

*ACTION IMPACT XXV - Patient Engagement in
Planning, Conduct & Implementation/Dissemination of CPR*

October 27, 2021

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5	INITIATIVE ON METHODS, MEASUREMENT, AND PAIN	
6	ASSESSMENT IN CLINICAL TRIALS	
7	IMPACT XXV	
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9	Patient Engagement in Planning,	
10	Conduct and Implementation/Dissemination of	
11	Clinical Pain Research	
12		
13		
14	Virtual Meeting	
15		
16	Wednesday, October 27, 2021	
17	11:00 a.m. to 2:30 p.m.	
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1	P R O C E E D I N G S	
2	(11:00 a.m.)	
3	Introductions, IMPACT Overview, and	
4	Meeting Objectives – Dennis Turk	
5	DR. TURK: I want to welcome you all to the	
6	XXV ACTT-IMPACT meeting. That means that we have	
7	been engaging in this process for probably about	
8	20 years, and 25 is because we've had more than one	
9	meeting. I want to welcome you for being here and	
10	to thank a number of people for setting this up.	
11	Of course I'm thanking you on behalf of	
12	Dr. Robert Dworkin, who is the director of ACTTION,	
13	and he is a professor universalis at the University	
14	of Rochester; universalis because he has more	
15	connections to any department than anyone in the	
16	history of the university. I also want to welcome	
17	you on behalf of the Executive Committee of	
18	ACTTION.	
19	Then I have to thank Valorie Thompson, who	
20	without, these meetings could not occur for all of	
21	the technical assistance. Valorie is from	
22	Innovations Research Group. She's the president;	

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1 and also to Carlos Rodriguez, who is the AV
2 director who helped set it up, and for those who
3 are listening earlier on having the troubles that
4 some of us were having on getting connected. So
5 thank you all for being here. I want to thank the
6 speakers as well who we'll hear more about.
7 Now, I mentioned the term "ACTTION" and
8 "IMPACT." Those are acronyms that Dr. Dworkin
9 created, and let me tell you a little bit of what
10 they are for those who are not familiar with it.
11 So what is IMPACT? It's the Initiative on
12 Methods, Measurement, and Pain Assessment in
13 Clinical Trials, IMPACT, and that's what's been
14 going on for a number of years. It's an
15 international consortium of participants from
16 academic research; governmental agencies -- and you
17 can see some of them listed there -- industry;
18 consulting companies; and research organizations,
19 as well as consumer.
20 I'm using word "consumer" versus patient
21 advocates because there are also other advocates
22 from family who tend to be involved with ACTTION,

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1 or other significant others. The mission of
2 IMPACT is to suggest methods for improving the
3 design, execution, and interpretation of clinical
4 trials of treatments for pain.
5 IMPACT is part of ACTTION, another acronym
6 which stands for the Analgesic, Anesthetic, and
7 Addiction Clinical Trials Translations,
8 Innovations, Opportunities, and Networks. And
9 given the number of words there, ACTTION is the
10 acronym that we're going to be using throughout
11 this meeting.
12 What is ACTTION? ACTTION is a
13 public-private partnership with the U.S. Food and
14 Drug Administration. The mission of ACTTION is to
15 identify, prioritize, sponsor, coordinate, and
16 promote innovative activities -- with a special
17 interest in optimizing clinical trials -- that will
18 expedite the discovery and development of improved
19 analgesic, anesthetic, addiction, and peripheral
20 neuropathy treatments for the benefits of the
21 public health.
22 Before I just say this, let me just mention

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1 that IMPACT existed prior to the existence of
2 ACTTION and was merged into ACTTION. So it's one
3 of the activities, these meetings that we have, the
4 IMPACT meetings, which are just part of what
5 ACTTION does, and you'll hear more about that.
6 So who is IMPACT and who has been involved?
7 Well, for the 25 meetings that we've had, we've had
8 over 25 different participants, including this one.
9 The participants have been from academic and
10 related organizations from 150 different academic
11 institutions, organizations, and health systems
12 from 14 different countries, and they're listed
13 there if you're interested in that. So we are
14 truly international.
15 Investigators and officials from national
16 and international governmental regulatory, as well
17 as research agencies, have been involved, and those
18 are listed: the DEA, DoD, EMA, FDA, Health Canada,
19 NIH, MHRA, and a bunch of acronyms that you can
20 read yourself. So we've had lots of involvement.
21 We've had over 50 different pharmaceutical
22 and device companies who have provided support

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1 periodically for different meetings and for
2 different projects. We've also had representatives
3 from seven different consumer advocacy groups. And
4 again, I'm not using patient, I'm using consumer
5 because there are people who have chronic pain but
6 may not be patients, so therefore I'm using that
7 term.
8 We've had consulting companies and research
9 organizations over the 25 meetings from 23
10 different groups. So as you can see, it's quite a
11 diverse group of people. But you are really who
12 IMPACT is; that is you're participating in this
13 particular meeting and you are contributing to what
14 we hope to do, and we'll go over the objectives
15 shortly.
16 So keep in mind that I thanked all those
17 other people, but I really need to thank you as
18 well for participating, and that includes
19 international people who have been involved in
20 other meetings, but it's particularly in this
21 meeting who have given the time that was on the
22 West Coast. So our time is quite different from

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1 someone who might be in UK.
 2 So thank you all for being here and taking
 3 part in this meeting, which will extend over three
 4 different days, or parts of three different days,
 5 with approximately 3 hours/3and a half hours over
 6 those days. We'll go over the agenda very quickly,
 7 and you'll get a sense of what those times are
 8 going to be.
 9 We greatly appreciate you all taking your
 10 time out of your very busy schedules to participate
 11 in this meeting. This is a virtual meeting. It's
 12 our second virtual meeting. The previous IMMPACT
 13 meetings, people have actually come and spent time
 14 always in the Washington DC area. So therefore,
 15 the amount of time at those meetings, which is over
 16 usually two to two and a half days, has extended
 17 well beyond what we can do in this particular
 18 meeting.
 19 So we do appreciate your being here. We
 20 acknowledge that people have busy schedules. But
 21 to the extent that it's possible, when we see the
 22 objectives, you'll understand why we would like to

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1 encourage you, strongly urge you, to participate in
 2 as much of the meeting as you can so that you'll
 3 understand where things are developing and where
 4 we're going.
 5 What do IMMPACT and ACTTION do? Well, we
 6 have consensus meetings. We publish consensus
 7 statements, systematic reviews, methodological
 8 papers with diagnostic criteria and
 9 classifications. Many of you are familiar with
 10 those; you've seen them.
 11 We conduct and commission the development
 12 and publication of review papers and different
 13 topics, which you may have seen over the 151
 14 approximate that we've published, and conduct and
 15 support scientific research. We actually fund some
 16 different research projects, which you can learn
 17 more about, and I'll tell you how to access
 18 information about those if you're interested.
 19 We sponsor collaboration with international
 20 organizations for the development and dissemination
 21 of diagnostic criteria and classifications. We
 22 have been involved in support of the publication of

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1 a number of diagnostic classification papers.
 2 We've had them all -- I think all -- published in
 3 Pain, and then we've created a volume put together
 4 of all these papers and made them available to all
 5 members of the International Association for the
 6 Study of Pain in a hardback version that was sent
 7 to all members approximately maybe a month ago.
 8 We support educational initiatives. To
 9 date, there have been over 150 IMMPACT and ACTTION
 10 articles that have been published. These have been
 11 in major journals. There's a mistake on this
 12 slide. I checked recently, and it's now over
 13 900 different scientific journals, ranging anywhere
 14 from addiction medicine, anesthesiology, women's
 15 health, and veterinary medicine.
 16 Interestingly, most recently, a number of
 17 legal and juvenile delinquency publications have
 18 obtained access to some of the criteria, some of
 19 the studies, and some of the statistical methods
 20 that we publish. So it's sort of gratifying to see
 21 that the outreach is way beyond just the area of
 22 pain and addiction, but to a whole variety of

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1 different journals. And if anybody has great
 2 interest, I'll be happy to send you a list of
 3 900-plus journals, where we've published things.
 4 Since 2003, the IMMPACT and ACTTION
 5 publications, according to Google Scholar as of two
 6 or a few days ago, are over 14,000 times. So it's
 7 not just that we publish these, but they do
 8 actually seem to be having some impact -- pardon
 9 the pun -- by the fact that they're getting cited
 10 in numbers of different journals, but also numbers
 11 of times. So that gratifies those of us that are
 12 involved, including the many of you who are
 13 involved in those publications.
 14 If you have interest -- and I know you can't
 15 read those on your screen -- in learning more about
 16 any of the things that I've said, any of the
 17 previous meetings and the manuscripts that we've
 18 published by people who've attended these meetings,
 19 and copies of some of the slide presentations,
 20 those are all available.
 21 If you're interested in the IMMPACT
 22 meetings, you can go to IMMPACT, and make sure you

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1 have two M's, I-M-M-P-A-C-T.org. If you only put
2 one M, you will end up with all kinds of
3 interesting topics, not necessarily ones you want
4 to be in.
5 If you want to go to learn more about
6 ACTTION and the activities, and the range of things
7 we've accomplished and that we've tried to
8 undertake, and directions we're going, you can go
9 to A-C-T-T-I-O-N.org, ACTTION, and that way you can
10 find out a lot more than I can possibly talk about
11 in this very brief introduction.
12 What are the meeting objectives? And this
13 is really the most important thing that I'm going
14 to say to you right now; that is what we want to
15 accomplish. In every one of our meetings, our goal
16 is to have specific directions we go, specific
17 objectives, and specific outcomes of products that
18 we try to do to make sure that we benefited from
19 the speakers and discussions, and disseminate that
20 information as widely as possible.
21 So our objectives for this meeting are to
22 understand the history of best practices associated

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1 with incorporating "patients as partners" -- and
2 that's in quotes -- in the life cycle of clinical
3 pain research. We also hope to have an objective
4 that we review how research funding and regulatory
5 agencies are supporting the incorporation of
6 patients and other stakeholders in the planning,
7 conduct, and dissemination of clinical pain
8 research. The third objective is to identify
9 strategies to overcome significant barriers to
10 incorporating patient engagement and research life
11 cycle.
12 The next objective is to learn from clinical
13 research studies that are incorporating patient
14 engagement in planning, conduct, dissemination, and
15 implementation of clinical pain research, including
16 the incorporation of diverse populations. And the
17 last objective -- and this is one that hopefully
18 all this information and all of the discussions
19 will work toward -- is to develop consensus
20 recommendations to aid the international pain
21 research community on best practices, as well as
22 specific how-to guidance for incorporating patients

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1 as partners in the research life cycle.
2 If in fact you've been involved with other
3 IMMPACT meetings or if this is new to you, what we
4 try to do is to have a number of presentations over
5 the three days. There's approximately three to
6 four different presentations each day with, then,
7 lots of question and answers, and then discussion,
8 all going toward the goal of the last day of trying
9 to come up with a set of recommendations for what
10 we assert truly might benefit from what we've done.
11 Now, I should thank someone particularly now
12 for this part of it, or actually two people,
13 Dr. Robert Kerns and Christin Veasley. Dr. Kerns
14 is a professor of psychiatry, neurology, and
15 psychology at Yale University, and Christin
16 Veasley, who is the founder and director of The
17 Chronic Pain Research Alliance, a major
18 organization trying to bridge the gaps between the
19 clinical research side and the consumer, the
20 patients as partner side of this meeting.
21 Without these two people, we could not have
22 pulled off this meeting. They did a tremendous

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1 amount of work, as you will see. For those of you
2 that are our speakers, you've had lots of contact
3 with them, but they've also gone out of their way
4 to help develop the content, the topics, and the
5 speakers to do all the inviting and to set all this
6 up. So in a very few minutes, I will shut up, and
7 I will turn this over to Bob Kerns and Chris
8 Veasley, as they will give you their perspectives
9 and then move on to the presentations.
10 Before we do that, I also want to thank the
11 last person, Simon Haroutounian. Simon has
12 volunteered, or been coerced or encouraged, to
13 serve as the rapporteur.
14 What he will do is in addition to
15 presenting, he will also be taking notes trying to
16 summarize things as they go along and will begin
17 crafting and developing the first -- or one if
18 there may be more, but at least the first of the
19 manuscripts that we're trying to develop with our
20 considerations and recommendations for those in the
21 field; so the people that I've mentioned that I
22 wanted to thank, in addition to Valorie and Carlos.

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

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

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

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

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

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

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

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

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

7 General housekeeping. This is important.
 8 These are going to be the last two slides that I
 9 have, and I'll turn this over to Chris and Bob.

10 All meeting participants will be muted during the
 11 presentations and unmuted during the Q&A
 12 discussion. Use the raised-hand button located on
 13 the reactions menu found in the bottom bar of the
 14 Zoom screen to ask a question or to engage in
 15 discussion.

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

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

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

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

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

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

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

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

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

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1 this particular meeting here that we're spending.
 2 So I'm looking forward to an exciting
 3 meeting and to the debate and discussion so that we
 4 can, in fact, do something to improve the field.
 5 Thank you very much, and welcome to the XXV IMPACT
 6 meeting.

7 Welcome and Charge
 8 Robert Kerns and Christin Veasley
 9 DR. KERNS: Thank you, Dennis.
 10 Bob Kerns here from Connecticut. I'm
 11 delighted to welcome you on behalf of myself and
 12 Chris Veasley, and I'll turn things over to her in
 13 just a minute. We're delighted to have your
 14 participation over these next three days. It's
 15 really been a terrific team effort involving many
 16 of you who are participants, and we look forward to
 17 a great meeting.

18 This meeting is in the context of what
 19 Dennis already suggested, ACTION and IMPACT, and
 20 one of the working groups within ACTION is a group
 21 that was organized by Chris and me a couple years
 22 ago -- a few years ago, actually -- called PROCESS,

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1 Public Relations and Communication and Education
 2 Strategies, written here as an acronym.
 3 As I said, Chris and I co-chair this. Our
 4 working group has focused on developing a range of
 5 initiatives designed to disseminate information
 6 about ACTION's multiple activities, particularly
 7 research studies, diagnostic criteria, et cetera,
 8 that Dennis has already articulated, but
 9 particularly with a focus on communicating with a
 10 range of stakeholders beyond researchers, including
 11 clinicians, students and trainees, persons with
 12 pain, and the general public.

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

22 Ultimately, the book went to all the members

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

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

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

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1 organizational skills and communication skills that
 2 we're able to do this. So thank you.
 3 I think this is where I turn things over to
 4 Chris Veasley.
 5 Chris, please, take it away.
 6 MS. VEASLEY: Thanks, Bob. And I just want
 7 to extend my thanks to Bob and Dennis, and the
 8 entire ACTION Executive Committee for support of
 9 this really important meeting today.
 10 I'm going to start off by addressing the
 11 proverbial elephant in the room -- if my slides
 12 will advance, there we go -- and what we're really
 13 doing here is challenging the traditional research
 14 model that really states that only those that have
 15 advanced training and degrees are the ones who can
 16 be unbiased in developing rigorous methodologic
 17 clinical research, to the pushback from patients
 18 who have many, many years of lived experience with
 19 their individual illnesses, who can also contribute
 20 in developing and adding value to the development
 21 of rigorous clinical research.
 22 This is a quote from a paper from Applied

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1 Clinical Trials, and it says, "Once regarded as,
 2 quote/unquote, 'subjects who had research performed
 3 on them,' patients are now contributing across the
 4 spectrum of clinical development, including the
 5 design and planning of research protocols,
 6 selection of outcomes and endpoints, development of
 7 recruitment and retention strategies, and
 8 dissemination of results."
 9 There's a lot of added value to
 10 incorporating people with lived experience into the
 11 development of planning and research. Now, there's
 12 been some pushback in terms of, yes, the typical
 13 person with lived experience doesn't have training
 14 in statistics, or pharmacy, or development of
 15 clinical trial protocols, but I would suggest that
 16 even in the context of a greater team of developing
 17 clinical pain research, you wouldn't expect that
 18 the statistician on your team is making decisions
 19 about pharmacy issues, and so on and so forth.
 20 There's a big team that all comes together and
 21 works cooperatively to develop rigorous clinical
 22 research.

