ACTTION IMMPACT XXV - Patient Engagement in Planning, Conduct & Implementation/Dissemination of CPR

October 28, 2021

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ACTTION

INITIATIVE ON METHODS, MEASUREMENT, AND PAIN ASSESSMENT IN CLINICAL TRIALS

IMMPACT XXV

Patient Engagement in Planning, Conduct and Implementation/Dissemination of Clinical Pain Research

Virtual Meeting

Thursday, October 28, 2021

11:00 a.m. to 2:30 p.m.

C O N T E N T S

C O N T E N T S (continued)

P R O C E E D I N G S

(11:00 a.m.)

Welcome and Housekeeping – Bob Dworkin

DR. DWORKIN: Welcome back, everybody. Thank you for rejoining us for the second day of the IMMPACT XXV meeting. I'm Bob Dworkin. I think we had a consensus already, after only one day of a three-day meeting. And it seems clear to me, and I think to a bunch of us who talked after the meeting yesterday, that the consensus is that the meeting was incredibly interesting and valuable in terms of what was discussed, what was presented in the presentations, the questions, and the discussion. So that was one consensus.

The second consensus is that Chris Veasley and Bob Kearns did an absolutely fantastic job of putting together the agenda. So we already have, after only one-third of the meeting being complete, two consensuses. I don't know; is that consensi? I should check. One of us should check whether it's consensuses or consensi.

But we've got two consensuses. I'm not sure

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whether that's publishable in and of itself. We could ask Frank Keefe and Mark Jensen tomorrow 0whether that would be a publication. But I think I'm equally convinced that the next two days of the meeting are going to provide lots of additional information, and that Simon is going to be able to draft an absolutely terrific and potentially major contribution to the literature, based on this meeting. So welcome back, everybody.

The housekeeping is the same as yesterday with one major exception. We have now allowed chat. Chat should be used primarily for references to articles, links, that kind of thing, and that will all be collated and aggregated after the meeting, and distributed in whatever way is most appropriate and most valuable.

If for some reason you need to put a comment in the chatbox, that's ok, too. But given how much is going on at these meetings simultaneously and parallel, we can't guarantee that someone will be monitoring the chatbox for comments and suggestions, but we'll do our best.

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I think everything else was already reviewed ably yesterday by Dennis. Nothing else has changed, and the publication policy remains the same. We will end promptly today at 2:30 and resume tomorrow at 11 a.m.

As this slide indicates, if you have any questions about anything, please contact Valorie, or me, or Dennis, or certainly Bob Kerns and Chris Veasley. But I am happy to reintroduce Bob and Chris, and I think Chris will be leading today, so please take it away, Chris.

MS. VEASLEY: Thanks, Bob.

It's great to have power today in the northeast, and to be back home, and to have had a shower, and heat. So I'm happy about that. But I concur with you, day 1 was terrific. We really had some great discussions.

As I mentioned yesterday as we wrapped up, today we're really trying to get into the how-to's, so we don't want to just leave people with this 30,000-foot overview. Although best practices, and values, and all those things are absolutely

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critical, we really want to give investigators who will be reading the manuscript very practical guidance for how they can, if they're already doing engagement, improve it, and if they're not doing it, how to start it.

So, we've organized a series of four talks this morning that will go through each step of the research life cycle. And I'm pleased to introduce our first two speakers, Karen Morales and Gail Graham, who are both with the PATIENTS Program at the University of Maryland School of Pharmacy. Karen is the associate director of engagement for the program, and Gail is a patient consultant.

So you take it away.

Presentation – Gail Graham

MS. GRAHAM: Hello, everyone. My name is Gail Graham. In 1997, I was diagnosed with HIV positive. Once I was diagnosed, I decided that I wanted to learn as much as possible about HIV so that I could tell others about it in hopes of preventing them from going through the different things that I went through to help them deal with

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the stigma, and to help them deal with finding the correct specialists.

Also I was a single mom of two kids, so, basically, I just wanted to live long enough to see my kids graduate. At that time, the life expectancy wasn't really that long.

But fast forward to 2007, and my best friend was going to a church and she invited me to come. The church was Mount Lebanon Baptist Church, and I liked it. So she asked me one day when will I join the church, and I said, "Well, I need to talk to the pastor because I don't want to bring the stigma of HIV to the church."

When I met with the pastor and I told him my story, he said, "Gail, this is your ministry." Now, I thought he was a little crazy because he didn't really know me, but he was cute. But I still wanted to go there anyway. A year later, we started the Mount Lebanon Baptist Church HIV/AIDS Outreach Services.

This church is actually located in a zip code in Baltimore, which has one of the highest

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rates of HIV and AIDS, and I became very protective of my community. We had different organizations and companies coming in, and they wanted to get information from us. They were like helicopter research. They'd come in, get their information, then they'd leave, and it was of no benefit to my community as a whole.

So what ended up happening was when anybody came through and they wanted to do research surveys or whatever, they would always offer gift cards. For it being a food desert and for it being very, very low income, people decided that they were just going to tell the researchers whatever they wanted to hear so that they could get that gift card.

One day I was volunteering for my pastor's church, and he told me, "Gail, you're coming to this meeting." So when he says that, it's usually to give me more work, so I was like, "Nope, I don't want to go." But I ended up going to the meeting, and it was with the University of Maryland PATIENTS Program. Dr. Daniel Mullins was talking about the PATIENTS Program, and gave me a nice long spiel

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about what it was about. And when he finished, he said, "Well, Gail, do you think you'll be interested?" So I said, "Nope, not at all. I'm not interested."

He asked again after a while. He rephrased some things, and he said, "Well, now do you think you'll be interested?" And I said, "Nope, I'm still not interested." So he said, "Well, maybe one day, one of my post docs can meet with you just to see if you would change your mind." So I said ok, because at that point I just wanted to get out of the meeting.

So when the person came and they were talking about the same thing Dr. Mullins was talking about, I said no. So she said, "Well, do you think we can have a table at your World AIDS Day event?" That event is where we will give away free turkeys to anybody that got tested. So I was thinking I'm just going to put them to the side and watch them and make sure they don't really interact with my community.

Well, this organization showed up. They

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were the first ones to show up. They helped me set up. And then when the community came in, they said, "Well, can we go get doughnuts and coffee for them?" I was just so thankful, I said, "Sure."

So I ended up doing some other things, and then I remembered I'm supposed to be looking at them to make sure they're not really bothering my community, and I saw them sitting with my community and holding their hands, and actually listening to them. And for somebody that's HIV-positive, that touch is a mighty thing. So from that point on, I said, "Ok, Dr. Mullins. You have me."

One of the things I really want to leave you with is, trust is earned and trustworthiness is nurtured. That's one thing that the University of Maryland PATIENTS Program has done with my community. Thank you.

Presentation – Karen Morales

MS. MORALES: Thank you so much, Gail, for sharing your story, as you do so eloquently.

The PATIENTS Program started in 2013. Why do I start with the Voice of the Patient? Because

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the PATIENTS Program believes that patients and stakeholders are heard, inspired, and empowered to co-develop patient-centered outcomes research, and that the Voice of the Patient is the most important thing to us.

We start our engagements, all types of engagements, with the Voice of the Patient. Front and center is our advocate, Ms. Gail Graham, and I appreciate you for sharing your story.

Yesterday, we heard a lot. We heard a lot about statistics, we heard a lot about the need for engagement, and I valued that conversation yesterday so much; so much so that I actually added some things to my slides for today. But today we're talking about the planning process.

The PATIENTS Program has been in the process of transforming the research enterprise since 2013. In 2012, Dr. Mullins and the team created, or developed, an article about patient engagement, the 10-step Framework for Continuous Patient Engagement. We have now segregated that down to three phases, which is the planning phase, the

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doing phase, and the delivery phase.
We also call that listening, bridging, and delivering as well, which is another acronym we use, LBD, to say that in our first phase, we're listening to our patients. We're hearing from our partners about what their concerns are. There are three categories that patients have been able to assist in, and that's the topic selection in the planning phase; step 2 is prioritization; and framing the question.
In order to talk more in detail about the planning -- there's doing and delivering as well, but I think some others are going to talk about that, so I'm going to move on to slide number 3.
The planning phase, as I mentioned earlier, participants have worked with us at all levels. I think what we've learned over time is that it's very important that you set expectations from the very beginning of the planning process about who you're going to have involved in your project. Yesterday, I heard mentioned about having certain types of individuals on your team. Yes, you want

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to have equity in your teen. Yes, you want to have diversity in your team.
Right now, we're working on the project with the NIA, and one of our post docs feels that she's not the adequate person to be able to address the focus group participants in this particular project because she is not a person of color and we're interacting with African-Americans in this particular project. Well, that may be true, but there's no set answer.
While we do believe that you do want to have a diversity of participants, as well as a diversity of focus group leadership and focus group staff, or project staff, when you're setting your expectations from the beginning of your project, try to include what you're going to need from the very beginning; not bringing in someone to only do the focus group who's a person of color, but also having participants in your staff who can interact with their community or your community from the very beginning if you want diversity of the participants in your project.

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The next bullet you see is advisory boards. Our participants work with us from the very beginning, as I said, in the planning phase. They don't just come in on a project and give us our survey answers. Gail and others work with us as we're actually planning out what projects we're going to participate in, what we're going to do for the year.
We have stakeholder involvement from the very beginning of the actual planning phase. From the strategic planning phase of our program, they've become partners with our program, and they're now helping to set the agenda of what the PATIENTS Program is going to do and how we're going to do it.
Another thing we've learned is our use of language when we're communicating with our partners. Again, having language that your patient groups can understand, that's clearly understandable for them, is a critical component of your engagement efforts and your planning process from the very beginning as well, because if your

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language isn't accurate, isn't understandable, then it's of no significance. And you'll see, once I get through the slide, how language changed the question that was being posed in this particular study.
As I said earlier, topic selection, prioritization of your project, and framing the question are some areas that our participants have been able to assist us with in the planning process.
One of the critical components of planning is your pre-engagement. The PATIENTS Program has a concept of, again, you don't just -- as Gail mentioned -- come in and start engaging the community to participate with you, but you have a period of pre-engagement, a time where -- like Dr. Mullins did -- it wasn't a project that we went there for. He actually went there to engage the community, and he was engaging before we had a study that was active; so getting to know the community, understanding the community and your participants that you want to bring in, and not

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just telling them, okay, we want you to come in and do this for us, but understanding what their needs are, as well.

Engaging, you want to engage early and often. Early is before your project, and often is during certain intervals. You don't want to just wait until, again, your project needs a survey answer. You want to engage with them around their activities, as we did with Testing for Turkeys. And I've been to one, and trust me, Gail runs a smooth operation there, and it has been a successful event each opportunity I've had to participate; so kudos to Mount Lebanon and Gail.

Working with the community health workers and engagement specialists, we utilize them in that position and that role to engage with the community. Yes, Dr. Mullins goes out, I go out, but the staff who actually do the daily or weekly engagements are our community health workers and our engagement specialists. These are individuals who have a pulse of the community. These are individuals who are actually integrated within the

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community itself.

So while it's important to have, yes, the positions, it's also important to have someone who knows that community, who can interact from the perspective of an understanding of what's happening within that community.

As I mentioned yesterday, I do believe during the pandemic, we missed an opportunity. I know there were funding issues, things were shutting down, but I think we missed the opportunity to use community health workers to really make phone calls to touch base with the community that they knew to see how people were doing, and whether or not there were needs in the community. Some organizations did that, but I believe as a whole, we kind of all shut down, and in some ways we kind of missed that opportunity to utilize that position.

Pre-engagement includes our community events. We are constantly out in different community events. One of the things I was thinking about is how do I relate that to pain? How does

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that affect what we're talking about today in this particular conference? I'm assuming that there are conferences that highlight the pain perspective, and inviting community members to pain conferences -- not just the researchers, but also the community members -- to have an outlook as to what's transpiring will bring more community participation into this particular concept.

Community health fairs, our engagement, we constantly go to health fairs. That's one of the things that we find when we're able to garner more participation from our community. We've had a database of community participants that has reached about 4,500 participants in our database, and that was over a five-year period, where we were able to go out and engage with the community and come up with those numbers. We've since cleaned it and did some things with it, but 4,500 for about five years we thought was a pretty good number to have generated over that particular period of time of participants.

Now yes, some of them may have said they

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were there to get something. As Gail mentioned earlier, you really need to have a relationship with your community so that they believe and trust you, because it's one thing to trust the data that they're giving you. Sometimes you think you have good data, and the answers that you're getting are not true answers. They're just answers on your survey so that they can get the ending compensation or whatever it may be.

So what we've tried to do is show that we're trustworthy in that we come back to our communities. We don't do the helicopter research, and we actually learn what's important to the community. So those are some steps that you want to take in your pre-engagement efforts when you're planning your projects. Yes, it does require time. Yes, it does require commitment.

The next bullet I have is -- I'm going to go through this a little bit quicker because I see I have about five minutes left -- partnering with community churches, which Gail is from one of those churches that we partner with. We found that to be

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a helpful opportunity for the PATIENTS Program, community churches and educational institutions. We have a partnership with Morgan, and we engage with them and their community opportunities as well.

The planning phase, how am I doing this? Well, you have partners already that are working in the same field that you're in. Partnering with them is key to developing your current relationships. Trying to go out and generate new relationships isn't always the easiest thing to do, so you build off of the ones that you currently have, and that in turn builds -- oops, my phone in the background.

Sorry, ignore that. Engaging community clinics, senior centers, community associations, advocacy groups, and other institutions is what the engagement team of the PATIENTS Program does on an ongoing, steady basis to keep the pre-engagement efforts going, ongoing and continued.

We talked about continuous engagement as part of the planning process because we know when

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we're planning our studies, we also have to put in specific points where we're going to continue to engage our partners, our patients, our stakeholders.

We look at our patients as partners; not just as participants on the study, but as partners, and we ask them, what are you interested in? What do you want to know? Asking and not telling is something that we've heard from our partners that, basically, the PATIENTS Program ask; they don't tell.

Because we do ask, we found their investment in our program to be highly significant. And like Gail, there are several others who come back on an ongoing basis. And you would wonder, are they going to get tired of working with you after a while?

Gail, are you tired of working --

MS. GRAHAM: No.

(Laughter.)

MS. MORALES: Excellent.

Gail has been working with us for at least

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six years, about six years.

MS. GRAHAM: Eight, I think, yes.

MS. MORALES: Eight? I'm sorry?

MS. GRAHAM: Eight.

MS. GRAHAM: Eight. Okay; eight years.

So it's been a journey for Gail as well. So not only has it been a learning process for us, but we're learning from Gail, and she in turn learns from us. So that bidirectional opportunity has been ongoing. Your partners will be invested if you're asking them what their needs are, and they'll invest with you as well.

Respecting and valuing the community, those are critical values that we have learned, that the community members, they want to participate. They want you to respect what it is they have to say. And how do you do that, we'll hear about that in the dissemination process, I hope.

But feeding back to them what it is that we heard them say in the planning process has been absolutely critical. Our patients have said, "You know what? I didn't expect to get that back. I

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didn't expect to hear that you used something I said, and that you actually changed something."

I'm going to skip now because I see I'm running out of time, but some of the others here are using social media, newsletters, and all these things of building trust to stay engaged with the communities over periods of time.

The last box here talks about a specific study that we had, which was a RadComp breast cancer trial. Our patients helped to change the question that was being asked, which was, "Does proton therapy reduce major cardiovascular toxicity compared to photon therapy?" I can't even hardly say the word, right?

In a patient's voice, the question was changed to, "What type of radiation is better for heart health?" That's what we got from our patients. Does it answer the question that was originally proposed? The patients believe that it did, so the patients actually helped change what the question was that the study investigator was looking for. That's the planning process.

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The PATIENTS Program, as I said, we look at all phases of engagement throughout the planning, doing, and the delivery of processes, which is during the doing phase, which patients and stakeholders are participants and co-developing study protocols; reviewing or selecting survey instruments and choosing when and how to gather data; advising how to recruit, engaging, and retaining participants; and then, again, in delivering solutions. I would have been remiss if I hadn't gone through some of the things that we do as the PATIENTS Program in these two categories.

I'm going to finish up. Delivering solutions; patient advisory groups blogging about our studies. We have our patients who actually do videos for us, infographics, and help with developing manuscripts. Gail actually had a blog that she did with us, and that was her first time actually creating the publication that went into the publication sphere. We were proud to be able to have that, and we have another community partner who did the same.

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PATIENTS Day, we have a traditional event that we do at the end of it all, where our patients and our stakeholders hear all that we do throughout the year. Unfortunately, last year we couldn't do that. We're planning for 2022, and we're excited to be able to host the community.

This slide here just shows in red how the PATIENTS Program actually recruits faster. These are some other studies as we compared the PATIENTS Program to other studies that we've had, traditional studies here in blue, and the PATIENTS Program methods. So we can see we've actually recruited faster and have been able to have retention in our studies.

This slide here is showing the increase of our racial and ethnic diversity. At one point, this was what traditional studies showed for Caucasians, and now we see that we've expanded other groups over time. This is comparing to the PATIENTS Program, and this is traditional clinical studies. The PATIENTS Program, our numbers have increased in our African Americans. Our Hispanic

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patients and Latinos, there's been an increase in that area as well.

