And so don't take away that potential opportunity for your patient to bless someone else. Give them that opportunity to participate in volunteering for others. The other thing is talking about safety. So safety is oftentimes a concern for patients. So how are we going to make sure that we're going to keep them safe? What are the labs that are part of the study? What are the visits that are part of the study? And really using that teach-back to make sure that they understand that.

And of course, always letting patients know if you say, "Okay. It's not like you can't change your mind. If you start the trial, it seems like it's not working out for you, it's too much, this isn't what you thought it would be, you can always say, 'I don't want to participate anymore,' and that's an option." I think the other things that help in terms of facilitating access to trials is one, doing a warm handoff that same day. So if you are lucky enough to have a team and a coordinator, having somebody there to take that interested patient and go over the details of the study within a short period I think is helpful. And then the post visit or the follow-up, it's just making sure that you're following up with the patient soon after. You're closing the loop about one, any questions that they have. They don't have to be forced into giving an answer right there, but if they want time to

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think about it or talk about it with someone, make sure that you check in with them afterwards to see if they have any remaining questions, clear up any questions that they might have or barriers that might be in the way. And just making sure that the whole team, the research team is involved.

## **Monica E. Peek, MD, MPH, MSc:**

Great. So we can summarize this process as the first 24 hours, you want to identify eligibility, offer to the patient, and then do a warm handoff. By the second 24 hours, you want to have an eligibility decision. And then by the next 24 hours, so at 72 hours, three days, you want to have a navigator follow up. So a three-day process. So really just clicking along at a rapid speed.

## **Priscilla Pemu, MD, MS, FACP:**

And role clarity will speed this process. The clinicians make the offer and they link it to goals. Your nurses or APPs [advanced practice providers] will explain in plain language and use teach-back. Your coordinators and navigators will handle eligibility and logistics. The pharmacists and interpreters will ensure safe, language-concordant care, and your front desk and admins trigger and track the warm handoff. One team, one workflow. And navigators make trials very doable. They bring language and cultural match, they handle logistics, they help with scheduling, transport, forms. And the programs that add navigation will lift underrepresented participation from about 9% to 16% and double retention – and that is huge.

## **Monica E. Peek, MD, MPH, MSc:**

That's a pretty big percentage. And so we know that navigators have been so effective in doing so many things, and so to know that they can also work in clinical trial participation is really important to know. And so there are a lot of things that come up in visits and so we can actually address them in the way that we talk with patients. And so you'll see on this slide some things that you may have heard inadvertently, even if you're not talking about clinical trials. And so we're just going to try and address some of these. So Priscilla, I'll let you take the first one.

## **Priscilla Pemu, MD, MS, FACP:**

Okay. When someone worries about being used, basically I say you get to keep your usual care. The study adds more eyes on you. You decide at every step. As Lea Ann shared, just saying yes doesn't mean you're stuck with yes. You can continue to reevaluate. You can stop whenever you want. And then I pause and I ask, what would make this feel safe for you? And listen to what they share.

## **Lea Ann Chen, MD:**

Yeah. I want to reiterate sometimes to patients that safety and quality of care, it doesn't go down when you're in a study – and if anything, it goes up. It's more visits, it's more people checking in on you and making sure that things are going okay. And again, if something's not going right, if this isn't what you thought it would be, you can change course. The beauty of longitudinal care, both in clinical care but also in research, is that you can pivot after the initial decision.

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## **Monica E. Peek, MD, MPH, MSc:**

I think that one thing that some of our patients who come from historically oppressed and marginalized situations have a little less comfort with is the uncertainty. And it's because of so much of the uncertainty that has been baked into how people are being forced to live, and so that has a lot of negative connotations. And so the uncertainty of science may not feel quite so – like, what is happening here? And so we have to get used to normalizing this in how we talk about science and discovery, and also just saying, listen, Lea Ann, like you just said, we can set up a plan B before we start. So if X happens and this isn't what you expected or something isn't going the way that we want, we're going to do Y. And so people a lot of times can feel more comfortable if they know that there's a fallback plan so that they're not just floating in space with all of this existential angst.