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1 This is just a larger understanding that,
 2 really, in order to develop research that is both
 3 meaningful to people who have the condition for
 4 which you're studying, and also implementable, that
 5 there are a range of stakeholders who really should
 6 be engaged in the planning and conduct of research
 7 from its earliest stages, including patients and
 8 consumers, clinicians, insurers and payers,
 9 policymakers, and funders, and that's just to name
 10 a few.
 11 This is really a larger concept of what's
 12 called community-based participatory research,
 13 which is really we'd like to bring those principles
 14 into the clinical pain research strata, which is a
 15 partnership approach that equitably involves
 16 community members, organizational representatives,
 17 researchers, and others in all aspects of the
 18 research process.
 19 There's reciprocal appreciation of each
 20 partner's knowledge and skills at every stage of
 21 the project. All partners are considered equal and
 22 contribute expertise, as well as share in

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1 ownership, decision-making power, resources,
 2 credit, knowledge, and results, and all are really
 3 fully committed to producing outcomes that are
 4 actually usable to the community.
 5 This very highly scientific question at hand
 6 today is how can we advance patient engagement in
 7 the planning, conduct, dissemination, and
 8 implementation of clinical pain research, and how
 9 can we do it well? And by that I mean how do we
 10 avoid tokenism by just adding people to a list of
 11 project members, but actually have authentic
 12 engagement?
 13 In order to do that, we've brought all of
 14 you together, and we thank you so much for your
 15 participation. We have research funding agencies
 16 represented in this meeting, and people from
 17 regulatory agencies, and I would say not just in
 18 the United States, but international. We have
 19 clinicians, we have scientists, we have patients
 20 and persons with lived experience. We have
 21 industry members and journal editors. Because,
 22 really, in order to change the paradigm of how

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1 research is conducted, we need buy-in from all
 2 stakeholders that are involved, and we want to
 3 learn from you.
 4 So we really appreciate you coming together
 5 with us for these three days. We hope that you can
 6 participate in as much of the meeting as possible,
 7 and we look forward to really developing
 8 meaningful, consensus recommendations that will
 9 change the field.
 10 I'll turn it back over to you, Bob, to
 11 introduce our first speaker.
 12 DR. KERNS: Thank you, Chris, very much.
 13 It's my real pleasure to introduce Christine
 14 Goertz. Christine is the chair of the Board of
 15 Directors of the Patient-Centered Outcomes Research
 16 Institute, or PCORI, based in Washington, DC.
 17 She's also a professor in musculoskeletal research
 18 at the Duke Clinical Research Institute and
 19 director of System Development and Coordination for
 20 spine health in the Department of Orthopedic
 21 Surgery at Duke.
 22 Christine, we're running behind, but please

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1 don't short-change your own presentation. Do it at
 2 your own pace. We'll make up for the time later.
 3 With that, I'm going to hand things over to
 4 Christine Goertz.
 5 Presentation – Christine Goertz
 6 DR. GOERTZ: Thank you so much, Bob, for
 7 that kind introduction. It's such a pleasure to be
 8 with all of you today. I'm truly thrilled to have
 9 been asked to give these opening remarks to help
 10 set the stage for what looked to be three
 11 incredibly exciting days, but also because I'm
 12 really looking forward to the opportunity to learn
 13 from all of you. The topic of patient and
 14 stakeholder engagement pain research is critically
 15 important, and I thank IMMPACT and ACTTION for
 16 making it a priority issue at this year's meeting.
 17 As you heard from Bob, I'm a pain researcher
 18 and have been for more than 30 years now, and I
 19 wear a number of hats. Among them, I have the
 20 honor of serving as chairperson of the Board of
 21 Governors of the Patient-Centered Outcomes Research
 22 Institute, or PCORI, and it's primarily in that

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1 capacity that I'll be addressing you today.
 2 My goal is to give you an overview of
 3 patient engagement from PCORI's perspective,
 4 including some definitions, best practices, and
 5 lessons that we've learned over our first 10 years
 6 or so of doing this kind of research. I'd also
 7 like to discuss a few studies specifically on pain
 8 management and talk about how this work can help
 9 shape how we study pain in the future, using
 10 outcomes that really matter to patients.
 11 Just briefly, I want to provide an
 12 introduction to PCORI and a high-level view of
 13 PCORI's work on patient engagement, including
 14 lessons learned and challenges to doing it well.
 15 I'm going to focus on a few pain studies from our
 16 portfolio, with an emphasis on the role of patient
 17 engagement and shaping this work. I'll provide
 18 some resources for those who are interested in
 19 learning more about PCORI's work in stakeholder
 20 engagement, and then close with just a few
 21 take-home messages.
 22 I'd like to begin with a brief introduction

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1 to PCORI. I tend to think that everybody has heard
 2 of PCORI, but I know there may be some of you on
 3 this call that are not familiar with our
 4 organization. We're really unique with an
 5 interesting origin story that clearly illustrates
 6 the need for the kind of research and patient
 7 engagement that PCORI champions.
 8 We were established in 2010 by U.S. Congress
 9 as part of the Affordable Care Act legislation,
 10 which expanded healthcare coverage in the U.S., and
 11 lawmakers recognize that in spite of the plethora
 12 of traditional research that's been conducted, very
 13 often patients and those who care for them don't
 14 have the information that they need at the point of
 15 the bedside to properly guide healthcare decisions
 16 they face every day.
 17 Our organization was deliberately given the
 18 name of Patient-Centered Outcomes Research
 19 Institute as part of its authorization, emphasizing
 20 the need for research that engages patients and
 21 other stakeholders. Consequently, our research
 22 questions and our outcome studies must be of

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1 importance to patients and those who care for them,
 2 and the studies much engage patients and
 3 stakeholders as true partners in the research
 4 process.
 5 PCORI also prioritizes the dissemination and
 6 promotes the uptake of research findings. We want
 7 to ensure that the results of the research we fund
 8 are useful, that they're actionable, and accessible
 9 for both patients and stakeholders. As we all
 10 know, the best clinical research in the world is
 11 not of much use unless it's actually implemented
 12 into clinical practice.
 13 We have strived to translate patient
 14 centeredness into practice guided by our mission,
 15 which is that PCORI helps people make informed
 16 healthcare decisions and improves healthcare
 17 delivery and outcomes by producing and promoting
 18 high-quality and evidence-based information that
 19 comes from research -- and I really think it's this
 20 last part that's really unique to PCORI -- "guided
 21 by patients, caregivers, and the broader healthcare
 22 community."

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1 The primary vehicle through which PCORI
 2 accomplishes this mission is the funding of
 3 comparative effectiveness research, or CER, and
 4 specifically a type of CER called patient-centered
 5 outcomes research or PCOR.
 6 All the interventions in PCORI-funded
 7 studies have already been shown to be efficacious,
 8 however, there are questions that still remain
 9 about how effective they are, especially for
 10 particular populations under particular real-world
 11 circumstances.
 12 Research designs can include both
 13 randomized-controlled trials and observational
 14 studies that have to be designed to answer
 15 questions that matter most to patients, and what
 16 we've learned from talking to patients and other
 17 stakeholders over the last several years, but
 18 especially early on in our development, was that
 19 the following questions are things that really
 20 matter to patients and to other stakeholders.
 21 First of all, given my personal
 22 characteristics, conditions, and preferences, what

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1 should I expect to happen to me? What are my
 2 options? What are the potential benefits and harms
 3 of these options? What can I do as a patient?
 4 What can I do as a clinician to improve outcomes
 5 that are most important to patients? And finally,
 6 how can clinicians and healthcare systems work to
 7 help me as a patient make the best decisions about
 8 my health and my health care.
 9 Let me give an example. The PROSPER study
 10 focused on treatments for stroke. Patients
 11 received either blood thinners, statins, or no
 12 medicine. Patient involvement in the design of the
 13 study led to the measurement of outcomes that
 14 researchers had learned what mattered most to
 15 patients.
 16 As clinicians or scientists, the researchers
 17 might have chosen to measure survival rates, the
 18 severity of the stroke, or where patients were
 19 discharged to on leaving the hospital. But with
 20 guidance from patients, one of the study's primary
 21 outcomes was days spent at home rather than in a
 22 nursing home or a hospital.

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1 We've learned this and from the other
 2 studies that we've conducted, that what really
 3 matters to many patients are outcomes that are more
 4 related to the quality of life and functional
 5 measures rather than traditional clinical measures,
 6 though those are often measured in the same study.
 7 Patients can often identify real-world barriers to
 8 study completion that might not occur to
 9 researchers such as transportation issues for
 10 studies that require regular visits to a facility.
 11 Finally, patient input can lead to changes
 12 that seem really simple but that really matters,
 13 such as when it comes to informed consent. In one
 14 case, patient-led input helped the scientists
 15 realize that their form for informed consent was so
 16 dense and abstract that patients couldn't even
 17 understand the level of risk, so the form was
 18 rewritten into plain English.
 19 We realized early on that in order to do our
 20 work well, we needed to operationalize our
 21 definitions of key concepts. This includes being
 22 clear about what we mean when we say patient

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1 centeredness or patient and stakeholder engagement.
2 And to that end, to PCORI, patient-centered means
3 that the project aims to answer questions or
4 examine outcomes that matter to patients within the
5 context of patient preferences, and that research
6 questions and outcomes should reflect what is
7 important to patients, as well as to caregivers and
8 other stakeholders.
9 To us, patient and stakeholder engagement
10 means that patients are true partners in research,
11 not just subjects, and that there's active and
12 meaningful engagement among scientists, patients,
13 and other stakeholders, and that community,
14 patient, and caregiver involvement is already in
15 existence or there's a well-thought-out plan to
16 achieve this involvement within the context of the
17 research study.
18 This brings us to the heart of this kind of
19 patient-centered outcomes research engagement. The
20 model depicted on this slide captures the
21 foundational involvement of patients and other
22 stakeholders from all aspects of health care.

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1 Patients and other stakeholders participate in
2 active and meaningful ways all through the process,
3 as members of advisory panels that provide input
4 into PCORI's funding priorities; as members of our
5 merit review panels that determine which
6 applications we fund and the actual conduct of
7 research; all the way through to dissemination and
8 implementation of research findings.
9 So why do we do engagement work? There are
10 really four principal reasons; most importantly, to
11 make clinical research reflect the needs and values
12 of patients, caregivers, clinicians, and other
13 stakeholders.
14 Second, to improve the feasibility of doing
15 studies in real-world settings. It takes a lot of
16 time and effort, I can tell you personally, to
17 build the relationships and trust needed to conduct
18 research in community settings.
19 Third, to improve the relevance of and
20 encourage uptake and use of research results.
21 Results from studies done in real-world settings
22 are more likely to capture data that reflects the

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1 real needs of diverse populations across the
2 country. And finally, because PCORI researchers
3 and partners have found it to be valuable and
4 worthwhile.
5 This is the conceptual model that underpins
6 PCORI's s engagement work. When PCORI was
7 established, there was very little evidence to
8 guide what engagement in research should look like
9 and its impact on clinical research and ultimately
10 on health care and patients. We conceptualized
11 this issue and developed this model, which drew on
12 disciplines such as community-based participatory
13 research, as Chris outlined earlier, to show how
14 engagement helps achieve research that matters to
15 patients and the people who care for them.
16 On the left are the central elements of the
17 PCORI approach, the intensive portfolio management
18 and investments in dissemination and implementation
19 of research findings, and that all PCORI-funded
20 research is pragmatic and takes place in real-world
21 settings. Moving to the right, research that
22 matters includes the issues and outcomes of

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1 greatest interest to patients and those who care
2 for them. These inform our overall strategic
3 priorities, which include producing useful
4 information, speeding the uptake of that
5 information, and influence the culture of research
6 to be more patient-centered. On the far right, all
7 of this work is designed to produce better health
8 decisions, better health care, and improved health
9 outcomes overall.
10 In the early days, there was not a strong
11 evidence base to guide best approaches for engaging
12 patients and stakeholders. The end goal to improve
13 information to help patients make informed
14 decisions and outcomes that matter to them was
15 clear, but the mechanisms for achieving this were
16 not. Therefore, we did not specify engagement
17 activities that must take place in our funded
18 projects. We specified only that that engagement
19 must occur, and left it to investigators, and
20 patients, and other stakeholders to figure out the
21 what and how.
22 Since that time, we've learned a great deal.

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

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

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

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

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

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1 of people and organizations.

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

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

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

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

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

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

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

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1 pocket for psychiatric care. The research team
 2 then added new questions to the interview guide
 3 that improved data collection and gave the PI a
 4 more well-rounded perspective on the data.
 5 We believe that engagement benefits all
 6 stakeholders in the research enterprise. More
 7 specifically, for patients and other stakeholders,
 8 increased knowledge about an enthusiasm for
 9 research as well as new and better relationships
 10 can occur. For communities, the keys are the
 11 building of trust and increased awareness of
 12 different stakeholder perspectives, and for
 13 researchers, a deeper understanding of what's
 14 happening in the real world that these patients are
 15 experiencing and concerns for their study and
 16 concern for their study participants.
 17 I hope I've made a compelling case for why
 18 patient engagement is critically important, but I
 19 don't want to leave you with a sense that PCORI's
 20 figured out everything there is to know about
 21 engagement and that investigators simply have to
 22 apply a formula, and everything falls into place.

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1 Engagement can be challenging, and there's
 2 no one-size-fits-all model. Circumstances vary
 3 from study to study, depending on the population,
 4 the community's history with research and health
 5 care, and the outcomes being studied. There are an
 6 infinite number of variables.
 7 A number of common challenges that have been
 8 shared with us by PIs and patients and other
 9 stakeholders can be grouped into four main
 10 categories. Starting with the left, challenges
 11 related to infrastructure and resources include the
 12 need for readily available training as well as
 13 having funding and staff resources available for
 14 engagement and to compensate partners. Time is
 15 always a challenge for everyone. Patients, and
 16 stakeholders, and investigators lead complex and
 17 busy lives and have family responsibilities.
 18 Patients often have illnesses and other demands on
 19 their time as they are trying to meaningfully
 20 contribute to research.
 21 Next is people and teens. Conducting
 22 engaged research is a multistakeholder enterprise.