Thank you. Sorry. I think I went over by about a minute or so. My apologies.

Questions?

Clarifying Q&A

MS. VEASLEY: No problem, Karen and Gail. Thank you guys so much for kicking us off this morning and talking about the important work that needs to be done in the planning phase.

We have a few minutes for one or two clarifying questions. We just want to note that we have ample time for discussion at the end of the day, so if you have more deep-dive questions, please keep track of them throughout the day, and you can ask our speakers later in the day.

But if there are any clarifying questions for Karen and Gail at this point, please raise your hand emoji.

(No response.)

MS. VEASLEY: I don't see any. But, Karen, I'll pose this to you and to Gail.

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We've been talking about there's quite a dichotomy and diversity across institutions in the United States. I don't want to put you on the spot to give me an exact statistic, but how common is it for universities to have programs like this available?

MS. MORALES: I would say that it's becoming more common. We are in partnership with Johns Hopkins, who's also doing a community engagement. We're in partnership with Morgan. The PATIENTS Program came out of, I believe, seven institutions across the country who were also doing patient -- it was a grant funded by AHRQ, and there were seven other institutions that were doing the same thing.

So we've seen over time a growth in patient engagement and engaging patients around patient-centered outcomes research. I don't have the exact statistics, but it has grown over time.

MS. VEASLEY: That's great.

MS. MORALES: It wasn't very common when we first started, back in 2013.

MS. VEASLEY: Gail?
MS. GRAHAM: We're also developing the PATIENTS Academy, PATIENTS Professors Academy, so that we can work with other organizations and institutions throughout the United States, or further, to develop their communications with the community between researchers, between medical fields, patients, and other community advisory boards.
MS. VEASLEY: That's great.
Kathryn, I see you have a quick question.
DR. MARTIN: I sure do. Here in the UK, we are finding that, increasingly, patient public involvement is so important, but in the planning stages there aren't as many opportunities to actually fund it. Even if a research council is wanting PPI in a grant application, it isn't necessarily allowing for funds to do some of that work and renumerate [ph] appropriately.
What is going on in the U.S., and how, Karen, would you approach that, or have you gotten around to that in any way; not around it, but how

are you funding it?
MS. MORALES: The PATIENTS Program, as far as our funding for our pre-engagement, for our participants to actually be able to assist us with developing our research protocols, they're not all compensated opportunities. There have been some opportunities where our participants have been compensated for X, but haven't always been compensated for every phase.
Now, it's important. We do -- as Gail notes -- because she's been with us for eight years now, and she's been on this journey because of -- yeah, she's been compensated, but she also gives back her time when she's not compensated.
So I think part of that pre-planning phase, when you're developing those relationships, allows your participants to, again, realize that over -- it's a long-haul opportunity. It's not me coming in only now; it's me coming in as part of the journey with your organization.
We had a $5 million opportunity funding from AHRQ when we started, and part of it was you have

to figure when you're establishing your projects how you're going to incorporate the planning phase because that funding has to stretch, as we know. But when you develop your participant pool from the beginning, that will allow you an opportunity to work with participants who may not necessarily expect to have any type of funding right from that moment.
MS. VEASLEY: Thanks so much.
Bob, you have a quick question?
DR. DWORKIN: Yes, just a very quick question.
Very impressive data that you presented on the differences between the studies where patients were involved and those where patients weren't. Was that local data or just studies where Baltimore, the greater Baltimore area, was a site, or were those national and international data?
MS. MORALES: That's correct. Yes, It was national, and we are a site. So it was compared to other sites across the country. All of the data hasn't even been published yet, but this is coming

out now, and I expect to have the actual publication information soon. But this was compared to other sites across one project, yes.
DR. DWORKIN: So it's the Baltimore site versus other sites that actively engage patients.
MS. MORALES: Across the country.
DR. DWORKIN: Fascinating. Thank you.
MS. MORALES: Exactly.
MS. VEASLEY: Penney, a real quick question. We need to move on to the next speaker.
MS. COWAN: One of the things -- and I compliment you much for all that you've accomplished -- is that going into the community rather than working with healthcare providers really engages people a lot more. It's just a different approach that I think can be extremely successful. So I applaud you for that.
MS. MORALES: Thank you, Penney.
MS. VEASLEY: Alright. Thank you, Karen and Gail, for kicking us off so well this morning. We appreciate you being here and contributing.
Next, we're going to hear from Dr. Jonathan

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Jackson. He's the director of the CARE Research Center at Mass Gen and Harvard Medical School, and that stands for the Community Access, Recruitment, and Engagement Research Center. He's going to talk to us about how do we engage with diverse, hard-to-reach, and disparate populations.

Jonathan?

Presentation – Jonathan Jackson

DR. JACKSON: Thank you so much Chris. Hopefully, everybody can see me. I am thrilled to be here and thrilled to be able to talk to you about how we can prioritize and focus on the inclusion of marginalized, minoritized, and other hard-to-reach populations, or as many people in my line of work say, the hardly-reached populations.

What I'm hoping to do is to talk to you about how to make sure that you are advocating for this. Whether you are somebody who is designing research trials; whether you are participating; whether you are involved in the day-to-day operations and logistics, there's a role for everyone to play. And I'm going to give you kind

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of a whirlwind tour, and hopefully we'll be able to close any loops and gaps during the Q&A period.

I don't often like starting my talks with quotes, but sometimes the quote is just so good, and it sums up the problems just so nicely that you've got to start here. So this is a quote offered by Dr. Martin Luther King back in 1965 at the end of the Selma marches, where he said, "Of all forms of inequality, injustice in health care is the most shocking and inhuman."

While he was talking about the problems in access, the ongoing segregation and the separate but unequal care that many people were receiving back in the mid-60s, he was actually laying the groundwork for a much more serious and broader discussion of some of the concerns that kind of plague us today.

In particular, I think one of the things that we need to take away from this quote is the importance of thinking about justice in health care rather than thinking about it as a problem of lack of representation in clinical research or

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inequities. We're going to talk about that term "inequities" in just a few slides, but I really want you to focus on this idea of justice, which is going to be the heart of today's presentation.

Now, when we talk about clinical research and we talk about these marginalized, minoritized, hard-to-reach populations, you may think that the reason why we need to include them is because it is the moral thing to do; it is the correct thing to do. The problem with a moral argument in a highly operationalized, scientific enterprise is that it is hard to operationalize what morality looks like. Is it just a matter of trying to do the right thing or are we actually judged for doing the right thing at scale?

So let's try to think about the diversity problem through a slightly different lens. If we think about it as a scientific problem, it becomes easier to operationalize with our scientific practices. So if you think about the science, 1 in 5 approvals from the FDA over a period of about 5 or 6 years show that there was some sort of

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differential exposure or response just as a function of racial or ethnic group.

So imagine that. You're getting through all the trials, the first in human, the phase 2, and the phase 3. It goes up for FDA approval. The FDA approves it, and then you find out, kind of in this postmarket analysis, that it doesn't actually work the same for everyone everywhere, on the basis of something like race and ethnicity. That shows that we have a problem of generalizability and that the science is not quite as rigorous or robust, or perhaps as nuanced, as we need it to be.

Now, when we talk about pain management in particular, there's a rich history of difficulties of trying to make sure that we have appropriate diversity and representation in our research studies. Work by Karen Anderson did a really great selective review in Journal of Pain. We've got work by Carmen Green and others and Salimah Meghani. All of them really show that there's a rich history of a lack of diversity that gives way to some of the disparities that we see when it

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comes to pain outcomes.
Now, I think that the problem is actually a little bit more complex than that. It's not just the fact that we're seeing problems after FDA approval, we're seeing problems in terms of just overall diversity, but if we think about the actual research statistical models that we're building, if we have some sort of differential selection, or differential rates of retention or attrition in our trials -- let's say that all of the rich people are able to stick with our studies, whereas people who don't have as much money drop out -- that's going to skew our baseline estimates of causal factors, which means that we aren't quite as confident that our statistics are showing us what we think they're showing.
If we don't recruit representatively, what does that look like? The reason why I'm using this term "representative" is to distinguish it from diverse. Right now, the way that we are thinking about recruiting diversely is that we kind of have, again, this sort of separate but equal system where

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all of the privileged people will come in through our usual clinical workflow, and then the diverse people require some kind of additional outreach. So we'll go into community environments, whereas the more privileged population get recruited through a clinic. What does that mean if we do that? What does that do to our models?
I want to show you an example from one of the areas where I originally did my training, which is in Alzheimer's disease and dementia, looking at the change in risk. Don't worry if you're not necessarily very comfortable with Kaplan-Meier curves. It's not a big deal. What this curve is simply showing is the rate of progression of people who have mild cognitive impairment, sort of like a pre-dementia, and how they eventually convert or progress to frank dementia. The steeper the curve, the quicker the rate of progression is for individuals.
What you see here is a comparison between white people, in red, and black people, that are kind of represented in this bluish teal.

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Ultimately, what we know and what I'm going to say is, irrespective of looking at the slide, one thing that we do know for sure is that black people are about 2 to 4 times as likely as white people to progress to frank dementia -- we know that; we know that based on lots and lots of studies done over a couple of decades now -- but what you see here from this slide, it shows you exactly the opposite. It's showing you that the steeper rate, that faster decline, that faster rate of progression, is coming from the white group, not the black group.
So you might be thinking, "Okay, alright, Jonathan. Look, I don't know a lot about Kaplan-Meier curves. Maybe they just mislabeled it. Maybe this is supposed to be the black group; this is supposed to be the white group." It's not the case; I promise. I talked to the group that published this. They double-checked.
What's really remarkable is that this is one of the largest studies in that field, so this represents 6,000 individuals that have been tracked at 59 sites across the United States. So what is

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going on here?
The truth of the matter is that this is not comparing white people and black people. This is comparing that separate but equal system of recruitment that currently dominates our diversity efforts. So what we've got here is all of the white people are presenting to a memory clinic and all of the black people are coming out from community settings.
So the truth of the matter is that you're not really comparing apples to apples here; you're comparing apples and oranges. You've got a bunch of people who are presenting to a memory clinic, so of course they're more likely to have memory and dementia problems, whereas the black people, who we know are at a higher risk for dementia, are coming from a community setting, which is going to have a lower rate of memory concerns and the likely incidence of dementia.
What we have here is a problem, and this is a problem that we are likely to face if we continue our separate but equal method and systems of

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recruitment. We've got to be better than that; otherwise, we're likely to exacerbate these disparities while we're trying to claim to overcome them.

Now I want to talk to you a little bit about what we mean, or what I mean, specifically when I've been using this term "disparities." Historically, all differences between groups were kind of lumped into this single term, "essentialized or biological disparities" with an underlying assumption that that these differences between groups were inherent, that they were somehow immutable.

Nowadays, we understand that while there may be some, maybe, biological differences between groups, social inequities drives a lot of the differences that we observe. However, I think it's important to recognize that even this parsing leaves a whole lot to be desired and often puts the blame and the onus on the very groups that we're trying to rescue, that we're trying to save, those vulnerable underserved and marginalized groups.

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So what I've been doing, what I propose, is that what we actually think of as disparities looks a little bit more complicated. It looks a little bit more like this, and it kind of reconnects this work of disparities with domains where we as researchers have the ability and, frankly, the responsibility to assess model and limit.

If we use pain management as an example, what we historically thought of as racial differences to pain was initially inherent. We thought that some groups felt pain and some groups just didn't, and that's justifying all sorts of atrocities that are kind of littered throughout the history of the way that we treat pain and manage pain. But in reality, the difference in these groups is much more complex. So maybe -- maybe, just maybe -- there is some inherent difference.

But before we can come to that conclusion, before we can be confident in that conclusion, we have to think about selection bias, for example. So we have to think about those who we bring into our studies of pain management in the first place.

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And, obviously, in recent history that tends to favor much more privileged populations. And assuming we get past this period, we can't jump to assuming that the racial differences, or gender differences, or educational differences are inherent, that they're biological; we have to go through each of these steps.

So after selection bias, we have to think about measurements in terms of the validity of different pain-rating scales as they interact with culture and pain presentations for populations that are not well represented in research due to selection bias.

Then once we get here, there are also perioperative implementation biases in terms of how patients are prepped and how they're treated and cared for. And then, obviously, beyond that, there are additionally social inequities that leave some groups to have better or worse access to care and, of course, pain management in the first place. Then there are environmental factors that compound these social inequities that affect both chronic

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and acute pain.

So if, and only if, you can apportion a variance appropriately and tease out these other four buckets, and you still have some left over that explains the differences between groups, you might be able to conclude that there's somehow a biological difference between the two. However, most of our research, most of our work, most of our recruitment for research, it doesn't necessarily go through these very careful methods of analysis.

In order to contextualize what I'm going to be talking about next, most of what we think of when it comes to disparities are just lumped into these two groups and a little bit of this one. What I'm going to be highlighting is the opportunity to understand and address issues that may be related to selection bias and implementation bias.

So let's talk about why we can't recruit diversity or why we can't recruit representatively, which I think is the better term. It turns out that it doesn't matter what kind of work you do,

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what kind of research you're looking in, it really comes down to these top 10 reasons, ranging from lack of awareness of research opportunities; to limited diversity on study staff; different kinds of problems with selection and eligibility criteria; and the fact that people don't really know what they're getting out of it, so they have an insufficient return to value.

So the problem is not that we don't understand what the problem is. The problem is that, just like the questions that we just heard before, we have limited time, limited expertise, limited tools, and limited resources. How can we tackle all 10 when we've also got to do the study, and we've got to do maybe five or six other studies on top of it? For patients, how can we be expected to navigate all 10 of these barriers, in most cases, when we've got a whole life to attend to?

Now, what we do at my group within the CARE Research Center is we present this problem differently. Instead of saying there's a top 10 list of reasons, good luck in figuring it out, what

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we have done instead is we've tried to present this as a workflow problem, where you need to address earlier problems within the workflow before you can see downstream results.

So you can actually take this top 10 list of reasons, and then map them onto a very ordered workflow, which I want to just emphasize maps on very well to some of the talks that we've heard earlier about these pre-engagement activities, these pre-recruitment activities.

You need to start with identifying a sampling frame, so that's being very clear about who is eligible and likely to be interested in your study, and then you need to move on to making sure that you build clear awareness. In the previous talk, we heard a little bit about attending health fairs and going into churches. And that's not necessarily to throw a study at someone; that's to tell people why it's important to stay engaged with this stakeholder group, what research can do more generally, and then you start to build these processes related to engagement, and trust, and

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interest in education. And as you can see, you can map on all 10 of these lists of reasons to different aspects of this workflow.

So ultimately, you end up with this kind of recruitment funnel that really focuses on this problem selection bias. And what I think is really important to emphasize here is that everything that we think of in our research studies is in this red box. The other five stages of decisional stakes that patients and participants need to go through are usually not covered in our research protocols. So privileged people can dance through these other steps and jump right into our prescreening or screening protocols. Everyone else -- and I mean everyone else -- will usually get hung up at one of these stages, so we need to have a plan to address those.

So how can we start to do that? Let me give kind of broad advice. This is a paper published with a couple of colleagues of mine, Andrea Gilmore-Bykovskyi and Consuelo Wilkins. We wrote it about a year ago, and it was published in Trends

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in Molecular Medicine. It really talks about this problem of justice, and it focuses on six really crucial principles of research justice.

These are the things that you have to do in order to not only improve diversity, and recruitment, and inclusion in your research studies, but to really serve justice, to truly empower and focus on the marginalized, hard-to-reach, hardly-reached populations.

What we have here is first a problem of data fidelity. You have to strengthen regulations around reporting and compliance and transparency because we don't fully know the scale of the problem, because when it comes to trying to identify and track how diverse and representative our studies are, there are usually a lot of holes, a lot of gaps, and relatively poor data fidelity. I think we also need to identify, measure, and systemically address exclusionary research, and of course that means an end to ongoing research practices that are unethical or ethically gray, or, frankly, out-and-out abusive.

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So we have to recognize that the problem is we often tell ourselves that science is objective, so we assume that because we are doing science, we, too, are objective, but reality is that it's just the opposite. Because we are flawed and subjective in our reasoning, that waters down the quality of our science.

We have to make sure that our assessments and our measures aren't necessarily validated on highly biased samples. We have to make sure we're taking a hard look at lots of research practices that we don't even question.

Like, for example, many of our research studies have a de facto English language requirement. There is nothing about speaking English that gets in the way or that contributes to our scientific enterprise. So if we are, without even asking a question, assuming that all of our research participants speak college-level English, then we are diminishing the quality, the reproducibility, and ultimately the rigor and the integrity of our research science.

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So we have to move beyond proportional representation, not just for races, different races and ethnicities, but thinking a little bit more broadly beyond that.

But if I do have to make one comment on race, I'm going to take a strong stance here. And again, this is something that many researchers haven't even questioned. We must stop, ending our basis, for using whites as a referent group in our research models. Frankly, there is very, very little utility to including race as a variable in our research. It's good for helping us understand our demographics, but it's of limited value elsewhere.