## **Lea Ann Chen, MD:**

Exactly. And as you were saying about the uncertainty, there may be uncertainty about, for example, the trial or the study drug and whether or not it works, but we should try to remove any of that uncertainty as it relates to the study. So for example, how much might this cost me? Does it cost me for me to come and park for the study visit? Is that going to be covered? If I experience an adverse reaction, is the study sponsor going to cover the cost or is my insurance going to cover the cost? Do I have to cover the cost? Those are important things to know and explain. We won't know perhaps whether you get placebo or drug, but these are the things that we know and we'll take care of for you.

## **Monica E. Peek, MD, MPH, MSc:**

Yes. Two questions that have come up that I'm just going to briefly hit. One says, "What should I say if a Spanish-speaking patient asks about a clinical trial flyer in our waiting room and we don't yet have translated materials?" Either one of you want to take that?

## **Priscilla Pemu, MD, MS, FACP:**

We don't have it now, but we'll get it to you in such and such amount of time.

## **Monica E. Peek, MD, MPH, MSc:**

Honesty is always the best policy. So yeah, this is our limitation. We don't have it yet. And if you hadn't planned on translating it...maybe you don't have a large Spanish population and this is the only Spanish speaker who happened to come to you. There are a lot of ways...ChatGPT. A lot of things that are now at our disposal that weren't available even a few years ago to make a lot of services and things that we do a lot easier now than they would've been in the past. Another person asks semi-relatedly about patients who are undocumented and worried about privacy. And so how do we address their immigration concerns when discussing clinical trial participation?

## **Priscilla Pemu, MD, MS, FACP:**

Prior to now, when I've had studies where – I was in the All of Us research program that had asked a lot of people. Basically if there were policies for instance that required an ID [identification] or certain things, we changed them so that people didn't...you know, there is not a research-related reason why a person has to

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submit a government-issued ID. Now if there is a study that has a research-related reason, that's a whole different conversation. So think through the barriers that suggest a loss of privacy or make them feel more vulnerable and ask yourself, is that a requirement to answer the question that that study needs to answer? And if it is not, then there is an opportunity to do something about it.

## **Monica E. Peek, MD, MPH, MSc:**

Totally. All right. So we are going to hear again from our patient navigator Ms. Valarie Worthy, and she's going to talk about her role as a trusted community resource and some strategies that she's used to engage patients who are mistrustful of clinical trials. So let's take a look at this video.

## **Valarie Worthy, MSN, RN:**

Not developing a relationship with that patient. Patient wants to know that it's a team effort and that they are part of that team. They're part of that decision-making process, that you thought of them as a person and not a number, and that you really care about their decision. And that if they have questions, they're not intimidated by even the thought of asking a question. You've gone through the discussion, maybe talked about the clinical trial, and then pause to say, "Now, how can I help you? What have I missed? What questions do you have? Did I meet your need today?"

I would say imagine that this is your family member and you have to try to explain to them that they have cancer and what is the best course? And think about your parent, your sister, your child, brother that is there alone and someone explaining to them about a major choice that they have to make. What would you say and what would you want that person to say to your family member? Just treat people the way that you would want to be treated and the way that your family member would want to be treated. If you do those things, you'll build a relationship with patients, patients will feel comfortable asking you questions, and they will share their biggest desires after the – "this is what I want to happen," and their biggest fears and you will be able to treat them holistically. That would be my advice.

## **Monica E. Peek, MD, MPH, MSc:**

So while trial enrollment really is important to think about the process, it's also important to think about the relational aspects that may actually be more part or more important to the big picture in getting patients to say yes to trial enrollment. So creating emotionally safe spaces, engaging in shared decision-making where patients feel comfortable asking questions. All of those are equally important to the first 24 hours, making sure they're eligible. The second 24 hours – all of that is key. But if patients don't feel like this is going to be a safe space for them and I can ask questions and make sure this is the right thing for me, then that whole process is really for nothing. And so we have to be able to walk and chew gum at the same time. We have to be able to care and to have logistics down at the same time.

So I like busting myths. There's another one that clinical trials are just way too complicated for community practice. And that may have been the case in the past, but isn't as much today. And so Lea Ann, I'm going to ask you to quickly run through why and how that may be the case.