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1 It involves integrating stakeholders with specific
 2 perspectives and interests with trained CER
 3 researchers who also have their own perspectives
 4 and interests. They need to balance all of these
 5 perspectives, and interests can often be
 6 challenging.
 7 Another challenge is in recruiting
 8 participants who truly represent the diversity of
 9 individuals with conditions or with the
 10 circumstances under study. Organizational barriers
 11 remain for PCORI's funded PIs. A good example is
 12 that some IRBs do not always understand the way in
 13 which an engaged patient or other stakeholder is
 14 fundamentally different from a research project.
 15 Investigators have also run into challenges in
 16 allowing for the time and flexibility to maximize
 17 the input from engaged partners and funded
 18 projects.
 19 Finally, balancing views and priorities;
 20 this is perhaps the greatest challenge. For
 21 example, randomized-controlled trials, while seen
 22 as the gold standard in clinical research, can be

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1 viewed as unjust or unfair by patients and
 2 community members, and they may be unwilling to
 3 participate or are concerned about participating in
 4 these projects. And it's not just patients who
 5 have concerns or differing views. For example,
 6 clinicians do not always agree whether treatments
 7 really represent equipoise.
 8 In reality, generating high-quality,
 9 high-impact research has many challenges: ethical
 10 review, safety assurance, rigorous methods, among
 11 others. Engagement, especially when new, can be
 12 genuinely disruptive.
 13 I love this quote from one of PCORI's funded
 14 PIs from the University of Kentucky, who makes the
 15 key point that, "It is absolutely fundamental to
 16 have people from the community who are the
 17 interface for the participants in the project, and
 18 that really becomes evident when you don't do it."
 19 This underlines the point about the importance of
 20 trust, which is noted as one of the key benefits of
 21 engagement to communities.
 22 Many communities have good historical

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1 reasons not to trust researchers or healthcare
2 institutions, so taking the time and making the
3 effort required to build that trust is absolutely
4 essential to productive patient engagement.
5 I hope the walk through some of PCORI's work
6 on patient engagement has been helpful and given
7 you a deeper understanding of what PCORI has been
8 doing in this growing field, and I look forward to
9 hearing more about what many of you on this call
10 are also doing.
11 Now, I'd like to focus specifically on a few
12 studies related specifically to pain. The first
13 example is the VOICE study, a study of patients at
14 Veterans Affairs facilities who have chronic pain
15 despite using opioid medicines. Patients were
16 assigned to one of two groups. One group worked
17 with a pharmacist care manager and primary care
18 providers to find effective pain medicine options.
19 The other group works with a clinician and mental
20 health provider to help them set and meet personal
21 health goals.
22 In both groups, patient care is coordinated

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1 with their primary care provider, and they receive
2 support to reduce their opioid use if they wish.
3 Patients who are taking very high doses of opioids
4 may be selected, by chance, to switch to
5 buprenorphine.
6 This study provides a really good example of
7 well-constructed and sustained patient engagement
8 strategy driven by a committee of 10 veterans,
9 5 men and 5 women, with chronic pain, who formed
10 the Veterans Engagement Panel or VEP. The panel's
11 contribution to the study began early on with
12 providing solutions to transportation barriers
13 identified to attend an initial 2-hour visit with
14 study coordinators, including discomfort, cost, and
15 a lack of availability.
16 When the COVID-19 pandemic struck, the VEP
17 helped craft protocols to allow study activities to
18 take place virtually, including ways to make
19 potential study enrollees feel comfortable on video
20 and creating rapport with researchers, and
21 recommending a compilation of a list of no-cost
22 virtual pain management options, such as online

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1 yoga and meditation to be shared with enrollees.
2 The most important decision that patients
3 influenced in the study was the decision to make
4 the intervention about improving pain management
5 with tapering of patients agreed, rather than about
6 opioid tapering as a primary goal. Following
7 patient input, the research team revised the goals
8 in its proposal to improve pain management while
9 decreasing opioid use and to focus on shared
10 decision-making about tapering, rather than
11 requiring agreement to taper at the point of
12 enrollment.
13 This study by Dr. Beverly Thorn was one of
14 our earliest pain studies funded by PCORI. The
15 study compared patients receiving usual care with
16 those receiving group education classes or
17 cognitive behavioral therapy, with both
18 interventions adapted for patients with relatively
19 low literacy levels. Patients and clinicians were
20 involved in designing the study and adapting the
21 educational and therapeutic materials for the
22 literacy level of the patients in the study, which

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1 was at the 7th or 8th grade level, and the study
2 found that both education and CBT resulted in lower
3 levels of reported pain than usual care.
4 The IMPOWR study compares the effectiveness
5 of two kinds of active pain management treatment of
6 patients who are prescribed long-term opioids in
7 primary care and pain clinics in four western
8 states.
9 The goal was to respond to the despair
10 patients can feel at not knowing how to reduce
11 long-term opioid use due to the fear of
12 experiencing pain and distress through determining
13 which of two types of pain management classes is
14 best for reducing pain and pain interference,
15 increasing function, and reducing opioid use.
16 The research team created a study advisory
17 board and conducted a national patient panel survey
18 mechanism to get input on key issues from a larger
19 more diverse group of patient stakeholders as
20 needed. Patients were also heavily involved in
21 recruitment strategies, and they continue to
22 provide feedback on how to recruit during COVID-19.

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1 One key takeaway from this study as a result of
2 patient input was increased awareness of the
3 crucial importance of the patient-clinician
4 relationship when enrolled in health research.
5 A final example of this study is the STAMP
6 study, which compares mindfulness meditation with
7 cognitive behavioral therapy for chronic low back
8 pain. The study design, methods, and outcome
9 measures were all informed by patient stakeholders,
10 their family members, patient advocates,
11 clinicians, leaders of health systems, and
12 community advisors on research design and
13 strategies.
14 The PI also held a focus group of patients
15 and queried individual and family members and
16 clinicians regarding the study outcomes. All
17 groups identified reducing pain and disability as
18 the top priority and improving quality of life and
19 reducing opioid dose as important secondary goals.
20 One interesting note in this study is that
21 the research team had initially called the study
22 HEALTHY MIND/HEALTHY BACK. Patient advisors for

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1 the study said that they found this name
2 stigmatizing and condescending. It seemed to imply
3 that there was something wrong with their minds or
4 their own fault that they had back pain. Together,
5 the researchers and patients came up with a new
6 name, Strategies to Assist with the Management of
7 Pain or STAMP.
8 PCORI's learning about engagements are far
9 from complete of course, and here's your chance to
10 get involved. We currently have a new project
11 underway that's seeking input to inform the
12 potential development of a new funding initiative
13 on the science of engagement. This initiative will
14 help address high-priority knowledge gaps on
15 approaches for effectively engaging diverse
16 stakeholders through the research process.
17 We're seeking input from interested
18 potential applicants, patients and other
19 stakeholders, and organizations who participate in
20 research or engage communities. You can find the
21 request for information on the PCORI website at
22 pcori.org/soe if you're interested in providing

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1 comments, which are due on November 19th.
2 I'd also like to briefly mention these two
3 resources for investigators and for patients and
4 other stakeholders they may have recruited to their
5 teams. The first is the Research Fundamentals
6 course, which provides a great foundation of
7 knowledge about PCOR and CER. There's also a new
8 module on Building Effective Multi-Stakeholder
9 Research Teams, which provides guidance and
10 resources to help teams work effectively together.
11 I hope this overview of patient engagement,
12 as conceptualized and studied by PCORI, has been
13 helpful. You'll learn more about PCORI's
14 engagement work during the panel discussion later
15 today, and then on Friday from PCORI directors,
16 Kristin Carman and Laura Forsyth.
17 Before we transition to questions, I want to
18 emphasize the following takeaways from this talk.
19 First of all, patient engagement matters. It
20 really must be an integral part of clinical
21 research projects from the very beginning, and that
22 patients need to be actively and meaningfully

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1 involved from the development of research
2 priorities all the way through dissemination and
3 uptake of findings.
4 Second, engagement takes time, effort, and
5 patience, and it must be tailored to the needs of
6 the specific community in which the research is
7 taking place. Building trust is key. Many
8 communities have good historical reasons to
9 distrust research and institutions, generally, so
10 it's important to devote the necessary time and
11 effort to build relationships with community
12 leaders and brokers to build trust over time.
13 Participants in PCORI research describe
14 engagement as an integral and valuable part of
15 projects. It can be challenging, and it's not
16 always wholly successful or unsuccessful, but it
17 often helps to highlight looming problems and to
18 solve many of the challenges of doing pragmatic,
19 real-world research and providing answers to the
20 questions that matter most to patients.
21 Patient engagement can improve the relevance
22 of research results, which encourages an uptake of

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1 those results into clinical practice. Results from
2 studies approached this way are more likely to
3 capture data that reflects the real needs of the
4 diverse populations across the country and across
5 the globe.
6 Finally, balancing the needs and interests
7 of everyone involved in a research
8 project -- including researchers, patients, and
9 other stakeholders -- can be challenging, as can
10 recruiting participants who truly represent the
11 diversity of individuals with conditions or
12 circumstances under study.
13 In the field of pain research, application
14 of these engagement principles is truly in its
15 infancy, and as yet, there are few studies that
16 have engaged patients as partners, as you will hear
17 in more detail from others very shortly.
18 As a pain researcher for over 30 years, I
19 think it's possible that in our pursuit for the
20 holy grail of biomarkers for pain, we've been too
21 dismissive of the patients' experience of pain, how
22 they perceive it, and what is most important to

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1 them in reducing pain, improving functionality, and
2 reducing dependence on opioids.
3 We're not going to know what really matters
4 to patients unless we're asking them. Our
5 misperception that patient-reported outcomes are
6 really soft measures, instead of looking at it from
7 that perspective, we really need to double down and
8 get patients even more involved in shaping our
9 study outcomes and helping to design studies from
10 the very beginning.
11 As they always say at the end of every day
12 journal article, "more research needs to be done."
13 There's no area of science where this is more true
14 than pain. I look forward to seeing how this
15 meeting helps us shape the body of evidence
16 regarding patient engagement over time, as the
17 voices of patients and others take root in the
18 growing field of patient engagement and clinical
19 pain research.
20 Thank you for your time this morning. I'm
21 happy to take any clarifying questions that you
22 might have if we have time to do so.

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1 Clarifying Q&A
2 DR. KERNS: Thank you, thank you, thank you,
3 Christine. This is just what the proverbial
4 patient asked for, or ordered, so thank you.
5 We are running a little bit behind, but I
6 think that's ok. I want to make sure that we give
7 our audience/participants an opportunity to ask
8 maybe one or two clarifying questions to begin
9 with. We'll see how it goes. I don't want to cut
10 this short; it's important.
11 Any questions from the audience? If you
12 have a question or comment, I guess put your hand
13 up in the reaction space.
14 I see Ian. Please go ahead.
15 DR. GILRON: Sure. Thank you.
16 Can you hear me, Bob?
17 DR. KERNS: Yes, we can.
18 DR. GILRON: Great.
19 Thank you, Christine, for an excellent
20 presentation. I just wanted to ask you, there's a
21 difference between a patient advocate or a patient
22 partner. What experience have you had with

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1 providing specific training to become patient
2 advocates or partners, and have there been
3 developed any specific training programs for that
4 purpose?
5 DR. GOERTZ: For the most part, we have
6 worked with investigators to train patients that
7 are specific to that particular study or
8 population, but that is definitely something that
9 general training is critically important. We have
10 developed some tools that are available on our
11 website, and both Kristin and Laura can talk more
12 about -- Kristin in particular can talk more about
13 some of those tools, and give you more detail about
14 what some of those tools look like.
15 But you're exactly right that there is a
16 difference between patients and patient advocates,
17 and PCORI engages both of those groups. Not only
18 do we work with individual patients, but also with
19 patient advocacy groups, and they are involved as
20 partners, as well, in many of our research
21 projects.
22 DR. KERNS: Thank you for the question, Ian.

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

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1 Jeremy Taylor?
 2 MR. TAYLOR: Hi. Thank you. It's been
 3 shaking me to ask a question because I'm on the
 4 program later, but I couldn't resist this one.
 5 Thank you, Christine, a really interesting
 6 talk. I'm a great fan of PCORI. We don't quite
 7 have anything exactly the same in the UK. My
 8 question was really about the influence of PCORI
 9 and whether you have sensed the extent to which the
 10 PCORI approach has had an impact and influence over
 11 other research funders, particularly in the States,
 12 but possibly more broadly. I'm interested if
 13 you've picked up any sense of that.
 14 DR. GOERTZ: Well, Jeremy, there's no doubt
 15 that this idea of patient centeredness and patient
 16 stakeholder engagement in research, that
 17 conversation has really changed over the last 10 or
 18 11 years that PCORI has been in existence. I hope
 19 that we're able to take credit for some of that
 20 change.
 21 You'll hear from other funders later on
 22 today talking about patient centeredness and

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

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

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1 to make sure that when we're engaging patients,
 2 that we're really listening to what they have to
 3 say and that we're able either to be able to
 4 incorporate their input into this kind of research,
 5 or that we're able to have a conversation with them
 6 so that at least there's mutual understanding about
 7 why that might not be possible.
 8 My experience in talking with patients that
 9 have been involved with PCORI research projects is
 10 that they do feel heard, and that they do feel that
 11 this project has changed and they have had an
 12 impact on the research because of that level of
 13 engagement. But is there more work to be done?
 14 Absolutely, there's more work to be done, and
 15 that's something that we need to continue to be
 16 vigilant about.
 17 DR. KERNS: Well, thank you again,
 18 Christine. Thanks for that question, Isabel; a
 19 great way to kick off our day.
 20 We're going to move on to our next
 21 presentation. This is the first of two
 22 commissioned reviews. The first one is going to be

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1 presented by Simon Haroutounian, and I hope I
 2 didn't butcher your name. Simon is associate
 3 professor of anesthesiology and chief of clinical
 4 pain research at the Washington University Pain
 5 Center, and he's chief of the Division of Clinical
 6 and Translational Research in the Department of
 7 Anesthesiology at the Washington University in the
 8 St. Louis School of Medicine.
 9 Simon, take it away.
 10 Presentation – Simon Haroutounian
 11 DR. HAROUTOUNIAN: Thanks so much, Robert.
 12 Hi, everyone. As Bob pointed out, and
 13 correctly pronounced, my name is Simon
 14 Haroutounian. In the next 20 minutes or so, I will
 15 be presenting here some of the highlights from a
 16 narrative review we're just wrapping up on
 17 partnering with patients in clinical trials on pain
 18 management. Unsurprisingly, you will hear several
 19 themes that are actually consistent with what
 20 Dr. Goertz presented in her excellent talk.
 21 So to start, I'm taking credit for
 22 presenting this data from this review, but it has

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1 been really a team work of about 2,000
 2 contributors, most of whom are present on the talk.
 3 And I really want to thank specifically my
 4 brilliant colleague, Katie Holzer, for putting
 5 really a major effort into this review, and really
 6 there are quite a few people who've helped with
 7 this.
 8 I will start by saying that the involvement
 9 of patients as partners in clinical research have
 10 been studied, obviously, in different therapeutic
 11 areas, mainly with a particular emphasis on cancer
 12 and HIV. That's probably one of the reasons we're
 13 here today, that there's really no guidance for
 14 best approaches on how to partner with patients
 15 when it comes to clinical trials on pain
 16 treatments.
 17 There are a lot of open questions on what
 18 are the best ways to identify patient partners, how
 19 to select the patient who will become a research
 20 partner; how to engage them meaningfully across the
 21 various stages of study design, study contact, data
 22 analysis, and interpretation; as well as

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1 dissemination and refining the potential
 2 implementation of the research in the clinical
 3 setting.
 4 The goals of the narrative review, or
 5 scoping review, is really to understand the current
 6 landscape of how to engage patients as partners in
 7 clinical research, in general, and then
 8 specifically to focus on the pain field.
 9 As we fully recognize, there are several
 10 stakeholders around the table; it's not only
 11 patients. Gilron, for example, mentioned the
 12 patient advocates and other stakeholders, but the
 13 review specifically was focused on patients as
 14 partners, so the scope of it, to some extent, is
 15 relevant to me.
 16 I'll skip this one.
 17 The way we approached the scoping reviews,
 18 we had one of our experienced medical librarians
 19 help us conduct a literature search to identify
 20 potential papers that would feed into this review,
 21 and we focused primarily on the papers from the
 22 past decade.

