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

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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

Wednesday, October 27, 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.)

Introductions, IMMPACT Overview, and Meeting Objectives – Dennis Turk

DR. TURK: I want to welcome you all to the XXV ACTT-IMMPACT meeting. That means that we have been engaging in this process for probably about 20 years, and 25 is because we've had more than one meeting. I want to welcome you for being here and to thank a number of people for setting this up.

Of course I'm thanking you on behalf of Dr. Robert Dworkin, who is the director of ACTTION, and he is a professor universalis at the University of Rochester; universalis because he has more connections to any department than anyone in the history of the university. I also want to welcome you on behalf of the Executive Committee of ACTTION.

Then I have to thank Valorie Thompson, who without, these meetings could not occur for all of the technical assistance. Valorie is from Innovations Research Group. She's the president;

and also to Carlos Rodriguez, who is the AV director who helped set it up, and for those who are listening earlier on having the troubles that some of us were having on getting connected. So thank you all for being here. I want to thank the speakers as well who we'll hear more about.

Now, I mentioned the term "ACTTION" and "IMMPACT." Those are acronyms that Dr. Dworkin created, and let me tell you a little bit of what they are for those who are not familiar with it.

So what is IMMPACT? It's the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials, IMMPACT, and that's what's been going on for a number of years. It's an international consortium of participants from academic research; governmental agencies -- and you can see some of them listed there -- industry; consulting companies; and research organizations, as well as consumer.

I'm using word "consumer" versus patient advocates because there are also other advocates from family who tend to be involved with ACTTION,

or other significant others. The mission of IMMPACT is to suggest methods for improving the design, execution, and interpretation of clinical trials of treatments for pain.

IMMPACT is part of ACTTION, another acronym which stands for the Analgesic, Anesthetic, and Addiction Clinical Trials Translations, Innovations, Opportunities, and Networks. And given the number of words there, ACTTION is the acronym that we're going to be using throughout this meeting.

What is ACTTION? ACTTION is a public-private partnership with the U.S. Food and Drug Administration. The mission of ACTTION is to identify, prioritize, sponsor, coordinate, and promote innovative activities -- with a special interest in optimizing clinical trials -- that will expedite the discovery and development of improved analgesic, anesthetic, addiction, and peripheral neuropathy treatments for the benefits of the public health.

Before I just say this, let me just mention

that IMMPACT existed prior to the existence of ACTTION and was merged into ACTTION. So it's one of the activities, these meetings that we have, the IMMPACT meetings, which are just part of what ACTTION does, and you'll hear more about that.

So who is IMMPACT and who has been involved? Well, for the 25 meetings that we've had, we've had over 25 different participants, including this one. The participants have been from academic and related organizations from 150 different academic institutions, organizations, and health systems from 14 different countries, and they're listed there if you're interested in that. So we are truly international.

Investigators and officials from national and international governmental regulatory, as well as research agencies, have been involved, and those are listed: the DEA, DoD, EMA, FDA, Health Canada, NIH, MHRA, and a bunch of acronyms that you can read yourself. So we've had lots of involvement.

We've had over 50 different pharmaceutical and device companies who have provided support

periodically for different meetings and for different projects. We've also had representatives from seven different consumer advocacy groups. And again, I'm not using patient, I'm using consumer because there are people who have chronic pain but may not be patients, so therefore I'm using that term.

We've had consulting companies and research organizations over the 25 meetings from 23 different groups. So as you can see, it's quite a diverse group of people. But you are really who IMMPACT is; that is you're participating in this particular meeting and you are contributing to what we hope to do, and we'll go over the objectives shortly.

So keep in mind that I thanked all those other people, but I really need to thank you as well for participating, and that includes international people who have been involved in other meetings, but it's particularly in this meeting who have given the time that was on the West Coast. So our time is quite different from

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someone who might be in UK.

So thank you all for being here and taking part in this meeting, which will extend over three different days, or parts of three different days, with approximately 3 hours/3and a half hours over those days. We'll go over the agenda very quickly, and you'll get a sense of what those times are going to be.

We greatly appreciate you all taking your time out of your very busy schedules to participate in this meeting. This is a virtual meeting. It's our second virtual meeting. The previous IMMPACT meetings, people have actually come and spent time always in the Washington DC area. So therefore, the amount of time at those meetings, which is over usually two to two and a half days, has extended well beyond what we can do in this particular meeting.

So we do appreciate your being here. We acknowledge that people have busy schedules. But to the extent that it's possible, when we see the objectives, you'll understand why we would like to

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encourage you, strongly urge you, to participate in as much of the meeting as you can so that you'll understand where things are developing and where we're going.

What do IMMPACT and ACTTION do? Well, we have consensus meetings. We publish consensus statements, systematic reviews, methodological papers with diagnostic criteria and classifications. Many of you are familiar with those; you've seen them.

We conduct and commission the development and publication of review papers and different topics, which you may have seen over the 151 approximate that we've published, and conduct and support scientific research. We actually fund some different research projects, which you can learn more about, and I'll tell you how to access information about those if you're interested.

We sponsor collaboration with international organizations for the development and dissemination of diagnostic criteria and classifications. We have been involved in support of the publication of

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a number of diagnostic classification papers. We've had them all -- I think all -- published in Pain, and then we've created a volume put together of all these papers and made them available to all members of the International Association for the Study of Pain in a hardback version that was sent to all members approximately maybe a month ago.

We support educational initiatives. To date, there have been over 150 IMMPACT and ACTTION articles that have been published. These have been in major journals. There's a mistake on this slide. I checked recently, and it's now over 900 different scientific journals, ranging anywhere from addiction medicine, anesthesiology, women's health, and veterinary medicine.

Interestingly, most recently, a number of legal and juvenile delinquency publications have obtained access to some of the criteria, some of the studies, and some of the statistical methods that we publish. So it's sort of gratifying to see that the outreach is way beyond just the area of pain and addiction, but to a whole variety of

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different journals. And if anybody has great interest, I'll be happy to send you a list of 900-plus journals, where we've published things.

Since 2003, the IMMPACT and ACTTION publications, according to Google Scholar as of two or a few days ago, are over 14,000 times. So it's not just that we publish these, but they do actually seem to be having some impact -- pardon the pun -- by the fact that they're getting cited in numbers of different journals, but also numbers of times. So that gratifies those of us that are involved, including the many of you who are involved in those publications.

If you have interest -- and I know you can't read those on your screen -- in learning more about any of the things that I've said, any of the previous meetings and the manuscripts that we've published by people who've attended these meetings, and copies of some of the slide presentations, those are all available.

If you're interested in the IMMPACT meetings, you can go to IMMPACT, and make sure you

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have two M's, I-M-M-P-A-C-T.org. If you only put one M, you will end up with all kinds of interesting topics, not necessarily ones you want to be in.

If you want to go to learn more about ACTTION and the activities, and the range of things we've accomplished and that we've tried to undertake, and directions we're going, you can go to A-C-T-T-I-O-N.org, ACTTION, and that way you can find out a lot more than I can possibly talk about in this very brief introduction.

What are the meeting objectives? And this is really the most important thing that I'm going to say to you right now; that is what we want to accomplish. In every one of our meetings, our goal is to have specific directions we go, specific objectives, and specific outcomes of products that we try to do to make sure that we benefited from the speakers and discussions, and disseminate that information as widely as possible.

So our objectives for this meeting are to understand the history of best practices associated

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with incorporating "patients as partners" -- and that's in quotes -- in the life cycle of clinical pain research. We also hope to have an objective that we review how research funding and regulatory agencies are supporting the incorporation of patients and other stakeholders in the planning, conduct, and dissemination of clinical pain research. The third objective is to identify strategies to overcome significant barriers to incorporating patient engagement and research life cycle.

The next objective is to learn from clinical research studies that are incorporating patient engagement in planning, conduct, dissemination, and implementation of clinical pain research, including the incorporation of diverse populations. And the last objective -- and this is one that hopefully all this information and all of the discussions will work toward -- is to develop consensus recommendations to aid the international pain research community on best practices, as well as specific how-to guidance for incorporating patients

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as partners in the research life cycle.

If in fact you've been involved with other IMMPACT meetings or if this is new to you, what we try to do is to have a number of presentations over the three days. There's approximately three to four different presentations each day with, then, lots of question and answers, and then discussion, all going toward the goal of the last day of trying to come up with a set of recommendations for what we assert truly might benefit from what we've done.

Now, I should thank someone particularly now for this part of it, or actually two people, Dr. Robert Kerns and Christin Veasley. Dr. Kerns is a professor of psychiatry, neurology, and psychology at Yale University, and Christin Veasley, who is the founder and director of The Chronic Pain Research Alliance, a major organization trying to bridge the gaps between the clinical research side and the consumer, the patients as partner side of this meeting.

Without these two people, we could not have pulled off this meeting. They did a tremendous

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amount of work, as you will see. For those of you that are our speakers, you've had lots of contact with them, but they've also gone out of their way to help develop the content, the topics, and the speakers to do all the inviting and to set all this up. So in a very few minutes, I will shut up, and I will turn this over to Bob Kerns and Chris Veasley, as they will give you their perspectives and then move on to the presentations.

Before we do that, I also want to thank the last person, Simon Haroutounian. Simon has volunteered, or been coerced or encouraged, to serve as the rapporteur.

What he will do is in addition to presenting, he will also be taking notes trying to summarize things as they go along and will begin crafting and developing the first -- or one if there may be more, but at least the first of the manuscripts that we're trying to develop with our considerations and recommendations for those in the field; so the people that I've mentioned that I wanted to thank, in addition to Valorie and Carlos.

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This is just the agenda, and I'm not going to go over this for you, but you can get a sense of the range of people who are involved. It's available if you're interested in seeing all the people who are presenting and their credentials. They'll be introduced as they do their presentations, and also the people who are attending who or not presenting.

So those materials are available and may already have been distributed. I know, Valorie, you distributed to the speakers. I don't know, but I assume you may have distributed beyond.

This is the agenda for the first day. Let's go on to the second day. This is a list of the different topics of speakers that we're going to have. You'll notice that we have a lot of time for clarifying questions and built in a significant amount of time for discussion.

What we've learned in all of our previous meetings is that the discussion, that's kicked off by the different presentations, really is the meat of what this meeting does. We have to hash out,

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understand, discuss, debate, if you will, and come to some decisions that we hope to then draft up into a manuscript.

By the way, when we get to the point about authorship, I'll tell you in advance that when Simon drafts up the manuscript, it will be circulated. You'll have opportunities -- those who choose to be authors -- to comment on those and to add ideas, thoughts, disagreements, and suggestions. He will have the unenviable task of trying to integrate all this information. You'll probably see it at least one more time, if not two more times, before we get ready for submitting this publication.

So Simon is going to have a lot of work to be doing, and he may end up going back to some of you to clarify any of the things that went by too quickly for him.

The third day, there you can see at the end the discussion 12:45 to 2:30 on the East Coast of the United States. That's when there will really be a lot of discussion, trying to see if we can

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pull this information together. So while you've been processing and listening to different presentations, that's our goal, is to get to the point where we can come up with some recommendations and considerations to help the field.

General housekeeping. This is important. These are going to be the last two slides that I have, and I'll turn this over to Chris and Bob. All meeting participants will be muted during the presentations and unmuted during the Q&A discussion. Use the raised-hand button located on the reactions menu found in the bottom bar of the Zoom screen to ask a question or to engage in discussion.

The chat function will not be available during the meeting. Email Valorie Thompson with any comments requiring immediate attention, and you can see her email address there. She will do her best, as she did to help me out, to help you out. Breaks have not been scheduled in the agenda. Please take a break when you need to, but try to be

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involved as much as possible in the meeting and come back as soon as you can.

This meeting is being audiotaped. You should have already seen that. That's because they'll be a transcript made of this meeting, which will become available for anyone who wants to see it. It will be posted on the ACTTION website. The transcripts, PDFs, and the slides will all appear in about 6 to 8 weeks of the meeting; that is, the slide presentations.

For speakers, if there are any slides that are proprietary or you choose or feel should not be put in the public domain, you should remove those before we actually mount those up.

Per the updated publication policy, anyone -- and we hope it's all of you; all of you will be invited -- desiring to be a co-author on the manuscript, developed based on the meeting, must -- and the word "must" is an exclamation point -- attend all three days of the meeting.

Now, we are aware that sometimes you have to tune in and out of the meeting, and it may not be a

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hundred percent possible to be there for every particular minute, but it really is important. And the reason for this is because we want you to have the benefit of the presentations, the information, the discussions, and to really help us craft this manuscript.

So you will be strongly encouraged, and we know if you're watching. We're going to keep track of you and how long you've been on the Zoom calls. So we'll know who's been saying that they've been here but hasn't really been. So keep your computers on and stay in the Zoom meeting. Should you require an update of the publication policy, again, you can contact Valorie Thompson, and that's vthompson@mac.com.

So unless Bob Dworkin or Valorie have anything they want to add, I will turn the meeting over to the people who really deserve all of the credit, and I've tried to mention that; and that is to Bob Kerns and to Chris Veasley, who, really, it was their conception, their idea, their discussions, and their encouragement that led to

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this particular meeting here that we're spending.

So I'm looking forward to an exciting meeting and to the debate and discussion so that we can, in fact, do something to improve the field. Thank you very much, and welcome to the XXV IMMPACT meeting.

Welcome and Charge

Robert Kerns and Christin Veasley

DR. KERNS: Thank you, Dennis.

Bob Kerns here from Connecticut. I'm delighted to welcome you on behalf of myself and Chris Veasley, and I'll turn things over to her in just a minute. We're delighted to have your participation over these next three days. It's really been a terrific team effort involving many of you who are participants, and we look forward to a great meeting.

This meeting is in the context of what Dennis already suggested, ACTTION and IMMPACT, and one of the working groups within ACTTION is a group that was organized by Chris and me a couple years ago -- a few years ago, actually -- called PROCESS,

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Public Relations and Communication and Education Strategies, written here as an acronym.

As I said, Chris and I co-chair this. Our working group has focused on developing a range of initiatives designed to disseminate information about ACTTION's multiple activities, particularly research studies, diagnostic criteria, et cetera, that Dennis has already articulated, but particularly with a focus on communicating with a range of stakeholders beyond researchers, including clinicians, students and trainees, persons with pain, and the general public.

One of our major accomplishments, as Dennis alluded to, was an ACTTION guide to clinical trials of pain treatments. Many of you on this call contributed to that, and there were a number of individual papers that were invited and were published separately. Then all of it was published as a book, and we appreciate the support from Pain reports that published this in the International Association for the Study of Pain.

Ultimately, the book went to all the members

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of the IASP, as Dennis mentioned. I should say that this was a shared collaboration with Bob Dworkin and Dennis Turk, but also Mike McDermott and Chris.

These are the members of our planning committee for this meeting, so thank you to all of you who contributed, both in helping us define the scope and plan for the meeting, in general, and then to several of you who have played really critical roles in fleshing out the details of the meeting and helping us engage stakeholders who are participating with presentations, really, from around the world. So we thank all of you.

I want to particularly thank Simon, who's been a great collaborator and partner thus far and will be working on preparing the manuscript as a result of this meeting. I want to, again, thank Dennis and Bob for their leadership, and a special thanks to Valorie, who just has been extraordinary, as I'm sure all of you recognize, for helping and, really, taking the lead in organizing this meeting and all the details. It's truly a testament to her

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organizational skills and communication skills that we're able to do this. So thank you.

I think this is where I turn things over to Chris Veasley.

Chris, please, take it away.

MS. VEASLEY: Thanks, Bob. And I just want to extend my thanks to Bob and Dennis, and the entire ACTTION Executive Committee for support of this really important meeting today.

I'm going to start off by addressing the proverbial elephant in the room -- if my slides will advance, there we go -- and what we're really doing here is challenging the traditional research model that really states that only those that have advanced training and degrees are the ones who can be unbiased in developing rigorous methodologic clinical research, to the pushback from patients who have many, many years of lived experience with their individual illnesses, who can also contribute in developing and adding value to the development of rigorous clinical research.

This is a quote from a paper from Applied

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Clinical Trials, and it says, "Once regarded as, quote/unquote, 'subjects who had research performed on them,' patients are now contributing across the spectrum of clinical development, including the design and planning of research protocols, selection of outcomes and endpoints, development of recruitment and retention strategies, and dissemination of results."