I know that's a bit of a hot take. I'm happy to talk about that in the QA. But I want to get to the other three elements of trying to serve justice in research opportunities.

We also have to think about building sustained reciprocal relationships with marginalized communities. That of course means that the key goal is to stop centering research

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goals on individual researchers and the larger institutions that work with it. That means focusing on patient-centered outcomes, but also patient-centered partnerships; ensuring that patients have the opportunity to design not just a secondary or tertiary outcome in a research study, but that they have an opportunity to design the whole thing.

If we don't need to have a study visit every two weeks, is there any way to consolidate those study visits? Is there any way to think about measuring what the participants' experience has been like, especially in pain trials where there is often a huge placebo effect, for example? Understanding what the participant is going through, what their subjective experience is like, and using that to improve the fidelity of our research studies isn't just good for the participant. It's not just good for the patient; it's good for us as research scientists.

So by building these reciprocal, mutually beneficial relationships with marginalized

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communities, we can really start to serve justice while also creating a much higher standard of science.

This is, frankly, a note to self, of anything. We need to recognize that there are multiple sciences here of research participation and inclusion, and we've got to start addressing them. We need to think about the mechanisms that govern study design, that govern recruitment, engagement, retention, things that we don't spend enough time thinking about as researchers.

We need to ensure that we take the responsibility to address those research barriers. That top 10 list of research barriers I highlighted earlier is not a suggestion. It's not a list of something to get to if you have time. And it's certainly not something that we need to be putting the onus on our research participants to navigate.

Then finally, we also have to recognize that there is an indelible connection between research and health inequities. Without serving justice in research, we will not be able to solve health

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inequities. It is more than just including race as a term in our multilinear model. We have to make sure that we start to build an infrastructure.

There was a question earlier about how do you support this deep level of community engagement and participant engagement if nobody's going to give you any money to do it. The best way to do that is to build larger systems that are a bit more thoughtful and inclusive.

Actually, I do have a good example of that. I'm running a little bit low on time, so I'm going to skip past this example of looking at pragmatic trials, and instead talk about what we're doing now in a large investigational clinical trial network that's called EPPIC-Net, that looks at phase 2 pain studies. What we do is try to build an infrastructure for the individual studies that are coming through the pipeline within this large clinical trial network, and that means being really creative with funding, as Bob Dworkin can attest since he's one of the PIs.

But I think you have to understand that it's

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not just about doing one thing. It's not just about going to a black church, but it's about engaging in processes that build awareness, so having a brand identity campaign; having a website; being present on social media; ensuring that you're cultivating local partnership activities that serve community needs and community interests.

When you have a site-selection protocol at the study design phase, make sure that you're selecting sites that are able to reach out and engage with diverse communities, rather than just engaging with name-brand academic medical centers or the friends that you went to graduate school with.

Now, when it comes to the other aspects of this recruitment funnel, making sure that you have detailed recruitment and feasibility guidelines that help ensure that you're not screening out any population that's underprivileged.

Ensuring that you're including the patient voice, for EPPIC-Net, we've got the patient voice at two levels. We have an overall patient advisory

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board that helps us navigate to the operations of the network as a whole, but then for individual research studies that are coming through that network, we incorporate that patient voice again to review the details of each study to say this is going to work, this is not going to work; and hey, if you're going to be looking at this particular pain indication, this is how I would know if it was working for me or not.

So by making sure that you're incorporating the patient voice, not as an afterthought, not as a one-time activity, but continually and at multiple levels of design, you'll be able to take a look at that.

One of the future aspects that we're going to be doing within this network is doing a retrospective analysis on how burdensome the study was. We'll be looking at individuals who dropped out of the study, as well as those who stayed in, what was hard, what was easy, and what was worthwhile.

So again, focusing on what is valuable to

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the individuals who may be benefiting from this research, either directly or in the long-term, is the best way to ensure not only that you're centering that voice, not only that you're achieving those levels of diversity and inclusion, but also so that you're doing damn good science.

Ultimately, I think that out of all the words that I've said, the best way to sum up is something that MC Hammer wrote himself on Twitter back in February, which is simply that, "When you measure, you need to include the measurer." And that is the best way to sum up all of my advice here. That is how you truly include a diverse and representative population.

Alright. Hopefully, there's time for at least a couple of questions, but thank you for your time.

Clarifying Q&A

MS. VEASLEY: Thank you, Jonathan. That was terrific.

John Farrar, you've got a question for Jonathan?

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DR. FARRAR: Yes.
Jonathan, great talk, and very important. I think the Alzheimer's slide that you showed is one of the best examples I've seen of something that people have begun to worry about, and I just wondered what your thoughts were. I have seen very few studies that actually comment on the selection bias of access to care in the large database studies that are now being done, and it has been a been a significant concern, and it sounds like it really ought to be.
I just wondered what your thoughts were on that issue. The differences between race, and socioeconomic class, and so on, depend on whether people actually access care adequately to be recorded.
DR. JACKSON: I have a lot of opinions, a lot of very loud opinions on this topic. I think ultimately what we're going to have to do is that there's going to ultimately be a step change in the way that we think about differential and different aspects or different orthogonal levels of selection

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bias in our research studies.
I think that it's going to take a few years for this to settle. It's going to take a few years for this to move from disease area to disease area. But ultimately, I think we're going to look back on this time the way that we look back on scientific studies from the 1940s, which is it's interesting, it's an idea, but there were a lot of things that they didn't realize, so we're going to have to do some of that stuff over again.
In the meantime, there are some short-term steps that we can do. Epidemiology in particular has developed this concept of transport tools or transportation tools. So inverse probability weighting, G-estimation are really great bridge measures that I think will become much more common, especially as our sample size gets a little bit bigger in clinical trials, and they can be much more robust to things like inverse probability weighting.
IPW, just as a quick example, takes this idea of saying you've got like maybe a couple of

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people that belong to this particular group or identity. Can you extrapolate from those and impute as though you had a representative sample? So it's not perfect, but it is a really great measure of data imputation, and it's something that I'm hoping to bring to EPPIC-Net next in the near future as kind of an estimate.
But I think that's going to be our immediate next step, so using some of these transportation tools to do a retrospective analysis to see if these studies actually have this problem of sampling bias that affects their causal reasoning. But in the long term, I think we're going to have to start to build in protocols that think about these things far earlier in the process than at the stage of peer review, or after peer review, which is the state right now.
DR. FARRAR: Thank you.
MS. VEASLEY: Thanks.
Isabel, you have a question?
MS. JORDAN: Hi. Thank you. That was a great talk. I really appreciate it.

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One question that I have, and something that I've been thinking about a lot, is that when folks generally talk about hardly reached populations, it often gets missed, disability as identity, and that as a population, we're often overlooked and are intersectional with a lot of other populations, and just are often missed as a separate group, and I'm curious about your thoughts on that.
DR. JACKSON: You know, I don't think I could put it any better than you put it. I think the disability community is almost entirely left out of these conversations, and I think it's a real shame because what I think is that the disability community is the perfect way to highlight not only the intersectional aspects that are really crucial when it comes to studying these things, but also the fact that there are often overlapping conditions or morbidities that effectively bar this group from participating at all under this guise of very paternalistic reasoning that it's for their own good.
That kind of highlights the central concern

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of clinical trials, is that we think about the risks of inclusion, but we never consider the risks of exclusion. I think a classic example of this -- just to kind of go a little bit outside of your question and then come back -- is the way that we've been thinking about the COVID-19 trials, where we excluded children and we excluded people who were pregnant, to the fact that there was very, very confusing advice and a much longer extension to the pandemic because we only thought about the risks of inclusion, and we had to kind of grip with the risks of inclusion as a society.

Now, with the disability community, we have this very paternalistic concern about the risks of inclusion, but there's no society to grapple with the risks of exclusion because society in general effectively erases disability as any kind of issues.

I'm getting on a soapbox, so I apologize. But I do think that this is an enormous problem, and I think it highlights kind of the diversity within individual communities. So there's no way

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to talk about a canonical or a standard disabled person, but you also can't talk about -- a canonical or standard -- a woman, or a black person.

So I think if we can do a better job of centering the disability community, it will help us understand how to grapple with all these other groups that we're trying to include in research studies that we tend to reduce to monoliths.

So I don't have any great suggestions, apart from being really thoughtful, about our inclusion and exclusion criteria in particular, but also thinking about especially the built social and structured environment that's required to access research studies.

The pandemic brought with it a lot of opportunities to re-examine that, and I think that we've done a very haphazard job of thinking about decentralized or virtual trials, and thinking about effectively democratizing or spreading access to research studies that are a bit more thoughtful and a bit more inclusive.

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So I think that there's a lot of work to be done, and I really, really hope that if we can start to center the community of individuals who are disabled or living with a disability, it will help us unlock some of these other problems that feel so intractable.

MS. JORDAN: Thanks.

MS. VEASLEY: Jennifer, do you have a real quick question before we move on?

DR. GEWANDTER: Well, mine's not super quick, so maybe I can ask him in the next part.

MS. VEASLEY: Are you going to be able to stay with us, Jonathan, until the end of the day, or do you have to jump off?

DR. JACKSON: I will be able to pop in and out, but I should be back for a little bit later, yes.

MS. VEASLEY: Well, why don't you ask it, then, Jennifer, so we have plenty of time for discussion later. Go ahead.

DR. GEWANDTER: Sure.

I guess my question is, I liked your

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framework where you used all these different places that we can possibly intervene, instead of just thinking about this as general disparities in biology. But from a practical perspective, trying to find these underserved populations in the clinic isn't going to happen.

So I guess my question is, as you said, we shouldn't put race in the model. So do you think that part of the solution is putting other things in the models, as well, or different things that are more representative of our actual selection biases versus race as a kind of marker of that?

Is that one of the ways you think we can address this problem, at least in the more shorter terms? These systems are not going to change overnight, but we want to try to address these problems quicker than just that bigger change.

DR. JACKSON: I think there are kind of two answers to your questions. Number one, race shouldn't be in our models because I think, 999 times out of 1,000, we are not trying to say that the amount of melanin in someone's skin has

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some sort of differential effect on our outcomes.
Race is almost always either a kind of a data reduction tool or a proxy for something else, but it's not a great proxy for any of those things. So instead of using it as a substitute variable, let's just actually measure the things that we think are the drivers of that.
Now, the second thing is about trying to drive recruitment to our research studies. I think we need to think beyond the clinic wherever we can for research studies, but the bigger problem is that we try to, again, sort of reduce groups to monoliths. So we assume we're going to get like our regular population through the clinic, and then we're going to try to diversify by reaching outside of the clinic. And we sort of assume that maybe all of our people of color will come from some other setting.
Now, that's going to set you up for the kind of data that I showed earlier from Alzheimer's disease, where you end up comparing apples and oranges. Instead, we really need to be thoughtful

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about how to be more inclusive in our research studies from the very beginning.
Early data from my group really shows that it's not just one bubble that we're trying to pop here, but there are usually like two or three bubbles. So it turns out that most of the time in our clinic settings, we can get some semblance of that diversity that we're looking for -- maybe not all of it, but at least some of it -- so then we can start to implement models like I was talking about earlier, inverse probability weighting and G-estimation, to help bridge the gap the rest of the way while we're trying to work on these larger structures to be more inclusive in the first place.
So it's sort of a three-step solution in order to try to address this. But the bottom line is that using race as a variable in our research studies is not going to help us. We're really going to regret this. It's going to be like a bad haircut that we got in high school in 10 to 15 years time.
DR. GEWANDTER: Thanks.

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MS. VEASLEY: Thanks so much, Jonathan. I hope you're able to join us later on for some discussion.
So we're going to move on to our next set of speakers. We have Dr. Kathryn Martin and Lynn Laidlaw, who are from The Institute of Applied Health Sciences at the University of Aberdeen, all the way from Scotland.
Go ahead.
Presentation – Kathryn Martin
DR. MARTIN: Lynn and I are very, very pleased to be here today and choose to speak with everyone about the how tos, I guess, of incorporating patient partners in the conduct of clinical pain research. Lynn had reminded me earlier about the great quote by George Bernard Shaw, "The British and Americans are two great peoples divided by a common tongue." This is really putting the onus back on the importance of terminology.
It was noted yesterday, so I'll just briefly mention that today in our presentation we'll be

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using the term "patient and public involvement" or PPI, and we are following the NIHR involved definition of this as we conceptualize it as unique and different from participant, participation, or engagement.
Lynn?
Presentation – Lynn Laidlaw
MS. LAIDLAW: This slide comes from a paper that was published this year called, More Than a Method, which discuss productive tensions, and, crucially, it was co-authored by some patient partners. We really like this because it just represents that patient public involvement isn't a tick box; that patients should be at the axis from which activities evolve from. So it's a fluid process. It's a changing dynamic. It's not an absolute, and, crucially, it's not a method.
So therefore, you can't just tick off a list of patient public involvement and consider it involvement. There's no minimum, no maximum, and it's context-specific and value-specific as well.
DR. MARTIN: We must, really, at the start

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here think about the values that are forging the foundation, that true north of patient and public involvement. We believe we should be involving people with lived experience of chronic pain for the right reasons. We have to do this for the right reasons.

We want to approach this first with the commitment of equality in the relationship and be mindful that the power imbalances that can emerge between researchers and patient partners are ever there, that could bubble to the surface. So we want to consider the importance of truth and honesty of working with patient partners to ensure that there's a certain level of transparency across the working teams about all the research aims and the activities that go in there. This was noted earlier. Gail and Karen talked about this level of truth, transparency, and trust.

Inclusivity we believe is of utmost importance, such that patient partners are involved in and about all of the aspects of the research and not being constrained to just tokenistic

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activities, as this tickbox exercise, if you will. Rather, we believe that the opportunities should exist for involvement across the project, from establishing the methods and the primary outcomes, all the way through to data analysis and manuscript preparation.

We think that space should be dedicated for an idea exchange, allowing the patient partner the ability to act as a critical friend. And from this very critical element, trust, it can flourish and continue to support the establishment of good working relationships.

We think that an important part of the team's core values is always to be mindful of the human experience, and indeed all people are maybe more than their level of experience however they bring that, from a research perspective or from a lived experience. We do think it's important to avoid boxing people in and only see them as one thing or another. This is especially so of people with lived experience of chronic pain.

We think that each patient partner is unique

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in their own experience, and for many, it might be even a complex medical and personal journey complete with the emotions that have brought them there to become involved in research in the first place. So while we have identified these values as central to patient and public involvement, we think that there shouldn't be a set list of right or wrong values. Instead, it has to be a collective identification of these values from the team to ensure that there's buy-in and to ensure that involving people with lived experience of chronic pain is not and should not be purely transactional.

MS. LAIDLAW: Thanks, Kathryn.

So we've heard earlier from Karen and Gail that involving patient partners at the beginning with the planning of research is so important, but likewise this must continue once funds have been identified and the research begins in earnest.

This can bring into focus what is most important to people living with chronic pain. Where many of the methods may have been established and identified during the planning process, people

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living with chronic pain should be involved in the identification of primary outcomes. These need to be meaningful to people living with chronic pain and sensitive to change; otherwise, we would suggest that the studies are disadvantaged from the outset.

The kind of idea of rubbish in/rubbish out makes a lot of sense to me in this because if you don't ask the right question, it doesn't matter how sophisticated your methods are and how wonderful your research team is. If you don't ask the right research question, one that's meaningful to people living with chronic pain, then I would question how successful your research has been.

A real-world example of this is a study that identified the primary outcome for people with chronic pain as being able to exercise for 30 additional seconds on a treadmill. And while this may have scientific merit and the rationale for being chosen, how meaningful is it for that person living with chronic pain?

The same goes for these 6-minute walk tests

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or walking up the stairs. And perhaps the question is not can it be done, but what is the impact afterwards on the person living with chronic pain and how long the recovery is?

People have spoken about how patient partners must be consulted on study activities and thinking for the timing of the clinic visits and activities that might take place. A lot of time when I'm in conversation with researchers, it's like, "Oh well, people are coming to the hospital anyway, so we can just ask them to do this and that, or we don't need to pay for their traveling expenses." To me, that just makes it a bit transactional because I think you should always offer travel reimbursement and meals and snacks to ensure people's comfort, and all these elements impact recruitment and retention.

I think in methods, there are some real productive tensions here -- isn't there? -- between what's measurable versus what's meaningful. Do we only measure what's measurable, not what's meaningful to people? When we're using things like

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forms or validated questionnaires, what do we mean by validated and from whose perspective? Because often these weren't validated on diverse populations. I think chronic pain and questionnaires around catastrophization can be seen as patient blaming, and can be really tricky.

Finally, in ethics, in the UK we're moving towards a situation where research teams may not get ethical approval if they can't demonstrate that they've meaningfully involved patient partners or members of the public when designing or developing the research project, and that's certainly something that I would support.

Over to you, Kathryn.

DR. MARTIN: Thanks, Lynn.

Following then from the methods, we really want folks to be thinking about the data because we do believe that researchers should be working with patient partners in this area. But it's often an area where patient partner involvement can be overlooked and certainly may not be considered easy or as streamlined as it could be.