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

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

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1 up with meaningful patient engagement as
 2 partnership research.

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

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

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

22 The FDA identified the importance of patient

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1 engagement, really, quite a few years ago, in the
 2 '80s when an office to work with patient advocates
 3 was established. But in the search, in this
 4 review, we didn't see any major programs that would
 5 develop up until about 2012. FDA established the
 6 Patient-Focused Drug Development, or the PFDD
 7 program, and later on the Office of Health and
 8 Constituent Affairs, and later some newer programs
 9 that are related to the Patient Science and
 10 Engagement Program, as well as the Patient
 11 Engagement Collaborative. I think the FDA
 12 currently is making substantial effort in this
 13 particular area.

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

22 In terms of other examples -- and they're

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

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

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

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

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

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

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

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1 issues, other funders may not be on the same page
 2 and may not allocate the appropriate amount of
 3 resources to address some of those shortcomings.
 4 In terms of barriers, as well as factors
 5 that can facilitate meaningful patient involvement
 6 in research, again, as a part of reviewing those
 7 different papers, as specific examples, we've
 8 summarized some key points that can potentially be
 9 helpful for us as we summarize the different
 10 presentations over the next few days to try to come
 11 up with some of the important things we need to
 12 consider for meaningful engagement of patients,
 13 specifically in pain research.
 14 As we were reviewing some of the examples
 15 from either non-pain-related areas or pain-related
 16 areas and what meaningful patient engagement can
 17 look like, there are some areas that are much more
 18 advanced, such as HIV trials, where there have been
 19 more than a hundred trials with meaningful patient
 20 engagement. Some of the neurology networks, such
 21 as the Neurological Emergencies Treatment Trials
 22 Network, have a long history of bringing patients

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1 to their conferences, specifically allocating
 2 workshops and conferences to build those bridges,
 3 and that has really resulted in a higher rate of
 4 studies where there is meaningful patient
 5 engagement.
 6 The rheumatology field has done similar
 7 things over the years with really substantial
 8 involvement in patients and study design in
 9 determining important and clinically relevant
 10 patient outcomes. But in a recent systematic
 11 review, actually it was shown that when we looked
 12 at the rheumatology journals between 2016 and 2020,
 13 only about 2 percent of trials published in
 14 rheumatology journals actually had meaningful
 15 patient partner involvement in those clinical
 16 trials. I think in our field, in pain medicine,
 17 we're probably far behind that, even though there
 18 are no specific numbers for it.
 19 Let me skip some of this for the sake of
 20 time.
 21 A couple of issues that I want to highlight
 22 in terms of efforts that have been made

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1 specifically in clinical pain trials, I would say
 2 that our review identified mostly gaps that need to
 3 be filled. There were some examples where patients
 4 who participated in the clinical trials were
 5 interviewed, and barriers were identified for
 6 patients even willing to participate in clinical
 7 trials or what their experiences have been.
 8 In some cases, patients, for example, who
 9 participated in pain trials didn't necessarily know
 10 what the trial was about. For example, there was a
 11 study where the intervention, which was according
 12 to telephone-based CBT therapy, was supposed to
 13 prevent widespread chronic pain after an acute pain
 14 episode. And even though it was a well-designed
 15 study, when patients were interviewed, some of them
 16 didn't even understand that that was the goal of
 17 study, the intervention they received. They were
 18 thinking that this is a new intervention for their
 19 acute or subacute pain episode.
 20 So there's definitely a lot of areas for
 21 improvement for us in terms of pain research. Some
 22 important areas that also require attention is

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1 really thinking about how to identify patient
 2 partners that can represent the interests of a
 3 study's target treatment population, and how do we
 4 think about, perhaps, underrepresented groups
 5 because there are underrepresented groups that may
 6 be more vulnerable to pain or to chronic pain.
 7 There are several examples of groups such as
 8 women, people of color, and maybe members of the
 9 LGBTQ community, et cetera. They may be more
 10 vulnerable, more susceptible, to certain chronic
 11 pain conditions. How do we make sure that our
 12 patient partners, who help us design and conduct
 13 the studies, are actually representative of the
 14 diverse populations that the study is trying to
 15 target?
 16 Another issue is that multicenter clinical
 17 trials really tend to be conducted in large
 18 academic centers and, again, some patient
 19 populations -- for example, rural or otherwise,
 20 under-resourced communities -- tend not to be
 21 represented. These are important points, and we
 22 need to think about what we can do to improve.

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

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

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

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

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

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

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1 for reflection would be really important.

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

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

22 Financial resources sometimes can be a

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

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

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

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

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1 pain treatments. It is really important to start
 2 the involvement of patient partners early and make
 3 sure it's meaningful. It seems like if it's done
 4 appropriately, it can really help improve the
 5 design, the conduct, interpretation, dissemination,
 6 as well as implementation of the clinical research.
 7 The environment should be such that it
 8 allows patient partners to articulate their
 9 experience and bring their shared experience to the
 10 table for this engagement to be meaningful.
 11 Research output that is real transparent is
 12 perceived as more trustworthy, and it's worth that
 13 effort, again, in my opinion.
 14 Although formal guidance on patient
 15 engagement in clinical pain trials really is not
 16 yet available, I think offering guidance on the
 17 implementation of core principles to optimally fit
 18 individual pain studies, hopefully with the help of
 19 the presentations and the output from this meeting,
 20 we can all move the field of pain research towards
 21 more meaningful and impactful clinical trials.
 22 Thanks for your attention.

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1 Clarifying Q&A
 2 DR. KERNS: Just super. Thank you, Simon.
 3 Good. We'll take one or two questions.
 4 Lynn Laidlaw?
 5 MS. LAIDLAW: Hi. Thank you. Great
 6 presentation. Thanks. I just had a question.
 7 Did you include any patient partners in the
 8 review, and did you work at the agree literature?
 9 DR. HAROUTOUNIAN: Yes. That's a fantastic
 10 question. If I look at the list of the authors of
 11 this review, Chris Veasley was one of our
 12 co-authors and provided really meaningful input to
 13 the interpretation of the literature that we're
 14 able to identify. But other than that, it's a
 15 narrative literature review, so we mostly polled a
 16 particular path to extract the information from the
 17 papers and summarize them for the different
 18 stakeholders to provide some important feedback.
 19 DR. KERNS: Thank you.
 20 DR. HAROUTOUNIAN: But that's really
 21 interesting food for thought because I think as
 22 we're thinking about partnering in clinical trials,

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1 I personally haven't thought about specifically
 2 having patient partners and systematic reviews, and
 3 meta-analysis, and that type of work where, again,
 4 things are done in a very formal way, and maybe the
 5 interpretation, there's less room for it. But I
 6 think it's a fascinating idea that may change the
 7 way we look at things or maybe even ask the
 8 questions.
 9 DR. KERNS: I think it's a great question,
 10 and I would harken back to Chris' opening comments
 11 and framing of this meeting and that she was
 12 careful to talk about the broader area of clinical
 13 pain research, not just clinical trials. So I
 14 think one might say -- and I think it's leading us
 15 in the direction of considering, really, all
 16 aspects of our scholarship in science. I think
 17 that's a really important potential and provocative
 18 point, but thank you for raising it.
 19 John Farrar?
 20 DR. FARRAR: Hi, Simon. It's great to see
 21 you, even if it's just on Zoom; a very nice talk.
 22 As a general principle for this whole meeting, one

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1 of the other questions that come up is how to
 2 engage all people who are involved in the research,
 3 but certainly our clinical patient partners, in
 4 being productive in the process.
 5 One of the things that certainly is true
 6 about pain research in general, and especially with
 7 use of opioids and other things, is that there are
 8 very strong feelings about some of these things.
 9 In one of the studies that I've been part of, we
 10 made a conscious point to discuss people's opinions
 11 and whether they could be -- it's sort of like
 12 picking a jury, right? I mean, you don't want
 13 everybody to be the same on the jury, but you do
 14 want people who can be open-minded about things and
 15 who are willing to collaborate.
 16 I just wondered whether you had seen in your
 17 review any sort of thoughts or comments about those
 18 kinds of things. Obviously, it applies to other
 19 things as well.
 20 DR. HAROUTOUNIAN: Thank you, John. This is
 21 a very good comment. It's not explicitly
 22 addressed, particularly in terms of solutions for

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1 it. I think this is something that comes pretty
 2 often as one of those barriers; how do you manage
 3 conflicting opinions or strong opinions within the
 4 group, or potentially conflicting opinions between
 5 the investigators and the partners?
 6 The theme that came up, really, is allowing
 7 the space and time for reflection and being
 8 open-minded and collegiate, and setting the
 9 expectations both in terms of the rules of
 10 engagement and accept being open and accepting
 11 different opinions.
 12 That seemed to be the general approach, but
 13 I can't recall seeing anything specifically or a
 14 strategy to address, for example, potential
 15 discrepancies between, let's say, two patient
 16 advocates that advocate for two different
 17 approaches or two different things. It was mostly
 18 presented as one of those barriers that meaningful
 19 and thoughtful approach can potentially try to
 20 overcome, but I think it's definitely a challenge.
 21 DR. FARRAR: Thank you.
 22 DR. KERNS: We're pulling a little behind.

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1 Chris, if you have a follow-up to that, or I
 2 should call on Christine Chambers, who also has her
 3 hand raised.
 4 MS. VEASLEY: I do just have a super quick
 5 follow-up, which is to say that we're going to talk
 6 about this a little bit more on day 3 in terms of
 7 journal editors and what's actually reported, is
 8 that likely the results of what we're seeing are
 9 very skewed because most studies that are doing
 10 engagement aren't even reporting on what type of
 11 engagement they're doing.
 12 So I think we have to look at these reviews
 13 with that lens, that we're likely not getting a
 14 full picture of everything that's being done in the
 15 [inaudible - audio gap].
 16 DR. KERNS: Thanks, Chris.
 17 I'll take one more comment or question from
 18 Christine Chambers.
 19 DR. CHAMBERS: Hi there. Thanks, everyone,
 20 for this really great meeting and conversation.
 21 I'm really delighted to be here and delighted to
 22 see this being discussed.

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1 I just wanted to mention that I have engaged
 2 patient partners in scoping and systematic reviews
 3 and have patient partners actually embedded within
 4 student dissertation committees. So happy to
 5 comment, and maybe Isabel and I will discuss that a
 6 little more tomorrow in our talk.
 7 I also just wanted to mention that I don't
 8 think the chat function is enabled on the Zoom
 9 call, and I probably would have just made a comment
 10 there rather than taking up screen time. So I
 11 wonder if it's possible to have that enabled just
 12 to allow for sharing of links.
 13 Also, speaking around accessible inclusion
 14 for patients and partners, some people might feel
 15 more comfortable contributing to the conversation
 16 in the chat, rather than on video. So I just
 17 wanted to flag that for a consideration. Thank
 18 you.
 19 DR. KERNS: Yes, we did talk about that in
 20 the planning. I don't know how Bob, or Dennis, or
 21 Valorie, or Carlos think about reopening the
 22 chatbox. I think it could serve a useful purpose,

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1 especially around sharing links.
 2 So we're going to need to move on. I saw
 3 Jeremy's hand up briefly, but I think we really
 4 should move on to the next presentation.
 5 This is the major findings from another
 6 systematic review, Ewan McNicol and McKenzie
 7 Ferguson. Ewan is the associate professor in
 8 pharmacy practice at MCPHS University School of
 9 Pharmacy, at the Tufts University School of
 10 Medicine in Boston, Massachusetts; and McKenzie
 11 Ferguson is associate professor in pharmacy
 12 practice at Southern Illinois University at
 13 Edwardsville School of Pharmacy in Edwardsville,
 14 Illinois. Take it away.
 15 Presentation – McKenzie Ferguson
 16 DR. FERGUSON: Thank you for that
 17 introduction. I purposely kept my camera on for
 18 the session, and denied myself a bathroom break at
 19 the hope that I could slim down a little of my talk
 20 so that we can stay on time.
 21 So to start, I have a special thanks to Bob
 22 and Dennis and the planning team for the guidance

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1 that they gave us in our review, and also thanks to
 2 Annie and a colleague of mine, Karin, who assisted
 3 us with some data extraction.
 4 Ewan McNicol and I were charged with doing a
 5 systematic review to evaluate perspectives about
 6 study design directly from patients that are
 7 affected by pain, depression, and anxiety. We made
 8 every attempt to do a very exhaustive literature
 9 search, and our inclusions were fairly
 10 straightforward. We really wanted to capture
 11 patient perspectives. It could be related to
 12 anything foundational to the clinical trial design
 13 or things that included barriers or motivating
 14 factors to participation.
 15 Our exclusions were really any mixed sample,
 16 where we couldn't pull out a patient perspective,
 17 or if a study reported nearly a reason for
 18 attrition or declination, if there was no added
 19 qualitative component directly from the patient,
 20 those were exclusions.
 21 I'd also like to point out that we excluded
 22 any focus that only targeted treatment-specific

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1 preferences. And as Chris Veasley just mentioned
 2 to Dr. Goertz, it's important that we realize that
 3 engagement may be part of the planning process and
 4 conduct of clinical studies, but we may rarely see
 5 this actually published within research findings.
 6 In our literature search, we searched across
 7 four different databases, and we quickly learned
 8 that there were some challenges with the way that
 9 patient engagement was described in the literature,
 10 so we had to broaden our vocabulary to try to make
 11 sure we were capturing as much as we could within
 12 the area of pain, depression, and anxiety. But I
 13 will say that when we started screening
 14 660 abstracts, we decided that if the study
 15 addressed any psychiatric condition, even outside
 16 of depression or anxiety, we elected to keep it in
 17 our results as long as it met criteria for
 18 inclusion.
 19 We reviewed 61 full-text articles, and we
 20 ended up extracting 34 total studies, but you will
 21 see we extracted 35 total reports because we did
 22 have one study that actually completed two distinct

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1 phases of data collection amongst two different
 2 samples, so we were able to capture those
 3 perspectives separately. I also would like to
 4 agree that in the context of only identifying
 5 34 total studies, Dr. Goertz is correct in perhaps
 6 noting that engagement within pain-related research
 7 is still in its infancy.
 8 In terms of our study features, most of our
 9 studies focused on pain, and within the pain, some
 10 of them were mixed features. Eight of our samples
 11 addressed depression only. We had no studies that
 12 focused on patients with anxiety and their
 13 perspectives. We had two studies that mixed. It
 14 was mostly pain to begin with, but 20 to 40 percent
 15 of the population had a noted depressive disorder.
 16 And the one other study there was a study in
 17 patients with Parkinson's disease that had reached
 18 the point that it was affecting their mental
 19 health.
 20 In terms of the different diagnoses of pain,
 21 one thing that I think is important is that we have
 22 a lot of variation here, but very few of our