There's a lot of added value to incorporating people with lived experience into the development of planning and research. Now, there's been some pushback in terms of, yes, the typical person with lived experience doesn't have training in statistics, or pharmacy, or development of clinical trial protocols, but I would suggest that even in the context of a greater team of developing clinical pain research, you wouldn't expect that the statistician on your team is making decisions about pharmacy issues, and so on and so forth. There's a big team that all comes together and works cooperatively to develop rigorous clinical research.

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This is just a larger understanding that, really, in order to develop research that is both meaningful to people who have the condition for which you're studying, and also implementable, that there are a range of stakeholders who really should be engaged in the planning and conduct of research from its earliest stages, including patients and consumers, clinicians, insurers and payers, policymakers, and funders, and that's just to name a few.

This is really a larger concept of what's called community-based participatory research, which is really we'd like to bring those principles into the clinical pain research strata, which is a partnership approach that equitably involves community members, organizational representatives, researchers, and others in all aspects of the research process.

There's reciprocal appreciation of each partner's knowledge and skills at every stage of the project. All partners are considered equal and contribute expertise, as well as share in

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ownership, decision-making power, resources, credit, knowledge, and results, and all are really fully committed to producing outcomes that are actually usable to the community.

This very highly scientific question at hand today is how can we advance patient engagement in the planning, conduct, dissemination, and implementation of clinical pain research, and how can we do it well? And by that I mean how do we avoid tokenism by just adding people to a list of project members, but actually have authentic engagement?

In order to do that, we've brought all of you together, and we thank you so much for your participation. We have research funding agencies represented in this meeting, and people from regulatory agencies, and I would say not just in the United States, but international. We have clinicians, we have scientists, we have patients and persons with lived experience. We have industry members and journal editors. Because, really, in order to change the paradigm of how

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research is conducted, we need buy-in from all stakeholders that are involved, and we want to learn from you.

So we really appreciate you coming together with us for these three days. We hope that you can participate in as much of the meeting as possible, and we look forward to really developing meaningful, consensus recommendations that will change the field.

I'll turn it back over to you, Bob, to introduce our first speaker.

DR. KERNS: Thank you, Chris, very much.

It's my real pleasure to introduce Christine Goertz. Christine is the chair of the Board of Directors of the Patient-Centered Outcomes Research Institute, or PCORI, based in Washington, DC. She's also a professor in musculoskeletal research at the Duke Clinical Research Institute and director of System Development and Coordination for spine health in the Department of Orthopedic Surgery at Duke.

Christine, we're running behind, but please

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don't short-change your own presentation. Do it at your own pace. We'll make up for the time later.

With that, I'm going to hand things over to Christine Goertz.

Presentation – Christine Goertz

DR. GOERTZ: Thank you so much, Bob, for that kind introduction. It's such a pleasure to be with all of you today. I'm truly thrilled to have been asked to give these opening remarks to help set the stage for what looked to be three incredibly exciting days, but also because I'm really looking forward to the opportunity to learn from all of you. The topic of patient and stakeholder engagement pain research is critically important, and I thank IMMPACT and ACTTION for making it a priority issue at this year's meeting.

As you heard from Bob, I'm a pain researcher and have been for more than 30 years now, and I wear a number of hats. Among them, I have the honor of serving as chairperson of the Board of Governors of the Patient-Centered Outcomes Research Institute, or PCORI, and it's primarily in that

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capacity that I'll be addressing you today.

My goal is to give you an overview of patient engagement from PCORI's perspective, including some definitions, best practices, and lessons that we've learned over our first 10 years or so of doing this kind of research. I'd also like to discuss a few studies specifically on pain management and talk about how this work can help shape how we study pain in the future, using outcomes that really matter to patients.

Just briefly, I want to provide an introduction to PCORI and a high-level view of PCORI's work on patient engagement, including lessons learned and challenges to doing it well. I'm going to focus on a few pain studies from our portfolio, with an emphasis on the role of patient engagement and shaping this work. I'll provide some resources for those who are interested in learning more about PCORI's work in stakeholder engagement, and then close with just a few take-home messages.

I'd like to begin with a brief introduction

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to PCORI. I tend to think that everybody has heard of PCORI, but I know there may be some of you on this call that are not familiar with our organization. We're really unique with an interesting origin story that clearly illustrates the need for the kind of research and patient engagement that PCORI champions.

We were established in 2010 by U.S. Congress as part of the Affordable Care Act legislation, which expanded healthcare coverage in the U.S., and lawmakers recognize that in spite of the plethora of traditional research that's been conducted, very often patients and those who care for them don't have the information that they need at the point of the bedside to properly guide healthcare decisions they face every day.

Our organization was deliberately given the name of Patient-Centered Outcomes Research Institute as part of its authorization, emphasizing the need for research that engages patients and other stakeholders. Consequently, our research questions and our outcome studies must be of

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importance to patients and those who care for them, and the studies much engage patients and stakeholders as true partners in the research process.

PCORI also prioritizes the dissemination and promotes the uptake of research findings. We want to ensure that the results of the research we fund are useful, that they're actionable, and accessible for both patients and stakeholders. As we all know, the best clinical research in the world is not of much use unless it's actually implemented into clinical practice.

We have strived to translate patient centeredness into practice guided by our mission, which is that PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-quality and evidence-based information that comes from research -- and I really think it's this last part that's really unique to PCORI -- "guided by patients, caregivers, and the broader healthcare community."

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The primary vehicle through which PCORI accomplishes this mission is the funding of comparative effectiveness research, or CER, and specifically a type of CER called patient-centered outcomes research or PCOR.

All the interventions in PCORI-funded studies have already been shown to be efficacious, however, there are questions that still remain about how effective they are, especially for particular populations under particular real-world circumstances.

Research designs can include both randomized-controlled trials and observational studies that have to be designed to answer questions that matter most to patients, and what we've learned from talking to patients and other stakeholders over the last several years, but especially early on in our development, was that the following questions are things that really matter to patients and to other stakeholders.

First of all, given my personal characteristics, conditions, and preferences, what

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should I expect to happen to me? What are my options? What are the potential benefits and harms of these options? What can I do as a patient? What can I do as a clinician to improve outcomes that are most important to patients? And finally, how can clinicians and healthcare systems work to help me as a patient make the best decisions about my health and my health care.

Let me give an example. The PROSPER study focused on treatments for stroke. Patients received either blood thinners, statins, or no medicine. Patient involvement in the design of the study led to the measurement of outcomes that researchers had learned what mattered most to patients.

As clinicians or scientists, the researchers might have chosen to measure survival rates, the severity of the stroke, or where patients were discharged to on leaving the hospital. But with guidance from patients, one of the study's primary outcomes was days spent at home rather than in a nursing home or a hospital.

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We've learned this and from the other studies that we've conducted, that what really matters to many patients are outcomes that are more related to the quality of life and functional measures rather than traditional clinical measures, though those are often measured in the same study. Patients can often identify real-world barriers to study completion that might not occur to researchers such as transportation issues for studies that require regular visits to a facility.

Finally, patient input can lead to changes that seem really simple but that really matters, such as when it comes to informed consent. In one case, patient-led input helped the scientists realize that their form for informed consent was so dense and abstract that patients couldn't even understand the level of risk, so the form was rewritten into plain English.

We realized early on that in order to do our work well, we needed to operationalize our definitions of key concepts. This includes being clear about what we mean when we say patient

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centeredness or patient and stakeholder engagement. And to that end, to PCORI, patient-centered means that the project aims to answer questions or examine outcomes that matter to patients within the context of patient preferences, and that research questions and outcomes should reflect what is important to patients, as well as to caregivers and other stakeholders.

To us, patient and stakeholder engagement means that patients are true partners in research, not just subjects, and that there's active and meaningful engagement among scientists, patients, and other stakeholders, and that community, patient, and caregiver involvement is already in existence or there's a well-thought-out plan to achieve this involvement within the context of the research study.

This brings us to the heart of this kind of patient-centered outcomes research engagement. The model depicted on this slide captures the foundational involvement of patients and other stakeholders from all aspects of health care.

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Patients and other stakeholders participate in active and meaningful ways all through the process, as members of advisory panels that provide input into PCORI's funding priorities; as members of our merit review panels that determine which applications we fund and the actual conduct of research; all the way through to dissemination and implementation of research findings.

So why do we do engagement work? There are really four principal reasons; most importantly, to make clinical research reflect the needs and values of patients, caregivers, clinicians, and other stakeholders.

Second, to improve the feasibility of doing studies in real-world settings. It takes a lot of time and effort, I can tell you personally, to build the relationships and trust needed to conduct research in community settings.

Third, to improve the relevance of and encourage uptake and use of research results. Results from studies done in real-world settings are more likely to capture data that reflects the

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real needs of diverse populations across the country. And finally, because PCORI researchers and partners have found it to be valuable and worthwhile.

This is the conceptual model that underpins PCORI's s engagement work. When PCORI was established, there was very little evidence to guide what engagement in research should look like and its impact on clinical research and ultimately on health care and patients. We conceptualized this issue and developed this model, which drew on disciplines such as community-based participatory research, as Chris outlined earlier, to show how engagement helps achieve research that matters to patients and the people who care for them.

On the left are the central elements of the PCORI approach, the intensive portfolio management and investments in dissemination and implementation of research findings, and that all PCORI-funded research is pragmatic and takes place in real-world settings. Moving to the right, research that matters includes the issues and outcomes of

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greatest interest to patients and those who care for them. These inform our overall strategic priorities, which include producing useful information, speeding the uptake of that information, and influence the culture of research to be more patient-centered. On the far right, all of this work is designed to produce better health decisions, better health care, and improved health outcomes overall.

In the early days, there was not a strong evidence base to guide best approaches for engaging patients and stakeholders. The end goal to improve information to help patients make informed decisions and outcomes that matter to them was clear, but the mechanisms for achieving this were not. Therefore, we did not specify engagement activities that must take place in our funded projects. We specified only that that engagement must occur, and left it to investigators, and patients, and other stakeholders to figure out the what and how.

Since that time, we've learned a great deal.

We've tried to make the most of what has ended up being a natural learning laboratory by studying engagement in every aspect of what we do to develop that body of evidence on how to engage individuals and organizations, on how to better support our awardees, and to answer the questions about what happens when you engage patients and other stakeholders in research.

PCORI gathers data from research projects, from externally-led studies and evaluations, and from the practice-based experience of the core engagement officers who have been providing real-time consultative guidance and technical assistance to study teams who are doing engaged research.

There have now been several studies of engagement in PCORI projects and high-level themes have emerged. We know that engagement influences study conceptualization, execution, and development of materials, as well as the way study tests are carried out, how engagement is designed and practiced, and researchers understanding the needs

of people and organizations.

I'd like to go into more detail on one particular recent qualitative study of the ways in which patients and other partners influence and impact PCORI projects.

What we did is we had a study that looked at a stratified purposeful sample of 58 PCORI-funded research projects, and researchers not affiliated with PCORI conducted one hour, in-depth interviews with both project PIs and stakeholder partners. The study considered two important research questions: how does engagement influence the planning and conduct of PCORI-funded studies and what impacts to the study result from that influence?

The researchers identified five main types of influence exerted over the study by stakeholders and classified each study in one of these categories. The five categories were co-producing in which partners and researchers work together and collaborate; redirecting, where the partners shift the direction of the study based on the input they

received; refining, where partners edit or modify the proposed study; confirming, where partners validate existing plans; and limited or no influence. In these cases, partner input could not be implemented.

The study identified five areas in which patients and other stakeholders influence studies. These are user orientation and acceptability. This gets at the way in which engagement helps align study goals with the interests and needs of patients and clinicians to expand their willingness to participate, considering issues such as burden, usability, and alignment with our preferences, values, and needs; feasibility, referring to the interventions, enrollment, and data collection that are doable in real-world settings; study quality, where engagement can enhance the rigor and comprehensiveness of studies, as well as the quality of materials and products of studies; relevance, ensuring that results are applicable and important for decision-making; and then finally, engagement scope and quality.

Partner input can impact engagement process itself, ensuring that engagement processes are effective and stakeholders are well equipped to engage in the study.

There are a couple of examples from the qualitative study to help make these concepts more concrete. In this study, the team was planning to evaluate interventions to improve the quality of life for Latina breast cancer survivors and their caregivers.

After engaging with patients and other partners, the research team expanded eligibility criteria to any survivor regardless of time since diagnosis. They reduced the number of intervention sessions, which improved participation and retention, and they ensured that interventions included workshops on topics important to patients and caregivers, such as stress and sexual intimacy next slide.

In this example, a patient partner explained to a researcher that information can be missing from claims data because many patients pay out of

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pocket for psychiatric care. The research team then added new questions to the interview guide that improved data collection and gave the PI a more well-rounded perspective on the data.

We believe that engagement benefits all stakeholders in the research enterprise. More specifically, for patients and other stakeholders, increased knowledge about an enthusiasm for research as well as new and better relationships can occur. For communities, the keys are the building of trust and increased awareness of different stakeholder perspectives, and for researchers, a deeper understanding of what's happening in the real world that these patients are experiencing and concerns for their study and concern for their study participants.

I hope I've made a compelling case for why patient engagement is critically important, but I don't want to leave you with a sense that PCORI's figured out everything there is to know about engagement and that investigators simply have to apply a formula, and everything falls into place.

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Engagement can be challenging, and there's no one-size-fits-all model. Circumstances vary from study to study, depending on the population, the community's history with research and health care, and the outcomes being studied. There are an infinite number of variables.

A number of common challenges that have been shared with us by PIs and patients and other stakeholders can be grouped into four main categories. Starting with the left, challenges related to infrastructure and resources include the need for readily available training as well as having funding and staff resources available for engagement and to compensate partners. Time is always a challenge for everyone. Patients, and stakeholders, and investigators lead complex and busy lives and have family responsibilities. Patients often have illnesses and other demands on their time as they are trying to meaningfully contribute to research.

Next is people and teens. Conducting engaged research is a multistakeholder enterprise.

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It involves integrating stakeholders with specific perspectives and interests with trained CER researchers who also have their own perspectives and interests. They need to balance all of these perspectives, and interests can often be challenging.

Another challenge is in recruiting participants who truly represent the diversity of individuals with conditions or with the circumstances under study. Organizational barriers remain for PCORI's funded PIs. A good example is that some IRBs do not always understand the way in which an engaged patient or other stakeholder is fundamentally different from a research project. Investigators have also run into challenges in allowing for the time and flexibility to maximize the input from engaged partners and funded projects.

Finally, balancing views and priorities; this is perhaps the greatest challenge. For example, randomized-controlled trials, while seen as the gold standard in clinical research, can be

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viewed as unjust or unfair by patients and community members, and they may be unwilling to participate or are concerned about participating in these projects. And it's not just patients who have concerns or differing views. For example, clinicians do not always agree whether treatments really represent equipoise.

In reality, generating high-quality, high-impact research has many challenges: ethical review, safety assurance, rigorous methods, among others. Engagement, especially when new, can be genuinely disruptive.

I love this quote from one of PCORI's funded PIs from the University of Kentucky, who makes the key point that, "It is absolutely fundamental to have people from the community who are the interface for the participants in the project, and that really becomes evident when you don't do it." This underlines the point about the importance of trust, which is noted as one of the key benefits of engagement to communities.

Many communities have good historical

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reasons not to trust researchers or healthcare institutions, so taking the time and making the effort required to build that trust is absolutely essential to productive patient engagement.

I hope the walk through some of PCORI's work on patient engagement has been helpful and given you a deeper understanding of what PCORI has been doing in this growing field, and I look forward to hearing more about what many of you on this call are also doing.

Now, I'd like to focus specifically on a few studies related specifically to pain. The first example is the VOICE study, a study of patients at Veterans Affairs facilities who have chronic pain despite using opioid medicines. Patients were assigned to one of two groups. One group worked with a pharmacist care manager and primary care providers to find effective pain medicine options. The other group works with a clinician and mental health provider to help them set and meet personal health goals.

In both groups, patient care is coordinated

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with their primary care provider, and they receive support to reduce their opioid use if they wish. Patients who are taking very high doses of opioids may be selected, by chance, to switch to buprenorphine.

This study provides a really good example of well-constructed and sustained patient engagement strategy driven by a committee of 10 veterans, 5 men and 5 women, with chronic pain, who formed the Veterans Engagement Panel or VEP. The panel's contribution to the study began early on with providing solutions to transportation barriers identified to attend an initial 2-hour visit with study coordinators, including discomfort, cost, and a lack of availability.