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Data collection, analysis, and sense-checking activities really can enhance the research, study findings, and the contextualization of that, but it does require a certain level of commitment on the part of the researchers, as well as patient partners, because both groups need to overcome biases that might be associated with being involved with the data and the handling of that.

Beyond having patient partners maybe pilot paper electronic surveys to ensure the acceptability and accessibility of instruments, and instructions even, as well as understanding how long it might take, for instance, for a participant to complete it, it's really an instrumental element of patient partners picking up on logistical issues and things like skip patterns and things that don't make sense once someone with lived experience is going through it.

We do think the patient partners should be considered in joining, say, as a researcher in some of the steps of the process of running a study, and they might even be open to helping to collect data.

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For example, they might undertake training to actually conduct qualitative interviews and think about, say, focus groups. They might actually become involved in data analysis and helping the researchers look for patterns of missing data or even undertaking thematic analysis of collected qualitative data.

Finally, the sense of sense-checking exercises and discussions with patient partners really can help the research team put the data into context. A master student working on a research project with me recently, we did a sense-checking activity with individuals, and it was just absolutely fantastic to see their interpretation of the data and get them formally involved, the patient partners formerly involved with the data. We don't want people to be limited by lack of thought or imagination, and careful reflection of where that can happen is important.

There are a number of resources in journal articles discussing how to build patient partners into this process and how to involve

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multidisciplinary people on teams. Nicola Gray has written a really wonderful piece, and then Louise Locock has written a really great piece about having analytic conversations with patient partners.

I'll just leave for this slide that there's a patient partner in Birmington [ph], Margaret O'Hara, who has a real web presence on Twitter, and she's always a very big advocate of checking your models and getting patient partners involved in that analysis, because the more perspectives, the stronger the relevance will be back to people living with chronic pain.

MS. LAIDLAW: Thanks, Kathryn.

I think we can all agree that communication is really important. People want to participate in research. A lot of people have altruistic motives for doing that, but with the best will in the world, people are not going to participate in your research if you make it too burdensome. I think we've heard a lot today in terms of involving patient partners in that, that your communication

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should be culturally competent and sensitive.

I just wanted to speak a bit about the participant information sheet. The question I would ask is whose participant information sheet is it anyway? Do we tell potential trial participants what they want to know, or what we want to tell them, or think that we should know? I think the issues here are do we need an 18-page participant information sheet? How can we ensure that there is informed consent if people can't understand the information that they've been given? Have participant information sheets become legal documents and people become covering themselves, rather than what they should be, which is a fundamental part of the ethics process?

It's really challenging. I understand the challenges here. I understand that there can be pushback from sponsors and legal departments, but I think it's something that we've got to get right. In the UK, the Health Research Authority has distinct ethics, and the work package at the moment -- which I'm involved in -- and one of the

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work streams in that is to look at participant information sheets and to try and do better.

If there's not clear communication about the expectations put on participants once they agree to take part in research studies or trials, misunderstandings can exist, and participants may not be a hundred percent sure of what they signed up for. In fact, research by Katie Gillies and colleagues in Aberdeen has indicated that people often drop out of research because dates and expectations are unclear, and some people didn't even know that they dropped out of research.

The final thing I would say in communication is that it's so important to keep people updated throughout the study and also with the results, because to not do so is actually, I think, quite rude. I know that I wouldn't participate in research anymore that won't tell me what the findings were. I think that this can leave people feeling used and that researchers are dismissive of their human experience.

The next this is emotions and feedback, and

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this is, of course, tied to communication, but we felt it was deserving of its own space. I encourage you to think about emotions as they relate to everyone on the research team. Patient partners, particularly those living with chronic pain, are bringing their whole self to the discussions, and sometimes individual responses can impact on everyone. That's why we need regular meetings, and email communications are essential.

It's about creating time and space, safe space, for reflection and opportunities for receiving and providing feedback to one another. I know that we think researchers are babies -- don't we? -- and then if some people tell us our baby is ugly, that can be really difficult to hear sometimes. But it's vital that patient partners feed back to the research colleagues and that researchers are able to accept that feedback. Again, this harkens back to the values underpinning patient public involvement, ensuring space for challenging discussions and promoting critical thought, but done professionally.

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DR. MARTIN: Thanks so much, Lynn.
This is an important area, I think, to think about, and certainly I had raised it earlier. I know in my role here as champion PPI in Aberdeen, this is always at the forefront of a researcher's mind.
It's really important to think about costs because involvement is not free, and then there's this power dynamic that's inherent even in the way that we discuss this as researchers and with our patient partners. Terms like "payment, reimbursement, or a thank you," these all come up, and words matter. I personally like to use the word "renumeration" [ph]. It's I guess what I prefer, but offering renumeration is a way to acknowledge that time is valuable to those individuals living with chronic pain who wish to take part in research. A lot of individuals may have left employment due to their health or their condition, and those funds can really help to facilitate involvement, particularly from those who are seldom heard in research.

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So what's the right amount? Everyone always wants to know, "Well, how do I cost this in and what do I do?" There are, at least in the United Kingdom, guides of how to cost for involvement to ensure that patient partners are being renumerated appropriately, and consistently, and fairly for their time and resources.
Planning involvement activities and costing those in is, again, essential to ensuring that there are funds available to undertake meaningful PPI. Less so are funds available for the earlier initial planning stages, although that's not necessarily what we're meant to cover here. But really, money is always essential, isn't it?
I think we can facilitate involvement by ensuring how patient partners maybe have a choice in how they'll get renumerated. Sometimes outlaying funds to travel to meetings may mean that they can't attend, so it's important to think through the study timeline and identify when and how patient partners might be contributing, whether there will be any costs that they have to bear

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initially, and trying to proactively plan, and make that process as easy as possible so they don't have to front that.
We have found that bank transfers can be really challenging. Some patient partners might not have access to a bank account, and offering cash is not always a lot of institutions, so vouchers, or gift cards, and pre-loaded cash cards can be a viable solution. But even involvement comes with tax obligations that could threaten government benefits for some patient partners, at least here in the UK. So there has to be an open conversation about the true cost of involvement between the patient partner and the research team to make sure we can facilitate that involvement whenever possible.
I think it's really important here to highlight that there are so many other ways to facilitate involvement beyond cash, or gift vouchers, or payments; not that they should be in lieu of, but they can go along side of it. For instance, ring-fencing funds for computing, Wi-Fi

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isn't free, so that cost is borne somewhere else. A lot of patient partners that we work with have Page-Go [ph] telephones, mobile phones, so they have to do a top-up for their connectivity. If they're using it for involvement activities, they can't use it to speak to friends, or family, or their work, and thinking about purchasing computer or other techware that could be useful to them.
The other thing, it goes for electricity costs. If people are on prepayment electricity meters, thinking through that they need to use their electricity for involvement, we may have to compensate in addition to that as well.
Thinking through other things like honorary university staff positions can allow for patient partners to have access to things like email accounts, even Microsoft Office Suite, things we take for granted as researchers as being linked in with universities. This could be especially useful for accessing software, things like teams meetings that, at least here in Aberdeen, is our preferred method. We're not allowed to use Zoom because of

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security reasons, so other patient partners find -- I know Lynn does -- that it's very difficult to attend meetings as an external attendee.

So sometimes we have to make sure that we provide training about systems and setting aside funds for other trainings, and even attending local, international, or national conferences wherever possible.

MS. LAIDLAW: We encourage you to think cake, a fruit cake to be precise. A lot of good work often gets done over a fine cup of coffee and cake, and this speaks to the relational aspect of working with patient partners. Really, at this moment this is what we feel is missing during these virtual times, but also because this image of the fruit cake will help reinforce the importance of baking patient and public involvement into your process and into your research because it can't just be added on the top like icing on top of the cake.

Careful consideration needs to be given to

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all these elements because funding agencies support tokenistic activities, I think especially in the UK where patient partners are increasingly doing grant reviews and sitting on funding subcommittees. When in doubt, seek help. Admit that you don't know how to do it and ask for help.

We'd really like to stress that patient and public involvement is not a methodology; rather, it's a carefully constructed set of relationships, and it's about conversations, and it's about collaboration, and these need to be nurtured. No one will care about your research more than the people living with chronic pain because research is hope. If I didn't feel that the unique insight of patients could help, then I wouldn't waste your time, and I wouldn't waste mine either. The impact of research mixed with policy can have a major impact on people's lives and their well-being, and that's why this matters.

DR. MARTIN: As Rachel mentioned yesterday, the Advanced Pain Discovery Platform is a five-year, $24 million pound initiative funded

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through the government's Strategic Priorities Fund, and it's delivered in partnership through a number of government funding agencies, the charity, Versus Arthritis and Eli Lilly.

This is something that I wanted to highlight because this is a project, a consortium, that Lynn and I are working on together. This is the PAINSTORM. This is the Partnership for Assessment and Investigation of Neuropathic Pain: Studies Tracking Outcomes, Risks and Mechanisms. Within this consortium, we're seeking, through a program of work, to look at individuals living with or at risk of neuropathic pain; improve the way that neuropathic pain is assessed; how it impacts on daily life; how it's measured; and to learn more about genetic risk factors using biomarkers, tissue samples, and imaging to better understand the mechanisms and to think through about maybe developing causal models of psychosocial risk factors; so seven work packages, very in-depth.

We have right from the start engaged with four patient partners -- Lynn is one of them -- who

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are living with neuropathic pain from different health conditions.

Lynn, do you want to come in and say a little bit more about how -- well, you've been embedded into the process from early on when we were initially starting conversations about submitting a grant proposal for this, but how things have gone and involvement to date?

MS. LAIDLAW: I think we've had some productive tensions, haven't we? We've had some challenging conversations, and I think that the patient partners have got in about, as we would say in Scotland, the grant application before it was submitted, and obviously so excited that we're funded.

I think that we have made a difference because we've been allowed to make a difference. Some of the things that we've changed is just the recognition that there's been very little qualitative research on people's lived experience of neuropathic pain, so we've brought that in. We've brought in some different patient cohorts,

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and one of the patient partners proposed a series of podcasts, and we're being really keen for the research team to adopt some creative methodologies and whatever, as well. So I think it really has been a partnership and a collaboration, which has been fantastic.

DR. MARTIN: Watch this space, right?

MS. LAIDLAW: Yes.

DR. MARTIN: We're just on the beginning of this for your journey, so there will be lots to talk about and meetings to come.

We have some further readings, as we mentioned throughout the presentation, additional studies and research, another blog from Simon Stone, and things that folks might be interested in as they carry out their research.

The final slide, I love Rodin's Thinker, and it's a nice picture to encapsulate this idea of let's keep thinking about how we involve patients in chronic pain research and pain research in general, and thinking of ways that we can do that. Lynn is prolific on Twitter. She's amazing.

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Follow her. I'm a bit more analog, if you will. Just send me an email if you want to stay in touch.

I think, overall, we don't want anyone to think of this as a process and that there's any one set methodology, but rather to actually stop and think of the different stages of conducting research and where patient partners can be embedded, utilized, and brought in to make things much stronger and robust. So there we are. Thank you very much.

Clarifying Q&A

MS. VEASLEY: Thank you both. That was truly a terrific talk.

Simon has his hand raised very quickly, so I'll let you ask your question.

DR. HAROUTOUNIAN: Yes. Sorry for the premature hand raise. Kathryn and Lynn, thank you for the fantastic presentations. It was really insightful.

Kathryn, when you were talking about involvement across the process, you did mention that it's important to involve patient partners, or

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PPI, in the section of data analysis as well, sort of interpretation, and this has been a somewhat controversial point where people have been arguing back and forth.

I was wondering if you have perhaps some examples of how to meaningfully engage patients in that specific area of data analysis and potentially interpretation.

DR. MARTIN: Sure. The two papers that I mentioned that are there -- I think ultimately you're so right. I think it's about coming away from our biases of giving over control, but it doesn't have to be here's a data set; now go off and do it. I think it works really well when you actually are able to have that conversation and plan out the analysis, and are these the questions we should be asking. It sort of goes back to that planning phase and setting your aims and objectives, but getting individuals involved at the different stages.

We've talked a little, Lynn and I, about qualitative work, and when the researcher goes

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away, to actually think about developing and reading through the interview guides and the data that come from interviews.

The themes that emerge might be all generated by the researcher, so it would actually be interesting to then go back to the individuals themselves, to the patient partners, or even participants for that matter, and go back and say, "These themes that we've generated from your data, were these accurate? Are these themes relevant? Do you see the same themes when you read the transcript guides?" and getting individuals and training them to do some research alongside us.

Lynn, do you have any good examples?

MS. LAIDLAW: I've used the analytic conversations method with Louise Locock. I've been funded to do some patient light research, a small piece of qualitative research, and we have recruited a patient advisory group who's going to be helping us with the qualitative analysis. We're using a framework approach, and they're going to be helping us build the framework as well.

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Actually, I talk about some of the pushback that I've had from researchers when I have volunteered to help with the qualitative analysis, and it's been suggested that patient partners come from a position of bias. But I would say that everyone comes from a position of bias.

What sometimes feels really uncomfortable to me is that if I'm participating in the qualitative interview, I give my insights, and then researchers take that away, and they analyze it using frameworks that have no meaning for me. And they assign meaning to what I say, and that might not be what I meant. I think if we're looking at robustness, for want of a better word, it's about completing the circle, and to make sure that we're not missing anything.

DR. HAROUTOUNIAN: Thank you so much.

So is it a notion that data analysis might be uncomfortable for patient partners? Is it just a paternalistic sort of view that researchers might hold, rather than truly involved in that meaningful conversation and being open to hearing what the

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patient partners actually think about that?

DR. MARTIN: Absolutely.

MS. LAIDLAW: Yes.

DR. MARTIN: Sorry, Lynn. We're in agreement there.

It's interesting. In a recent patient partner group I was at, folks said, "We really want to be used wherever we're most useful." You will undoubtedly get different patient partner groups, whether they're advisory committees or whatnot, and people from all sorts of backgrounds and all sorts of interests. And they bring with them their own experiences, their own expertise, and their own interests.

Some people won't touch data with a 10-foot pole, but others might be interested or intrigued. And actually, if you sent them on a statistics course, and they were interested in learning and wanted to work alongside some of the researchers, then surely that is a wonderful opportunity to work with patient partners in a way that is meaningful and beneficial to everyone.

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I don't know how many people want to sit and learn data, but I think that we could harness our patient partners, and experiences, and expertise in a way that maybe we haven't yet because we've been a bit uncomfortable with that.

So again, Lynn, don't you think that that's part of that pushback in the conversation, that it's going places where maybe we haven't always gone?

MS. LAIDLAW: Absolutely. I think this speaks to sometimes patient public involvement in research is a bit transactional. I just always want more. I'm just one of these people that always want more, and I just want to push back. And while I'm happy to look at patient materials and whatever, if I'm being asked to comment on a document that's already written, that's just moving words around the spreadsheet when actually I don't want barriers put on my involvement. And this is why it comes back to these conversations, the relationships, and the collaboration.

In honesty as well, if you can't

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involve -- I need to know what I'm signing up for. If you only want me to become involved in a participant information sheet, then tell me that at the start, and then I can have some choice over whether I become involved or not. But I wouldn't be interested in working on that basis.

DR. HAROUTOUNIAN: Thank you so much.

MS. VEASLEY: Yes, that's a great point, Lynn, about trustworthiness, transparency in the process, and bi-directional communication, and continued communication. So thank you both, again, for a really terrific talk.

We're going to move on to our last talk of the day, and I'm really pleased to introduce Dr. Christine Chambers. She and I met about four years ago at a Banbury conference, and I just have to say that after about 25 years of being involved in science meetings, she was the very first scientist that I ever heard talk about anything past the point of actually publishing a scientific paper and talking about actual dissemination or implementation efforts of the research that's

coming out of her lab and others.
She's the professor of psychology, and neuroscience, and pediatrics at Dalhousie University, and her partner Isabel Jordan is the strategic lead for patient partnerships within her lab. So I'm really pleased to introduce both of you.
Presentation – Christine Chambers
DR. CHAMBERS: Thanks, Chris. It's great to be here and really appreciate that kind introduction. Thank you again for inviting us here today to talk about meaningful and active patient engagement as part of the dissemination and implementation phase of clinical pain research.
Before we start, we would like to offer land acknowledgments in Canada. A land acknowledgement is an act of reconciliation that involves making a statement recognizing the traditional territory of the indigenous people who called the land home before the arrival of settlers, and many cases still do call it home.
So I'm speaking today to you from Halifax,

Nova Scotia, Canada, which is located in Mi'kmaq, the ancestral and unceded territory of the Mi'kmaq people.
Presentation – Isabel Jordan
MS. JORDAN: And I'm speaking to you today from the traditional unceded territories of the Squamish people, also known as Squamish BC, where I'm grateful to live, learn work, and play.
DR. CHAMBERS: First to introduce ourselves, as Chris mentioned, I'm a clinical psychologist and health researcher who has studied children's pain management for over 25 years. My focus has been generating new knowledge on the role of families and a variety of psychosocial factors in children's pain, with a particular interest in what parents say and do and how that influences children's pain experiences.
I lead a research lab that's based at our local children's hospital, and I also serve as the lead of a new federally funded national knowledge mobilization network that launched in 2019 called Solutions for Kids in Pain, also known as SKIP.