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1 studies, most of them, did not report comorbid
 2 medical conditions in the samples, so it was likely
 3 that pain, depression, and anxiety coexisted
 4 amongst many of the populations; yet, it just
 5 wasn't consistently reported in the findings.
 6 In terms of the study methods utilized -- so
 7 this will be very brief -- most of our findings
 8 were components of survey-based methods, and that's
 9 probably not surprising because it was a more
 10 efficient way to capture a larger sample. Other
 11 study methods were things like individual
 12 interviews, mixed methods, and focus groups. So a
 13 lot of the data that we ended up reviewing was
 14 qualitative in nature, thematically presented with
 15 lots of quotes, and very few actually gave
 16 quantitative numbers for us to assemble. So you'll
 17 see me present the information from that
 18 standpoint.
 19 Getting into some of the findings, we're
 20 going to spend a little bit of time talking about
 21 the demographics of the perspectives that we
 22 gathered because we think it's important to know

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1 whose perspectives we're basing some of our
 2 considerations on, and some of the limitations
 3 perhaps with that.
 4 Most of our studies assessed the patient
 5 perspective as the primary objective of the
 6 research. For 12 of our included reports, it was a
 7 component of a randomized-controlled trial and a
 8 feasibility study, three of which were for patients
 9 with depression.
 10 Though most of our study sites we could
 11 determine were located in metropolitan areas, there
 12 was only one study that actually described where
 13 the sample was from in terms of being rural or
 14 urban. We also had most of our samples from
 15 patients outside of the United States. Ten of our
 16 studies were focused entirely in the United States
 17 and three were mixed.
 18 Most of our studies utilized active
 19 recruitment strategies to recruit patients for the
 20 prospective analysis. A few used mixed strategies.
 21 A lot of this included things like targeting
 22 directly from clinic records or targeted

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1 registries, mailed invitations, or general
 2 practitioner referral.
 3 Most of our studies had some or past current
 4 trial participation, but this is largely diluted by
 5 those studies that were also part of the pilot and
 6 feasibility analyses. In many of the other
 7 studies, it simply wasn't noted if they had past
 8 trial research experience.
 9 Most of our samples, also the perspectives
 10 provided were from adult-based populations,
 11 although we did have two studies that focused on
 12 pediatric patients, one that was in an assessment
 13 of patients with Duchenne muscular dystrophy and
 14 their caregivers, that related more towards the
 15 invasiveness of study procedures, and the other
 16 which dealt with adolescents affected by
 17 depression.
 18 Also, we had several studies that, based on
 19 study demographics, recruited and enrolled mostly
 20 older patients, and three of these were for
 21 pain-related conditions, one was for depression,
 22 and one was in that study with patients with

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1 Parkinson's disease who had mental health
 2 complications as a result of that.
 3 Within the sampling also, there was one
 4 study that purposely sampled disadvantaged women
 5 affected by depression. For studies that reported
 6 sex, most of the samples were represented by female
 7 perspectives. Also, I took note that 10 of our
 8 studies required English literacy as a component to
 9 participation in providing their perspectives.
 10 This slide depicts the lack of, really,
 11 overall diversity within the perspectives that
 12 we're presenting today. Race was only reported in
 13 15 out of our 35 reports, and within that, most of
 14 the studies had patients largely identifying as
 15 White/Caucasian. This was all -- except in one
 16 study you can see from the slide, the Taylor study.
 17 This study was conducted out of New Zealand, and it
 18 was focused on a mostly male population with gout,
 19 and it was an outcomes-focused study. But in that
 20 study, 14 percent of the population identified as
 21 Asian and the remaining were described as New
 22 Zealand, European, Maori, and Samoan.

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1 A few other notable mentions from this slide
 2 is that there were two studies that had around
 3 30 percent of a mixed racial representation, the
 4 Cheung study and the Smith study, and for both of
 5 these studies, they utilized accommodation of
 6 recruitment strategies, which may have benefited
 7 their level of diversity.
 8 Other important study features that we
 9 thought were important to collect as it related to
 10 perspectives, but we ended up finding out that it
 11 was fairly infrequently reported and inconsistently
 12 reported even in those that did, was the level of
 13 education of people who were providing their
 14 perspectives, the number who were living with
 15 someone else in the household, whether or not the
 16 patients were able to be employed or if they were
 17 disabled, and the disease duration and severity.
 18 Now we're going to start with barriers to
 19 study participation. The way this graphic is set
 20 up is that on the left in green, you'll see those
 21 are the studies reflecting patients with pain, and
 22 on the right, you'll see the patients affected by

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1 mostly depression but also that added mental health
2 assessment.
3 To begin, seven studies reported that a lack
4 of information or misunderstanding of information
5 was noted as a barrier to participation, and this
6 was evenly split, for the most part, between pain
7 and depression. But some things that stand out are
8 fear of interventional risks; distrust of
9 healthcare providers; too many study procedures;
10 fear of inadequate treatment; and disease life
11 stressors more commonly noted as a barrier among
12 patients with pain.
13 Discomfort and embarrassment with study
14 procedures, on the other hand, was more commonly
15 noted as a barrier to participation among patients
16 with depression. Specific comments related to this
17 were things like feeling the nature of the
18 questions they were being asked were quite
19 intrusive or feeling self-conscious with the
20 questions; some embarrassment with bringing up
21 their personal past and history; and the symptoms
22 of their illness that were causing anxiety and

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1 discomfort.
2 In terms of distrust of healthcare
3 providers, that was noted as general skepticism of
4 clinical research. Then it was also noted, in a
5 study of patients with sickle cell disease in that
6 partnership with Voice of the Patient and FDA, that
7 hospital staff and the research teams lacked some
8 cultural sensitivity and also lacked awareness of
9 the challenges faced by patients affected by sickle
10 cell disease.
11 As it relates to disease-related stigma, we
12 had one study that assessed chronic pain in
13 patients that had in the past received opioids, and
14 there was fear of labeling or judgment, and it
15 presented a barrier to recruiting those patients
16 for participation.
17 I'll continue to discuss barriers as I move
18 into more specific trial design features, starting
19 with recruitment, randomization, and blinding.
20 Personal referral was noted as something
21 that actually encouraged willingness to
22 participate, and this is noteworthy because it was

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1 in two studies that included patients with
2 depression. Randomization was a common theme that
3 was a source of concern, confusion, and discomfort
4 for participants, and three studies remarked that
5 adding an element of choice in the randomization
6 process would enhance willingness to participate.
7 Two of those studies were in women with pelvic
8 pain, specifically endometriosis, and the other was
9 in patients affected by osteoarthritis.
10 Four studies noted concerns with blinding,
11 so much so that they would not agree to participate
12 in the study if they were blinded, and of course
13 having sufficient information was a concern across
14 many studies. A lack of overall detail about the
15 study and expectations of participation was noted,
16 as was a lack of detail about studied risks. One
17 study suggested incorporating a video into the
18 process and also adding more time for discussion of
19 information as a way to perhaps improve this.
20 So compensation is clearly something that
21 needs to be considered in our recruitment of
22 patients in studies, so having enough compensation

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1 was something that affects willingness to
2 participate. Also noted were things like the
3 ability to continue therapy after the treatment is
4 over. In particular, this was noted in a study
5 with patients that are affected by spinal stenosis
6 and their concerns with the ability to afford
7 co-pays for rehab and therapy services once the
8 study compensation has ended.
9 Another study noted that they wanted
10 coverage for study-related injury in their
11 willingness to participate, and another
12 survey-based assessment gathered that perhaps
13 weekly compensation for both time and travel would
14 better engage patients in their willingness to
15 participate.
16 Distance is fairly self-explanatory.
17 Distance and transportation for interventional
18 visits and monitoring and follow-up is something
19 noted. And I think it's particularly important to
20 note that when a condition becomes particularly
21 disabling and affects a patient's ability to travel
22 easily, this is particularly problematic. In the

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1 distance and travel category, we had two studies
 2 that were noted among older populations as this
 3 being a concern in their willingness to
 4 participate.
 5 Of course there are concerns with too many
 6 study sessions, too many interventional procedures,
 7 and too much monitoring. So anytime we can reduce
 8 those number of visits, particularly in-person
 9 visits, it seems to generally improve willingness
 10 to participate.
 11 A lack of information, as I kind of already
 12 stated, about the complete expectations for part of
 13 participation was noted, so anytime we can clarify
 14 information or revisit information, I think that
 15 would be something that may help improve
 16 willingness to participate.
 17 One exception, most people wanted reduced
 18 number of visits and reduced study durations, and
 19 the exception to this were two studies of women
 20 with pelvic-pain endometriosis. When they were
 21 surveyed in about a three-year duration of study,
 22 the majority of them were agreeable to that study

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1 duration, and noted that they appreciated to have
 2 the extra window of time for the added monitoring
 3 and the time for their body to adjust to the
 4 changes in the treatment strategies that were
 5 utilized.
 6 The choice of intervention and the choice of
 7 control was affected by many factors. Again, our
 8 charge wasn't to focus on treatment-specific
 9 preferences, but you'll see some of that bleed into
 10 some of the discussion here.
 11 The choice of intervention as it relates to
 12 patients with pain and their willingness to
 13 participate is heavily influenced by their past
 14 experience with other treatment options. Also, an
 15 influencing factor on the choice of intervention is
 16 the route of administration and the inconvenience
 17 of having an inconvenient route of administration.
 18 Something that was encouraging is that among
 19 patients with chronic pain who had a history of
 20 opioid use, the majority of the patients were
 21 willing to accept enrollment into an opioid
 22 tapering study.

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1 When we targeted in on the study specific to
 2 headache, which included migraine, some of the
 3 things that were noteworthy within the choice of
 4 intervention and control here was that the majority
 5 of participants with headache would participate in
 6 a placebo-controlled study, and they wouldn't
 7 actually consider it unpleasant to find out that
 8 they were responsive to placebo. The one thing
 9 that they expressed in terms of a study design
 10 feature as a preference was the ability to decide
 11 when to treat an acute attack.
 12 Now flipping over to the choice of
 13 intervention for patients with depression, it was a
 14 little bit mixed here. For some, counseling was
 15 not an intervention that they were interested in
 16 receiving. For two other studies, there was a
 17 distinct preference toward an intervention that was
 18 psychotherapy in lieu of a medication-based
 19 treatment option.
 20 We did have one study that assessed a
 21 deceptive trial design in patients with depression,
 22 and it had a very, very small focus group of five

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1 patients. It was actually part of a larger
 2 assessment that also gauged perspectives from
 3 general practitioners and psychiatrists. But in
 4 all of those patients, they were unwilling to
 5 participate in an authorized deceptive or post hoc
 6 deceptive design.
 7 The other thing that I'd like to point out
 8 in terms of interventions in patients with
 9 depression is that as part of a pilot study, there
 10 was one assessment that we reviewed where the
 11 interventions were three different types of
 12 psychotherapy. And though it was very clear to the
 13 researchers, the subtle differences in those three
 14 different types of psychotherapy, when the
 15 participants were surveyed after the study was
 16 completed, it became clear that very few actually
 17 had an understanding of the different treatment
 18 options they were potentially going to receive as
 19 part of randomization.
 20 Lastly, some other things that affect
 21 willingness to participate as it relates to
 22 interventions particularly is the fear of side

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1 effects, both known side effects and how they would
2 be managed, and then also unknown or rare adverse
3 effects.
4 The desire to have access to current and
5 past treatments really rested heavily on the fears
6 noted of inadequate treatment, so fears related to
7 inadequate treatment and the ability to take
8 medications that they're currently on. Most of
9 these features were noted among patients with pain,
10 and patients with pain also noted fears related to
11 withdrawal if they have inadequate treatment.
12 Also, there were fears or basically
13 unwillingness to participate if they were likely to
14 receive treatments that had been ineffective in the
15 past. Patients wanted to not have the ability to
16 receive something that they had already tried and
17 failed. One study that assessed patients with
18 depression also suggested and wanted a tailored
19 treatment approach, even within the context of
20 study design. Tailoring in that study was noted as
21 tailoring to symptoms and past side effects.
22 Moving into outcomes, with outcomes and data

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1 collection, outcomes were not the original core
2 focus of what we wanted to gauge from a perspective
3 standpoint, but once we pulled our full text, we
4 did include anything that was outcome-focused, and
5 we had a total of six reports that focused entirely
6 on outcome-specific preferences.
7 The good news here is that the previous work
8 of IMMPACT, published by Dr. Turk in 2008 and
9 colleagues, is that much of what we gathered
10 aligned with those perspectives, meaning that
11 patients largely want outcomes that are focusing on
12 functional improvement, quality of life, and pain
13 relief. This also is alignment with what
14 Dr. Goertz presented with the PCORI findings.
15 When it comes to methods of data collection,
16 of course patients want less invasive measures;
17 even as simple as a blood test was deemed as a
18 deterrent to participation. If more invasive
19 procedures are part of study design, one study was
20 able to show that with higher compensation, you
21 would get perhaps more willingness to participate.
22 When it comes to data collection methods,

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1 other things that were noteworthy were that four of
2 our studies assessed data collection or collected
3 data within the patient's home. Two of these were
4 among patients with depression and two others were
5 among patients with pain. Other modes of data
6 collection that were noted as acceptable included
7 tablet-based collection of data for psychological
8 well-being and was largely acceptable among
9 patients with depression.
10 Keeping research questionnaires manageable
11 was a very big factor in willingness to
12 participate. Some of the themes that were noted
13 are that patients don't like lengthy
14 questionnaires, and patients don't like when the
15 questionnaires have repetitive questions or when
16 they're difficult to understand and answer. And
17 there's no free textbox to clarify that they're
18 confused when they don't necessarily know what
19 you're asking.
20 Also, not surprisingly, less frequent data
21 collection is preferred over more frequent, and a
22 less time-consuming data collection method is

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1 preferred. Studies also noted that they wanted
2 consistency within the research assistance as
3 something that affected their willingness to
4 participate.
5 I'm kind of moving into motivating factors
6 before I cover some general considerations based on
7 some of the information I presented. It's so
8 encouraging to know that most patients' desire to
9 help others is a very strong motivating factor for
10 participation in clinical trials. Staff rapport is
11 also ranked very highly, and the motivators that we
12 found in patients with pain and depression are
13 consistent across bigger, systematic reviews among
14 broader patient populations, so this is no
15 different.
16 I also think it's noteworthy to point out
17 that outcome feedback is a big motivator for
18 patients with depression. Several of those studies
19 noted that patients like to see their progress over
20 time in a consistent pattern, and three studies
21 noted the desire to receive their study results as
22 a motivating factor for participation.