When the COVID-19 pandemic struck, the VEP helped craft protocols to allow study activities to take place virtually, including ways to make potential study enrollees feel comfortable on video and creating rapport with researchers, and recommending a compilation of a list of no-cost virtual pain management options, such as online

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yoga and meditation to be shared with enrollees.

The most important decision that patients influenced in the study was the decision to make the intervention about improving pain management with tapering of patients agreed, rather than about opioid tapering as a primary goal. Following patient input, the research team revised the goals in its proposal to improve pain management while decreasing opioid use and to focus on shared decision-making about tapering, rather than requiring agreement to taper at the point of enrollment.

This study by Dr. Beverly Thorn was one of our earliest pain studies funded by PCORI. The study compared patients receiving usual care with those receiving group education classes or cognitive behavioral therapy, with both interventions adapted for patients with relatively low literacy levels. Patients and clinicians were involved in designing the study and adapting the educational and therapeutic materials for the literacy level of the patients in the study, which

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was at the 7th or 8th grade level, and the study found that both education and CBT resulted in lower levels of reported pain than usual care.

The IMPOWR study compares the effectiveness of two kinds of active pain management treatment of patients who are prescribed long-term opioids in primary care and pain clinics in four western states.

The goal was to respond to the despair patients can feel at not knowing how to reduce long-term opioid use due to the fear of experiencing pain and distress through determining which of two types of pain management classes is best for reducing pain and pain interference, increasing function, and reducing opioid use.

The research team created a study advisory board and conducted a national patient panel survey mechanism to get input on key issues from a larger more diverse group of patient stakeholders as needed. Patients were also heavily involved in recruitment strategies, and they continue to provide feedback on how to recruit during COVID-19.

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One key takeaway from this study as a result of patient input was increased awareness of the crucial importance of the patient-clinician relationship when enrolled in health research.

A final example of this study is the STAMP study, which compares mindfulness meditation with cognitive behavioral therapy for chronic low back pain. The study design, methods, and outcome measures were all informed by patient stakeholders, their family members, patient advocates, clinicians, leaders of health systems, and community advisors on research design and strategies.

The PI also held a focus group of patients and queried individual and family members and clinicians regarding the study outcomes. All groups identified reducing pain and disability as the top priority and improving quality of life and reducing opioid dose as important secondary goals.

One interesting note in this study is that the research team had initially called the study HEALTHY MIND/HEALTHY BACK. Patient advisors for

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the study said that they found this name stigmatizing and condescending. It seemed to imply that there was something wrong with their minds or their own fault that they had back pain. Together, the researchers and patients came up with a new name, Strategies to Assist with the Management of Pain or STAMP.

PCORI's learning about engagements are far from complete of course, and here's your chance to get involved. We currently have a new project underway that's seeking input to inform the potential development of a new funding initiative on the science of engagement. This initiative will help address high-priority knowledge gaps on approaches for effectively engaging diverse stakeholders through the research process.

We're seeking input from interested potential applicants, patients and other stakeholders, and organizations who participate in research or engage communities. You can find the request for information on the PCORI website at pcori.org/soe if you're interested in providing

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comments, which are due on November 19th.

I'd also like to briefly mention these two resources for investigators and for patients and other stakeholders they may have recruited to their teams. The first is the Research Fundamentals course, which provides a great foundation of knowledge about PCOR and CER. There's also a new module on Building Effective Multi-Stakeholder Research Teams, which provides guidance and resources to help teams work effectively together.

I hope this overview of patient engagement, as conceptualized and studied by PCORI, has been helpful. You'll learn more about PCORI's engagement work during the panel discussion later today, and then on Friday from PCORI directors, Kristin Carman and Laura Forsyth.

Before we transition to questions, I want to emphasize the following takeaways from this talk. First of all, patient engagement matters. It really must be an integral part of clinical research projects from the very beginning, and that patients need to be actively and meaningfully

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involved from the development of research priorities all the way through dissemination and uptake of findings.

Second, engagement takes time, effort, and patience, and it must be tailored to the needs of the specific community in which the research is taking place. Building trust is key. Many communities have good historical reasons to distrust research and institutions, generally, so it's important to devote the necessary time and effort to build relationships with community leaders and brokers to build trust over time.

Participants in PCORI research describe engagement as an integral and valuable part of projects. It can be challenging, and it's not always wholly successful or unsuccessful, but it often helps to highlight looming problems and to solve many of the challenges of doing pragmatic, real-world research and providing answers to the questions that matter most to patients.

Patient engagement can improve the relevance of research results, which encourages an uptake of

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those results into clinical practice. Results from studies approached this way are more likely to capture data that reflects the real needs of the diverse populations across the country and across the globe.

Finally, balancing the needs and interests of everyone involved in a research project -- including researchers, patients, and other stakeholders -- can be challenging, as can recruiting participants who truly represent the diversity of individuals with conditions or circumstances under study.

In the field of pain research, application of these engagement principles is truly in its infancy, and as yet, there are few studies that have engaged patients as partners, as you will hear in more detail from others very shortly.

As a pain researcher for over 30 years, I think it's possible that in our pursuit for the holy grail of biomarkers for pain, we've been too dismissive of the patients' experience of pain, how they perceive it, and what is most important to

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them in reducing pain, improving functionality, and reducing dependence on opioids.

We're not going to know what really matters to patients unless we're asking them. Our misperception that patient-reported outcomes are really soft measures, instead of looking at it from that perspective, we really need to double down and get patients even more involved in shaping our study outcomes and helping to design studies from the very beginning.

As they always say at the end of every day journal article, "more research needs to be done." There's no area of science where this is more true than pain. I look forward to seeing how this meeting helps us shape the body of evidence regarding patient engagement over time, as the voices of patients and others take root in the growing field of patient engagement and clinical pain research.

Thank you for your time this morning. I'm happy to take any clarifying questions that you might have if we have time to do so.

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Clarifying Q&A

DR. KERNS: Thank you, thank you, thank you, Christine. This is just what the proverbial patient asked for, or ordered, so thank you.

We are running a little bit behind, but I think that's ok. I want to make sure that we give our audience/participants an opportunity to ask maybe one or two clarifying questions to begin with. We'll see how it goes. I don't want to cut this short; it's important.

Any questions from the audience? If you have a question or comment, I guess put your hand up in the reaction space.

I see Ian. Please go ahead.

DR. GILRON: Sure. Thank you.

Can you hear me, Bob?

DR. KERNS: Yes, we can.

DR. GILRON: Great.

Thank you, Christine, for an excellent presentation. I just wanted to ask you, there's a difference between a patient advocate or a patient partner. What experience have you had with

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providing specific training to become patient advocates or partners, and have there been developed any specific training programs for that purpose?

DR. GOERTZ: For the most part, we have worked with investigators to train patients that are specific to that particular study or population, but that is definitely something that general training is critically important. We have developed some tools that are available on our website, and both Kristin and Laura can talk more about -- Kristin in particular can talk more about some of those tools, and give you more detail about what some of those tools look like.

But you're exactly right that there is a difference between patients and patient advocates, and PCORI engages both of those groups. Not only do we work with individual patients, but also with patient advocacy groups, and they are involved as partners, as well, in many of our research projects.

DR. KERNS: Thank you for the question, Ian.

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Thanks for your response, Christine.
Penney Cowan?
MS COWAN: I just wanted to say we've been involved in chronic pain, and I've been involved in many of these PCORI projects. One of the things that I don't think she mentioned is that not only does it provide them with the opportunity to get involved in research, but what I have seen and heard from our members is it really enhances that relationship with their own personal healthcare providers, giving them a voice. It makes them stronger. It makes them more advocates in their own health care, and then they share with others their experience.
So I think that was one important takeaway that I don't think you hear that often, but it's really important. Thank you.
DR. GOERTZ: Thank you, Penney, for making that point. You are right, that that is incredibly important. Thank you.
DR. KERNS: Thank you, Penney.
Two more questions, and then we'll move on.

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Jeremy Taylor?
MR. TAYLOR: Hi. Thank you. It's been shaking me to ask a question because I'm on the program later, but I couldn't resist this one.
Thank you, Christine, a really interesting talk. I'm a great fan of PCORI. We don't quite have anything exactly the same in the UK. My question was really about the influence of PCORI and whether you have sensed the extent to which the PCORI approach has had an impact and influence over other research funders, particularly in the States, but possibly more broadly. I'm interested if you've picked up any sense of that.
DR. GOERTZ: Well, Jeremy, there's no doubt that this idea of patient centeredness and patient stakeholder engagement in research, that conversation has really changed over the last 10 or 11 years that PCORI has been in existence. I hope that we're able to take credit for some of that change.
You'll hear from other funders later on today talking about patient centeredness and

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patient engagement. There have been many groups that have been thinking along those lines for a long time, but I think PCORI was the first to make it fundamental to everything that we did.
When we first started bringing patients on board, for instance as part of our merit review process, that was a pretty novel concept at that time. It wasn't unprecedented, but it wasn't common. I think it's more common now, and just the idea of bringing stakeholders on board as part of the investigative team is much more common now across many funders.
More and more researchers, researchers that I've talked to, tell me, "Well, I started out getting patients more involved because it was required by PCORI, but now I won't do any study without it, regardless of who the funder is."
DR. KERNS: Thank you, Jeremy, for your question and to Christine for your response.
One more question or comment from Isabel Jordan.
MS. JORDAN: Good morning. I see I've got a

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very cheeky background from my last meeting. I'll get rid of that. These are my friends.
I have some curiosity around the idea or the concept of training patient partners to fit into the research environment versus the need to train those in the research environment to create spaces that welcome patient partners as they are, especially as we move from a model that has engaged folks that already kind of fit into that space, rather than looking at engaging patient partners with an equity and diversity lens. And I'm curious how PCORI is addressing that.
DR. GOERTZ: Well, I could not agree with you more, Isabel. There's no reason to bring patients as stakeholders onto the studies to get them to think what we already think. We really need to make sure that we are open to what they have to say.
I think when I talked earlier about some of the challenges, and that everyone has their own perception of how a study should look, that is in large extent what I was referring to. But we need

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to make sure that when we're engaging patients, that we're really listening to what they have to say and that we're able either to be able to incorporate their input into this kind of research, or that we're able to have a conversation with them so that at least there's mutual understanding about why that might not be possible.

My experience in talking with patients that have been involved with PCORI research projects is that they do feel heard, and that they do feel that this project has changed and they have had an impact on the research because of that level of engagement. But is there more work to be done? Absolutely, there's more work to be done, and that's something that we need to continue to be vigilant about.

DR. KERNS: Well, thank you again, Christine. Thanks for that question, Isabel; a great way to kick off our day.

We're going to move on to our next presentation. This is the first of two commissioned reviews. The first one is going to be

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presented by Simon Haroutounian, and I hope I didn't butcher your name. Simon is associate professor of anesthesiology and chief of clinical pain research at the Washington University Pain Center, and he's chief of the Division of Clinical and Translational Research in the Department of Anesthesiology at the Washington University in the St. Louis School of Medicine.

Simon, take it away.

Presentation – Simon Haroutounian

DR. HAROUTOUNIAN: Thanks so much, Robert.

Hi, everyone. As Bob pointed out, and correctly pronounced, my name is Simon Haroutounian. In the next 20 minutes or so, I will be presenting here some of the highlights from a narrative review we're just wrapping up on partnering with patients in clinical trials on pain management. Unsurprisingly, you will hear several themes that are actually consistent with what Dr. Goertz presented in her excellent talk.

So to start, I'm taking credit for presenting this data from this review, but it has

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been really a team work of about 2,000 contributors, most of whom are present on the talk. And I really want to thank specifically my brilliant colleague, Katie Holzer, for putting really a major effort into this review, and really there are quite a few people who've helped with this.

I will start by saying that the involvement of patients as partners in clinical research have been studied, obviously, in different therapeutic areas, mainly with a particular emphasis on cancer and HIV. That's probably one of the reasons we're here today, that there's really no guidance for best approaches on how to partner with patients when it comes to clinical trials on pain treatments.

There are a lot of open questions on what are the best ways to identify patient partners, how to select the patient who will become a research partner; how to engage them meaningfully across the various stages of study design, study contact, data analysis, and interpretation; as well as

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dissemination and refining the potential implementation of the research in the clinical setting.

The goals of the narrative review, or scoping review, is really to understand the current landscape of how to engage patients as partners in clinical research, in general, and then specifically to focus on the pain field.

As we fully recognize, there are several stakeholders around the table; it's not only patients. Gilron, for example, mentioned the patient advocates and other stakeholders, but the review specifically was focused on patients as partners, so the scope of it, to some extent, is relevant to me.

I'll skip this one.

The way we approached the scoping reviews, we had one of our experienced medical librarians help us conduct a literature search to identify potential papers that would feed into this review, and we focused primarily on the papers from the past decade.

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We looked at the papers that were identified with specific search terms that were relevant to patients as partners or stakeholder involvement in clinical trials and in pain specifically. We looked at the references of the identified papers, but we also looked at various websites of regulatory agencies, funding agencies, as well as healthcare agencies to pool the information to inform this review.

The way the narrative review draft is currently outlined -- and I will more or less follow the same outline to present some of the key findings -- is that we talked a little bit about the evolution of patient engagement in clinical trials, both in terms of the national U.S. perspective and the international perspective, and then we reviewed some of the patient engagement processes in terms of how to recruit patient partners, what are the perceived benefits of meaningful patient engagement and potential downsides, as well as what are the potential barriers and facilitating factors to actually end

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up with meaningful patient engagement as partnership research.

I'll bring some examples on the landscape of patient engagement in non-pain and then pain-related areas, and then I will summarize some of those key findings.

An important push, at least in the United States, really started with the publication of the Institute of Medicine report in 2009 on Initial National Priorities for Comparative Effectiveness Research. As Christine presented, that was maybe the trigger that PCORI was founded in 2010.

PCORI had really been extremely successful in placing the patient focus really in the spotlight. These initiatives by PCORI are not necessarily occurring in isolation. There are a lot of important organizations we have embraced on the issue of patient involvement as partners in research, some more and some less. Some examples are here on the slide. For example, the VA has launched a very successful program.

The FDA identified the importance of patient

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engagement, really, quite a few years ago, in the '80s when an office to work with patient advocates was established. But in the search, in this review, we didn't see any major programs that would develop up until about 2012. FDA established the Patient-Focused Drug Development, or the PFDD program, and later on the Office of Health and Constituent Affairs, and later some newer programs that are related to the Patient Science and Engagement Program, as well as the Patient Engagement Collaborative. I think the FDA currently is making substantial effort in this particular area.

The NIH has several types of programs to support patient engagement. Mostly it started as cancer trials. It was really interesting and heartwarming to see some of the newer initiatives. For example, the HEAL Initiative has launched a patient engagement working group earlier this year that could have more focus specifically on pain research.

In terms of other examples -- and they're

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actually a lot, but just a few to mention -- the UK has really a long history in championing patient engagement in clinical studies or clinical trials, here starting with the INVOLVE program and currently with the National Institute of Health Research and Patient and Public Involvement, or the PPI program.

Recently, there's been a UK interagency development, or collaboration, for developing standards for public involvement in research, and that output is really an interesting paper to look at that covers many of the points that we will address today.

The European Medicines Agency, the EMA, that was formed in 1995 also has had several initiatives, again, mostly focused on drug development, to some extent similar to the FDA, but has been involved in patient partners quite from its beginning in making sure that the drug development is indeed patient-centered and patient focused. SPOR is another example of the Canadian initiative to highlight patient engagement in

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clinical trials.
Summarizing some of the findings from the review, there have been several papers with different recommendations for what successful patient engagement looks like. Again, each of them focuses on, to some extent, different areas; for example, core areas where specific standards need to be developed, what are the key ingredients to achieve successful patient engagement, et cetera.
But overall -- and this might be too small for you to see -- when we look at the recommendations that the different organizations or different research groups presented, they're quite common themes across those recommendations, that the opportunities to engage patients need to be inclusive.
There is a key factor of working together, working in collaboration, between the investigators and the patient partners. That whole concept of mutual support and learning, both, the investigators need to be open to learn how to work with patients and accommodate their needs, as well

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as maybe some training that the patient partners need to help them better be more comfortable maybe in an environment they might not be used to; for example, clear communication, setting expectations, and setting up governance structures that can assess how meaningful the engagement is.
Many of those compounds can be synthesized eventually to -- we're hoping at the end of these three days -- do something that we can bring specifically to study some pain treatments.
In terms of specific strategies to recruit patient partners, as a part of this review there were a couple of things that were identified; mostly that the researchers are talking about three models of finding patient partners. Some discussed the more traditional model, where on a case-by-case basis, depending on what type of research the researchers are doing, they would reach out and find a particular partner to be involved in the research.
There is more emphasis on this third-party model where, basically, the researchers consult

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outside sources, where they can tap into existing patient directories to search and find a matched patient based on their needs. There are also some local or regional patient directories where a patient can sign up if they're interested in the initiatives, and then researchers can tap into those resources.
Depending on the particular needs, there are several things that can be done within each of those domains to reach out or find patient partners, whether it's social marketing or community outreach to identify a specific subgroup of patients, or it could be partnering recruitments when you're collaborating with advocacy groups or charitable organizations to find specific patient partners.
I'll skip this one.
As we were reviewing those different papers that were identified, there's a lot of work focusing on perceived benefits but also challenges that are associated with engaging patients in studies. Some of these are highlighted here.