SKIP's mission is to improve children's pain management through coordination and collaboration. So in addition to the work that I've done generating new knowledge as a scientist in my research lab, I'm also committed to mobilizing it through SKIP.
Just of note, in 2020, I took on a new role as scientific director of one of the 13 institutes of the Canadian Institutes of Health Research, which is the Canadian version of NIH.
MS. JORDAN: I come to this work from a background of lived experience. I have two kids, both of whom have chronic pain. Twenty years ago, my oldest, Zachary, was born. When he was about a year-and-a-half old, we started on a diagnostic journey to learn why he wasn't developing like other kids. This was a path that kept us deeply embedded in a health system where he didn't fit in, where our roles became that out of advocates, care coordinators, and researchers to try to figure out what was going on.
As we traveled between clinics, and

specialists, and systems of care, we had a unique view on the gaps and enablers while we were learning on our feet; and sadly, most often we learned after the fact, as in after we found the gaps that caused harm. Eventually this led my husband and I to be co-founders of the Rare Disease Foundation, a national foundation in Canada, where we collaborated with other parents, clinicians, and researchers to share our knowledge to improve the lives of those with rare disease, and eventually led me to work with researchers as a person with lived experience across the country.
DR. CHAMBERS: So you might be wondering how we met. We actually met online through our Twitter feeds early in 2015. I was using social media to share my research, and when I started my It Doesn't Have to Hurt Initiative, I was looking to engage parents, and I met Isobel.
It Doesn't Have to Hurt was a CIHR-funded science media partnership with a major Canadian digital marketing agency that had extensive experience in the Canadian mom social media space.

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Our goal was to increase parents' awareness and use of research evidence about children's pain through the co-creation of a branded content campaign called, It Doesn't Have to Hurt.

MS. JORDAN: We actually finally met in person when I came to Halifax, way across the country, to participate in the It Doesn't Have to Hurt launch event in 2015, and we've been collaborating ever since. Now I work with Christine and her team strategically in patient partnerships in her research lab, and I serve as co-chair of the Patient and Caregiver Advisory Committee at Solutions for Kids in Pain, as well as working with several other researchers in both sharing my lived experience, as well as mentoring them on how to do patient partnership in an authentic way.

So why now? I think a lot of us know that data illustrated by story or narrative can have greater impact. Patient partners can not only contribute to that narrative; we can help ensure that language and images used are accessible, and

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we also have access to networks outside of academia where research results can be disseminated.

DR. CHAMBERS: My why, I'll confess, the first time I ever engaged a patient partner in a project was because I had to. The granting agency required that it acknowledges or be engaged in the project, so I did, and it's been a whole shift in perspective for me.

As a researcher, I always felt that I had patients' best interest at heart; after all, I'm a parent myself. But I started to realize the limitation of only bringing the researcher perspective to my work. I'll give you an example.

I was a co-investigator on a randomized trial of co-bedding to reduce pain in preterm twins in the neonatal intensive care unit. I had reviewed all the ethics of materials and approved the consent forms. But a few years into the study, I actually gave birth to a set of late preterm twins who were enrolled in the study because they met eligibility criteria. And all of a sudden, when I was reading the consent form as a caregiver

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and a parent/patient, I saw it in a completely different way.

There have been so many benefits to engaging patients in my research and in my lab. We now engage patients at every step of the way, from idea generation to publication. We'll give you one example.

We were developing a two-minute animated network video for our Solutions for Kids in Pain network launch. We were working with the video producer, and we sought feedback from a variety of stakeholders, including Isabel.

MS. JORDAN: I'm a disabled woman, and I have two disabled kids. This is a big portion of who our audience is and who we reach in the work at SKIP. I noticed in the whole video, there was no disability representation in any of the children, and I let Christine know it was really important.

DR. CHAMBERS: So I flagged this for the video producer who added in a child in a wheelchair in one section of the video, and we thought that would address the concerns. So I happily sent the

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revised video back to Isabel to review.

MS. JORDAN: And I have to say, it was great to get that immediate response from Christine, because I've done this before, where I wasn't listened to before. So I was sitting in the airport in Vancouver waiting for my flight to go to Halifax for the launch event, where this video would be seen for the first time, and I looked at the video, and it was worse. They made it worse.

The disability representation was of a sad, little wheelchair user in the middle of happy, able-bodied children. I had to let Christine know, and it was 24 hours before the launch.

DR. CHAMBERS: Right. So we talked, and we came up with a solution to insert the child in the wheelchair in a scene holding hands alongside other children so it would appear more natural and integrated. We were really down to the wire, but this feedback made a critical difference.

So this is just one example. Patient partners have helped us in so many other ways like this to interpret findings by providing context.

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They support our recruitment and engage their networks to promote sharing. They've introduced us to new partner organizations, and they suggest unique models of dissemination. But I have to admit that I was reluctant to agree to give a presentation today here on engaging patients in the dissemination/implementation of research because I don't believe it's appropriate to just engage patients at this stage.

In my experience, successful dissemination and implementation hinges on patient engagement throughout earlier stages, and we've had some fantastic presentations today illustrating that. Successful partnerships between researchers and patients are dependent on building relationships. I'm convinced that knowledge mobilization is all about relationships.

Patients can't be expected to promote or be engaged in sharing the results of research if they haven't been part of shaping. In our, It Doesn't Have to Hurt project, parents were involved in shaping and launching the project. They led us to

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topics they wanted to know more about. They co-created the content. They vetted everything, just like the scientists vetted it before it went live.

So as a result, Canadian parents actually became empowered to be the primary disseminators of our research on children's pain, and because of parents, the project was a huge success. We went on to win all kinds of awards in the science and health space, but also in the marketing and digital publishing spaces. But the success with our dissemination was built on strong relationships and a foundation of quality engagement throughout the project, not just at the end.

MS. JORDAN: Just as Christine said, principles of engagement, regardless of where you're putting them, whether at the beginning of a project or a dissemination, are the same. I'd really like to take a little pause here and talk for a moment about respect and safety in engagement and partnership and what that means.

As patient partners, we're coming from a

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really vulnerable place. We are low on a power hierarchy that needs to be recognized. We bring expertise that's often formed through trauma, and we're trusting researchers to create opportunities that will respect us as full team members.

How do you do that? It starts by valuing the expertise we bring, by creating safety for sharing our knowledge and by recognizing that our values may look different from yours. But mostly recognize this. We're not here for you to take care of, even though that could be something that you feel from a really good place in your heart. We're here for you to work with. We are partners in a piece of shared work.

DR. CHAMBERS: Another way to demonstrate respect for the expertise, experience, and skills that patient partners bring to the team is through providing fair compensation. Compensation is so important for equal opportunity patient engagement. I'm here today because it's part of my job. I get paid to do the work that I love to do.

Many patient partners take time away from

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their families and may incur additional costs like caregiving expenses to participate. Financially compensating patient partners for their time and expertise, in addition to covering any expenses in advance related to their participation is equitable. It respects their vulnerability and removes barriers. In particular, marginalized populations are confronted with financial and social determinants that are often barriers to engagement, so compensation is a way to engage a more diverse group of perspectives.

I highly recommend this publication. It's one of several that Isabel and I provided in advance of the meeting. Isabel's a co-author on this paper, and it really does a deep dive on some of these issues related to equity, different motivations, respect for vulnerability, commitment, and barrier removal.

Many organizations are developing compensation policies and guidelines for assigning financial value to patient expertise and are available publicly. You can review ours on the

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"Patients Included" section of our Solutions for Kids in Pain website, kidsinpain.ca, and I'll paste that in the chat after the presentation.

MS. JORDAN: Another way to show respect for us is to include patients in dissemination opportunities like inviting them to conferences. This goes beyond that inspiring patient's story to kick off a conference that has often been the traditional way to include patients in conferences. Inviting patient partners to co-present -- like Christina and I are doing here, and you've seen earlier as well today -- not only makes often for more memorable presentations, it also models engagement while practicing engagement.

For folks organizing conferences, the patientsincluded.org charter has a self-accreditation guideline on how to start down that journey of authentically and safely including patients in conferences. The charter clauses include things like having patients as part of organizing committees; patient partners participating in conference content, as well as

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having them in the audience; supporting patients' travel expenses; and meeting our disability requirements. Of course, partnering with patients, co-presenting means supporting our efforts in preparation. Some people might need more support or less support, and compensating us for our time.

DR. CHAMBERS: Along with co-presenting the work at conferences and other public speaking engagements, another way to let patients in, and open doors, and respect them as full team members is to create opportunities for authorship by inviting them to engage in co-authorship on published manuscripts. There's a great paper here that discusses and provides guidance on authorship with patient partners.

Researchers need to adopt a wide variety of dissemination avenues, including both these traditional opportunities of presentation and publication, but also non-traditional opportunities such as co-creating infographics and visual summaries; co-engagement with news and media; co-writing blog posts, newsletters, and social

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media posts about the work.

So where to start? When I first started engaging with patients as partners in research, this was new territory for me. I didn't know what I was doing or how to do it right. And even though I was trained as a clinician, a clinical psychologist -- I knew how to interact with patients, or I thought I did -- nothing in my training had prepared me for how to engage with patients in this way. In fact, my clinical training had enforced boundaries, and role differentiation, and hierarchies that actually made it harder for me to engage with patients in my research.

I was anxious that I would be a burden or be asking too much of parents who had many, many challenges on their plates related to their families and their children. Sometimes as a researcher, my projects had firm timelines and deadlines that were not flexible, so I set up a panel of parents so that no one parent would feel all the responsibility was on them to engage in the

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project.

At the beginning of the project, it was hard, but as I went along, I sought input and guidance. I could see it was making the project better, and so could the parents. So I kept asking, and gradually got more comfortable, and didn't feel as though it was a burden. Parents who were able to contribute did, and it was their choice.

So my advice to other researchers is it's ok to start small and gradually, but just to start. Some examples; the next time you're writing a grant application, consider adding a patient as a collaborator or co-investigator, which will help facilitate your engagement in dissemination and implementation later. Ask if they're interested in co-creating a dissemination plan or any materials.

Invite a patient partner to attend your lab meeting. I recommend this to my basic science colleagues all the time. I've met so many colleagues in basic science whose trainees and themselves say they've never even had a chance to

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meet a patient with pain until much further along in their career.

Invite a patient to attend a conference and cover their expenses, or invite them to judge posters. It's such a valuable experience for poster presenters to engage with patients about their work. As conference organizers, you can co-present the research with a patient partner -- I do this all the time -- and invite a patient partner to join your students thesis or dissertation committee. We also do this in my lab.

MS. JORDAN: I'd just like to underline a little bit of what Christine says about this. One of the worst feelings I've ever had is being the only patient partner on a research project. The feeling that I have to be "the" patient voice is particularly unfair for a couple of reasons.

One is that I can't represent all people; I can only talk about my own experience. And as a person with chronic illness who parents two people with chronic illness, when things go awry in any of our lives, my choices can often be to either

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neglect myself or my family or attend a lab or research meeting. So I can either choose to know that no patient voice will be at that meeting or make myself more ill, and that's just fundamentally unfair to everybody.

I'd also like to underline how important it is to have a mosaic of engagement in any research project. We all as patient partners have a variety of ways that we can contribute, and no way is better than others. So from a full co-investigator on a project to being able to consult on a infographic are all valid and important ways to contribute.

From project to project or day to day, we might have different ways that we're capable of contributing or have the capacity to contribute, and the more variety of opportunities you create within the project, the more diversity of opportunity and information you're going to be able to get from your patient partners.

We'd all like a checklist of engagement, something that will tell us how to do this right

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and how we can keep from failing. So many folks I have spoken to in a mentoring capacity have given voice to fears about engaging with patient partners, fears that they'll make a mistake, that they'll cause offense or, worse, that they'll cause harm.

I'm here to let you know that no checklist will keep you from making mistakes, and in fact we're all learning together. I know it's really hard to let go and begin a process that's outside of your comfort zone, but honestly, the biggest gift you can give yourself is to let go of your assumptions about what and how patient partners can contribute, and just ask us. These conversations can feel awkward, but the more you initiate them, the easier that they'll get to navigate.

In good engagement opportunities, you can co-create a safety net that's under all of us, one made of mutual respect, clarity, and open conversations. Patient partnership isn't something you do right. Different people need different tools. It's okay to make mistakes if you

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acknowledge them and commit to learning. There's no checklist for patient partnership done well. Every person you work with will have unique perspectives, challenges, barriers, and gifts.

DR. CHAMBERS: From the researcher perspective, I think fear really does hold a lot of researchers back. Many researchers and clinicians, again, have been trained that there's distance between researchers and patients. So you will make mistakes, and as Isabel said, just be sure you learn from them.

Patient engagement in research is a really different kind of relationship with a patient than perhaps you've considered, so it may be uncomfortable, and feel vulnerable, and that's ok. Recognize barriers and perceived hierarchies. Pretending they don't exist doesn't fix anything or help anyone.

Good patient engagement means giving up control and relinquishing some of your power, and that's really hard for researchers and academics to do because we are socialized to be control freaks.

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So you have to be open to new perspectives and ideas, create space for conversations, and not limit or direct them.

When you're engaging patient partners in your research and in the dissemination and implementation of the results, demonstrate partnership like Isabel and I are doing right now. Don't just talk about partnership; do it. I won't give a talk about patient engagement or partnership without presenting alongside a patient partner. And yes, it is more work. Yes, it takes more preparation for Isabel and I to co-deliver, but it's the right thing to do.

MS. JORDAN: It's more fun, too.

Lately I've been thinking about patient engagement like going for a hike. It's a journey that you're in together. We all go on a hike with different experiences. Maybe you grew up near the woods. Maybe you're new to the forest. Maybe you've been lost in the woods before and are cautious to try again.

We can all use a trail map to start off the

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journey, but each of us may need different resources: a hat, hiking boots, walking stick, and maybe chocolate-filled granola. Walking together, each with the resources, we can learn together and learn from one another, respecting and valuing each for what we bring. Thank you.

Clarifying Q&A

MS. VEASLEY: Thank you both. That was terrific. I have lots of questions, but I'll open it up to the group first.

(No response.)

MS. VEASLEY: Okay. Well, I'll ask my questions then. I'm curious. I have two questions. One's for you, Isabel, and the other I think is for both of you.

My first is, Christine, you said you started doing this because you're required to via funding. My question is, how do we change the perspectives of investigators to do this and to do it well? Like you said, you can start small and grow; or do you think we can do that without making it a requirement of funding; or do you think that's the

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only way we're really going to enact kind of widespread change?

Then my question for you, Isabel, is about -- and I completely agree with you. I've been that one patient advocate on many panels, committees, and advisory groups over the years. Given the logistics of the fact that you can't include any number of people on a committee or a particular project, I guess the question is, how do we know who to include and how many to include in a particular project?

As you mentioned, there are many different ways of including people across. You can do larger survey samples or so on and so forth, but when you're putting together a stakeholder advisory group or a patient panel, how do we know whether we need 2, or 5, or 15, especially with chronic pain, which can be so diverse and dichotomous between people?

MS. JORDAN: Christine, do you want to do yours first, and I'll do mine?

DR. CHAMBERS: Sure.

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Chris, I'll go back to the earlier question on how to encourage patient engagement, I guess, in the research environment. Of course, now I'm wearing a hat as a funder, as well, through the Canadian Institutes of Health Research. In my own experience, I don't know that I would be doing this had I not been required at a couple of stages to engage patients partners, and then have the opportunity to realize how impactful it was.

So I think requiring it for certain types of funding opportunities is an important lever, and I think we need to use all the levers that we have to make change.

That said, I also believe that we need to engage or expose trainees to this as early as possible. I think we really need to give careful thought to how we embed these perspectives in training. I'll say at the North American Pain School, for example, that I co-direct with Jeff Mogil, we have had patient partners participating, helping to shape the program, and engaging with all of our trainees, and I know that those interactions

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have led to really important perspective shifts on the parts of trainees.

So I think there are lots of intervention points in the system where we can encourage people to embrace patient engagement.

Isabel, did you want to speak to Chris' question around numbers and how many?

MS. JORDAN: I'm just going to add something to yours, too. Sorry; I'm obnoxious that way.

I'm a big believer that it's important to have those requirements for engagement, but I also think it's fundamentally unfair to require researchers to do patient engagement when we haven't given them the tools to how to do it well. And it's unfair to the researchers, but it's also unfair to the patient partners because it doesn't create safety for good engagement opportunities.

So I think that training piece is really important, but not just for the trainees, but also for the senior researchers and the mid-career researchers. I think we need to find ways to help give them the tools to do it well because,

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otherwise, people are going to get a grant that requires patient engagement, it's not going to go well, and then they'll walk away from it. They'll be that person that got lost in the woods, and they're like, "I'm not going for a hike again. That just did not work out well for me." So I think it's really important to have those carrots along with the sticks and do that.