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## Lea Ann Chen, MD:

Sure. I think as it's increasingly recognized that our trials are not reflective of study populations, I'm seeing even my industry colleagues saying, "We don't want your ivory tower academic medical center patients. We want real patients and are willing to put in resources to help make that easier." And so many trials are designed for community implementation. There's patient advocacy groups, for example, that will list clinical trials for that disease so you can just go to their website and figure out where the nearest center is and what sorts of trials are out there. There's more and more trials that are available where part of it is by telemedicine or you can do e-consent to make it easier for patients. They may not necessarily even have to come in to do a visit, and they're trying to make protocols more simple. So there's a whole field of science now, right? Like this pragmatic clinical trials to really have trials baked into the workflow of your day-to-day care. And also I think sometimes there's this perception that all studies are randomized placebo controlled studies. That's not true. Some of them are just safety registries. Patients just consenting to be pinged or texted to make sure that they're okay. Some of them are prevention studies or digital health interventions. And so it's not that every trial is a big deal. There are also trials that are for the amount of commitment or resources you have.

## Monica E. Peek, MD, MPH, MSc:

Yeah. Great point. And so to make trials workable, we just need three basic steps: start small, build momentum, get easy wins, and then measure impact. And so I'll move to the next slide and talk about community network and the reach and knowing that it comes from lots of different spaces. Again, we're not just thinking about what can happen in the academic setting that we want to think about showing up at health fairs, partnering with schools and patient groups, using the local media to explain the benefits in plain language so that people on the radio are hearing about it. Every touch point, you're going to get a real person who may call back. Are you advertising on the bus? Thinking about from the provider side, we have research practice networks where we can set up peer mentoring and offer short continuing education courses on research communication, things like what we're doing right now. A lot of times we have quality improvement collaboratives. You can join a research collaborative to help you figure out how to do this that you may not have been trained as a clinician investigator. And so all of these are things that help lift this off the ground for everyone. And because it's a win-win, we want everyone to be represented in these trials.

And so after today's discussion, our last audience response question: we want to know what might be your very next step.

Excellent. So I think most everyone is going to – the majority of people are going to just try and find out what's available in your area. And I think that's a great next step because that was the biggest barrier in the first place: "I have no idea what's going on." So I think that most people are going to take the next step and figure out what is going on. So I think that's great.

So we're going to end today...almost end by thinking about some SMART goals. And those are goals that are specific, measurable, attainable, relevant, and timely or time-bound. And so these are things that you can think about doing like practicing cultural humility, turning communication and barrier closure into workable steps. And so just thinking about some of these goals. I'm going to let you look over them. Lea Ann, is there anything that you want to highlight with these SMART goals?

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## **Lea Ann Chen, MD:**

I think here are a number of tips and there are a number of them. So pick and choose the ones that work for you and for your practice. And it's a process, but I think just getting a few enrollments, getting a few trials under your belt will really facilitate future participation.

## **Monica E. Peek, MD, MPH, MSc:**

Excellent. Any last parting comments, Priscilla?

## **Priscilla Pemu, MD, MS, FACP:**

I really want to plug the navigators. Think about those people in your practice who ask the most questions, who seem to be the most concerned. They tend to be the ones that if you can get them to understand the need, they form the best navigators. So anyone who has a lot of questions, a lot of concerns, look at them again. Invite them in and teach them. I think they would be a really great addition to your practice as a navigator.

## **Monica E. Peek, MD, MPH, MSc:**

Excellent. It's always like the person who asked the question gets volunteered for the program.

## **Priscilla Pemu, MD, MS, FACP:**

No. No. The fact that they're thinking enough to ask all those questions and have that level of dissatisfaction is always the key. That's been my experience.

## **Monica E. Peek, MD, MPH, MSc:**

Exactly. Exactly. No. I'm with you 100%.

This recording will be available on the CME Outfitters health access hub, along with other resources for both clinicians and patients. The hub also offers tools to help you build skills for creating a welcoming and inclusive environment. There are other activities in this series that can also be found on our health and access hub, and we encourage you to check all of those out.

So Lea Ann and Priscilla, thank you, thank you, thank you for your insights today. Thank you to the CME Outfitters team for partnering with our program. Together we can all broaden our access to our patients to clinical trials and ultimately improve the care for everyone. Thank you so much. And with that, I will just say good night. Have a wonderful evening, and thanks again for joining us.