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Again, I won't go through all of them, but obviously some of the perceived benefits are related to improve the relevance of research to patient priorities.
Patients can really bring their experience to significantly contribute to trial design and selection of outcomes; improved patient information; and accessibility of the material that is going to be shared with future participants. Patient engagement can really improve enrollment, but also decrease attrition, and also improve things like dissemination and implementation of findings.
Some challenges of course are related to things like increased time and cost, as well as fear of symbolism or tokenism as mentioned before, and really meaningful involvement of patient partners who really need to address, to some extent, some of those barriers. Again, while funders like PCORI really pay attention and appreciate those challenges, and perhaps allocate specific resources to addressing some of those

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issues, other funders may not be on the same page and may not allocate the appropriate amount of resources to address some of those shortcomings.

In terms of barriers, as well as factors that can facilitate meaningful patient involvement in research, again, as a part of reviewing those different papers, as specific examples, we've summarized some key points that can potentially be helpful for us as we summarize the different presentations over the next few days to try to come up with some of the important things we need to consider for meaningful engagement of patients, specifically in pain research.

As we were reviewing some of the examples from either non-pain-related areas or pain-related areas and what meaningful patient engagement can look like, there are some areas that are much more advanced, such as HIV trials, where there have been more than a hundred trials with meaningful patient engagement. Some of the neurology networks, such as the Neurological Emergencies Treatment Trials Network, have a long history of bringing patients

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to their conferences, specifically allocating workshops and conferences to build those bridges, and that has really resulted in a higher rate of studies where there is meaningful patient engagement.

The rheumatology field has done similar things over the years with really substantial involvement in patients and study design in determining important and clinically relevant patient outcomes. But in a recent systematic review, actually it was shown that when we looked at the rheumatology journals between 2016 and 2020, only about 2 percent of trials published in rheumatology journals actually had meaningful patient partner involvement in those clinical trials. I think in our field, in pain medicine, we're probably far behind that, even though there are no specific numbers for it.

Let me skip some of this for the sake of time.

A couple of issues that I want to highlight in terms of efforts that have been made

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specifically in clinical pain trials, I would say that our review identified mostly gaps that need to be filled. There were some examples where patients who participated in the clinical trials were interviewed, and barriers were identified for patients even willing to participate in clinical trials or what their experiences have been.

In some cases, patients, for example, who participated in pain trials didn't necessarily know what the trial was about. For example, there was a study where the intervention, which was according to telephone-based CBT therapy, was supposed to prevent widespread chronic pain after an acute pain episode. And even though it was a well-designed study, when patients were interviewed, some of them didn't even understand that that was the goal of study, the intervention they received. They were thinking that this is a new intervention for their acute or subacute pain episode.

So there's definitely a lot of areas for improvement for us in terms of pain research. Some important areas that also require attention is

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really thinking about how to identify patient partners that can represent the interests of a study's target treatment population, and how do we think about, perhaps, underrepresented groups because there are underrepresented groups that may be more vulnerable to pain or to chronic pain.

There are several examples of groups such as women, people of color, and maybe members of the LGBTQ community, et cetera. They may be more vulnerable, more susceptible, to certain chronic pain conditions. How do we make sure that our patient partners, who help us design and conduct the studies, are actually representative of the diverse populations that the study is trying to target?

Another issue is that multicenter clinical trials really tend to be conducted in large academic centers and, again, some patient populations -- for example, rural or otherwise, under-resourced communities -- tend not to be represented. These are important points, and we need to think about what we can do to improve.

To try to wrap up my talk here, I would like to summarize three key points that emerged from this review, the highlights of which I tried to present here.

In terms of perceived benefits and disadvantages of patients being as partners in clinical trials, I think the group that is participating in the meeting today may be a little bit biased from that perspective, as we all clearly think that there is substantial benefit to it, but at least data suggests that patient involvement as partners can really improve trial design and protocol appearance. It can help enhance recruitment and patient retention in trials. It can improve the relevance of the research question and also outcome measures for patients as the end users.

With patient participation, I think the relevance of the research to the public can be improved, and that can help disseminate the results. Also, the messages, or this sort of involvement, really provides patient-focused value

messages and also increases opportunities for funding from organizations such as PCORI.

Potential disadvantages that were highlighted are focused on things like meaningful patient engagement and really may require more time commitment and also can increase the cost. The lack of training of both investigators and patient partners can be an issue that, again, needs to be addressed appropriately. There might be some suggestion to the research scope from the patient partners that might not be feasible to implement, and some of those challenges need to be addressed appropriately.

In terms of principles of how to meaningfully engage patients, some of the key themes that came from reviewing the literature were really that the goals of the clinical trials should align with patient priorities and that the selected patient partners really should represent the population of interest. Patient engagement should really be active, purposeful, and authentic, rather than passive or symbolic. I think allowing time

for reflection would be really important.

Sometimes there is a need to implement diverse and maybe creative forms of engagement with individual projects. Providing ongoing training and support both for researchers and patient partners seems to be a critically important theme that comes up. Also, really fostering mutual respect and value between all the team members and stakeholders need to be critical, and also really reviewing and evaluating the research program to understand how meaningful this collaboration and partnership is and what are the things that can be done to improve.

Lastly, I think in terms of when we're thinking about potential barriers and facilitating factors to implication and engagement, some of the barriers really need to relate to the time that it takes to build those relationships. The first endeavor, especially from the researcher side but also from the patient side, can be quite overwhelming.

Financial resources sometimes can be a

barrier; how do we compensate patient partners appropriately for their time and effort. There is still a lack of public awareness about the need and the impact of patient engagement and, really, we all have a role in promoting that further.

Sometimes the lack of consistent terminology to describe patient engagement in research can be a barrier because even when you're doing a literature search, you cannot always identify the right paper because, still, researchers used quite variable terminology.

However, if we have clear descriptions, clear responsibilities and expectations, there is adequate compensation and adequate training, and this camaraderie that is built between researchers and patient partners, those can really facilitate this partnership.

To summarize this talk, data from trials testing pain treatments are relatively scarce, but there's some substantial evidence that can be extrapolated from other therapeutic areas to optimize patient engagement in clinical trials for

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pain treatments. It is really important to start the involvement of patient partners early and make sure it's meaningful. It seems like if it's done appropriately, it can really help improve the design, the conduct, interpretation, dissemination, as well as implementation of the clinical research.

The environment should be such that it allows patient partners to articulate their experience and bring their shared experience to the table for this engagement to be meaningful. Research output that is real transparent is perceived as more trustworthy, and it's worth that effort, again, in my opinion.

Although formal guidance on patient engagement in clinical pain trials really is not yet available, I think offering guidance on the implementation of core principles to optimally fit individual pain studies, hopefully with the help of the presentations and the output from this meeting, we can all move the field of pain research towards more meaningful and impactful clinical trials. Thanks for your attention.

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Clarifying Q&A

DR. KERNS: Just super. Thank you, Simon. Good. We'll take one or two questions. Lynn Laidlaw?

MS. LAIDLAW: Hi. Thank you. Great presentation. Thanks. I just had a question. Did you include any patient partners in the review, and did you work at the agree literature?

DR. HAROUTOUNIAN: Yes. That's a fantastic question. If I look at the list of the authors of this review, Chris Veasley was one of our co-authors and provided really meaningful input to the interpretation of the literature that we're able to identify. But other than that, it's a narrative literature review, so we mostly polled a particular path to extract the information from the papers and summarize them for the different stakeholders to provide some important feedback.

DR. KERNS: Thank you.

DR. HAROUTOUNIAN: But that's really interesting food for thought because I think as we're thinking about partnering in clinical trials,

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I personally haven't thought about specifically having patient partners and systematic reviews, and meta-analysis, and that type of work where, again, things are done in a very formal way, and maybe the interpretation, there's less room for it. But I think it's a fascinating idea that may change the way we look at things or maybe even ask the questions.

DR. KERNS: I think it's a great question, and I would harken back to Chris' opening comments and framing of this meeting and that she was careful to talk about the broader area of clinical pain research, not just clinical trials. So I think one might say -- and I think it's leading us in the direction of considering, really, all aspects of our scholarship in science. I think that's a really important potential and provocative point, but thank you for raising it.

John Farrar?

DR. FARRAR: Hi, Simon. It's great to see you, even if it's just on Zoom; a very nice talk. As a general principle for this whole meeting, one

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of the other questions that come up is how to engage all people who are involved in the research, but certainly our clinical patient partners, in being productive in the process.

One of the things that certainly is true about pain research in general, and especially with use of opioids and other things, is that there are very strong feelings about some of these things. In one of the studies that I've been part of, we made a conscious point to discuss people's opinions and whether they could be -- it's sort of like picking a jury, right? I mean, you don't want everybody to be the same on the jury, but you do want people who can be open-minded about things and who are willing to collaborate.

I just wondered whether you had seen in your review any sort of thoughts or comments about those kinds of things. Obviously, it applies to other things as well.

DR. HAROUTOUNIAN: Thank you, John. This is a very good comment. It's not explicitly addressed, particularly in terms of solutions for

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it. I think this is something that comes pretty often as one of those barriers; how do you manage conflicting opinions or strong opinions within the group, or potentially conflicting opinions between the investigators and the partners?

The theme that came up, really, is allowing the space and time for reflection and being open-minded and collegiate, and setting the expectations both in terms of the rules of engagement and accept being open and accepting different opinions.

That seemed to be the general approach, but I can't recall seeing anything specifically or a strategy to address, for example, potential discrepancies between, let's say, two patient advocates that advocate for two different approaches or two different things. It was mostly presented as one of those barriers that meaningful and thoughtful approach can potentially try to overcome, but I think it's definitely a challenge.

DR. FARRAR: Thank you.

DR. KERNS: We're pulling a little behind.

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Chris, if you have a follow-up to that, or I should call on Christine Chambers, who also has her hand raised.

MS. VEASLEY: I do just have a super quick follow-up, which is to say that we're going to talk about this a little bit more on day 3 in terms of journal editors and what's actually reported, is that likely the results of what we're seeing are very skewed because most studies that are doing engagement aren't even reporting on what type of engagement they're doing.

So I think we have to look at these reviews with that lens, that we're likely not getting a full picture of everything that's being done in the [inaudible - audio gap].

DR. KERNS: Thanks, Chris.

I'll take one more comment or question from Christine Chambers.

DR. CHAMBERS: Hi there. Thanks, everyone, for this really great meeting and conversation. I'm really delighted to be here and delighted to see this being discussed.

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I just wanted to mention that I have engaged patient partners in scoping and systematic reviews and have patient partners actually embedded within student dissertation committees. So happy to comment, and maybe Isabel and I will discuss that a little more tomorrow in our talk.

I also just wanted to mention that I don't think the chat function is enabled on the Zoom call, and I probably would have just made a comment there rather than taking up screen time. So I wonder if it's possible to have that enabled just to allow for sharing of links.

Also, speaking around accessible inclusion for patients and partners, some people might feel more comfortable contributing to the conversation in the chat, rather than on video. So I just wanted to flag that for a consideration. Thank you.

DR. KERNS: Yes, we did talk about that in the planning. I don't know how Bob, or Dennis, or Valorie, or Carlos think about reopening the chatbox. I think it could serve a useful purpose,

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especially around sharing links.

So we're going to need to move on. I saw Jeremy's hand up briefly, but I think we really should move on to the next presentation.

This is the major findings from another systematic review, Ewan McNicol and McKenzie Ferguson. Ewan is the associate professor in pharmacy practice at MCPHS University School of Pharmacy, at the Tufts University School of Medicine in Boston, Massachusetts; and McKenzie Ferguson is associate professor in pharmacy practice at Southern Illinois University at Edwardsville School of Pharmacy in Edwardsville, Illinois. Take it away.

Presentation – McKenzie Ferguson

DR. FERGUSON: Thank you for that introduction. I purposely kept my camera on for the session, and denied myself a bathroom break at the hope that I could slim down a little of my talk so that we can stay on time.

So to start, I have a special thanks to Bob and Dennis and the planning team for the guidance

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that they gave us in our review, and also thanks to Annie and a colleague of mine, Karin, who assisted us with some data extraction.

Ewan McNicol and I were charged with doing a systematic review to evaluate perspectives about study design directly from patients that are affected by pain, depression, and anxiety. We made every attempt to do a very exhaustive literature search, and our inclusions were fairly straightforward. We really wanted to capture patient perspectives. It could be related to anything foundational to the clinical trial design or things that included barriers or motivating factors to participation.

Our exclusions were really any mixed sample, where we couldn't pull out a patient perspective, or if a study reported nearly a reason for attrition or declination, if there was no added qualitative component directly from the patient, those were exclusions.

I'd also like to point out that we excluded any focus that only targeted treatment-specific

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preferences. And as Chris Veasley just mentioned to Dr. Goertz, it's important that we realize that engagement may be part of the planning process and conduct of clinical studies, but we may rarely see this actually published within research findings.

In our literature search, we searched across four different databases, and we quickly learned that there were some challenges with the way that patient engagement was described in the literature, so we had to broaden our vocabulary to try to make sure we were capturing as much as we could within the area of pain, depression, and anxiety. But I will say that when we started screening 660 abstracts, we decided that if the study addressed any psychiatric condition, even outside of depression or anxiety, we elected to keep it in our results as long as it met criteria for inclusion.

We reviewed 61 full-text articles, and we ended up extracting 34 total studies, but you will see we extracted 35 total reports because we did have one study that actually completed two distinct

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phases of data collection amongst two different samples, so we were able to capture those perspectives separately. I also would like to agree that in the context of only identifying 34 total studies, Dr. Goertz is correct in perhaps noting that engagement within pain-related research is still in its infancy.

In terms of our study features, most of our studies focused on pain, and within the pain, some of them were mixed features. Eight of our samples addressed depression only. We had no studies that focused on patients with anxiety and their perspectives. We had two studies that mixed. It was mostly pain to begin with, but 20 to 40 percent of the population had a noted depressive disorder. And the one other study there was a study in patients with Parkinson's disease that had reached the point that it was affecting their mental health.

In terms of the different diagnoses of pain, one thing that I think is important is that we have a lot of variation here, but very few of our

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studies, most of them, did not report comorbid medical conditions in the samples, so it was likely that pain, depression, and anxiety coexisted amongst many of the populations; yet, it just wasn't consistently reported in the findings.

In terms of the study methods utilized -- so this will be very brief -- most of our findings were components of survey-based methods, and that's probably not surprising because it was a more efficient way to capture a larger sample. Other study methods were things like individual interviews, mixed methods, and focus groups. So a lot of the data that we ended up reviewing was qualitative in nature, thematically presented with lots of quotes, and very few actually gave quantitative numbers for us to assemble. So you'll see me present the information from that standpoint.

Getting into some of the findings, we're going to spend a little bit of time talking about the demographics of the perspectives that we gathered because we think it's important to know

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whose perspectives we're basing some of our considerations on, and some of the limitations perhaps with that.

Most of our studies assessed the patient perspective as the primary objective of the research. For 12 of our included reports, it was a component of a randomized-controlled trial and a feasibility study, three of which were for patients with depression.

Though most of our study sites we could determine were located in metropolitan areas, there was only one study that actually described where the sample was from in terms of being rural or urban. We also had most of our samples from patients outside of the United States. Ten of our studies were focused entirely in the United States and three were mixed.