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

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

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

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

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

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

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

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

22 I also think that we maybe need also more

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

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

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

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1 read the article by Chambers -- adding the value of
 2 that qualitative mixed-methods component into the
 3 randomization or into the process of building a
 4 randomized-controlled trial.
 5 So whether it's a pre-trial doing a
 6 qualitative assessment to proactively engage
 7 acceptability of the study design from our key
 8 stakeholders; or to identify recruitment and
 9 retention issues; or how to enhance diversity; or
 10 whether it's embedded and threaded directly into
 11 the main trial or completed after the trial is
 12 over, the value that that can bring to have
 13 long-term gains for improving efficiency and
 14 validity of our findings is probably something to
 15 be considered.
 16 So with that, I'll open it up to questions.
 17 Clarifying Q&A
 18 DR. KERNS: Thank you very much. That was
 19 terrific.
 20 I'll take one question. I want to make sure
 21 that we move on to the sponsor's bundles funders
 22 panel. It's a lot of people, and I want to make

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1 sure we give them ample time.
 2 So any clarifying questions for McKenzie?
 3 (No response.)
 4 DR. KERNS: By the way, I'll say that we've
 5 done some back-channeling about the chat function,
 6 and we're going to hold off for now and discuss
 7 this in a debriefing that the core team involved in
 8 planning this meeting will have later today.
 9 So I don't see any hands up; or wait. Maybe
 10 I -- hold on.
 11 Any hands up? Any questions?
 12 (No response.)
 13 Panel Discussion
 14 DR. KERNS: Alright. Then we'll move on.
 15 Thank you again, McKenzie and Ewan.
 16 We'll move on to the next session, which is
 17 an exciting panel of research agency funders.
 18 Chris and I both worked on organizing this, but
 19 I'll have the pleasure of making the introductions
 20 today.
 21 So first up is my colleague, David Atkins.
 22 He's director of the Health Services Research and

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1 Development Service in the office of Research and
 2 Development in the Department of Veterans Affairs
 3 Central Office, or headquarters, in Washington DC.
 4 David?
 5 Presentation – David Atkins
 6 DR. KERNS: Hey. Thank you. I was
 7 panicking a little bit. I couldn't find my mute
 8 button.
 9 I will keep my comments short because the
 10 review that we just heard, the two reviews we just
 11 heard, have made many of my points for me.
 12 Are my slides up and visible to people? I
 13 saw them before, and now I'm not seeing them.
 14 Okay.
 15 I think the nice review we heard from Simon
 16 really made all of these points, which this is just
 17 a motivation that I had in Health Services Research
 18 of recognizing that we needed to take on the issue
 19 of veteran engagement more seriously, and this
 20 happened about five years ago.
 21 I think all of these were in the summary
 22 points from the review; that we felt it would give

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1 us more meaningful research questions; that we
 2 would get a better discussion of what the important
 3 endpoints were; and that we would understand
 4 whether our data really represented the important
 5 issues for our populations.
 6 But we are also very interested in the other
 7 direction, which is how can we use engagement to do
 8 a better job at disseminating innovations that
 9 we're working in the VA with veterans as part of
 10 that process and, also, how do we improve our
 11 communications about research and the importance of
 12 research to veterans?
 13 I'll say as an introduction that in Health
 14 Services Research here, we have always been
 15 stakeholder-driven. We recognize that our
 16 stakeholders include the health system that we're
 17 trying to influence, they include policymakers,
 18 everywhere from Congress to our leadership, but
 19 they obviously include veterans as well.
 20 The path that we took, as I said, started
 21 about five years ago. We explicitly built on what
 22 we learned from PCORI. We had my old boss, Jean

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1 Slutsky, come to talk to our center directors, and
2 we gave a very general mandate that all of our
3 research centers -- we had 18 at the time -- had to
4 establish a veteran stakeholder group and begin to
5 use it in developing their research projects.
6 We did not give them a very explicit roadmap
7 of what we thought that should look like. We
8 thought we would learn from different approaches
9 that those groups took. But what we did at the
10 same time was we established a better engagement
11 work group to link the work of those centers, and
12 we gave them some funding to do a number of things.
13 One, they developed a conceptual model to
14 explain how veteran engagement would change the
15 process of research. They promoted sharing and
16 communication across what were essentially 18
17 slightly different models doing it. They organized
18 cyber seminars.
19 Then they developed a toolkit for places
20 that were slower in standing this up to guide them
21 through the process of how do you plan for this;
22 how do you convene patient stakeholders; how do you

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1 run the process effectively; and then how do you
2 evaluate whether it's working to do what you can
3 do.
4 So that was all fairly generic patient
5 engagement, but over the recent couple of years,
6 we've focused more on engagement around specific
7 areas of our research, starting with women's
8 health, where we have a very active women's health
9 research group, and then getting into pain and
10 opioids, and to suicide.
11 We established a consortium for research on
12 pain and opioids, and this was meant to build a
13 community of researchers that would do a number of
14 things; one, to build collaborations across our
15 national network of researchers; to build more
16 effective partnerships with our clinical leadership
17 and with veterans; and then to do a better job of
18 telling the story about our successes.
19 So as part of that process, the consortium,
20 what we call ACOR, set up a veteran engagement
21 panel of 12 veterans chosen for their
22 geographic -- being from around the country, but

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1 also for representation of different groups. They
2 all had experience with chronic pain and/or opioid
3 use.
4 This panel has been quite effective in
5 providing feedback, especially for early-career
6 investigators when they have an idea; when they
7 want to get some of the feedback that's just been
8 discussed about the acceptability of an
9 intervention; about ways-to-recruit strategies; and
10 how to communicate results. That process has been
11 going on for about two years now with generally
12 good reception.
13 I'll close with just some general comments
14 to make sure I don't intrude too much on other
15 people's time. This is really talking about
16 high-level engagement advice across a research
17 program. If you're going to set up a panel like
18 this and you're going to bring researchers to draw
19 on this panel, we found that it's helpful to
20 prepare researchers how to get the most of that;
21 that they need to frame the kind of feedback that
22 will be most useful. So we've set up a group to

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1 prepare them and make that feedback useful.
2 As I said, the feedback has been generally
3 quite positive from investigators who value the
4 advice that they're getting. It's changed
5 certainly recruitment strategies. It's shaped
6 somewhat interventions.
7 The other thing we've learned is that
8 veterans want to be informed about the pace of
9 progress, and this applies at a high level, but
10 also patients involved in projects. They're
11 sometimes dismayed that the pace of research is
12 much slower than they anticipate. So at an
13 individual project level, our projects have
14 developed ways to communicate back to patients
15 along the way so that they know that things are
16 progressing and things are being learned, even
17 though the project may be years from actually being
18 published in the literature.
19 I want to close with just recognizing that
20 this is sort of high-level veteran engagement, but
21 at an individual project level, we've been
22 requiring attention to veteran engagement for the

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1 past four years, so there's a separate section that
 2 they have to write plans on this. Obviously,
 3 that's a much more detailed level of engagement
 4 that we look for.
 5 We have always emphasized mixed-methods
 6 research in Health Services Research in the VA, so
 7 it's very typical for a project to include,
 8 phase 1, a refinement of intervention that will
 9 draw on veteran input and other stakeholder input
 10 in that process. That is probably more the rule
 11 than the exception in our research since we are not
 12 generally funding large, multi-site, clinical
 13 trials from the beginning.
 14 I will say just in closing that one
 15 challenge is often that we want to build
 16 flexibility into those proposals, that they can
 17 take the input of veterans and shape the
 18 intervention and shape the outcomes. For
 19 reviewers, they sometimes don't like to see too
 20 much left to that process. They want to know
 21 exactly what intervention is going to be delivered
 22 or they may want more detail about timelines.

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1 So while we've had some very successful
 2 projects using what we call EBQI, evidence-based
 3 quality improvement, that has an implicit
 4 assumption that the process will change the design
 5 and intervention along the way, I'd say we still
 6 have this tension between what we leave to evolve
 7 as a part of that process versus how much we
 8 specify up front.
 9 So I'll close there and look forward to
 10 hearing from my colleagues.
 11 DR. KERNS: Thank you very much, David.
 12 That was terrific. And I particularly appreciate
 13 the transparency and openness to where some of the
 14 strengths are, what you're trying to do, and where
 15 you appreciate some of the tensions, and gaps, and
 16 opportunities. We won't take questions now. We'll
 17 have hopefully some time for, really, panel
 18 discussion, Q&A, and commenting from the group.
 19 We'll move on to our next presenter. This
 20 is Dr. Rebecca Baker, who likely many of you know.
 21 Dr. Baker is the director of Helping End Addiction
 22 Long-Term, or HEAL Initiative, within the National

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1 Institutes of Health, and is located in Bethesda,
 2 Maryland.
 3 Dr. Baker?
 4 Presentation – Rebecca Baker
 5 DR. BAKER: Hello, everyone. Good afternoon
 6 from Bethesda, Maryland. Thank you for the time to
 7 take part in today's really interesting meeting.
 8 I've already learned a lot and very pleased to tell
 9 you about what we're doing in HEAL.
 10 As a reminder, I think many of you are part
 11 of the initiative and have contributed a lot
 12 already, but as a reminder, what we are seeking to
 13 do is provide scientific solutions to the rapidly
 14 evolving crisis of opioid misuse, addiction,
 15 overdose, and underlying crisis of pain management.
 16 We've been at this for a while, and yet last year
 17 was the worst year on record for drug overdoses in
 18 the United States. Over 90,000 Americans died of a
 19 drug overdose. These are people who are dear to us
 20 and lives that can be saved with evidence-based
 21 interventions.
 22 Unfortunately, the majority of these

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1 overdoses continue to involve opioids, primarily
 2 driven at this point by powerful synthetic opioids
 3 like fentanyl. We're also seeing demographic
 4 changes and increase in health disparity
 5 populations and in Black, American Indian, and
 6 Alaska Native populations.
 7 This is what we in the Helping to End
 8 Addiction Long-Term Initiative are seeking to
 9 address, and yet we also recognize that to provide
 10 durable and lasting solutions, we're also going to
 11 need to address the need of the over 50 million
 12 Americans in chronic pain.
 13 Most people with a substance-use disorder
 14 also experience pain, but then the numbers of
 15 people with pain are much larger, and as we've
 16 heard, it's a big driver for why people seek
 17 medical care and how comfortable they are in their
 18 life. Of those 50 million Americans, about half of
 19 them experience severe pain on a daily basis;
 20 20 million, such high-impact chronic pain that they
 21 can't go about things that are important to them.
 22 We rely on opioids for addressing a lot of

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

8 In the next slide, I tell you a little bit
 9 about what we've done so far in HEAL. Launched in
 10 2018, we've now directed over \$2 billion in
 11 research, over 600 different projects across the
 12 country in nearly every state. It won't surprise
 13 this group, but we've really had to -- especially
 14 in the pain domain -- across disciplines,
 15 communities, and settings. You can't do this just
 16 in isolation. So through the initiative, we've
 17 worked to engage with research participants,
 18 patients, and stakeholders as well, in addition to
 19 our traditional research community, academic labs,
 20 and medical centers.

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

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

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

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

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

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

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

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

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

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

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1 we are seeking to improve patient participation and
 2 research.
 3 Some of that has led to specific funding
 4 opportunities, so ways for researchers to get
 5 additional financial resources from the NIH to
 6 enhance engagement and inclusion in their studies
 7 beyond just strategies for recruitment and
 8 retention, which is, heretofore, what they might
 9 have focused on.
 10 Those awards have resulted in additions to
 11 studies to develop culturally relevant recruitment
 12 and research materials; some toolkits to share
 13 information about the health conditions being
 14 studied, and the community is specific to an
 15 individual research study; enhancing access to
 16 materials, and that can be different languages or
 17 other barriers to accessing materials; specifically
 18 supporting the addition of patient navigators to
 19 help people with lived experience through our
 20 studies; and the creation of community advisory
 21 boards so that the study can be conducted in the
 22 context of the community where the research

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1 but we picked a few really terrific people to take
 2 part in this group.
 3 They include people with lived experience
 4 using drugs, patients, advocates, family members,
 5 and caregivers, all giving us advice on the ways
 6 that the issues faced by people affected by pain
 7 and addiction could be researched and what outcomes
 8 would be meaningful to those groups.
 9 One of the first things that we've gotten
 10 started to work on is really doing an inventory of
 11 what is already out there. The survey results were
 12 very interesting for me to hear, collecting
 13 information about what patient engagement efforts
 14 are already underway in their cities and ways that
 15 we could expand on that, or bring up the floor and
 16 make sure that the majority of our studies have
 17 some meaningful patient engagement.
 18 Here is a little bit more about the recently
 19 awarded launched program, Integrative Management of
 20 Chronic Pain and OUD for Whole Recovery or IMPOWR.
 21 This program seeks to address the needs of people
 22 who experience pain who also have a history of

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1 participants live, and in their families and
 2 caregivers.
 3 Toward the governance goal, we've created
 4 the HEAL Community Partner Committee, and I'm very
 5 pleased Chris Veasley has agreed to take part in
 6 that and is already taking a huge leadership role
 7 in making sure that that group does everything it
 8 can to contribute to the overall meaningfulness of
 9 the HEAL Initiative and our research.
 10 In the past year, we launched a new program
 11 called IMPOWR, which focuses on people who
 12 experience pain who also have a history of a
 13 substance-use disorder or are in treatment for
 14 substance-use disorder, and really using that as a
 15 test case for integrating research participants
 16 into study design from the beginning.
 17 The next slide is a few words about the
 18 Community Partner Committee. HEAL has so many
 19 different studies. As I said, we have 600
 20 different projects, so we can't reflect all of
 21 those different perspectives and all of the
 22 different research participants in those studies,

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1 opioid misuse. What we find is that this is
 2 actually the majority of the people with
 3 substance-use disorders that also have pain.
 4 Sometimes it contributed to their disorder;
 5 sometimes it's just left untreated because they
 6 don't feel like they have effective options.
 7 These individuals also suffer from a really
 8 fragmented system receiving treatment, and then
 9 limited work resources for high-quality and
 10 evidence-based care. This program is really
 11 working together with the patients and people with
 12 pain to develop integrated interventions, focusing on
 13 the whole patient. That includes, a lot of times,
 14 people with pain that have co-occurring,
 15 conditions, including other aspects of their
 16 health, and then directly addressing some of the
 17 factors related to stigma and health disparities
 18 that keep people from receiving high-quality pain
 19 management
 20 This has really been our first effort
 21 through a HEAL program to establish a nationwide
 22 stakeholder engagement effort, and one that we hope

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

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

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

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

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1 of projects, which in our world is sort of
 2 assessing whether or not they're funded, in well
 3 over 300 projects. So the scale of this, I think,
 4 is important in the context of the work that we do.
 5 So where did we begin? As Dr. Goertz
 6 mentioned to you, when PCORI started this, it
 7 started off with an expectation. You are going to
 8 engage people. That expectation was there because
 9 board members determined that PCORI being
 10 patient-centered meant having the outcomes that
 11 mattered and research topics that mattered to
 12 patients and other stakeholders. And one key way
 13 of achieving that, in addition to the board itself,
 14 which is also multi-stakeholder, was to have
 15 wholesome engagement throughout that pipeline I
 16 shared with you.
 17 But the question arose at the time, which
 18 was a broad standard, you should and must engage
 19 across the projects, but how to do it, and projects
 20 didn't really understand that. So the rubric that
 21 you see before you -- it's a much shortened version
 22 of that -- was essentially developed actually in

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1 concert with the Patient Engagement Advisory Panel.
 2 We try to give guidance to projects in the field
 3 about what engagement might look like.
 4 What you will see here are two really
 5 critical underpinning concepts to this, and I think
 6 it kind of comes back to some of the conversations
 7 we've been having, which is engagement can and
 8 should occur throughout the life cycle of the
 9 project. Dr. Goertz shared with you a lot of what
 10 we've learned about engagement through those parts
 11 of the project, but it's what basically PCORI said;
 12 it can and should throughout the life cycle of the
 13 project.
 14 Then secondarily, there needed to be
 15 underlying values. These are the PCOR principles,
 16 and these principles are important and I think
 17 actually reflect some of the conversation you're
 18 having here today, because PCORI makes a
 19 distinction -- and you saw this in Dr. Goertz's
 20 presentation -- between what we would call input,
 21 which is you're essentially doing research on
 22 people.