As to your other question about the numbers, it's kind of what we said before. There's no one answer. When I'm entering folks on their projects as opposed to being the patient partner with lived experience, what I often tell people is, "What population is your study research targeting, who are you talking about, and is that being represented in your group?"

If it's an advisory group, when I work as an advisor, my job isn't necessarily to provide my lived experience but to help access communities that can give more information on what their experiences are like.

I used to work for a national healthcare

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quality improvement organization as a patient partner, and there was an expression there about the big bird and the little birds. And as a patient partner there, I was the big bird, but my job was to find lots of the little birds in the communities that we were accessing so that it wasn't all about what I thought was happening, but my job was to find other communities so that it wasn't all about my lived experience.

So I don't have a neat and tidy answer for you because it really depends on the project, and it's always going to depend on budgeting as well. Do you have budget for a 10-person -- that's actually too big, too many people -- an 8-person advisory committee that can then go out into their communities? Do you just have the funds for two people who are patient partners that are really good at engagement and can then create an engagement plan for your project?

That's not an easy answer, and I'm sorry I can't be more specific.

MS. VEASLEY: Well, it was kind of a trick

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question, so I was hoping that you'd kind of talk about the strategic framework. One of the things that we'd like to do through this meeting and the publication that comes out of it is to help people think about, strategically, who do I need to? What methods do I need to engage? How many? What's the diversity? So, I'm glad --

MS. JORDAN: I was going to say, one of the things that I like to think about is, in my own personal and family's health journey, we had a terrible time. I could tell you stories that will curl your toes, and we are incredibly privileged. One of the things that kind of drove me into doing the things that I do is that I think with all this privilege and things look so badly, what happens with other folks that don't have the privileges we have?

One of the things that I often think about is, if we can make research better or health care better for the people who have the biggest barriers, then everybody else is taken care of. I really think that we need to work hard to have the

folks who haven't been heard and haven't been represented traditionally, and make sure we find ways for them to be comfortable, and safe, and create safety for them to have their voices heard, because after that, everybody else will be taken care of, too.

MS. VEASLEY: Absolutely.

Just one last question before we open up to general discussion; I'm curious about your position within Christine's lab, and I'd like to hear from both of you.

One, Christine, what made you go to the point of actually incorporating somebody who's actually in charge, strategically in charge of this, and then what the role is for Isabel -- if either one of you want to answer it or both of you -- within your lab? It's very rare that you actually see someone that's in this type of a role within a research lab. I find it very interesting, and I think people could learn from that.

DR. CHAMBERS: Yes. This has really been an evolution over the last five or, I guess, six

years, where initially when I started our patient engagement work, I was working on a shoestring budget. And I'll say that there are ways that you can do patient engagement that are not super resource-intensive, and I had a really, really limited budget for the work that we did.

But as time grew, or as time passed, it was just clear that this external advisory capacity that we set up for the panel was really useful for the project in that there started to be this disconnect between what I was doing and the work that was happening with the co-investigators and the experiences that my staff and trainees were having.

So by bringing Isabel into the lab and actually carving out a patient partner leadership role, that she helped to co-create -- I mean, she really helped map this out, which is fantastic, and I'll let her speak to that of course -- it's been amazing to have her in the lab. My trainees meet with her. She comes to our lab meetings. The questions she ask at different stages of the

project are incredible. She helps my trainees figure out what kind of patient partners, or networks, or organizations they should tap into for their research.

So it's really just been an evolution. And now over at SKIP, we also employ someone with lived experience, so it's just become something that is baked into what we do, and it's very different from how I ran my research lab for many, many years, so it's a departure.

I will acknowledge I have a stable funding situation right now. That is not always the case for researchers, so that is something that I feel very fortunate to be able to do right now.

Isabel, did you want to add to that?

MS. JORDAN: I don't have a lot to add to that. But I'll tell you what I find exciting about doing this work with your lab is that I can see -- I mean, the work that you were doing with your trainees before, that I would get involved with if I got pulled into a project or people that I know would be on a project, there was an ethic

within your lab of patient partnership, but it was more -- I don't want to say ad hoc, but there was a certain institutional knowledge within your lab of like, "Oh, what do I do next?" or they talked to a more experienced trainee or somebody on staff that had done the work before.

What I'm doing now, alongside with the mentoring, is trying to create a more organized system that they can go to, guideline documents so that if somebody more experienced, when they move on and away from the lab, that institutional knowledge doesn't leave; or if Christine's not available or a staff person isn't available, then the trainee can start down that path on their own with their project, and then meet with me saying, "This is what I've done so far; here's where I am," and then get input from me.

I think that lets them have a bit more independence on starting that patient partnership journey, rather than going, "This is really scary." I think that's really important to be able to feel like they have the tools to start down that path.

I'm finding it really exciting to do this work with them.

Discussion and Development of Recommendations for Publication

MS. VEASLEY: Absolutely. Absolutely.

Alright. Well, we're going to open it up to all panelists, all discussants, so please feel free to ask questions of each other; or attendees, please feel free to ask questions of the panelists or each other.

(No response.)

MS. VEASLEY: And I know this group is not shy, for sure, but I'll start with a question.

Jonathan, are you still on?

DR. JACKSON: Yes, I'm here.

MS. VEASLEY: I really appreciated your presentation today, and obviously if we're going to generate data that's meaningful to the masses, we have to diversify our clinical trial population.

I was just wondering if you could kind of bridge the gap between how important it is to actually include diverse populations in the

planning and conduct of trials itself as a means of increasing diversity in the trial, and if you could give us some concrete examples of ways in which either you're doing that through EPPIC-Net or some other work that you're doing.

DR. JACKSON: Yes. I think this is an easy question to answer in that it is absolutely paramount to make sure that patients are included as early as possible in the design phase of our research studies. It's really the only way that you're going to be able to successfully and confidently achieve the diversity and the representation that you're looking for, no matter what it is that you're trying to study.

That is mainly because we as researchers -- and this is something that I often say in my talks -- we forget how weird we are. People don't know what research is. They certainly don't know what clinical research is, and we talk about it with other people who already know what research is. So we miss a lot of the very, very common blind spots, gaps, and pitfalls that make it

hard to participate in a study, and I think especially hard to remain engaged with a study. So bringing participants on board as early as possible is really, really vital.

There are a few ways to do this really well. The most common way is to leverage something that's called the Community Engagement Studio. The CE Studio approach was developed out of the Vanderbilt-Meharry Group by Consuelo Wilkins and her team a few years ago. There are a few great publications on it, and I would say it's pretty much state-of-the-art.

What's different about the CE Studio than your typical patient advisory board or an advisory group is that in a CE Studio, you have community experts and patient representatives as co-creators in your research design, and it is a very iterative process. So instead of saying, "Here's our protocol; give us feedback in the next 48 hours," you bring them on and you treat community partners and patients as co-investigators in your study. You pay them for their time. You give them credit

on your publications. You really bring them into the design process, and that has yielded fantastic and phenomenal results I think all across the country.

Within EPPIC-Net, I mentioned that we are doing kind of a two-stage process where we have a patient advisory board to talk to us about the structure of EPPIC-Net and answer the big questions: What kind of outcomes should we be looking for? What are some common pitfalls that we need to be thinking about across all of our trials?

That has yielded really, really great results. That has meant that new protocols that are coming down our pipeline are being more thoughtful for funding for elder, and childcare, and even for pet care; thinking about scheduling patient visits outside of bankers hours; thinking about lots of aspects of being flexible with the way that we talk about reimbursement, remuneration, and payments; making sure that we are having really thoughtful conversations about patient burden, so thinking about do we need to measure this

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particular outcome in this way or is there a simpler, easier, less invasive way of collecting this data.

Then in addition to having that kind of broad group to give us broad feedback, we do have a group of patients that are arranged in kind of a focus group setting to weigh in on protocols as they are written. So instead of writing it, getting it IRB approved, and then asking patients for their opinion, before, at the very early stages of that process, during the very frenzied protocol writing period, we are engaging with patient focus groups to talk to the people who are implementing the study, as well as people who are leading the various studies, in real time to talk about specific deliverables.

So I think this two-stage process is our version of that CE Studio approach, where we are giving patients lots of opportunities to weigh in on the way that we construct the design trials, the way that we evaluate trials for success, and making sure that we are compensating for their time and

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treating them as experts.

There are lots and lots of other things that you can do related to raising awareness such as having a really great patient-facing website, a strong social media presence, making sure that there's effectively no wrong way to access information about a particular study, and then also tapping into patient centricity models for future design.

So instead of saying we've got so-and-so company that is interested in trying a therapeutic, you're asking participants and patients what kind of pain relief they're looking for, where they've had particular trouble, and then going out and looking for particular vendors or industry sponsors that may be willing to provide some sort of treatment for that; so really designing research studies from the perspective of that patient centricity.

I know your question was about diversity, but it turns out that designing for diversity means you really need to design from a very

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patient-centric perspective. In this case, the two approaches are effectively identical.

There are lots of other things that we need to think about. One of the things that I think is not considered widely enough is thinking about site selection, because more and more studies are getting larger and larger. There are lots and lots of different groups that are involved. We tend to pick the groups that we've worked with before. We tend to pick the groups with a famous PI that we've heard of, and that means that we tend to have a relatively narrow range of who can be involved in the study.

By thinking a little bit more broadly about who can participate in research studies, who can support sites, who can help with that engagement and initial recruitment effort, that gives us a leg up on thinking more broadly about who can be involved in the research process.

I won't bore you with all of the details that we're doing, but we are seriously rethinking what research has to look like. Instead of

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thinking that it has to come from a very small, narrow set of very elite universities and academic medical centers, we are starting to re-examine that question much more broadly because we can provide that very centralized infrastructure and support to make sure that all sites are able to recruit in a timely and efficient way.

MS. VEASLEY: Absolutely. Thanks.

Here's the number one question we get from investigators, which is how do I find these people? It's a logistical question. If you have not been engaged in doing this before -- Christine mentioned that her and Isabel connected over Twitter -- how do you go about finding people in the community -- and Gail touched on this earlier -- that are representative of the population that you're studying, and you do have diversity, and you're reaching hard-to-reach populations?

DR. JACKSON: I think all of us speakers are going to have an opinion on this, but I would say in my experience -- and I'll give a very brief

answer; I promise -- if you have some way of engaging the community, or even community stakeholders, it is really not so hard to find the group that you're looking for.

There's a reason why I told that really terrible dad joke at the beginning of my talk about thinking from hard to reach to hardly reached. It turns out that there are lots and lots of avenues to reach exactly the group that you're hoping to. It just requires you to kind of move outside of your workflow for a day or two. And if you can make a little bit of time, it turns out that you'll yield really large benefits. It is really not so hard to reach these groups that we're dying to reach.

MS. JORDAN: I have -- sorry.

Christine, did you want to go first?

I have a friend who's great at community outreach, and it's not so hard. It means leaving your office, and grabbing a coffee with somebody, and making that first step and asking. Again, it can be a scary thing, and it can be a vulnerable

thing, but you know what you're studying. You know what represents a disease group or a pain condition.

There are patient groups out there. There are community groups out there. There are communities of care out there. And people understand if you're going to them with clarity and openness, and are willing to forgive a lot if you go there with clarity and openness, and saying this is what I'm doing and this is what I'm looking for. And be honest with them about that, and don't expect people to come to you; go to them.

MS. VEASLEY: Yes, absolutely.

Christine, did you want to piggyback off that? And then we'll go to a couple other questions.

DR. CHAMBERS: Sure. I see a few other hands up, too. But just to say, in the early days, I didn't have a lot of infrastructure to support the reach out, so I really just crowd-sourced over social media and got an incredibly diverse group of participants or patient partners. And because the

project itself was all digital, we were able to engage people who were living in rural areas, so it was really fantastic.

In our SKIP network, we actually have a database of patient partners. We have an open call for patient partners who would like to volunteer where they can express interest in different types of engagement activities, so, yes, I'd like to be involved in media or I'd like to be involved in this. When we have opportunities arise, we can actually reach out to specific patient partners who are registered with us, and they know that they'll be compensated. So that's been a really fantastic way to do it.

Recently, one of my students needed to find some patient partners in the arthritis space, and Isabel helped her come up with an outreach plan. Our national arthritis society ended up doing a huge outreach for her, and she had the problem of having too many patient partners who wanted to participate and having to navigate that. So yes, actually people are happy to help, and there are

different ways to approach it, informally and formally.

MS. VEASLEY: Right. Thanks.

Karen, I think you were next.

MS. MORALES: I just wanted to mention the concept of a trusted messenger. When you're interacting with a specific organization or group that has that specific expertise in the area you're looking for, you kind of get a better turnout from the community organization for your particular study.

One of the things I also want to mention is renumeration [ph] is important, but there are opportunities where you can do things for your partners that will assist as well, such as we've had opportunities where we've gone and actually participated in the events of our partners, where we may not have been able to compensate them initially earlier on, but because we went there and we did something that helped their particular efforts, that was compensation in their eyes; or we were able to create a video for them that they were

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able to put on their site, which generated income for them; or we were also able to help with completing a resume.

So there are crafty ways to be able to assist your community partners outside of providing finance. Finance is always important. I never want to say that you don't offer financial incentives, but there are other ways to compensate your community partners that will also be appreciated outside of the financial component.

MS. VEASLEY: Absolutely. One of the main themes that we've heard from people in terms of why they don't continue is because they never heard back. So they were more than happy to start the engagement process and to contribute, but then they felt like the scientists came in, they got the information they needed, or the participation that they needed, and they left. And they never heard whatever happened to this study, what were the outcomes of this study, and how was my contribution to the study meaningful or how did it impact the study. I think that's really an important point.

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Lynn, I think you're next.

MS. LAIDLAW: It's interesting. I speak about how hard it was for me to become involved, and the amount of time and effort, and knocking on doors, and emailing, and jumping up and down saying, "Involve me," and people didn't want to. And yet, on the other hand, I hear researchers saying, "Well, I can't find people to involve," so some of us have to work really, really hard.

I was thinking about what Jeremy said yesterday about working with communities. What is our definition of communities? Because sometimes it seems like it's too easy to reach out to a patient organization, but who's that patient organization not engaging with, or who's that community organization not engaging with?

I was involved in a couple of organizations, and then when I didn't become involved with them anymore, I was thrown off the stuff that I was involved with. Now, I hadn't changed, my experiences hadn't changed, but because I wasn't representative now of the organization, that was a

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problem.

That's the other thing I kind of wanted to mention, this thing of representativeness. I think as we move now towards EDI -- inclusivity, diversity, equality -- it's really, really important, but sometimes it seems like, oh, if we involve someone from that ethnic community, or if we're involved with that disability, a big sigh of relief, that box is ticked, and now we have that.

It's more than that because you can't make one person, and would we expect the statistician to be representative of all statisticians, or epidemiologists? And we're not, but sometimes with patient partners, we're like Goldilocks porridge, and we have to be just right, either the right color, or the right gender, or whatever. And it's not us that have the power to say what's right; it's other people that seek to involve us.

So I think we just need to be very clear about how we're talking, what we're talking about, and how were defining some of these issues.

MS. VEASLEY: Yes, absolutely.

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Gail, I think you're next.

MS. GRAHAM: I wanted to piggyback on what you were saying, Chris, about coming in, getting information, and then leaving. We consider that as helicopter research. And that's why when you go back to that community, they don't want to give you authentic answers because you were working on earning their trust, but you left, so you became untrustworthy.

So it's important that once you engage these communities, that you nurture the community also, where you go to them respectfully, and you tell them about what you're thinking, and ask if they're interested or what would interest them, and to actually go back and let them know what their answers generated so you can disseminate that information back to them. It means a lot.

Again, when it comes to monetary things, my community, where my church is sitting, is a food desert. The University of Maryland had connections with the Maryland Food Bank, and they allowed us to get in contact with them, and we were able to do

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food drop-offs to the community, so that made a big difference. The community started looking for the University of Maryland and telling them different things that's going on. So where it started out with maybe blood pressure research things, they found out that that church had people there who are HIV-positive or people there who were diabetics. So you have a rich opportunity for other research studies.

But again, when you go into those communities -- especially if you go into a black community or Latino community -- you have to be honest about the fact that research messed up at one point. With the Henrietta Lacks study, with the Tuskegee Institute study, you have to acknowledge that, and then you have to let them know about the advancements that were made since then. One thing that I did, I was talking about clinical trials, but I never did one. So I did one so that I could go back to my community and say, "Look, this has changed dramatically." So that's just something to think about.

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MS. VEASLEY: That's great. I wanted to follow up with you on a question as well. You talked about your hesitancy in the beginning to become involved as a patient in patient engagement efforts with the University of Maryland. You talked about your diagnosis and the stigma around that.

Are there other reasons why you were hesitant to come on board, or what do you think the other reasons are, other than some of the ones that you just mentioned, the distrust and the historical perspective? Are there other major issues that you think impede people from making the decision to get more involved in advising in that way from the patient community?

MS. GRAHAM: Actually, I was thinking, okay, they just want to check off a box and they get somebody who was HIV positive to be a part of this, and that's all they were looking for me for; not that they would listen to what my thoughts were or anything would come of that. That was one of the things.