Most of our studies utilized active recruitment strategies to recruit patients for the prospective analysis. A few used mixed strategies. A lot of this included things like targeting directly from clinic records or targeted

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registries, mailed invitations, or general practitioner referral.

Most of our studies had some or past current trial participation, but this is largely diluted by those studies that were also part of the pilot and feasibility analyses. In many of the other studies, it simply wasn't noted if they had past trial research experience.

Most of our samples, also the perspectives provided were from adult-based populations, although we did have two studies that focused on pediatric patients, one that was in an assessment of patients with Duchenne muscular dystrophy and their caregivers, that related more towards the invasiveness of study procedures, and the other which dealt with adolescents affected by depression.

Also, we had several studies that, based on study demographics, recruited and enrolled mostly older patients, and three of these were for pain-related conditions, one was for depression, and one was in that study with patients with

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Parkinson's disease who had mental health complications as a result of that.

Within the sampling also, there was one study that purposely sampled disadvantaged women affected by depression. For studies that reported sex, most of the samples were represented by female perspectives. Also, I took note that 10 of our studies required English literacy as a component to participation in providing their perspectives.

This slide depicts the lack of, really, overall diversity within the perspectives that we're presenting today. Race was only reported in 15 out of our 35 reports, and within that, most of the studies had patients largely identifying as White/Caucasian. This was all -- except in one study you can see from the slide, the Taylor study. This study was conducted out of New Zealand, and it was focused on a mostly male population with gout, and it was an outcomes-focused study. But in that study, 14 percent of the population identified as Asian and the remaining were described as New Zealand, European, Maori, and Samoan.

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A few other notable mentions from this slide is that there were two studies that had around 30 percent of a mixed racial representation, the Cheung study and the Smith study, and for both of these studies, they utilized accommodation of recruitment strategies, which may have benefited their level of diversity.

Other important study features that we thought were important to collect as it related to perspectives, but we ended up finding out that it was fairly infrequently reported and inconsistently reported even in those that did, was the level of education of people who were providing their perspectives, the number who were living with someone else in the household, whether or not the patients were able to be employed or if they were disabled, and the disease duration and severity.

Now we're going to start with barriers to study participation. The way this graphic is set up is that on the left in green, you'll see those are the studies reflecting patients with pain, and on the right, you'll see the patients affected by

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mostly depression but also that added mental health assessment.

To begin, seven studies reported that a lack of information or misunderstanding of information was noted as a barrier to participation, and this was evenly split, for the most part, between pain and depression. But some things that stand out are fear of interventional risks; distrust of healthcare providers; too many study procedures; fear of inadequate treatment; and disease life stressors more commonly noted as a barrier among patients with pain.

Discomfort and embarrassment with study procedures, on the other hand, was more commonly noted as a barrier to participation among patients with depression. Specific comments related to this were things like feeling the nature of the questions they were being asked were quite intrusive or feeling self-conscious with the questions; some embarrassment with bringing up their personal past and history; and the symptoms of their illness that were causing anxiety and

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discomfort.

In terms of distrust of healthcare providers, that was noted as general skepticism of clinical research. Then it was also noted, in a study of patients with sickle cell disease in that partnership with Voice of the Patient and FDA, that hospital staff and the research teams lacked some cultural sensitivity and also lacked awareness of the challenges faced by patients affected by sickle cell disease.

As it relates to disease-related stigma, we had one study that assessed chronic pain in patients that had in the past received opioids, and there was fear of labeling or judgment, and it presented a barrier to recruiting those patients for participation.

I'll continue to discuss barriers as I move into more specific trial design features, starting with recruitment, randomization, and blinding.

Personal referral was noted as something that actually encouraged willingness to participate, and this is noteworthy because it was

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in two studies that included patients with depression. Randomization was a common theme that was a source of concern, confusion, and discomfort for participants, and three studies remarked that adding an element of choice in the randomization process would enhance willingness to participate. Two of those studies were in women with pelvic pain, specifically endometriosis, and the other was in patients affected by osteoarthritis.

Four studies noted concerns with blinding, so much so that they would not agree to participate in the study if they were blinded, and of course having sufficient information was a concern across many studies. A lack of overall detail about the study and expectations of participation was noted, as was a lack of detail about studied risks. One study suggested incorporating a video into the process and also adding more time for discussion of information as a way to perhaps improve this.

So compensation is clearly something that needs to be considered in our recruitment of patients in studies, so having enough compensation

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was something that affects willingness to participate. Also noted were things like the ability to continue therapy after the treatment is over. In particular, this was noted in a study with patients that are affected by spinal stenosis and their concerns with the ability to afford co-pays for rehab and therapy services once the study compensation has ended.

Another study noted that they wanted coverage for study-related injury in their willingness to participate, and another survey-based assessment gathered that perhaps weekly compensation for both time and travel would better engage patients in their willingness to participate.

Distance is fairly self-explanatory. Distance and transportation for interventional visits and monitoring and follow-up is something noted. And I think it's particularly important to note that when a condition becomes particularly disabling and affects a patient's ability to travel easily, this is particularly problematic. In the

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distance and travel category, we had two studies that were noted among older populations as this being a concern in their willingness to participate.

Of course there are concerns with too many study sessions, too many interventional procedures, and too much monitoring. So anytime we can reduce those number of visits, particularly in-person visits, it seems to generally improve willingness to participate.

A lack of information, as I kind of already stated, about the complete expectations for part of participation was noted, so anytime we can clarify information or revisit information, I think that would be something that may help improve willingness to participate.

One exception, most people wanted reduced number of visits and reduced study durations, and the exception to this were two studies of women with pelvic-pain endometriosis. When they were surveyed in about a three-year duration of study, the majority of them were agreeable to that study

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duration, and noted that they appreciated to have the extra window of time for the added monitoring and the time for their body to adjust to the changes in the treatment strategies that were utilized.

The choice of intervention and the choice of control was affected by many factors. Again, our charge wasn't to focus on treatment-specific preferences, but you'll see some of that bleed into some of the discussion here.

The choice of intervention as it relates to patients with pain and their willingness to participate is heavily influenced by their past experience with other treatment options. Also, an influencing factor on the choice of intervention is the route of administration and the inconvenience of having an inconvenient route of administration.

Something that was encouraging is that among patients with chronic pain who had a history of opioid use, the majority of the patients were willing to accept enrollment into an opioid tapering study.

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When we targeted in on the study specific to headache, which included migraine, some of the things that were noteworthy within the choice of intervention and control here was that the majority of participants with headache would participate in a placebo-controlled study, and they wouldn't actually consider it unpleasant to find out that they were responsive to placebo. The one thing that they expressed in terms of a study design feature as a preference was the ability to decide when to treat an acute attack.

Now flipping over to the choice of intervention for patients with depression, it was a little bit mixed here. For some, counseling was not an intervention that they were interested in receiving. For two other studies, there was a distinct preference toward an intervention that was psychotherapy in lieu of a medication-based treatment option.

We did have one study that assessed a deceptive trial design in patients with depression, and it had a very, very small focus group of five

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patients. It was actually part of a larger assessment that also gauged perspectives from general practitioners and psychiatrists. But in all of those patients, they were unwilling to participate in an authorized deceptive or post hoc deceptive design.

The other thing that I'd like to point out in terms of interventions in patients with depression is that as part of a pilot study, there was one assessment that we reviewed where the interventions were three different types of psychotherapy. And though it was very clear to the researchers, the subtle differences in those three different types of psychotherapy, when the participants were surveyed after the study was completed, it became clear that very few actually had an understanding of the different treatment options they were potentially going to receive as part of randomization.

Lastly, some other things that affect willingness to participate as it relates to interventions particularly is the fear of side

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effects, both known side effects and how they would be managed, and then also unknown or rare adverse effects.

The desire to have access to current and past treatments really rested heavily on the fears noted of inadequate treatment, so fears related to inadequate treatment and the ability to take medications that they're currently on. Most of these features were noted among patients with pain, and patients with pain also noted fears related to withdrawal if they have inadequate treatment.

Also, there were fears or basically unwillingness to participate if they were likely to receive treatments that had been ineffective in the past. Patients wanted to not have the ability to receive something that they had already tried and failed. One study that assessed patients with depression also suggested and wanted a tailored treatment approach, even within the context of study design. Tailoring in that study was noted as tailoring to symptoms and past side effects.

Moving into outcomes, with outcomes and data

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collection, outcomes were not the original core focus of what we wanted to gauge from a perspective standpoint, but once we pulled our full text, we did include anything that was outcome-focused, and we had a total of six reports that focused entirely on outcome-specific preferences.

The good news here is that the previous work of IMMPACT, published by Dr. Turk in 2008 and colleagues, is that much of what we gathered aligned with those perspectives, meaning that patients largely want outcomes that are focusing on functional improvement, quality of life, and pain relief. This also is alignment with what Dr. Goertz presented with the PCORI findings.

When it comes to methods of data collection, of course patients want less invasive measures; even as simple as a blood test was deemed as a deterrent to participation. If more invasive procedures are part of study design, one study was able to show that with higher compensation, you would get perhaps more willingness to participate.

When it comes to data collection methods,

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other things that were noteworthy were that four of our studies assessed data collection or collected data within the patient's home. Two of these were among patients with depression and two others were among patients with pain. Other modes of data collection that were noted as acceptable included tablet-based collection of data for psychological well-being and was largely acceptable among patients with depression.

Keeping research questionnaires manageable was a very big factor in willingness to participate. Some of the themes that were noted are that patients don't like lengthy questionnaires, and patients don't like when the questionnaires have repetitive questions or when they're difficult to understand and answer. And there's no free textbox to clarify that they're confused when they don't necessarily know what you're asking.

Also, not surprisingly, less frequent data collection is preferred over more frequent, and a less time-consuming data collection method is

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preferred. Studies also noted that they wanted consistency within the research assistance as something that affected their willingness to participate.

I'm kind of moving into motivating factors before I cover some general considerations based on some of the information I presented. It's so encouraging to know that most patients' desire to help others is a very strong motivating factor for participation in clinical trials. Staff rapport is also ranked very highly, and the motivators that we found in patients with pain and depression are consistent across bigger, systematic reviews among broader patient populations, so this is no different.

I also think it's noteworthy to point out that outcome feedback is a big motivator for patients with depression. Several of those studies noted that patients like to see their progress over time in a consistent pattern, and three studies noted the desire to receive their study results as a motivating factor for participation.

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Outside of altruism and staff rapport, I also think that these motivators really summarize the idea that patients are also motivated at the idea of finding better care and treatment, so that will be kind of the basis for some of our considerations.

Overall, I think we have to be very clear. Our samples and our perspectives lack diverse representation of views. This is sometimes a similar challenge that we're facing in clinical trial design; so direct, strategic recruitment, particularly to underserved populations, and utilization of community-based strategies is essential.

Also, I think it would be important for us to consider encouraging researchers to, at a minimum, collect but perhaps report reasons participants decline study participation and include and evaluate the demographics of those who are declining, as well as gauging more of a perspective on why people are declining participation.

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I also think that for some study populations with children, declinations are obvious. We saw this noted within our study of women with depression that are disadvantaged, that they lack child care. So they may want to participate, but they may not have the means or the support. Also as a note, I think that we need to perhaps find better ways to engage that direct referral from primary care providers because that was noted as something that enhanced engagement and willingness to participate.

From a design-related consideration, the rapport of the research team is essential, so of course having consistency with the way we train them, making sure they're trained with cultural sensitivity and, again, the awareness of the challenges faced by people affected by that pain and depression. I also think that we need to engage multiple forms of communicating information to patients that enroll and make sure that the research team is sensitive, a good listener, helpful and friendly, and can address fears and

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expectations of the enrolled participants, really, at every visit and consistently throughout. Also, having diversity within the research team would be an advantage as well.

Also, of course we want to make sure we're incentivizing and compensating patients appropriately, and perhaps we can consider this even after the study ends; so at least coming up with a plan for how the patient can continue to receive the care even after the study is over.

Consideration of adding an element of patient choice, perhaps this is within the process of randomization, or perhaps this is better targeted to a mode of data collection and is something that we should be more strategic with doing; so offering an in-person visit or an online mode of data collection and in-home visit, et cetera. Perhaps this may be a targeted approach for older patients or patients that are positioned in more rural areas away from immediate access to transportation.

I also think that we maybe need also more

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pragmatic ways for patient-based methods of data collection. We talk about pragmatism from routine clinical care, but pragmatism from the angle of the patient and what roles they can integrate into their daily lives to be a research participant without adding an immense amount of time and burden.

Lastly, I think it's important for us to be very well aware of the fact that though I'm presenting perspectives as it relates to trial design, you can see a lot within the perspectives that we gathered, that for many patients, their declination to participate or their willingness to participate in research is heavily influenced by the disease burden and their lived experience, and also some socio-demographic factors. It seems like design-specific considerations align with this, and making participation more convenient for them is important in the way that we recruit and retain patients.

I'd also like to end with the idea of -- O'Cathain in 2013 and in the pre-readings, I

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read the article by Chambers -- adding the value of that qualitative mixed-methods component into the randomization or into the process of building a randomized-controlled trial.

So whether it's a pre-trial doing a qualitative assessment to proactively engage acceptability of the study design from our key stakeholders; or to identify recruitment and retention issues; or how to enhance diversity; or whether it's embedded and threaded directly into the main trial or completed after the trial is over, the value that that can bring to have long-term gains for improving efficiency and validity of our findings is probably something to be considered.

So with that, I'll open it up to questions.

Clarifying Q&A

DR. KERNS: Thank you very much. That was terrific.

I'll take one question. I want to make sure that we move on to the sponsor's bundles funders panel. It's a lot of people, and I want to make

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sure we give them ample time.

So any clarifying questions for McKenzie?

(No response.)

DR. KERNS: By the way, I'll say that we've done some back-channeling about the chat function, and we're going to hold off for now and discuss this in a debriefing that the core team involved in planning this meeting will have later today.

So I don't see any hands up; or wait. Maybe I -- hold on.

Any hands up? Any questions?

(No response.)

Panel Discussion

DR. KERNS: Alright. Then we'll move on. Thank you again, McKenzie and Ewan.

We'll move on to the next session, which is an exciting panel of research agency funders. Chris and I both worked on organizing this, but I'll have the pleasure of making the introductions today.

So first up is my colleague, David Atkins. He's director of the Health Services Research and

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Development Service in the office of Research and Development in the Department of Veterans Affairs Central Office, or headquarters, in Washington DC.

David?

Presentation – David Atkins

DR. KERNS: Hey. Thank you. I was panicking a little bit. I couldn't find my mute button.

I will keep my comments short because the review that we just heard, the two reviews we just heard, have made many of my points for me.

Are my slides up and visible to people? I saw them before, and now I'm not seeing them. Okay.

I think the nice review we heard from Simon really made all of these points, which this is just a motivation that I had in Health Services Research of recognizing that we needed to take on the issue of veteran engagement more seriously, and this happened about five years ago.

I think all of these were in the summary points from the review; that we felt it would give

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us more meaningful research questions; that we would get a better discussion of what the important endpoints were; and that we would understand whether our data really represented the important issues for our populations.

But we are also very interested in the other direction, which is how can we use engagement to do a better job at disseminating innovations that we're working in the VA with veterans as part of that process and, also, how do we improve our communications about research and the importance of research to veterans?

I'll say as an introduction that in Health Services Research here, we have always been stakeholder-driven. We recognize that our stakeholders include the health system that we're trying to influence, they include policymakers, everywhere from Congress to our leadership, but they obviously include veterans as well.

The path that we took, as I said, started about five years ago. We explicitly built on what we learned from PCORI. We had my old boss, Jean

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Slutsky, come to talk to our center directors, and we gave a very general mandate that all of our research centers -- we had 18 at the time -- had to establish a veteran stakeholder group and begin to use it in developing their research projects.

We did not give them a very explicit roadmap of what we thought that should look like. We thought we would learn from different approaches that those groups took. But what we did at the same time was we established a better engagement work group to link the work of those centers, and we gave them some funding to do a number of things.

One, they developed a conceptual model to explain how veteran engagement would change the process of research. They promoted sharing and communication across what were essentially 18 slightly different models doing it. They organized cyber seminars.

Then they developed a toolkit for places that were slower in standing this up to guide them through the process of how do you plan for this; how do you convene patient stakeholders; how do you

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run the process effectively; and then how do you evaluate whether it's working to do what you can do.