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1 Now it's important and it's valuable
 2 qualitative research often about what do you think
 3 of this intervention, but it's focus groups, it's
 4 surveys, it's studies, where the research team
 5 knows what the questions are, and you're asking
 6 people to answer them, in essence.
 7 That is different than, as we were just
 8 talking about in terms of moving to collaboration
 9 and partnership, where you really have individuals
 10 as members of project teams. And as she showed you
 11 in those findings, you end up with a very different
 12 set of interactions where sometimes individuals --
 13 actually because they're there -- you may not even
 14 realize you had a question.
 15 But they're redirecting you and telling you,
 16 "Oh, by the way, that is never going to work." It
 17 could be the practicing physicians in a study on
 18 site saying, "The way you're doing this isn't going
 19 to work," or it's going to be patients saying,
 20 "Nobody's ever going to sign up for that the way
 21 that it is." So it's a really important piece to
 22 understand.

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1 Now, this was pretty broad; let a thousand
 2 flowers bloom. We did not dictate how you engage,
 3 just that it had to occur.
 4 This is just to remind you of what
 5 Dr. Goertz told you, that it's important. This
 6 was, in essence, sort of a natural laboratory; as I
 7 just mentioned to you the sheer numbers of projects
 8 and work with a similar context for the rubric, and
 9 PCORI, and the kind of technical assistance we
 10 provide. What we've learned builds the body of
 11 those activities.
 12 I think what I just really wanted to get
 13 across here is, one, it is feasible across a
 14 variety of stakeholders. It does influence the
 15 projects and the conduct of the studies. It
 16 influences what happens, it influences the quality,
 17 the feasibility, and those other things, and that
 18 is building on a large body of our internal
 19 research.
 20 Obviously, individuals can benefit, but so
 21 can communities and so can institutions. And
 22 individuals can benefit not only in terms of some

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1 of the things we heard about in terms of their own
 2 care and how they access it, but lots of other ways
 3 in terms of their life course. And of course, for
 4 physicians, for researchers, and others, you get
 5 that lived experience that's so crucial.
 6 What we have done -- and I just want to
 7 bring this back because the question came up -- is
 8 we have translated a lot of what we have learned to
 9 date into tools and resources, and those tools and
 10 resources, too, Dr. Goertz shared with you.
 11 One is research fundamentals, which does not
 12 say to patients and stakeholders, "You must be a
 13 comparative effect in this research to participate
 14 in our studies." It says, "If you want to know
 15 more about research, and you want to be more
 16 comfortable with it, and you also want to learn
 17 what patient-centered outcomes research mean, it's
 18 a great tool for people to use."
 19 We also have a building effective
 20 multi-stakeholder research teams training, and I
 21 just want to note, based on the question, it
 22 assumes all participants need to be trained for the

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1 interaction. It does not say we must teach
 2 patients; it says we must teach everybody to be an
 3 effective team. But the tool is tailored to the
 4 context of research, and clinical research, as
 5 opposed to potentially other kinds of research.
 6 So where are we going? Where are we
 7 heading? Well, we've had this rubric, we've done
 8 this research, but it's time to update it. Right?
 9 It was developed in 2014, as I mentioned. It was
 10 guidance on how and when, but there's a lot we have
 11 learned.
 12 The next version of the rubric that we are
 13 working on right now, and we anticipate to come out
 14 in the next year, will use the knowledge we've
 15 developed in our natural laboratory. It's going to
 16 address a lot of the facilitators and barriers in
 17 engagement we've just been discussing, and it's
 18 going to reflect our priorities for advancing
 19 engagement.
 20 The ultimate goal as we revise this is going
 21 to be to continue to support meaningful and
 22 sustainable engagement in CER and PCOR, and to

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1 influence research to be more patient-centered,
 2 relevant, and useful. But it will be different,
 3 and it is likely to really try to link better to
 4 the tools, the resources, but also push the field a
 5 little bit further.
 6 Although I can't tell you what it is because
 7 this will also take the input of members of our
 8 board, like Dr. Goertz, but ultimately, we
 9 anticipate we will move from a thousand flowers
 10 blooming to perhaps some stronger suggestions. It
 11 is not yet to the state of standards, which is why
 12 we'll go to the next slide, please, to remind you
 13 that we still have lots of questions.
 14 The rubric update is about bringing the
 15 rubric, which guides awardees about how to compete
 16 for PCORI work and how to conduct engagement in the
 17 projects more up to date with what we know. But as
 18 Dr. Goertz outlined for you, we have many other
 19 critical questions we think we need to answer.
 20 I won't belabor this other than to note she
 21 talked about it, and she also raised to the RFI we
 22 have out right now. I encourage everybody to

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1 please take a look at that.
 2 But where we're going is guidance for our
 3 awardees that fundamentally catches up with what
 4 we've learned, but also moving to a place where we
 5 really take to a new level and answer the kinds of
 6 questions with methodologies and approaches that we
 7 can't do right now because much of our work has
 8 been based on our programmatic research and program
 9 improvement research. But I think it's time for a
 10 more robust set of answers because we have that
 11 research to build on.
 12 So with that, I will turn it back over to my
 13 colleagues.
 14 Oh, and I just want to note for Isabel that
 15 I am a very big fan of Lucy Lawless, and I was
 16 delighted to see your screenshot. So don't feel
 17 bad about it. I thought it was terrific.
 18 DR. KERNS: Thank you, Dr. Carman, very
 19 much. I loved the way that you extended on what
 20 Christine, Dr. Goertz, brought forward earlier.
 21 And it does seem like there's important
 22 complementary perspectives shared, but also

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1 complementary perspectives across the sponsors and
 2 funders.
 3 So we'll move on to our next panelist, and
 4 this is Dr. Karim Khan. Dr. Khan is the scientific
 5 director of the Canadian Institutes of Health
 6 Research, the Institute of Musculoskeletal Health
 7 and Arthritis in Ottawa Ontario, Canada.
 8 Dr. Khan?
 9 Presentation – Karim Khan
 10 DR. KHAN: It is great to be part of this
 11 panel. And I've got an eye on the time, so I won't
 12 go over the five minutes so that we've got plenty
 13 of time for the discussion with folks.
 14 From Canada, just to give folks
 15 perspectives, it's great to be part of this IMMPACT
 16 meeting, and congratulations on the 25 years of
 17 work with IMMPACT, and using that word "IMMPACT"
 18 more broadly with the publications, and the
 19 grants, and the citations that we heard about
 20 earlier, but also the improvement of the health of
 21 the communities, Americans, Canadians, and people
 22 all around the world, which is true impact, like

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1 the non-academic impacts in addition to what's
 2 published.
 3 Great for CIHR, the Canadian Institutes of
 4 Health Research, to be represented here. You've
 5 heard from Canadian, Isabel Jordan, and you'll hear
 6 from Dr. Christine Chambers and Isabel Jordan in
 7 other sections. So it's great to be here from that
 8 Canadian perspective.
 9 I'm going to drill down and focus on some
 10 work from the Chronic Pain Network in Canada, one
 11 of five chronic disease networks that were funded
 12 by the Strategy for Patient-Oriented Research. So
 13 you can see, or hearing that, that the Strategy for
 14 Patient-Oriented Research, the CIHR -- Canada's
 15 equivalent of, quotes, "NIH" -- has invested in a
 16 strategy for patient-oriented research, and it's
 17 actually over \$100 million a year in Canadian
 18 dollars with matching funding, so 100 total, 50 to
 19 60 from the Canadian Institutes of Health Research.
 20 If we drill down to the Chronic Pain
 21 Network, I'll emphasize that acute pain is to be
 22 treated, and treated well, to avoid chronic pain,

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1 but if we focus on chronic pain as of now, it's
 2 understandable.
 3 I'm going to highlight the work of Dr. Dawn
 4 Richards, who would be familiar to many of you, and
 5 thanks to her for providing these inputs. I
 6 consulted with her, and she is both an academic and
 7 a person with lived experience of inflammatory
 8 arthritis -- she won't mind sharing that; she
 9 shares that publicly -- and one of the real stars
 10 of the field that we're talking about today.
 11 So I'm delighted to be able to pop her
 12 Twitter account on there for you, and you can
 13 follow her easily through email and other channels.
 14 She's a member of a lot of international spaces in
 15 this patient engagement domain, and she's of the
 16 Canadian Arthritis Patient Alliance. She's the
 17 co-chair of that. So she's a real star, so I
 18 encourage you to take a snip of that slide there
 19 with Dr. Dawn Richards, and she's been massively
 20 influential to the field.
 21 This is a busy slide. Feel free to take a
 22 photo of it, and it will end up in the material

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1 that you get. We've heard from a few people today,
 2 including most recently Kristin, where Kristin
 3 framed that it's never too early to start and it's
 4 never too late to start, and I couldn't underscore
 5 that more.
 6 So I'll just make the point that it needs to
 7 begin in the conceptual phase with authenticity; so
 8 not doctors or researchers going, "How can we get a
 9 patient to help us with this stuff? How can we
 10 check the box?" It's like to the patients and to
 11 people with lived experience, "What's bothering you
 12 right now? How can you be part of this
 13 experience?"
 14 It's co-creation. And although that word
 15 "co-creation" will be obvious to some people in the
 16 room, I'm still stunned by how there are these gut
 17 instincts and limitations to co-creation. And when
 18 you bring up co-creation, the classy thing is,
 19 "Well, what are you planning to do?" It's this
 20 obsession about details as if you've already built
 21 the thing. So no-no, we don't have any idea where
 22 we're going right now, and that is ok, and that's

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

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

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

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

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1 fellowships.

2 I just wanted to show the type of research
3 that the MRC actually funds. We fund largely
4 towards the underpinning and etiological research
5 end of the spectrum, so a lot of what we fund is
6 actually, basically, discovery science and
7 preclinical and early-stage clinical research.

8 I think that's quite important because it's
9 not always that there's a clear target patient
10 group for some of the research if it is discovery
11 science or basic physiology, and that can mean that
12 at times in the past, we've had difficulty in
13 trying to encourage our researchers who we fund to
14 actually take part in public involvement and public
15 engagement.

16 However, we do have a relatively good
17 history or tradition of public engagement more at
18 the end of engagement rather than actually
19 involving patients directly. And by that, I mean
20 that a lot of our public engagement activities have
21 focused around engaging the public in understanding
22 and supporting science, and increasing the interest

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1 of young people, and learning about careers, and
2 taking up careers in the life sciences.

3 So in many ways, this is what I'm calling
4 public engagement, although I realize public
5 engagement is a spectrum, and it's been used today,
6 obviously, to mean much deeper engagement, and what
7 we perhaps, certainly within MRC, tend to refer to
8 as public involvement.

9 One example of the type of engagement that
10 MRC undertakes is the MRC Festival. We have quite
11 a lively annual festival for medical research,
12 where MRC-funded units and institutes across the UK
13 put on a range of science activities over a period
14 of several weeks. And there's often an open
15 invitation to the public of all different ages to
16 join in and learn about scientific research.

17 We've also funded certain engagement
18 involvement activities. One example here is a
19 citizen science activity which was called Worm
20 Watch Lab, which was actually a genetic study where
21 members of the public were able to watch nematode
22 worms online, and then they participated by

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1 recording whenever an egg was laid.

2 On a slightly smaller scale at the level of
3 individual research studies, individual research
4 studies have been funded by the Medical Research
5 Council as part of the funding they receive for the
6 study to undertake innovative co-production
7 activity. For example, the film, Be Your Sister's
8 Keeper here was co-produced by a professional
9 filmmaker who worked with researchers and the women
10 sex workers in Nigeria in order to produce this
11 film that describe the research study and also the
12 context in which the work was being undertaken.

13 The AALPHI study is another example. This
14 is a study of a cohort of adults and adolescents
15 who were living long term with perinatal HIV, and
16 the researchers and young people co-produced a
17 range of materials which were particularly designed
18 to describe the findings of the study in ways that
19 were accessible and engaging to young people.

20 On my last slide, I just want to talk a bit
21 more about the public involvement that we've tried
22 to start weaving into the funding calls that we've

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1 been doing more recently. This is something that,
2 as I say, is a more recent thing, and something
3 that we're still very much testing out and finding
4 out what works.

5 The MRC really has not very often been able
6 to involve members of the public or patients in its
7 funding calls. And this is in large part because
8 we're not experienced in doing it, but also because
9 as a funder of basic science, it's sometimes been
10 difficult to identify and just involve patient
11 representatives or people who are able to
12 understand the technical level of the science, and
13 actually for them to be present on boards or on
14 funding panels who are reviewing what can be highly
15 technical grant applications, especially where, in
16 fact, at times the link to patient or clinical
17 health outcomes can be quite remote.

18 I do have two good examples, though,
19 recently, where we have embarked upon doing that,
20 and worked really quite hard to make that part of
21 the funding initiative. The first one here is the
22 Advanced Pain Discovery Platform, where the MRC

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1 partnered with a particular charity and funder
 2 called Versus Arthritis.
 3 Versus Arthritis, as a patient support group
 4 and a funder, facilitated contact with patients who
 5 were able to inform the funding initiative right at
 6 the very start. They supported us to appoint
 7 patient representatives on to the advisory board
 8 for the funding call. They ensured that the
 9 information about the call was written or used lay
 10 language to describe what it was about.
 11 They also helped us to develop a review
 12 panel where patients were the reviewers, and the
 13 patients were, therefore, able to contribute to the
 14 competitive selection process. And not all of the
 15 patients on the review panel, which was held
 16 separately, actually were then part of the more
 17 technical panel, but certain representatives did
 18 sit on that panel.
 19 So this partnership was a real success, and
 20 more importantly for the MRC, we actually gained
 21 valuable experience in public involvement and how
 22 we could weave it into our funding initiatives.