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Again, the history that we had with other organizations -- not just researchers, but other people coming in to our community -- and then not respecting the people in the community just soured me on research, and it just so happens a lot of them were researchers. So it soured me on that. So when I heard that it was a group of researchers coming, I was like, "No. Hell no, I don't want to be involved." But that was the reason why.

MS. VEASLEY: Yes, that's helpful. Thank you.

Isabel, I think you're next.

MS. JORDAN: Well, I think a lot about power hierarchies and how that can influence how a patient partnership can go or the nuances of it. And something that Lynn said made me think about it in terms of who is being asked to participate in these partnership opportunities. Because even in the patient community, there's a certain power to being part of patient groups that are already partnering with big research groups that can exclude others.

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I know that it can be easier to go to the patient groups that others have gone to or that you've traditionally gone to. But I think it's important to think about who hasn't been welcomed or who doesn't feel comfortable being part of those patient groups, and to look outside of those and think about who are the folks that are in those patient groups and where you can access them outside of those patient groups.

MS. VEASLEY: Yes, I think that's a critical point because it's an issue that we have. As a director of an advocacy organization, I can tell you that our patient population is not diverse. When you think about the overall percentage of people with any given medical condition, who associate with a nonprofit organization or advocacy group for that particular condition, it's a very, very small percentage.

So you can't just say, okay, we've done the advocacy group and we have a representative sample because it's not necessarily the case. There are many different ways in which you can identify

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patient partners -- both, like you said, as within organizations -- and there may be important differences.

Ian, I think you're next.

DR. GILRON: Yes. Thank you. Just a couple of comments, and then a specific question.

First of all, thank you so much to all of you, investigators and patient partners, for excellent talks and discussion today, and for your thoughtful passion in doing this. And just to say, for me, in open disclosure, quite honestly, this has been a relatively new concept for me as a researcher over the past, let's say, 5 to 8 years.

I'm one of the principal investigators on the Canadian Chronic Pain Network that Dr. Khan spoke about yesterday. And as you know, patient engagement was sort of an integrated aspect of the rollout of that research network and something that we all learned a lot about, and really looked at it as something novel, and that we wanted to roll it out slowly, and carefully, and advance things slowly, rather than be too ambitious and do things

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too quickly, and make mistakes, and have to retract in any way.

Just coming from that perspective, it has been, I would say, a positive experience. We've had some great partnerships. For example, Maria Hudspith from Pain BC, who is one of the leaders in patient engagement, helped us with careful selection of patient partners that you've discussed already.

I have a specific question that's kind of delicate and awkward, but it's worth pursuing. I guess from the perspective of an investigator who is looking for patient partners with their research, how much does the investigator really need to know about the clinical background of a specific patient partner, inasmuch as that clinical experience informs their ability to advocate on the basis of patients? How much of the clinical history should they know and is that even relevant when setting up a patient partnership?

MS. VEASLEY: Thanks, Ian. I think it's an important question and I'm glad you asked it. I'm

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going to invite some of our patient partners to respond. I have thoughts, but please go ahead.

MS. JORDAN: I don't mind taking that on. Thanks for that question, Ian.

I think there's a difference between a patient partner and an advocate, so I'm going to use the term "patient partner" because I think the role of the patient partner in a research project is really to provide their perspective on what that research question is and what your project is. I think their health and personal lived experience background needs to be relevant to the research question, and they need to be willing to bring that to the research project and to that question.

The details of their clinical background I think are for them to disclose as they feel is relevant, depending on what's happening in the research project, rather than for the researcher to ask them. If they're willing to be part of a research project, then they're already in the space of wanting to disclose some of that. But their ability to do that in a safe way that is minimally

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re-traumatizing requires the researcher to have a setup that creates that safety. That's a whole other talk that requires some things to be in place for that to happen.

Does that kind of address it a little bit?

DR. GILRON: Yes. Thank you.

MS. VEASLEY: Ian, I'm just curious. Maybe Penney or Lynn have some responses to that.

But I'm just curious why you asked the question. Have you had experiences where you included patient partners in a project and didn't ask that information, and then it turned out that their experience wasn't relevant to what you were hoping they could advise you on, or was it something else?

DR. GILRON: No. I don't have any specific experience that points to that question. It seems to be such an obvious question. And I'll be quite honest with you; part of taking this slowly, delicately, and carefully has been something that -- the work that we've been doing with patient partners within our network has not -- there's been

a lot of work with patient partners involved in the governance of the network and issues like that, where we're not necessarily working in the level of a clinical trial where it's investigator and patient-centered. We're working like as we are now, in a professional setting, where it would seem quite obvious that you wouldn't expect to hear details. And if someone discloses it on their own, you appreciate that, but certainly there's no expectation.

So yes, I don't have any specific reason to ask the question, but it would seem obvious that that patient partner's specific background is relevant to what context they can provide. It's just more of a theoretical question of when it comes to patient selection and screening for partnership, it's a theoretical question of whether this needs to be addressed, or should it, or how much should it.

MS. VEASLEY: Yes. And I think what Lynn said earlier about transparency on both sides is really important. For example, I was thinking if

you're doing a trial that's on opioid tapering, for example, just a hypothetical, having somebody who never took opioids probably wouldn't be a good advisor in that circumstance. I'm thinking about transparency on both sides, what you're looking for from the side of an investigative trial or pragmatic trial, whatever you're doing.

As Lynn mentioned earlier, be very frank about what kind of activities you're looking for them to do, then that way the partner can decide if they want to disclose that information, if they don't feel comfortable doing that, and also have a good idea of what it is and how they will be involved throughout the process so that they can make an informed decision about participating.

Penney, please weigh in.

MS. COWAN: One of the things that I've always been very careful about is not talking about any of my health care. I'm a person with pain, but it was never important, for me, for them to walk through the whole background or even what my condition is more so than what I can bring to the

table, which is the experience of that person living with pain and really understanding what their needs are, and listening to them for the last 40 years, and what are their questions.

As long as, I think, the person meets the criteria of the study -- in other words, if it's an opioid-use disorder study, then of course if they didn't take opioids, they're not appropriate. But maybe they are because maybe there was a reason that they didn't take it, and they may bring even a different -- I mean, you don't know.

I think it's individual. Some people are a lot more comfortable than others. I just don't want people to [inaudible - audio gap] -- and everyone knows this; not as a patient, I'm a [inaudible], and I've been talking about that to IMMPACT for many -- that's not who I am, and I guess I feel really strongly about that. But I do have a question.

MS. VEASLEY: Lynn, did you have a comment to Ian's question? And then we can move on to Penney's thought.

MS. LAIDLAW: Yes. I'll post it in the chat, but there was a really nice paper written last year called, Who Should I Involve with My Research and Why? I think it was really thinking very seriously about should it be patients with specific lived experience, should it be members of the public, and whatever, and the pitfalls that can happen with your research. So I'll post that.

I think this is such an interesting question. I didn't have a CV until I started getting involved in patient public involvement and research, and sometimes it's like, "Yeah, we want to involve you, but, actually, you know what? We want you to write these three paragraphs, these three wonderful paragraphs, and then after that, you might get through to the next section, and you'll be interviewed by three people over Zoom," or wherever.

Again, this always comes back to power: who is deciding what the criteria is; who is deciding how people will be chosen; who is deciding on putting in a CV on whatever; and what is the impact

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on inclusivity and diversity?
I was thinking back to an excellent point that Isabel made earlier about if people like me -- white, middle-class, educated people like me -- find it really difficult to get involved, then what chance does anyone else have? Because it goes back to this Goldilocks thing again; that I have to be just right, that I have no control over what just right looks like, and a lot of patient public involvement is about power. We just can't get away from the power angle.
MS. VEASLEY: Yes, that's an interesting point, and I thought about that earlier as well. From the scientific side, it's always thought, well, what additional training do patients need to be able to participate and advise in clinical research? But we also need to think about what training do clinical researchers need in order to understand patients, communication, moderation of discussions, involvement, and all kinds of things? And for the most part, they haven't been trained.
So there's training that needs to go both

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ways, and like you said, it's based upon equal value. First of all, everybody has to value each other equally, and to go from there.
I'd like to get back to this point of training in a minute but, Penney, please go ahead and ask your question.
MS. COWAN: I just had a question a little off -- well, maybe it's not off topic. We talked about dissemination and implementation, and I'm just wondering, when all is said and done -- I mean, so many people are now looking on the internet for information, and I know that the research papers are always written [inaudible - audio gap] -- they've come across my desk, and I've read [inaudible] of them, and many of them I struggle with. I don't understand them, and I have a pretty good background in all of this.
Is there any effort to make these simpler? Like the patient part you have, do they go out into the public and educate, or is there a consumer report based on the work that you've done? We've heard talks earlier from PCORI about shared

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decision-making, but if a provider gives you one of these research papers, it's going to be way over [inaudible - audio gap].
So in the end, after all is said and done, and all that research, when it comes down to shared decision-making and consumers actually looking at making a decision about one or two different, or maybe even three different, treatments, do they understand what they're reading, and is there any effort from any of you to actually get that information out to the public? I think that would be really important. Thank you.
By the way, you guys did a wonderful job. Thank you, all of you, for sharing. Great. Thank you.
MS. VEASLEY: Christine, did you have a response to that?
DR. CHAMBERS: Yes. I'll just jump in there. I completely agree, Penney. Once the publication is submitted, or as it's being published, there's so much more that we need to do. Patient partners can play a really critical role in

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helping to map out that dissemination plan. It could involve writing newsletters or blog posts with different patient organizations to share results. It could involve social media engagement, an Instagram live, or a Facebook chat.
We employed all of these strategies with our It Doesn't Have to Hurt project. This is exactly what the project was focused on. I was frustrated that all this science that I had contributed my whole career to wasn't getting used to the benefit of my own children when they were interacting with health care. So that's why we developed this whole campaign, leveraging social media.
But that is what our entire SKIP network is focused on, is taking content that would normally sit in a journal, buried behind a paywall, and working to figure out what's the best way to get in front of different knowledge-user audiences. Patients obviously are one knowledge-user audience, health professionals, policymakers, and increasingly we're writing policy briefs. We have them right now at the federal Canadian Pain Task

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Force that has been doing incredible work, but how do you make research digestible for policymakers?

So it's a great question. And I now ensure that all of my students, every time they publish a paper in a journal, also write some sort of blog post, often co-written with a patient partner, to help amplify and make sure that those results are shared in more accessible ways.

MS. VEASLEY: Thanks, Christine. I'm going to ask you another hard question, which is not all scientists feel that it's their responsibility or obligation to go past the point of writing a journal paper and to do dissemination or implementation work.

So I guess my first question to you is, how do we change the perceptions or the paradigm of the research life cycle to go beyond just publishing a paper -- and I'm not discounting the importance of that; it clearly is important -- and how do we change the perspectives of our funding agencies to maybe require some of that work beyond just publication of a paper?

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DR. CHAMBERS: Yes. I love that you ask that, Chris. Thank you so much, because not only do some scientists not see it as their role or their place, a lot of scientists, let's face it, aren't good at it. I've really reflected a lot on this because I think I've made a big dent in my own particular research area because I had an interest and ability to engage outside of traditional dissemination platforms.

Obviously, working closely with others, I was willing to put in the time to learn and build new relationships. Not everybody is going to have that interest, and I've reflected a lot on the inequities that that can create, and how and what types of knowledge get mobilized.

So is it fair that my research on children's pain has been put more into practice because I've had that interest? What about other areas of pain research, or health research more broadly?

I think it's important that everybody receive training, and it's the baseline level of awareness. There's an incredible course that my

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colleague, Melanie Barwick, in Toronto offers that's a knowledge translation course for scientists. I think it's fantastic, because some people will have the talent and interest; others won't.

It's not to say that we should expect it. We need people in their labs doing great work, although I think that work can be improved and enhanced by engaging different types of partners, and those partners then can take the lead. But also we do need dedicated funding. Just like we fund knowledge generation, we need to acknowledge that mobilizing knowledge is not just something you do on the side; that it does require dedicated expertise and resources.

We've been really fortunate to have funding from the federal government to do this, but not everybody who generates the knowledge should be -- sometimes it could actually be counterproductive. Those people could actually -- and I've seen this happen, where people have actually damaged relationships and put up

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walls where there shouldn't have been walls, that have actually impeded the ability to disseminate and implement; so recognizing this as a special area of expertise that requires resources, the right leadership the right infrastructure, and the right approach.

MS. VEASLEY: Yes, absolutely. I think it's going to take funders as well to come to the table and recognize the importance of that and put up resources to help investigators do that.

Like you said, it's another member of the team. You've added Isabel to your team as a lead of strategic partnerships with patient groups and others as a communications person needed to be brought to the team in order to identify -- I mean, we can't be experts in everything, but I do think there's an important role there for funders as well, and changing their perceptions.

Karen, you've had your hand up for a while. Please go ahead.

MS. MORALES: Yes. There's not a lot to add to what Christine just said because I think that's

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great. I just want to also include the idea of including dissemination at the very beginning in your planning process.

You can't all of a sudden come to this with, "Oh, we've done the study, and now let's figure out --" no, you have to include that as a metric of your planning process, and that dissemination needs to go out, yes, to your journals, to all of your publications, but also a one-pager back to the community that helped you generate the information from your study in a plain-language document.

What we try to do at the PATIENTS Program is to suggest that we put our plain-language document at a 6th-grade level of readability so that any and everyone who wants to read it hopefully can understand what it is that we're disseminating, and sometimes using graphics, always thinking about how can they better understand it. We have people who learn from different styles, and sometimes using graphics help some communities because you may not have people who are readers, and thinking about those who are blind, and those who have other

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languages.

We did an FDA study where we had the Spanish population, so we thought about that from the beginning, that we have to translate our results into Spanish as well. And that's exactly what we did in order to disseminate that information back to that community as well.

So I think your dissemination starts in your planning process as well, how you're going to disseminate, what that looks like, and what the audience is that's going to be receiving that information.

MS. VEASLEY: Absolutely. I'm actually involved in another committee with an institute within the National Institutes of Health that's looking at reducing health disparities in neurologic disease. I'm not a communications expert and was put in charge of a group just because I have a personal interest in communications about this, how do we communicate the findings of neurologic health research in an effort to reduce health disparities? And,

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actually, what you just said was one of the major recommendations that we made.

It can't be an afterthought. It can't be like, "Okay, we've done this. Before we move on to the next project, let's think about what we might want to say about it." It's got to be planned from the very beginning. A key part of being able to communicate findings is engaging with stakeholders, patients and other stakeholders, community stakeholders, from the very beginning of the project. Because you can't bring somebody to the table at the end of the project, and then say, "Here you go. Take this and give it around to everybody" if they haven't been involved with the project from the get-go; so very important points.

Isabel?

MS. JORDAN: There are some really great threads coming together here. I want to say this with total kindness to people. But one of the things that I did before my son was born is I was a technical writer, and I used to help lots of folks in business write things that they wanted to put

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into trade journals or they wanted to go out to the public, because they did lots of great things in business, but writing things that folks could understand outside of their specialty was not their strength.

I find this happens a lot in the research world. There are resources out there. There are plain-language writers that do incredible work. And what I find often when I see folks in science, folks in research who think they're writing in plain language, they're really not. And they're doing their best at it, but it's really hard for a lot of people to bust out of that bubble.

One way to do it, you can hire a plain-language writer, but you can also co-create with patient partners; not go to them for editing afterwards, but co-create with them what you are doing, because they will also tell you the points that are important to that community that you really need to focus on.

Also with that, doing things with graphics. I helped co-create an iPad version of a consenting

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document that had visuals to go with it, because when you're consenting for a biobank, you're in a moment of stress, and you can't understand things when you're in a moment of stress. This happens also for clinical trials sometimes, and you need things to help you understand things.

So creating those with patient partners can make sure that they're understandable for you. And I'll put a link for how to co-create patient-facing documents in the chat.

MS. VEASLEY: Yes, that's a great point.

I think another point that we don't really recognize is that failure to do dissemination efforts I think actually discourages people from participating in clinical research in the future, and we have a big problem right now with not having enough people to participate in clinical research.

John, go ahead.

DR. FARRAR: Thank you very much. I'm sorry. I had to drop off for the last 45 or 50 minutes, so if this has already been covered, please just let me know.

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One of the biggest issues these days is the mix of information and misinformation, and I wondered whether anybody had commented on that. So let me ask that first. If not, I'd like to speak about that briefly.

(No audible response.)

DR. FARRAR: No? Okay.

MS. VEASLEY: I think Kathryn maybe is going to respond, or Christine. Go ahead.

DR. MARTIN: My comment is about something entirely separate from his question.

Sorry, John.

MS. VEASLEY: Okay. No problem.

Christine, are you going to respond or no?

DR. CHAMBERS: Yes. I can just jump in there and say I completely agree, John. This is one of the reasons why I wanted to engage with dissemination/implementation around children's pain research because as a parent, I was seeing so many posts on social media that included misinformation. I think it's even more important that those of us in science, who understand science, are present and

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willing to engage to make sure that appropriate information is accessible.