So that was all fairly generic patient engagement, but over the recent couple of years, we've focused more on engagement around specific areas of our research, starting with women's health, where we have a very active women's health research group, and then getting into pain and opioids, and to suicide.

We established a consortium for research on pain and opioids, and this was meant to build a community of researchers that would do a number of things; one, to build collaborations across our national network of researchers; to build more effective partnerships with our clinical leadership and with veterans; and then to do a better job of telling the story about our successes.

So as part of that process, the consortium, what we call ACOR, set up a veteran engagement panel of 12 veterans chosen for their geographic -- being from around the country, but

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also for representation of different groups. They all had experience with chronic pain and/or opioid use.

This panel has been quite effective in providing feedback, especially for early-career investigators when they have an idea; when they want to get some of the feedback that's just been discussed about the acceptability of an intervention; about ways-to-recruit strategies; and how to communicate results. That process has been going on for about two years now with generally good reception.

I'll close with just some general comments to make sure I don't intrude too much on other people's time. This is really talking about high-level engagement advice across a research program. If you're going to set up a panel like this and you're going to bring researchers to draw on this panel, we found that it's helpful to prepare researchers how to get the most of that; that they need to frame the kind of feedback that will be most useful. So we've set up a group to

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prepare them and make that feedback useful.

As I said, the feedback has been generally quite positive from investigators who value the advice that they're getting. It's changed certainly recruitment strategies. It's shaped somewhat interventions.

The other thing we've learned is that veterans want to be informed about the pace of progress, and this applies at a high level, but also patients involved in projects. They're sometimes dismayed that the pace of research is much slower than they anticipate. So at an individual project level, our projects have developed ways to communicate back to patients along the way so that they know that things are progressing and things are being learned, even though the project may be years from actually being published in the literature.

I want to close with just recognizing that this is sort of high-level veteran engagement, but at an individual project level, we've been requiring attention to veteran engagement for the

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past four years, so there's a separate section that they have to write plans on this. Obviously, that's a much more detailed level of engagement that we look for.

We have always emphasized mixed-methods research in Health Services Research in the VA, so it's very typical for a project to include, phase 1, a refinement of intervention that will draw on veteran input and other stakeholder input in that process. That is probably more the rule than the exception in our research since we are not generally funding large, multi-site, clinical trials from the beginning.

I will say just in closing that one challenge is often that we want to build flexibility into those proposals, that they can take the input of veterans and shape the intervention and shape the outcomes. For reviewers, they sometimes don't like to see too much left to that process. They want to know exactly what intervention is going to be delivered or they may want more detail about timelines.

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So while we've had some very successful projects using what we call EBQI, evidence-based quality improvement, that has an implicit assumption that the process will change the design and intervention along the way, I'd say we still have this tension between what we leave to evolve as a part of that process versus how much we specify up front.

So I'll close there and look forward to hearing from my colleagues.

DR. KERNS: Thank you very much, David. That was terrific. And I particularly appreciate the transparency and openness to where some of the strengths are, what you're trying to do, and where you appreciate some of the tensions, and gaps, and opportunities. We won't take questions now. We'll have hopefully some time for, really, panel discussion, Q&A, and commenting from the group.

We'll move on to our next presenter. This is Dr. Rebecca Baker, who likely many of you know. Dr. Baker is the director of Helping End Addiction Long-Term, or HEAL Initiative, within the National

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Institutes of Health, and is located in Bethesda, Maryland.

Dr. Baker?

Presentation – Rebecca Baker

DR. BAKER: Hello, everyone. Good afternoon from Bethesda, Maryland. Thank you for the time to take part in today's really interesting meeting. I've already learned a lot and very pleased to tell you about what we're doing in HEAL.

As a reminder, I think many of you are part of the initiative and have contributed a lot already, but as a reminder, what we are seeking to do is provide scientific solutions to the rapidly evolving crisis of opioid misuse, addiction, overdose, and underlying crisis of pain management. We've been at this for a while, and yet last year was the worst year on record for drug overdoses in the United States. Over 90,000 Americans died of a drug overdose. These are people who are dear to us and lives that can be saved with evidence-based interventions.

Unfortunately, the majority of these

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overdoses continue to involve opioids, primarily driven at this point by powerful synthetic opioids like fentanyl. We're also seeing demographic changes and increase in health disparity populations and in Black, American Indian, and Alaska Native populations.

This is what we in the Helping to End Addiction Long-Term Initiative are seeking to address, and yet we also recognize that to provide durable and lasting solutions, we're also going to need to address the need of the over 50 million Americans in chronic pain.

Most people with a substance-use disorder also experience pain, but then the numbers of people with pain are much larger, and as we've heard, it's a big driver for why people seek medical care and how comfortable they are in their life. Of those 50 million Americans, about half of them experience severe pain on a daily basis; 20 million, such high-impact chronic pain that they can't go about things that are important to them.

We rely on opioids for addressing a lot of

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these health conditions and a lot of these individuals' pain management, so opioids can be very effective, but they also carry risks, not just the risk of addiction. So we are really working to pull together equities from across the National Institutes of Health to address these two interrelated crises.

In the next slide, I tell you a little bit about what we've done so far in HEAL. Launched in 2018, we've now directed over $2 billion in research, over 600 different projects across the country in nearly every state. It won't surprise this group, but we've really had to -- especially in the pain domain -- across disciplines, communities, and settings. You can't do this just in isolation. So through the initiative, we've worked to engage with research participants, patients, and stakeholders as well, in addition to our traditional research community, academic labs, and medical centers.

I think others have said it. Compared to other efforts that I've worked on at the National

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Institutes of Health, I think the engagement of people with pain and research is not as developed as it could be and as it is in certain research domains, so that's something where we feel like we can address it pretty rapidly.

We know pain matters to people, we know people seek medical help when they experience pain, and we also know we have a big opportunity and responsibility to conduct research on those pain conditions, so pulling those together is a really central goal of what we're doing in the HEAL Initiative.

In the next slide, I'll just mention a few of the areas where we have decided to focus towards this greater goal of enhancing stakeholder patient engagement in HEAL-sponsored research. Some of that is just taking the studies that we've already funded, of those 600, and saying how can we increase stakeholder engagement in those ongoing studies.

As the last presenter pointed out, research doesn't actually move that quickly, so sometimes

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even though something has started or it's been funded, it's not too late to go in and say, well, could you do this, or have you considered doing that? So taking some of these approaches for engaging stakeholders and building them into the research studies.

Another really important goal is formalizing the input provided by people with lived experience, including patients and stakeholders and people with pain, into our governance structure, so we've been working towards that. We also sought to develop, in the goal of providing to our community, some resources.

For the research community, we often hear complaints of, "Oh, we don't have enough time to do all of the things that NIH is asking us to do when we're preparing our application. It's quite cumbersome, and we need to build these very interdisciplinary teams in a short amount of time." So some of those resources would be helpful to them in designing high quality and be highly engaged with patient studies from the beginning.

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Also, a separate issue, but one that really does connect with our engagement efforts, is improving the recruitment, retention, and inclusion of underserved groups, minority groups, in our studies. A lot of times our researchers hope to do this and plan to do this, and then once the study's underway realize that their plan wasn't good enough, and our desired demographics of the study suffers; so providing them with strategies for making sure that the populations we study reflect the populations who are affected by the health condition, and in these cases, a lot of pain conditions.

In the next slide, I talk a little bit about what we've done toward these goals. Just like this, one of the strategies we've taken is to hold some really edifying workshops. I have learned more hearing from our researchers and research participants in these teachings and different learning opportunities in most of the NIH-sponsored workshops that I take part in. Those have driven us to really be concrete in some of the ways that

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we are seeking to improve patient participation and research.

Some of that has led to specific funding opportunities, so ways for researchers to get additional financial resources from the NIH to enhance engagement and inclusion in their studies beyond just strategies for recruitment and retention, which is, heretofore, what they might have focused on.

Those awards have resulted in additions to studies to develop culturally relevant recruitment and research materials; some toolkits to share information about the health conditions being studied, and the community is specific to an individual research study; enhancing access to materials, and that can be different languages or other barriers to accessing materials; specifically supporting the addition of patient navigators to help people with lived experience through our studies; and the creation of community advisory boards so that the study can be conducted in the context of the community where the research

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participants live, and in their families and caregivers.

Toward the governance goal, we've created the HEAL Community Partner Committee, and I'm very pleased Chris Veasley has agreed to take part in that and is already taking a huge leadership role in making sure that that group does everything it can to contribute to the overall meaningfulness of the HEAL Initiative and our research.

In the past year, we launched a new program called IMPOWR, which focuses on people who experience pain who also have a history of a substance-use disorder or are in treatment for substance-use disorder, and really using that as a test case for integrating research participants into study design from the beginning.

The next slide is a few words about the Community Partner Committee. HEAL has so many different studies. As I said, we have 600 different projects, so we can't reflect all of those different perspectives and all of the different research participants in those studies,

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but we picked a few really terrific people to take part in this group.

They include people with lived experience using drugs, patients, advocates, family members, and caregivers, all giving us advice on the ways that the issues faced by people affected by pain and addiction could be researched and what outcomes would be meaningful to those groups.

One of the first things that we've gotten started to work on is really doing an inventory of what is already out there. The survey results were very interesting for me to hear, collecting information about what patient engagement efforts are already underway in their cities and ways that we could expand on that, or bring up the floor and make sure that the majority of our studies have some meaningful patient engagement.

Here is a little bit more about the recently awarded launched program, Integrative Management of Chronic Pain and OUD for Whole Recovery or IMPOWR. This program seeks to address the needs of people who experience pain who also have a history of

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opioid misuse. What we find is that this is actually the majority of the people with substance-use disorders that also have pain. Sometimes it contributed to their disorder; sometimes it's just left untreated because they don't feel like they have effective options.

These individuals also suffer from a really fragmented system receiving treatment, and then limited work resources for high-quality and evidence-based care. This program is really working together with the patients and people with pain to develop integrated interventions, focusing on the whole patient. That includes, a lot of times, people with pain that have co-occurring, conditions, including other aspects of their health, and then directly addressing some of the factors related to stigma and health disparities that keep people from receiving high-quality pain management

This has really been our first effort through a HEAL program to establish a nationwide stakeholder engagement effort, and one that we hope

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to build on in our future research.
Reflecting on challenges, I think for us, because we target both people with pain and also people who use drugs and people with a substance-use disorder, there are a lot of variations in those populations. Sometimes you have people in a very clinical setting and sometimes you have them in a community setting. The types of people who are designing the study and delivering the intervention are now part of tracking the study.
It's just so different among all of those different groups, so I put that first and foremost, really recognizing that when you have such a multifactorial problem as pain or addiction, all of these players, and then all of their stigmas and histories, come into play, too.
For potential solutions, we're really working to -- as I mentioned, this inventory, combining that with literature and other promising practices -- provide resources for investigators, and to allow for that challenge to be a strength in

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that we have a wide net, in terms of our research community and our studies, to let that allow for some fresh ideas and flexibility about which approaches are going to work best and how we can meet our groups with IMPOWR.
Of course, we share the goal of this group and this group's discussion towards shifting patient engagement to really making people with pain and people with substance-use disorders partners in our research.
I think that's it for my formal presentation. I'd be happy to take part in the discussion after all my colleagues finish their talks.
DR. KERNS: Thank you, very, very much, Rebecca. That was terrific. Again, we'll save comments/questions for the panel discussion.
I think next up is Dr. Kristin Carman, who's director of public and patient engagement at the Patient-Centered Outcomes Research Institute, or PCORI, in Washington, DC.
Dr. Carman?

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Presentation – Kristin Carman
DR. CARMAN: Well, I am very happy to be here. Obviously, I'm following on Dr. Goertz's really rich presentation. I'm using some slides here; think of them more as anchor slides to kind of draw on some key concepts and to answer the questions about where we've been and where we're going to.
I do want to make just a couple of comments. I wrote down a couple of notes in response to a couple of the things I've heard. One of the things we like to remind people is it's never too early to engage individuals, but it's also never too late. I think that's really important and critical to remember. For all of us in this work, the art of the possible is earlier and better and builds trust, but it truly is never too late to start engaging with communities, and really understanding what they want, and what they need, and what matters to them, and how they best wish to be engaged in processes.
I put this slide back up for a reason, and I

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know Dr. Goertz shared this with you. But I think it's important to remember, for some of the context from when we talk about the rubric, that PCORI itself has funded to date about $3.3 billion in research funding and a variety of other kinds of funding. We've made 1800 awards. Many of those are research projects.
I actually, Dr. Goertz, don't remember the exact number of the research awards offhand, but we can say it's in the 5-6 hundreds. That was sort of the last number I used.
When you're looking at this pipeline, when we say we involve patients -- and all stakeholders, by the way, because it is a multi-stakeholder environment -- we are talking about having involved individuals in all of these processes, so hundreds and hundreds of research projects. We require and support involvement in the conduct of the research studies, hundreds, literally hundreds, of meetings and topic solicitation, and advisory panels.
Merit review came up as an example. We have had individuals participating in the merit review

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of projects, which in our world is sort of assessing whether or not they're funded, in well over 300 projects. So the scale of this, I think, is important in the context of the work that we do.

So where did we begin? As Dr. Goertz mentioned to you, when PCORI started this, it started off with an expectation. You are going to engage people. That expectation was there because board members determined that PCORI being patient-centered meant having the outcomes that mattered and research topics that mattered to patients and other stakeholders. And one key way of achieving that, in addition to the board itself, which is also multi-stakeholder, was to have wholesome engagement throughout that pipeline I shared with you.

But the question arose at the time, which was a broad standard, you should and must engage across the projects, but how to do it, and projects didn't really understand that. So the rubric that you see before you -- it's a much shortened version of that -- was essentially developed actually in

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concert with the Patient Engagement Advisory Panel. We try to give guidance to projects in the field about what engagement might look like.

What you will see here are two really critical underpinning concepts to this, and I think it kind of comes back to some of the conversations we've been having, which is engagement can and should occur throughout the life cycle of the project. Dr. Goertz shared with you a lot of what we've learned about engagement through those parts of the project, but it's what basically PCORI said; it can and should throughout the life cycle of the project.

Then secondarily, there needed to be underlying values. These are the PCOR principles, and these principles are important and I think actually reflect some of the conversation you're having here today, because PCORI makes a distinction -- and you saw this in Dr. Goertz's presentation -- between what we would call input, which is you're essentially doing research on people.

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Now it's important and it's valuable qualitative research often about what do you think of this intervention, but it's focus groups, it's surveys, it's studies, where the research team knows what the questions are, and you're asking people to answer them, in essence.

That is different than, as we were just talking about in terms of moving to collaboration and partnership, where you really have individuals as members of project teams. And as she showed you in those findings, you end up with a very different set of interactions where sometimes individuals -- actually because they're there -- you may not even realize you had a question.

But they're redirecting you and telling you, "Oh, by the way, that is never going to work." It could be the practicing physicians in a study on site saying, "The way you're doing this isn't going to work," or it's going to be patients saying, "Nobody's ever going to sign up for that the way that it is." So it's a really important piece to understand.

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Now, this was pretty broad; let a thousand flowers bloom. We did not dictate how you engage, just that it had to occur.

This is just to remind you of what Dr. Goertz told you, that it's important. This was, in essence, sort of a natural laboratory; as I just mentioned to you the sheer numbers of projects and work with a similar context for the rubric, and PCORI, and the kind of technical assistance we provide. What we've learned builds the body of those activities.

I think what I just really wanted to get across here is, one, it is feasible across a variety of stakeholders. It does influence the projects and the conduct of the studies. It influences what happens, it influences the quality, the feasibility, and those other things, and that is building on a large body of our internal research.

Obviously, individuals can benefit, but so can communities and so can institutions. And individuals can benefit not only in terms of some

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of the things we heard about in terms of their own care and how they access it, but lots of other ways in terms of their life course. And of course, for physicians, for researchers, and others, you get that lived experience that's so crucial.

What we have done -- and I just want to bring this back because the question came up -- is we have translated a lot of what we have learned to date into tools and resources, and those tools and resources, too, Dr. Goertz shared with you.

One is research fundamentals, which does not say to patients and stakeholders, "You must be a comparative effect in this research to participate in our studies." It says, "If you want to know more about research, and you want to be more comfortable with it, and you also want to learn what patient-centered outcomes research mean, it's a great tool for people to use."