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1 We've also gone further with a second
 2 funding call around adolescent mental health, where
 3 it was a similar process, but this time a different
 4 organization that we partnered with. The MRC
 5 involved a panel of young people in the design and
 6 conduct of the funding call; so again, not always
 7 an easy group to involve in a funding call, and
 8 actually taking part in the types of review and the
 9 committee processes that can be quite established
 10 and have a particular way of being managed. Again,
 11 we actually had a really successful experience
 12 here.
 13 So I think both of these initiatives
 14 highlighted for us the real benefits for the MRC
 15 working in partnership on public involvement
 16 activities. We really needed these partner
 17 organizations who had the contacts and the
 18 experience to help us include members of the
 19 public, include patients, and actually to learn
 20 ourselves how to do it for the future.
 21 So at the moment, public involvement
 22 engagement is an area that the MRC is working hard

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1 to develop, and we recognize that we don't have a
 2 long track record of doing this. We do need to
 3 find and develop approaches that work, particularly
 4 for the types of research that we fund and the
 5 specific funding approaches we use; so the
 6 preclinical and basic science research, and where
 7 there's not a specific patient group that we can
 8 target as the group to become involved.
 9 We can see that we do have good examples and
 10 best practices out there, so we're keen to actually
 11 find and adopt these, and bring them into our own
 12 ways of working. We've recently commissioned a
 13 mapping exercise as a first step in developing a
 14 new public involvement strategy for the MRC that we
 15 hope will address some of the difficulties that
 16 we've had in the past
 17 We also want to, from this mapping, actually
 18 understand what we already do well in this area.
 19 So we don't have a good understanding of what we
 20 are already doing, of what those we've funded are
 21 already doing, and perhaps are good examples for us
 22 to disseminate and let people know about, so that

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1 we can actually see them copied in future
 2 applications and future research that we fund.
 3 We really want to move forward to integrate
 4 best practice and public involvement into our
 5 everyday activities, our funding activities, so
 6 that we can actually get more value out of these
 7 research investments in the future. Thank you.
 8 DR. KERNS: Terrific. Thank you very, very
 9 much.
 10 Again, we look forward to discussion after
 11 our last presentation in this panel by Dr. Jeremy
 12 Taylor, director of Public Voice and Center for
 13 Engagement and Dissemination at the National
 14 Institute of Health Research, NIHR, in London,
 15 United Kingdom.
 16 Dr. Taylor?
 17 MR. TAYLOR: Thank you very much, Bob. I
 18 have to confess that I'm not a doctor.
 19 DR. KERNS: I realized that.
 20 MR. TAYLOR: I'm just plain Jeremy.
 21 Presentation – Jeremy Taylor
 22 MR. TAYLOR: You'll be relieved to hear also

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1 that I've only got three slides, and I'll try and
2 get through them as quickly as possible, so we've
3 got as much time as possible for discussion.
4 The NIHR, National Institute for Health
5 Research, is the other big funder of health-related
6 research in the United Kingdom. We work very
7 closely with the MRC, particularly actually in the
8 last year during the kind of COVID research
9 splurge, where there's a lot of joint funding
10 activity between NIH, UKRI, and MRC on vaccines,
11 treatments, and urgent public health research
12 related to COVID.
13 We've been around for longer. We started in
14 2006. What we tend to call patient and public
15 involvement has been a sort of standard expectation
16 right from the start. I noted Simon earlier talked
17 about terminology. Nobody uses consistent
18 terminology in this field. But when we talk about
19 patient and public involvement, we essentially mean
20 a lot of the things we've been talking about in
21 today's very enlightening session, essentially
22 ensuring a meaningful partnership with people with

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1 lived experience to ensure that they are able to
2 shape the research effort all the way through.
3 The quote at the bottom comes from some
4 guidance notes that NIHR produces for researchers.
5 "Public involvement can improve the quality and
6 relevance of research." And I guess the reason
7 that it's can, and not does, is because it depends
8 how well you do it.
9 We also refer, I think, to really important
10 broader democratic principles of citizenship,
11 accountability, and transparency. And to my way of
12 thinking, we do public involvement in research
13 because it ought to make the research better, but
14 also because it's about democratizing what should
15 be a jointly-owned and jointly-conducted
16 enterprise, not just something that's there to
17 preserve the people in white coats. So we have
18 both a kind of utilitarian and moral imperative to
19 get this right.
20 Going the Extra Mile was a big strategy
21 document that was developed in 2015, and it was a
22 10-year strategy for embedding and improving the

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1 way the National Institute for Health Research goes
2 about doing patient and public involvement. It set
3 out a number of very ambitious goals, one of which
4 was to make patient and public involvement more
5 inclusive, and diverse, and reflective of the
6 diverse community in the UK. In fact, that's
7 become a bigger priority over time.
8 It set a goal of moving away from more
9 tokenistic and mechanistic approaches to
10 involvement to, wherever possible, something more
11 like co-production and genuine partnership. It
12 advocated the development of standards that could
13 be used to help the research community do public
14 involvement well, and they became the UK Standards
15 for Public Involvement.
16 These are the UK standards in summary form,
17 and they cover essentially more relatable issues
18 that we've been discussing in the last three hours
19 about creating inclusive opportunities, which is
20 partly about being inclusive and diverse, and
21 finding people who can be part of the research
22 enterprise, but also making sure we don't put

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1 barriers in people's way.
2 A particular issue is making sure that
3 compensation, which we had to talk about payment
4 systems in the UK, works effectively and ensure
5 that people are not excluded from taking part in
6 research in one way or another because of financial
7 considerations.
8 Working together is all about actually
9 moving towards more of a partnership model and
10 making sure that that is genuine. Support and
11 learning is about lots of things. It is about
12 providing support and training opportunities for
13 patients, and we've had a bit of a discussion about
14 some of the controversial aspects of that, but it's
15 also about supporting the research community,
16 researchers, principal investigators, and research
17 teams to understand how to go about doing public
18 involvement in a good and effective way.
19 It is about governance and how people can
20 have real power and voice. We haven't talked too
21 much about power dynamics, but the governance
22 dimension is one of the strands where we get to

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1 grips with, well, who holds all the cards and can
 2 we be more democratic between the researchers, and
 3 the patients, and members of the public going
 4 forward.
 5 Communications, everything around plain
 6 English, about making things understandable, are
 7 really, really important, both in terms of people
 8 being involved in shaping the research effort and
 9 as participants in studies, and we've heard quite a
 10 bit about the latter.
 11 Then finally, making sure that we do
 12 everything we can so that that involving patients
 13 and the public in research leads to impact and
 14 makes a genuine difference. So those standards,
 15 they were developed in 2018. NIHR worked with
 16 other research funders and bodies across the UK
 17 health sector, and those standards, there's a job
 18 to do to embed them and to make them famous, and to
 19 help people use them to improve the way they do
 20 public involvement. But they're still very much a
 21 live and important part of the public involvement
 22 agenda in the UK.

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1 So we don't rest on our laurels. And this
 2 quote comes from a recent strategy document from
 3 the National Institute for Health Research that
 4 restates and updates its overall strategy for
 5 health research, Best Research for Best Health: The
 6 Next Chapter, it's called.
 7 In that document there is this quote, "We're
 8 guided by the strategy set out in Going the Extra
 9 Mile," that I just described, which had a vision of
 10 a population actively involved in research to
 11 improve health and wellbeing for themselves, their
 12 families, and their communities.
 13 Then it goes on to say, "We know that we
 14 have much further to go if we are to ensure that
 15 the involvement of diverse patients, service users,
 16 carers and communities in research is inclusive,
 17 consistently makes a difference, and avoids
 18 tokenism." That's a recognition that this is still
 19 work in progress. Although NIHR in UK terms set a
 20 lead for public involvement in research, we know we
 21 can do better.
 22 COVID and Black Lives Matter, between them

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1 in 2020, delivered a bit of a rude shock to the
 2 research community in terms of just exposing the
 3 degree of inequalities that exist in our society,
 4 in health and in the research community, and kind
 5 of increased the moral urgency around making sure
 6 that when we're engaging with patients and the
 7 public, we're doing that inclusively, and we're
 8 covering all the communities, not just some.
 9 The Black Lives Matter protests -- again, in
 10 the wake of the George Floyd murder -- gave both,
 11 in the US but also in the UK, a big stimulus to the
 12 debate about are we leaving black people out of
 13 research at all levels, including public
 14 participants, but also in the research community.
 15 So I just wanted to give you a sense that we
 16 still see there's a lot further to go in many of
 17 the dimensions we've been discussing today, and
 18 I'll stop there.
 19 Summary, Wrap-Up, and Reminders
 20 DR. KERNS: Thank you, Jeremy. That was
 21 just terrific. You ended -- and I think all of the
 22 presenters ended on this -- "We have much more work

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1 to do."
 2 I think we prepared a slide -- I don't know,
 3 Carlos, if it's possible to bring it up -- of just
 4 a small list of some of the opportunities, I would
 5 say, for incorporating patient education. It might
 6 reflect on this as we move into a little bit of a
 7 discussion. But I just want to say we will
 8 absolutely end at half-past this hour, regardless
 9 of how it goes.
 10 I see Andrew's hand up. Please, if you
 11 would like to make a comment, including the
 12 panelists, please raise your hand so I can call on
 13 you.
 14 Is this Andrew Rice?
 15 DR. RICE: Thank you very much, Bob, and
 16 thank you also, to you and the other organizers,
 17 for inviting Rachel and the UK participants.
 18 I've got a particular question. I guess
 19 Rachel could probably lead on this. Thank you also
 20 for giving the shout-out to the Advanced Pain
 21 Discovery Platform. There are a number of other
 22 people talking about it as well. For me, that was

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1 a big learning curve. I think we took a foot-step
2 forward in terms of engagement, but it also taught
3 me how much further we've got to go on this
4 journey.
5 But Rachel, you touched on an important
6 topic, which is the role of engagement in discovery
7 research. And we don't have the other UK funder
8 here, which is Wellcome Trust, but they've taken an
9 important strategic direction now, in that they're
10 really only funding discovery research and not
11 translation research, except in the areas of mental
12 health, global warming, and infectious diseases.
13 So I just wonder if we could discuss a
14 little bit more how basic science funders use
15 patient engagement at that really early step of
16 setting their priorities and deciding which calls
17 they're going to make. So it's a really
18 early-stage question I wanted to ask.
19 DR. KERNS: Thank you.
20 Go ahead, Rachel.
21 DR. KNOWLES: Thanks, Andrew. Yes, as I
22 say, I think we feel very much we're at the

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1 beginning of this journey. We really want to
2 explore very much how we can involve patients and
3 the public at every stage. So we are wanting to
4 look at whether we can actually involve people in
5 helping us think about the priorities and
6 particular areas of research, or particular topics,
7 in order to guide us, as well as how we actually
8 involve people individually or in the actual
9 research projects.
10 I think there are not clear ways to do it.
11 I think one of the things that, for me, is very
12 important is that we actually always step back and
13 think about, well, what's the purpose of this
14 public involvement/public engagement? What do we
15 want to get out of it? How do we think that this
16 is going to improve what we do? And therefore look
17 to actually have a targeted public engagement/
18 public involvement that actually really seeks to
19 contribute to what we're doing.
20 So it's not that we have a standard formula
21 for this is how we always do it, but that we
22 actually start to develop a suite of resources, a

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1 suite of ways of doing it, that we can actually
2 say, "Look, here are things; choose from these; and
3 what will actually work best in this situation?"
4 We really do try and explore the breadth of
5 what public involvement/public engagement could
6 mean, rather than focusing too narrowly on,
7 perhaps, patient involvement. And I say that,
8 really, because we're finding that patient
9 involvement isn't enough for the type of research
10 that we fund. So we really want to look broadly
11 and see what can we get out of public involvement
12 and how can we do it in the broadest sense.
13 DR. KERNS: Thank you, both.
14 Lee Simon?
15 (No response.)
16 DR. KERNS: Come off mute, Lee.
17 DR. SIMON: This has been a very interesting
18 meeting, and I just want to comment that OMERACT,
19 Outcome Measures in Rheumatology, has actually
20 incorporated patient research partners for the last
21 20 years; in fact, we have a handbook for them. We
22 have meetings for the patients. We educate the

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1 patients. The patients educate themselves. Every
2 single working group within OMERACT must have
3 patients associated with work. They are, in fact,
4 a self-sufficient group who meet on their own.
5 There was a paper by John Kirwan mentioned
6 previously in the early presentations, and there
7 have been multiple papers out of the patient
8 research partner group talking about their
9 involvement. One of the places that they've been
10 particularly involved has been in drug safety
11 working groups and in glucocorticoid working groups
12 about understanding the way that glucocorticoids
13 affect them as an anti-inflammatory, but also with
14 the side effects.
15 This is probably the most critical nature of
16 the kind of work that we do in trying to understand
17 the effect of therapeutics. They're also
18 incredibly important to identify the core domain
19 set that we're going to develop, or has been
20 developed, for each of the disease states that we
21 deal with, and they are integral to be able to
22 understand that, and then integral in understanding

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

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

17 Lynn Laidlaw?

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

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1 involvement.

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

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

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

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

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

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

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

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1 influences feasibility and rigor.

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

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

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

20 Dr. Khan?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 Simon?

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

22 I wanted to ask the panelists about their

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

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

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

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

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

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

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

15 Go ahead, Karen.

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

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

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

8 Rebecca?

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

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

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

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

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

1 Nothing's perfect, and we're still fighting
2 to get people vaccinated and to share the fruits of
3 the research with the communities, but it went a
4 long way, and people appreciated that. So I think
5 in that way, we've really advanced, but it also
6 helps to have our leadership saying this is
7 essential. So that has been a big part of our
8 driving force within the HEAL Initiative.
9 DR. KERNS: Well, thank you, and thank you
10 to all our presenters, panelists, and those who
11 spoke up in the Q&A and comment sections today, and
12 maybe a particular shout-out to our participants
13 who represent the community, that are the targets
14 of our research community of people with lived
15 experience, so thank you for that.
16 Chris, do you have any last words for today,
17 any hints about tomorrow?
18 MS. VEASLEY: No. Thanks, Bob. I think we
19 just had a really great first day. I think when we
20 first started having conversations about this
21 meeting, some folks wondered do we have enough to
22 talk about and is there enough being done out there

1 So I just want to thank everybody for our
2 great first day, and I look forward to tomorrow.
3 DR. KERNS: Terrific.
4 Bob, or Dennis, or Valorie, Carlos, any
5 instructions for tomorrow rejoining at
6 11:00 Eastern U.S. time?
7 MS. THOMPSON: The only thing I'll say is
8 that the same link that you used today to join us
9 will be the same link that you use throughout the
10 meeting.
11 DR. KERNS: Terrific.
12 Well, thank you again, everybody.
13 Oh. Go ahead, Bob.
14 DR. DWORKIN: I was just going to say I
15 think it was a great first day, and I look forward
16 to tomorrow and Friday.
17 Adjournment
18 DR. KERNS: Beautiful.
19 Alright. Well, thank you again, everybody,
20 and we'll reconvene tomorrow.
21 (Whereupon, at 2:30 p.m., the meeting was
22 adjourned.)

1 that we actually can have a full meeting on this.
2 And I think what today has shown us is that the
3 answer to that is overwhelmingly yes, which is very
4 encouraging.
5 So we do have a long way to go. Today was
6 really about identifying through the reviews; what
7 do we know in the literature; giving high-level,
8 30,000-foot views on best practices, principles;
9 and what are our agencies doing around this issue.
10 And really, tomorrow we're going to deep dive into
11 the how tos. We don't want to just give people
12 high-level recommendations of this is great, you
13 need to do it, but then not leave them with how do
14 you do it; not answering that question.
15 So tomorrow we're going to investigate each
16 step of the research life cycle and learn from
17 co-presentations between investigators and patient
18 partners in those studies about how exactly do we
19 plan, include patient engagement and planning, and
20 conduct; how do we reach diverse populations; and
21 how do we partner to do dissemination and
22 implementation?

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