One of the things that I found in the parent space is that a lot of websites and books that look really glossy and look really professional are completely not evidence based. And let's face it; we researchers often do a terrible job at creating websites and videos. We're in a white coat speaking off of a piece of paper, and that's not how different knowledge-user groups want to engage.

So I think we need to be present, but we need to kind of up our game and partner with people who know how to engage and be present in an accessible way. And that's really why I've been active on Twitter because I wanted people to know there was someone that they could follow to get cutting-edge evidence. We don't want people getting their health information from people like Jenny McCarthy or Gwyneth Paltrow, so we need to get more visibility.

I honestly think, and I'm so fascinated by what we're all living through right now, that we

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have failed when it comes to science communication and knowledge translation. Look, the vaccine was the easy part of what we're dealing with. Now it's the human behavior piece of that. I completely agree that the misinformation piece is fascinating, and we all have an important role to play, but our system hasn't been set up in such a way that really facilitates that.

DR. FARRAR: If I might just follow on with that, and then ask Gail or other of our partners, how do you decide where to go look for your information? It seems to me that getting our clinical and patient partners involved in that decision also is key. I mean, Twitter is fine if they find you and they follow you, but if they find somebody else who promises them a cure with a stem cell injection, and just fly down to Mexico, how do you decide? We have a good sense about what's evidence based and what's not. But, honestly, the rest of the world, there isn't an obvious place to do that.

Gail, I wonder if you could give us a

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thought about that or somebody else, too.
MS. GRAHAM: Well, to be honest, I used to be the Google queen, and each time something happened or I felt a certain way, I would Google my results, or whatever, and then look at what Google had.
But I trust my doctors, so I would go back to my doctor, and I would ask questions. My doctor is very receptive. I have an HIV specialist and I have a cardiologist, and they will answer any question that I have, and I trust them. They will also refer me to other -- if I wanted more information, they would give me the documents that I could look through, and if I had any questions, I could go back to them.
So that's one thing I tell patients, that they can feel free to go to their doctor. And if they don't feel comfortable with going to their doctor asking that question, maybe that's not the right doctor for you because your doctor should be a person that you trust and would give you the right information. I hope that answered that.

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DR. FARRAR: No. I love the answer. The problem, of course, is that doctors come in lots of flavors, too, and there are some doctors that are promulgating misinformation in the current COVID situation that is scary. So I agree with you; going and having a good doctor, and having somebody to approach.
But it also approaches the concept, Christine, that you were saying, is how do you decide how to put out the information? Should it be connected to a website? Should you get NIH to put it on the NIH website, or CDC, or someplace? I think there isn't an answer to all these questions, but I think it's clearly something that we ought to be considering in thinking about how to disseminate our information.
MS. VEASLEY: Yes. Thanks, John.
One of the other recommendations -- and it's interesting that you're bringing this up -- that came out of that work group is there's need to do qualitative research around communications; so you need to know who is the audience that needs to get

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this information.
Sometimes it might be primary care providers, or nurse practitioners, or clinicians. It's not always patients or the public, but who are those target audiences, going to those audiences ahead of time, and doing qualitative research, focus groups, surveys, and so on and so forth to learn from them: A, like you said, how do they get their information; what are their preferences; what type of information are they looking for; and what format might it be helpful. And getting that information in the beginning so that you're better equipped to be able to develop it at the end of a project.
Kathryn, I you had your hand up.
DR. MARTIN: I do. I don't want to take us off course from where we've come from, but I think it adds to it nicely, is thinking about the way in which we make this culture shift to try and ensure that patient partner involvement is happening and we're involving members of the community and the public in our research, because I feel as if

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sometimes there's a bit of skepticism around this.
I think, Chris, you were bringing this up in terms of the expertise, or should we be having other members of the team and different folks coming together with those other skills to take some of the pressure off of the researcher so they don't feel that they need to be the expert in all of the aspects when they undertake a patient and public involvement.
I have heard from colleagues that have said "Well, I really don't want to engage in that way. I don't want to involve patients, but I guess I'll have to because funding agencies are starting to ask for it." I think we need to ensure that the motivations for including members of the public and people's lived experience are quite pure, if you will, but also recognizing that there are going to be external pressures and factors, and people are going to try and do this, but maybe they don't want to.
So it's trying to bring that culture shift in so folks understand and see the benefits and the

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true values, and for those skeptics that if they don't get funding, then they'll start to do it. But I think it's about empowering them because I do think that there's a lot of confidence to do it well, and so then people are resistant. So I think it's identifying those other members with the expertise to facilitate it and to help researchers, whom maybe are a bit on the fence, to bring about that culture shift.

I have even heard people say, "Well, this is just a passing fad. In a few years --" I see Lynn smiling; I think she knows. But anyway, this is just a passing fad, and it will all be sort of over in a couple of years. I think actually, no, it isn't. It's here to stay, so we have to ensure that that work is being evidenced and that we're showing and demonstrating the impact. A lot of the research that was presented, some of the slides today on just that, was just so evident in how involvement can actually make such a huge difference in the outcome of the research.

So I just wanted to put that out there in

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that we have quite a bit of work because some of the people around the table, we've all drunk the Kool-Aid, I guess, because we know it works, and we enjoy it. But not everyone is going to be that, not every pain researcher, so we have a bit of work.

MS. VEASLEY: Yes, I totally agree with that. That's another one of the first questions we get, is what evidence do you have that this makes any difference? So tomorrow we're going to have a conversation about metrics, around measuring patients, and how do we measure patient engagement across the research life cycle and also with journal editors, because if we're measuring it, are we reporting it? Is it included in the manuscripts that are being reported and can we learn from that?

Another topic that came up is that we really need testimonies, scenarios of patients and investigators that have worked together as teams out there in the media, and available to investigators that they can actually see the change.

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As Christine mentioned earlier, before she did it, her views changed afterwards. And I've heard that from so many people. Not saying she was skeptical, but other people have gone into incorporating patient engagement, and they're completely skeptical that it would have any impact on their research, but they absolutely would not ever go back to not doing it after they started doing it. So I think we have a ways to go, but that measurement and reporting piece is so important.

Lynn, you've had your hand up for a while. Please go ahead.

MS. LAIDLAW: Just in the communication thing, communication has got to be two-way. I think often if there's a communication vacuum or an information vacuum, then people will fill it with a narrative that's easily accessible and people that want to engage with them.

We have to come to a stage where there's no such thing as a stupid question. That's really what I saw happen in COVID, that people had genuine

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concerns, and those concerns were dismissed by the establishment as being silly, and why would you think that? So people went elsewhere for their information? So communication has got to be two-way.

I think in terms of research results, it's who has more skin in the game. Who needs these research results? Certainly, in the UK, there's a lot known about self-management and about shared decision-making, but often it's manage your disease the way the clinician wants you to manage it, or shared decision-making is actually choose from one of the options that I'm presenting to you.

But I think if we disseminate research in a way that people understand, then what I really want to see is people taking that research and putting it down on the consultant's table and saying, "What about that? Could I have access to that treatment? Would that work for me?" And then, really, that's when we'd get to a situation where it's kind of parachuting and that we're not put into the kind of patient box, and just choose.

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So I think communication is really complex and it's multilayered, but sometimes we think of communication as you doing what we tell you to do.

MS. VEASLEY: Yes, absolutely. And I think that goes back to the importance of training on both sides of all partners involved in a research project on an equal basis and all the values that you brought up during your presentation as well.

Gail, your hand's up.

MS. GRAHAM: I just wanted to go back to John's comment, too. I know when COVID hit, our community relied a lot on the University of Maryland PATIENTS Program. They became a trusted source to us. As the University of Maryland was finding out about COVID, they gave us that information, whether they came to us, whether they developed a video with one of our community leaders on it that goes out on social media, or whatever; they gave us trusted information. If there was any misinformation, they came back and they said this is not correct, don't use these pills like such-and-such said. That's not the safe way to do it.

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So because they became a trusted source and they had other partners, they were able to reach a lot of people in Maryland -- not just Baltimore, but in Maryland -- as far as what's happening with COVID.

The researchers themselves, once you develop that relationship with your community partners, then they will be your source to disseminate that information back. If you explain it to them correctly, it will get out there to the community correctly if you make yourself available and you speak to the community. Like they said, "No question is a stupid question," but it is the way that you phrase some things that can come off a little harsh. So maybe working on that, too, will help reach more people.

DR. FARRAR: Thank you, Gail.

MS. VEASLEY: Absolutely.

Isabel?

MS. JORDAN: I find this conversation really interesting. Going back a couple of points about how you motivate or interest researchers on how to

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do patient-oriented research or patient partnership, like Christine said, she really wasn't interested in doing patient engagement until it was in a grant. I think that can be a great carrot for those who could be interested in it, even if they're skeptical, but I have some disquiet around making people do it who really don't want to do it because I think there's a danger presented to patient partners, like a very real danger of traumatizing us.

I know I've been in situations where -- I like to think now I'm pretty good at smelling out when I'm being put in a bad situation where my participation is going to be abused in such a way that I will be re-traumatized, but it still happens once in a while, and I see it definitely happen to folks who haven't been doing this for 13 years like I have.

So I think it's really an interesting problem to figure out how do you motivate people who are hesitant because of fear, or not having the tools, versus -- this could be a controversial

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opinion, but I just think people that don't want to do it should have access to those funds. I think more funds should be made available for funded patient partner research. But I think people that don't want to do it just shouldn't have access to those funds because they will do harm.

MS. VEASLEY: Yes. I really understand that perspective and certainly have been in that scenario as well. We posed the question yesterday, how do we do this and how do we do it well and avoid tokenism? Because so many of us have had that experience where we've been brought into a committee or whatever because they had to do it, and we've just sat there for however long and tried to participate, but weren't really valued. And it does harm; it definitely does.

Kathryn?

DR. MARTIN: So on that note, I completely agree. I think that this is one of the things that Lynn mentioned about a lot of patient insight partners or patient partners being brought on to teams reviewing grant applications. This is really

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quite common and becoming even more so across the different funding agencies in the UK, and even charitable organizations.

I think that it's -- Lynn might be able to say a bit more here -- quite, I suppose, easy for folks to spot the tokenism that actually is coming out -- sorry, it is getting late here, so that's why I'm tongue-tied -- and I think that's when people are actually getting downgraded on their scores, and they aren't getting funded. But I think, still, it's trying to persuade gently and demonstrate the value.

I know here in Aberdeen we've been doing a lot of trainings and a lot of posting of conversations around patient and public involvement, trying to get people who might be interested but that cautiously are hesitant and not quite sure, what do I do, and offering them true support for them to see, and having them come and observe.

Actually, I think that's the initial way forward. But I also think it's about training

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students at the undergraduate or masters level, and certainly of course our doctoral students and post docs, to get involved early as well because it's about training the next generation. So very quickly, I think that culture shift could happen, which is really exciting.

MS. VEASLEY: Yes, definitely.

Hannah?

DR. GROL-PROKOPCZYK: Hi. I have a question that's actually going back to Dr. Jackson's talks about representativeness. One thing I've learned from a number of IMMPACT meetings is that the people who are eligible for clinical trials are very often very different from the typical pain patients that clinicians see. The clinical trial participants may be excluded due to physical comorbidities, mental health comorbidities, drugs they're already taking, or whatnot.

It seems to me that if some of these comorbidities are more common in certain groups, those groups may end up being excluded, not deliberately, but just sort of as a byproduct of

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the inclusion criteria. So I wondered if part of trying to increase representativeness means taking some kind of stance about what kinds of trial designs are better.

Then another related question is thinking about patient roles at various stages of the whole research processes, and what does it mean if you have patients involved from the beginning, but it turns out that most of those patients wouldn't be eligible to participate in the trial itself?

Is that a problem or is that ok; and you just accept that patients, some can play a role in initial planning, and others can play a role in dissemination, and a different group of patients can be the ones who are actually part of the trial? Those are the two questions I had.

MS. VEASLEY: Yes, that's interesting because it relates back to a conversation that the meeting planners had last night, which is there isn't always going to be consistency or congruity between what the patients want and what the RFA states or what the researcher's interest is.

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So the point that you just brought up about comorbidities, our organization advocates for research particularly in women who have multiple chronic pain conditions and non-pain comorbidities, but as you said, in most clinical trials, you are excluded if you have multiple pain conditions, pain in multiple parts of your body, or you have non-pain comorbidities.

It's an interesting point because there's not always going to be hundred percent congruity between what the patients are telling you is important or meaningful for them. Obviously, if they're in a trial, they want to know if you do have a pain condition, plus sleep disorder, and mood disorder, they may want to know -- meaningful outcomes to them are not just whether their pain score decreased by two points on a scale but what their quality of life is and what the impact on these other conditions may be.

I'm interested to hear other's response to your question. I know some of our trialists on the meeting have opinions, because I know you.

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Simon, you want to tackle it?
DR. HAROUTOUNIAN: No, I can take it. I want to make one brief comment that it's not necessarily the specific RFA or research interest. I think for drug-related studies, oftentimes it's the regulatory perspective as well.
For example, you may have a drug trial where there might be a drug interaction, for example, with an antidepressant, and then the FDA may say, "Well, if you have any patients who are taking any antidepressants, you may not be able to enroll them." And you completely then exclude your entire patient population that may have coexisting antidepression, which may sometimes be really hard because then you have a very skewed sample of patients who may not even represent the condition if you're treating something like chronic neuropathic pain, or fibromyalgia, or something like that.
So rather than an answer, just another limitation or potentially another barrier.
MS. VEASLEY: Yes.

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Okay. We have five minutes left. Does anybody have one last burning question? I think today's discussion has been great.
John?
DR. FARRAR: Yes. I was searching around for my hand. With regards to the question before about the inclusion and exclusion of people, I think we need to be cognizant of the fact that not all trials and studies are created equal. In the era of an attempt to try and personalize medicine, getting back to what Dr. Jackson said, we need to understand what it is that we need to control for or consider when we include or exclude people.
Even the comment that was made about excluding kids from the initial COVID vaccine trials, yes, it delayed their getting the COVID vaccines and may have caused or resulted in more deaths than we might have thought. But their concern about taking vaccines with a brand new vaccine and its possible implications for kids would give one pause. If you caused abnormalities in kids with COVID vaccine, it would have set back

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the whole thing a huge amount.
I don't mean to make an argument that there's a right and wrong. What I'm saying is that there are other considerations that go into it. The first-time-in-human studies phase 1 trials, you would certainly not use children and you would not use pregnant women. You would use healthy adults as a primary because you're being careful. With a second phase 2 trial, you may also be much more restrictive.
What I've been hearing today, though, and it makes great sense, is that you have to be more inclusive in phase 3 trials, and you have to be very clear about what the goal is, and figuring out who it will work for and who it will not work for, and move towards a better understanding. That does create an increased cost for trials, so there's been a little bit of conversation about that.
I hope that helps to make it a little bit more understandable. But it's an issue of not using one brush to paint the landscape, but using and being careful about what we do, and being

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thoughtful.
MS. VEASLEY: I agree. I think that what you find is when you do get an engaged group of stakeholders involved in research, if you're open and transparent about that, and saying we want to study this, but in this particular type of study because of X, Y, and Z regulatory requirements and yaddi, yaddi, yadda, we can't, what you'll find is that people are actually receptive to that.
What normally happens is we say what we would like. The scientists say, "Well, that's not what we're doing," or "We can't do that," and then they don't have the conversation. When the conversation happens, I think you find that people are a lot more reasonable and understand that not all science is created equal and not every question can be answered with every study. But if there's a true partnership and team response there, or effort there, it does make a big difference, I think, on both sides.
Well, we have three minutes left. Today has been absolutely terrific. Just to give you a heads

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up for tomorrow, we're going to hear from another important stakeholder in the conversation tomorrow, industry, because they've been doing patient engagement for a long time as well. We're going to hear some perspectives from regulatory agencies in the U.S., Canada, and Europe.

We're going to have a talk tomorrow on how do we actually measure patient engagement and report on it, not just measuring it from the side of was it impactful or meaningful, but also talking maybe about, hopefully, how do we measure the impact on the investigators and change in perceptions and attitudes.

Then we're also going to have a conversation with some journal editors about are we reporting on this; are we measuring it; are we reporting it or do editors want to know about it; and what do we need to do to get buy-in on all levels to be able to encourage this across the board?

I'm going to ask if Simon, Bob, or Dennis have anything that they want to say in the next couple of minutes before we wrap up, and if not, we

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will see you here tomorrow morning at 11 o'clock Eastern.

Simon, anything?

DR. HAROUTOUNIAN: No. I think you did a terrific job, Chris. Anything I add would be a detriment.

MS. VEASLEY: I doubt that, but that's very kind of you to say.

Bob, Dennis, anything you'd like to add before we wrap up? And Bob Kerns, he apologizes. He had to leave a little early today, but I know he would have the same sentiments as I.

DR. DWORKIN: I'd just second what Simon said. I think you did a terrific job, Chris, and I look forward to tomorrow.

Adjournment

MS. VEASLEY: Okay. Everybody have a great afternoon, and we'll see you back on Zoom in the morning. Bye.

(Whereupon, at 2:30 p.m., the meeting was adjourned.)

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