We also have a building effective multi-stakeholder research teams training, and I just want to note, based on the question, it assumes all participants need to be trained for the

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interaction. It does not say we must teach patients; it says we must teach everybody to be an effective team. But the tool is tailored to the context of research, and clinical research, as opposed to potentially other kinds of research.

So where are we going? Where are we heading? Well, we've had this rubric, we've done this research, but it's time to update it. Right? It was developed in 2014, as I mentioned. It was guidance on how and when, but there's a lot we have learned.

The next version of the rubric that we are working on right now, and we anticipate to come out in the next year, will use the knowledge we've developed in our natural laboratory. It's going to address a lot of the facilitators and barriers in engagement we've just been discussing, and it's going to reflect our priorities for advancing engagement.

The ultimate goal as we revise this is going to be to continue to support meaningful and sustainable engagement in CER and PCOR, and to

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influence research to be more patient-centered, relevant, and useful. But it will be different, and it is likely to really try to link better to the tools, the resources, but also push the field a little bit further.

Although I can't tell you what it is because this will also take the input of members of our board, like Dr. Goertz, but ultimately, we anticipate we will move from a thousand flowers blooming to perhaps some stronger suggestions. It is not yet to the state of standards, which is why we'll go to the next slide, please, to remind you that we still have lots of questions.

The rubric update is about bringing the rubric, which guides awardees about how to compete for PCORI work and how to conduct engagement in the projects more up to date with what we know. But as Dr. Goertz outlined for you, we have many other critical questions we think we need to answer.

I won't belabor this other than to note she talked about it, and she also raised to the RFI we have out right now. I encourage everybody to

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please take a look at that.

But where we're going is guidance for our awardees that fundamentally catches up with what we've learned, but also moving to a place where we really take to a new level and answer the kinds of questions with methodologies and approaches that we can't do right now because much of our work has been based on our programmatic research and program improvement research. But I think it's time for a more robust set of answers because we have that research to build on.

So with that, I will turn it back over to my colleagues.

Oh, and I just want to note for Isabel that I am a very big fan of Lucy Lawless, and I was delighted to see your screenshot. So don't feel bad about it. I thought it was terrific.

DR. KERNS: Thank you, Dr. Carman, very much. I loved the way that you extended on what Christine, Dr. Goertz, brought forward earlier. And it does seem like there's important complementary perspectives shared, but also

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complementary perspectives across the sponsors and funders.

So we'll move on to our next panelist, and this is Dr. Karim Khan. Dr. Khan is the scientific director of the Canadian Institutes of Health Research, the Institute of Musculoskeletal Health and Arthritis in Ottawa Ontario, Canada.

Dr. Khan?

Presentation – Karim Khan

DR. KHAN: It is great to be part of this panel. And I've got an eye on the time, so I won't go over the five minutes so that we've got plenty of time for the discussion with folks.

From Canada, just to give folks perspectives, it's great to be part of this IMMPACT meeting, and congratulations on the 25 years of work with IMMPACT, and using that word "IMMPACT" more broadly with the publications, and the grants, and the citations that we heard about earlier, but also the improvement of the health of the communities, Americans, Canadians, and people all around the world, which is true impact, like

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the non-academic impacts in addition to what's published.

Great for CIHR, the Canadian Institutes of Health Research, to be represented here. You've heard from Canadian, Isabel Jordan, and you'll hear from Dr. Christine Chambers and Isabel Jordan in other sections. So it's great to be here from that Canadian perspective.

I'm going to drill down and focus on some work from the Chronic Pain Network in Canada, one of five chronic disease networks that were funded by the Strategy for Patient-Oriented Research. So you can see, or hearing that, that the Strategy for Patient-Oriented Research, the CIHR -- Canada's equivalent of, quotes, "NIH" -- has invested in a strategy for patient-oriented research, and it's actually over $100 million a year in Canadian dollars with matching funding, so 100 total, 50 to 60 from the Canadian Institutes of Health Research.

If we drill down to the Chronic Pain Network, I'll emphasize that acute pain is to be treated, and treated well, to avoid chronic pain,

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but if we focus on chronic pain as of now, it's understandable.

I'm going to highlight the work of Dr. Dawn Richards, who would be familiar to many of you, and thanks to her for providing these inputs. I consulted with her, and she is both an academic and a person with lived experience of inflammatory arthritis -- she won't mind sharing that; she shares that publicly -- and one of the real stars of the field that we're talking about today.

So I'm delighted to be able to pop her Twitter account on there for you, and you can follow her easily through email and other channels. She's a member of a lot of international spaces in this patient engagement domain, and she's of the Canadian Arthritis Patient Alliance. She's the co-chair of that. So she's a real star, so I encourage you to take a snip of that slide there with Dr. Dawn Richards, and she's been massively influential to the field.

This is a busy slide. Feel free to take a photo of it, and it will end up in the material

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that you get. We've heard from a few people today, including most recently Kristin, where Kristin framed that it's never too early to start and it's never too late to start, and I couldn't underscore that more.

So I'll just make the point that it needs to begin in the conceptual phase with authenticity; so not doctors or researchers going, "How can we get a patient to help us with this stuff? How can we check the box?" It's like to the patients and to people with lived experience, "What's bothering you right now? How can you be part of this experience?"

It's co-creation. And although that word "co-creation" will be obvious to some people in the room, I'm still stunned by how there are these gut instincts and limitations to co-creation. And when you bring up co-creation, the classy thing is, "Well, what are you planning to do?" It's this obsession about details as if you've already built the thing. So no-no, we don't have any idea where we're going right now, and that is ok, and that's

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the principle of co-creation.
This Chronic Pain Network has done a series of things which I'm going to move on from. We can skip that. But there's a lot of talk in this field, as we know, but the beauty of the SPOR program in this Chronic Pain Network, and Dawn Richards' work is she's delivering products, so it's beyond talk.
Now, the second point of the three slides is that there does need to be resourcing in addition to a budget and resource for communication. So you can't just make this happen and expect the volunteers to miraculously come up with time and money to do this. It has to be commitment. You heard that the CIHR made a commitment.
The institute that I'm assigned to, gov [indiscernible], we've made a financial commitment to pay for Dawn's time, and we've paid the volunteers who make up the committee that leads our work, and we paid for a video that tells researchers why to engage with patients.
We've heard the talk today about how to

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train patients. The specific training for patients and advocates is a topic that's come up today, and we've built that. Dawn is a couple of months away from launching a set of modules, and that took resources as well. So we're putting our dollars where our words are.
To finish with the last slide, you don't know what you're doing when you start off, and I say that explicitly and enthusiastically. Of course you don't know where you're going to start off because that's the essence of co-creation. Then there will be outcomes that you're not aware of, and that's the magic, and they will come. So it's the idea of being confident and believing in the co-creation process.
So my real summary word is to listen to the patient advocates. My history, I was a medical doctor before, engaging research, and the key to me being a medical doctor is to listen to the patients. And it sounds so simple, but it's done, I would argue, less than 10 percent of the time in any setting; listen, listen, listen.

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So let's do that in this business, the patient engagement business, genuinely empower, be authentic, and I'll finish by saying let's listen. Thank you very much.
DR. KERNS: Dr. Khan, that was just terrific. It just, again, complements the other presentations. It's wonderful. I personally am engaged with the Canadian Veterans Affairs Center of Excellence, Pain Center of Excellence, and it's wonderful to see the participatory engagement of veterans in the process, really, all along the continuum that we're talking about today. So it's a very concrete model of some nice success I've observed.
So with that, I'm going to turn to our next panelist. This is Dr. Rachel Knowles. She's the program manager for clinical research in the Medical Research Council in London United Kingdom.
Dr. Knowles?
(No response.)
DR. KERNS: Dr. Knowles, I think you're on mute.

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Presentation – Rachel Knowles
DR. KNOWLES: I apologize for that.
My name is Rachel Knowles. I'm program manager of clinical research at the Medical Research Council in the UK, and that's part of the wider funding organization, which is UK Research and Innovation.
I just wanted to describe the MRC as a funder. The Medical Research Council is part of UK Research and Innovation, or UKRI, which is the national funding body for science and research in the UK. UKRI was formed in 2018, so it's quite a young organization, but it was actually formed from the merger of seven different research councils, which are long established in the UK.
These different research councils, which are shown here, actually funded different scientific disciplines. But the MRC, or Medical Research Council, among them is the one that predominantly funds health and biomedical research. So in the last year, 2020 to '21, UKRI is wholly awarded around 3 billion in research grants and

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fellowships.
I just wanted to show the type of research that the MRC actually funds. We fund largely towards the underpinning and etiological research end of the spectrum, so a lot of what we fund is actually, basically, discovery science and preclinical and early-stage clinical research.
I think that's quite important because it's not always that there's a clear target patient group for some of the research if it is discovery science or basic physiology, and that can mean that at times in the past, we've had difficulty in trying to encourage our researchers who we fund to actually take part in public involvement and public engagement.
However, we do have a relatively good history or tradition of public engagement more at the end of engagement rather than actually involving patients directly. And by that, I mean that a lot of our public engagement activities have focused around engaging the public in understanding and supporting science, and increasing the interest

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of young people, and learning about careers, and taking up careers in the life sciences.
So in many ways, this is what I'm calling public engagement, although I realize public engagement is a spectrum, and it's been used today, obviously, to mean much deeper engagement, and what we perhaps, certainly within MRC, tend to refer to as public involvement.
One example of the type of engagement that MRC undertakes is the MRC Festival. We have quite a lively annual festival for medical research, where MRC-funded units and institutes across the UK put on a range of science activities over a period of several weeks. And there's often an open invitation to the public of all different ages to join in and learn about scientific research.
We've also funded certain engagement involvement activities. One example here is a citizen science activity which was called Worm Watch Lab, which was actually a genetic study where members of the public were able to watch nematode worms online, and then they participated by

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recording whenever an egg was laid.
On a slightly smaller scale at the level of individual research studies, individual research studies have been funded by the Medical Research Council as part of the funding they receive for the study to undertake innovative co-production activity. For example, the film, Be Your Sister's Keeper here was co-produced by a professional filmmaker who worked with researchers and the women sex workers in Nigeria in order to produce this film that describe the research study and also the context in which the work was being undertaken.
The AALPHI study is another example. This is a study of a cohort of adults and adolescents who were living long term with perinatal HIV, and the researchers and young people co-produced a range of materials which were particularly designed to describe the findings of the study in ways that were accessible and engaging to young people.
On my last slide, I just want to talk a bit more about the public involvement that we've tried to start weaving into the funding calls that we've

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been doing more recently. This is something that, as I say, is a more recent thing, and something that we're still very much testing out and finding out what works.
The MRC really has not very often been able to involve members of the public or patients in its funding calls. And this is in large part because we're not experienced in doing it, but also because as a funder of basic science, it's sometimes been difficult to identify and just involve patient representatives or people who are able to understand the technical level of the science, and actually for them to be present on boards or on funding panels who are reviewing what can be highly technical grant applications, especially where, in fact, at times the link to patient or clinical health outcomes can be quite remote.
I do have two good examples, though, recently, where we have embarked upon doing that, and worked really quite hard to make that part of the funding initiative. The first one here is the Advanced Pain Discovery Platform, where the MRC

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partnered with a particular charity and funder called Versus Arthritis.

Versus Arthritis, as a patient support group and a funder, facilitated contact with patients who were able to inform the funding initiative right at the very start. They supported us to appoint patient representatives on to the advisory board for the funding call. They ensured that the information about the call was written or used lay language to describe what it was about.

They also helped us to develop a review panel where patients were the reviewers, and the patients were, therefore, able to contribute to the competitive selection process. And not all of the patients on the review panel, which was held separately, actually were then part of the more technical panel, but certain representatives did sit on that panel.

So this partnership was a real success, and more importantly for the MRC, we actually gained valuable experience in public involvement and how we could weave it into our funding initiatives.

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We've also gone further with a second funding call around adolescent mental health, where it was a similar process, but this time a different organization that we partnered with. The MRC involved a panel of young people in the design and conduct of the funding call; so again, not always an easy group to involve in a funding call, and actually taking part in the types of review and the committee processes that can be quite established and have a particular way of being managed. Again, we actually had a really successful experience here.

So I think both of these initiatives highlighted for us the real benefits for the MRC working in partnership on public involvement activities. We really needed these partner organizations who had the contacts and the experience to help us include members of the public, include patients, and actually to learn ourselves how to do it for the future.

So at the moment, public involvement engagement is an area that the MRC is working hard

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to develop, and we recognize that we don't have a long track record of doing this. We do need to find and develop approaches that work, particularly for the types of research that we fund and the specific funding approaches we use; so the preclinical and basic science research, and where there's not a specific patient group that we can target as the group to become involved.

We can see that we do have good examples and best practices out there, so we're keen to actually find and adopt these, and bring them into our own ways of working. We've recently commissioned a mapping exercise as a first step in developing a new public involvement strategy for the MRC that we hope will address some of the difficulties that we've had in the past

We also want to, from this mapping, actually understand what we already do well in this area. So we don't have a good understanding of what we are already doing, of what those we've funded are already doing, and perhaps are good examples for us to disseminate and let people know about, so that

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we can actually see them copied in future applications and future research that we fund.

We really want to move forward to integrate best practice and public involvement into our everyday activities, our funding activities, so that we can actually get more value out of these research investments in the future. Thank you.

DR. KERNS: Terrific. Thank you very, very much.

Again, we look forward to discussion after our last presentation in this panel by Dr. Jeremy Taylor, director of Public Voice and Center for Engagement and Dissemination at the National Institute of Health Research, NIHR, in London, United Kingdom.

Dr. Taylor?

MR. TAYLOR: Thank you very much, Bob. I have to confess that I'm not a doctor.

DR. KERNS: I realized that.

MR. TAYLOR: I'm just plain Jeremy.

Presentation – Jeremy Taylor

MR. TAYLOR: You'll be relieved to hear also

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that I've only got three slides, and I'll try and get through them as quickly as possible, so we've got as much time as possible for discussion.

The NIHR, National Institute for Health Research, is the other big funder of health-related research in the United Kingdom. We work very closely with the MRC, particularly actually in the last year during the kind of COVID research splurge, where there's a lot of joint funding activity between NIH, UKRI, and MRC on vaccines, treatments, and urgent public health research related to COVID.

We've been around for longer. We started in 2006. What we tend to call patient and public involvement has been a sort of standard expectation right from the start. I noted Simon earlier talked about terminology. Nobody uses consistent terminology in this field. But when we talk about patient and public involvement, we essentially mean a lot of the things we've been talking about in today's very enlightening session, essentially ensuring a meaningful partnership with people with

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lived experience to ensure that they are able to shape the research effort all the way through.

The quote at the bottom comes from some guidance notes that NIHR produces for researchers. "Public involvement can improve the quality and relevance of research." And I guess the reason that it's can, and not does, is because it depends how well you do it.

We also refer, I think, to really important broader democratic principles of citizenship, accountability, and transparency. And to my way of thinking, we do public involvement in research because it ought to make the research better, but also because it's about democratizing what should be a jointly-owned and jointly-conducted enterprise, not just something that's there to preserve the people in white coats. So we have both a kind of utilitarian and moral imperative to get this right.

Going the Extra Mile was a big strategy document that was developed in 2015, and it was a 10-year strategy for embedding and improving the

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way the National Institute for Health Research goes about doing patient and public involvement. It set out a number of very ambitious goals, one of which was to make patient and public involvement more inclusive, and diverse, and reflective of the diverse community in the UK. In fact, that's become a bigger priority over time.

It set a goal of moving away from more tokenistic and mechanistic approaches to involvement to, wherever possible, something more like co-production and genuine partnership. It advocated the development of standards that could be used to help the research community do public involvement well, and they became the UK Standards for Public Involvement.

These are the UK standards in summary form, and they cover essentially more relatable issues that we've been discussing in the last three hours about creating inclusive opportunities, which is partly about being inclusive and diverse, and finding people who can be part of the research enterprise, but also making sure we don't put

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barriers in people's way.

A particular issue is making sure that compensation, which we had to talk about payment systems in the UK, works effectively and ensure that people are not excluded from taking part in research in one way or another because of financial considerations.

Working together is all about actually moving towards more of a partnership model and making sure that that is genuine. Support and learning is about lots of things. It is about providing support and training opportunities for patients, and we've had a bit of a discussion about some of the controversial aspects of that, but it's also about supporting the research community, researchers, principal investigators, and research teams to understand how to go about doing public involvement in a good and effective way.

It is about governance and how people can have real power and voice. We haven't talked too much about power dynamics, but the governance dimension is one of the strands where we get to

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grips with, well, who holds all the cards and can we be more democratic between the researchers, and the patients, and members of the public going forward.

Communications, everything around plain English, about making things understandable, are really, really important, both in terms of people being involved in shaping the research effort and as participants in studies, and we've heard quite a bit about the latter.

Then finally, making sure that we do everything we can so that that involving patients and the public in research leads to impact and makes a genuine difference. So those standards, they were developed in 2018. NIHR worked with other research funders and bodies across the UK health sector, and those standards, there's a job to do to embed them and to make them famous, and to help people use them to improve the way they do public involvement. But they're still very much a live and important part of the public involvement agenda in the UK.

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So we don't rest on our laurels. And this quote comes from a recent strategy document from the National Institute for Health Research that restates and updates its overall strategy for health research, Best Research for Best Health: The Next Chapter, it's called.

In that document there is this quote, "We're guided by the strategy set out in Going the Extra Mile," that I just described, which had a vision of a population actively involved in research to improve health and wellbeing for themselves, their families, and their communities.

Then it goes on to say, "We know that we have much further to go if we are to ensure that the involvement of diverse patients, service users, carers and communities in research is inclusive, consistently makes a difference, and avoids tokenism." That's a recognition that this is still work in progress. Although NIHR in UK terms set a lead for public involvement in research, we know we can do better.

COVID and Black Lives Matter, between them

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in 2020, delivered a bit of a rude shock to the research community in terms of just exposing the degree of inequalities that exist in our society, in health and in the research community, and kind of increased the moral urgency around making sure that when we're engaging with patients and the public, we're doing that inclusively, and we're covering all the communities, not just some.

The Black Lives Matter protests -- again, in the wake of the George Floyd murder -- gave both, in the US but also in the UK, a big stimulus to the debate about are we leaving black people out of research at all levels, including public participants, but also in the research community.

So I just wanted to give you a sense that we still see there's a lot further to go in many of the dimensions we've been discussing today, and I'll stop there.

Summary, Wrap-Up, and Reminders

DR. KERNS: Thank you, Jeremy. That was just terrific. You ended -- and I think all of the presenters ended on this -- "We have much more work

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to do."

I think we prepared a slide -- I don't know, Carlos, if it's possible to bring it up -- of just a small list of some of the opportunities, I would say, for incorporating patient education. It might reflect on this as we move into a little bit of a discussion. But I just want to say we will absolutely end at half-past this hour, regardless of how it goes.

I see Andrew's hand up. Please, if you would like to make a comment, including the panelists, please raise your hand so I can call on you.

Is this Andrew Rice?

DR. RICE: Thank you very much, Bob, and thank you also, to you and the other organizers, for inviting Rachel and the UK participants.

I've got a particular question. I guess Rachel could probably lead on this. Thank you also for giving the shout-out to the Advanced Pain Discovery Platform. There are a number of other people talking about it as well. For me, that was

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a big learning curve. I think we took a foot-step forward in terms of engagement, but it also taught me how much further we've got to go on this journey.

But Rachel, you touched on an important topic, which is the role of engagement in discovery research. And we don't have the other UK funder here, which is Wellcome Trust, but they've taken an important strategic direction now, in that they're really only funding discovery research and not translation research, except in the areas of mental health, global warming, and infectious diseases.

So I just wonder if we could discuss a little bit more how basic science funders use patient engagement at that really early step of setting their priorities and deciding which calls they're going to make. So it's a really early-stage question I wanted to ask.

DR. KERNS: Thank you.

Go ahead, Rachel.

DR. KNOWLES: Thanks, Andrew. Yes, as I say, I think we feel very much we're at the

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beginning of this journey. We really want to explore very much how we can involve patients and the public at every stage. So we are wanting to look at whether we can actually involve people in helping us think about the priorities and particular areas of research, or particular topics, in order to guide us, as well as how we actually involve people individually or in the actual research projects.

I think there are not clear ways to do it. I think one of the things that, for me, is very important is that we actually always step back and think about, well, what's the purpose of this public involvement/public engagement? What do we want to get out of it? How do we think that this is going to improve what we do? And therefore look to actually have a targeted public engagement/ public involvement that actually really seeks to contribute to what we're doing.

So it's not that we have a standard formula for this is how we always do it, but that we actually start to develop a suite of resources, a

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suite of ways of doing it, that we can actually say, "Look, here are things; choose from these; and what will actually work best in this situation?"

We really do try and explore the breadth of what public involvement/public engagement could mean, rather than focusing too narrowly on, perhaps, patient involvement. And I say that, really, because we're finding that patient involvement isn't enough for the type of research that we fund. So we really want to look broadly and see what can we get out of public involvement and how can we do it in the broadest sense.

DR. KERNS: Thank you, both.

Lee Simon?

(No response.)

DR. KERNS: Come off mute, Lee.

DR. SIMON: This has been a very interesting meeting, and I just want to comment that OMERACT, Outcome Measures in Rheumatology, has actually incorporated patient research partners for the last 20 years; in fact, we have a handbook for them. We have meetings for the patients. We educate the

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patients. The patients educate themselves. Every single working group within OMERACT must have patients associated with work. They are, in fact, a self-sufficient group who meet on their own.

There was a paper by John Kirwan mentioned previously in the early presentations, and there have been multiple papers out of the patient research partner group talking about their involvement. One of the places that they've been particularly involved has been in drug safety working groups and in glucocorticoid working groups about understanding the way that glucocorticoids affect them as an anti-inflammatory, but also with the side effects.

This is probably the most critical nature of the kind of work that we do in trying to understand the effect of therapeutics. They're also incredibly important to identify the core domain set that we're going to develop, or has been developed, for each of the disease states that we deal with, and they are integral to be able to understand that, and then integral in understanding

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the selection of instruments to measure those particular domains that are determined by consensus to be important. I just wanted to include that as well.

DR. KERNS: Thank you very much. I think that's very important feedback. I don't know if anybody has a comment or reflection; maybe Simon. To the extent that you believe OMERACT and its products are not well reflected in what's been talked about so far, please feel free to share something with Valorie in particular. We don't yet have the chat up, but I think we're also soliciting more input, and we'd be delighted to have anything that you think would be contributory and particularly complementary to what we've talked about.

Lynn Laidlaw?

MS. LAIDLAW: Hi. Great presentations, everyone. Thank you. So I thought it was interesting that Jeremy was the only person that mentioned power and power imbalances, what for me is absolutely fundamental to our understanding of

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involvement.

I just wanted to ask a general question. Are we at risk of seeing this through a very research lens? I heard a lot of talk about methods, when actually I haven't heard a lot around the values, the values around depending on what you do, rather than coming at this from a methodological research perspective. So I just wondered if anyone would like to comment on the power and the values issue. Thanks.

DR. KERNS: Comments from any of the panelists? Dr. Carman?

DR. CARMAN: Yes. I think it's a great question, and I think one of the challenges in a context like this is doing this very rapid fire. I think what I would say is a couple of things. Hopefully, you'll see in the rubric, power is a key part of this and how do you transfer power. I think one of the ways to think about power is through reciprocal relationships, sharing power, co-direction, and other things.

I think in our work, we've tried to be very

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cognizant that there are people -- and Laura will talk about this, actually, when she talks about measurement. People want different things from engagement. Individuals have goals. Researchers have goals. Institutions have goals. Why we have focused on research is to address two key issues: one, how do you do this better, and how do you help each of the participants in this relationship or this team to achieve their goals?

We do believe that that requires learning about how to do it because I don't think there's a roadmap for exactly how to do this in all our organizations. So there's the learning to do and the learning to make it more efficient and effective for all parties to achieve their goals.

I do think there's another piece, though. For those of us interested in more individuals doing this, who want to share what we think the value is, I think research can be necessary for other individuals. Show me. Show me what a difference it makes to engage people. Show me how it influences the project. Show me how it

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influences feasibility and rigor.

I don't think these things in our personal experience have to be in conflict. I do agree with you, though, they have to be very attentive to those dynamics and thinking about, from all parties' perspectives, what are they hoping to achieve, and how you help all parties as best you can achieve what they want to get out of engagement. Because ultimately, it's a pragmatic world, and we think that will lead to more uptake, and ultimately, as Dr. Goertz laid out, the kind of uptake of research that we're all looking for.

So I hope you don't feel like I'm pushing back on the question, but rather pointing out I think these things can be done in concert, in my experience.

DR. KERNS: Thank you very much. Thanks very much for that important question as well, Lynn.

Dr. Khan?

DR. KHAN: Really briefly, I do appreciate bringing power to the table, both in the talk and

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the question, power imbalance. Janz, who was the pioneer of that groupthink, made the point that the leaders need to get out of the room some of the time to facilitate and encourage the group to be engaged.

So I think collating is one thing, but really empowering the group when you're not in the room is equally important. And we've got a conference we're planning in 2022, where the patient group is owning the conference, and they're running the conference, and we're supporting them to where they want to go, rather than enabling co-creating and being stuck on.

So I think my last message would be, be authentic. If you're in these leadership roles, be authentic. If you're not authentic, just walk away. Don't do it. Don't pretend. Be authentic or don't do it.

DR. KERNS: I had one reflection, which is combining this question with the idea of training, and training for researchers, potentially, if it's not already integrated into the training plan.

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Upfront opportunity to address this issue of power dynamics in these teams likely is important, and I think all of us on the research side could benefit from thinking a little differently about this construct, so thank you very much.

Any other comments from any of the panelists, maybe even reflecting on what I have on the screen here as opportunities for future development? Maybe I'll also call on particularly -- okay. I see Jeremy has his hand up.

MR. TAYLOR: Yes, just to say the thing that particularly stands out in that slide for me is the lack of standing relationships with community organizations and patients. That's a big theme, I think, in the UK context, where we have started from the researcher point of view, as Lynn points out.

So a lot of the discourse around patient and public involvement has been framed around the pre-existing research effort. We've got this research we need to do; how do we get patients in

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the public involved in that? A well-meaning question. But it starts with researchers. It starts with the research processes and thinks about, okay, we need to get people in. We need to get them onto our committees. We need to get them onto our project steering groups. We want them to come to us.

I think what is the gathering force is the countervailing notion that, well, you should also be thinking about the communities and how to go to them; how to be in their spaces and in their mindsets; and to start a conversation; and to build trust and find out what matters to those communities and those people; not try and immediately co-op them into doing stuff that you want from them, but think about what they might need from you, and take time. Take time to build relationships. Park your own agenda. Get off your high horse.

It's very difficult to do that because it requires a shift in mindset. But increasingly we recognize in the UK that if you're serious about

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diversifying research and being genuinely inclusive, and ensuring that that leads to meaningful change to the research agenda, we have to do things differently. And building relationships with people where they are, not requiring them to come onto our pitch, I think is probably the biggest shift that we need to see, and it's not easy if you're starting from a different place.

DR. KERNS: As I reflect on this first day, I personalize it and think it's really hard to be a moderator when I have so many things I want to tell you about what I think about some of these issues. And I'm looking forward to sharing maybe some of my perspectives later in the upcoming couple days.

Our last comments are from Simon, and then Rebecca, and then I'm going to ask Chris Veasley if she has any closing comments for today.

Simon?

DR. HAROUTOUNIAN: Thanks. Thanks so much, Bob.

I wanted to ask the panelists about their

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thoughts or experience about how the patient engagement processes have changed in the last couple of years. A lot of work has been put into how to actually build those relationships that Jeremy was mentioning, sometimes as team-building activities, where you can actually meet people, engage with them, and do some sort of maybe off-work type of activity to build that energy and build that trust.

While these remote or Zoom-based communications, which have allowed some access to patient partners who would otherwise not have access to the conversation around the table, it also created some challenges -- at least the way I see it -- in terms of actually building that relationship and developing it.

I wonder what kind of thoughts people have about how much this may have impacted our ability to build some of those relationships, and what are maybe alternative ways of continuing doing the work in a meaningful way.

DR. KERNS: I think you're hitting on some

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great points, Simon. I'm going to, for the sake of time, note that the guts of tomorrow's session are these partnered presentations about the how tos, and different phases of the research cycle that will involve both people from the research side and people with lived-experience patients.

I think that would be a great opportunity to think about some -- I think some of the responses to your comments will come through there, but then we will have more time for discussion at the end of the day tomorrow to deliberate on that point.

Not to cut anybody off, would anybody specifically like to pick up on Simon's comment? Otherwise, I'll turn to Rebecca.

Go ahead, Karen.

MS. MORALES: Well, I just want to say that for us, the pandemic didn't stop us from engaging. We were able to successfully engage using focus groups on a virtual scale and also creating new social media avenues, so we continued our engagement efforts. But I don't want to talk too much because I do want to give Rebecca her time.

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But I will say that the pandemic, while it was harmful, I think it was a missed opportunity also to use community health workers doing engagement during that time because of funding issues, but we can talk about that tomorrow.

DR. KERNS: Great. Thank you, Karen; very important points.

Rebecca?

DR. BAKER: Thanks. Yes. I'm reflecting on the question, Simon. I think being virtual flattened everything. On one hand we got a lot of input, that if people had had to travel to Bethesda and attend one of our in-person meetings, we may not have received; but on the other hand, it's just in this sea of input and information, and the connectedness and meaningfulness really depends on how much you put into it. So for some of our researchers, they put a lot in and they got a lot out, but it's not across the board.

I wanted to reflect on the earlier comment about principles and values because I feel very comfortable about the HEAL Initiative saying that

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it is one of our principles. Our goal is to provide scientific solutions to the opioid crisis, and this cannot be done without working hand in hand with patients, people's lived experience.

I suppose it is a little utilitarian. We have a goal, and this is an essential component part of our effort. But I feel like I put that value-based approach out there a lot, and I think that it really helps when it's echoed by our leadership.

So my observation over the past couple of years at NIH has been that the launch of the All of Us Research Program, and most recently, the Community Engagement Alliance, which was part of our effort to test COVID vaccines among diverse research communities, was really building that community connection. So not just saying I need this percentage of people with these letters next to their names, but going to the individuals in the communities who have those networks, have those connections outside of medical settings, and saying you are part of our strategy.

Nothing's perfect, and we're still fighting to get people vaccinated and to share the fruits of the research with the communities, but it went a long way, and people appreciated that. So I think in that way, we've really advanced, but it also helps to have our leadership saying this is essential. So that has been a big part of our driving force within the HEAL Initiative.

DR. KERNS: Well, thank you, and thank you to all our presenters, panelists, and those who spoke up in the Q&A and comment sections today, and maybe a particular shout-out to our participants who represent the community, that are the targets of our research community of people with lived experience, so thank you for that.

Chris, do you have any last words for today, any hints about tomorrow?

MS. VEASLEY: No. Thanks, Bob. I think we just had a really great first day. I think when we first started having conversations about this meeting, some folks wondered do we have enough to talk about and is there enough being done out there

that we actually can have a full meeting on this. And I think what today has shown us is that the answer to that is overwhelmingly yes, which is very encouraging.

So we do have a long way to go. Today was really about identifying through the reviews; what do we know in the literature; giving high-level, 30,000-foot views on best practices, principles; and what are our agencies doing around this issue. And really, tomorrow we're going to deep dive into the how tos. We don't want to just give people high-level recommendations of this is great, you need to do it, but then not leave them with how do you do it; not answering that question.

So tomorrow we're going to investigate each step of the research life cycle and learn from co-presentations between investigators and patient partners in those studies about how exactly do we plan, include patient engagement and planning, and conduct; how do we reach diverse populations; and how do we partner to do dissemination and implementation?

So I just want to thank everybody for our great first day, and I look forward to tomorrow.

DR. KERNS: Terrific.

Bob, or Dennis, or Valorie, Carlos, any instructions for tomorrow rejoining at 11:00 Eastern U.S. time?

MS. THOMPSON: The only thing I'll say is that the same link that you used today to join us will be the same link that you use throughout the meeting.

DR. KERNS: Terrific.

Well, thank you again, everybody.

Oh. Go ahead, Bob.

DR. DWORKIN: I was just going to say I think it was a great first day, and I look forward to tomorrow and Friday.

Adjournment

DR. KERNS: Beautiful.

Alright. Well, thank you again, everybody, and we'll reconvene tomorrow.

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

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