Transcript
Matters of Engagement podcast
Episode: “REBs and Patient Partnership”
https://mattersofengagement.com

00:00
Jennifer: Hi there, Jennifer here, I'm just popping in to let you know a couple of things. So this is our second last episode of Season 2. One more to go after this, and then a short break as we research our next topics. And a quick word about this one: this topic is Patient Partnership and Research Ethics Boards. It's inspired by an event I moderated on behalf of Child-Bright in December, which actually was about Ethics and Patient-oriented Research more broadly. We definitely think this episode stands on its own and doesn't require that you go watch the video of the event to get something out of it. But we also think that event is worth your time! Go check it out. There's a link in the show notes. Okay, let's roll it...

00:51
Jennifer: Hello, and welcome to Matters of Engagement, a podcast exploring the complex world of patient engagement and partnership. I'm Jennifer Johannesen.

01:00
Emily: And I'm Emily Nicholas Angl.

01:05
Jennifer: Back in December, I moderated a panel on behalf of Child-Bright. They're a research network that aims to improve life outcomes for children with brain-based developmental disabilities and their families. And they do this through research activities, knowledge translation, training, and citizen engagement. The panel session was called Roles and Relationships: Ethical Considerations Related to Involving Children and Parents in Patient-Oriented Research. The panel was convened on Zoom, had five panelists plus me and ran for 90 minutes. This episode is about that session. You can find the video of the event on the Child-Bright website. There's a link to it in the show notes.

01:51
Jennifer: You might be wondering how this episode came to be? Well, in my early planning conversations with Dan Goldowitz, one of the Scientific Co-Directors of Child-Bright, we talked about the idea of extending the conversation beyond the event itself. And that's actually one of the great things about online events these days. If they're set up to be recorded, you can watch or listen to them whenever it's convenient for you. But more importantly, you can also refer to the material later and build on it. It can be disappointing to let a good event languish! I'm glad we have an opportunity to carry on parts of the discussion.

02:29
Emily: Yeah, so I attended the session as an audience member. And obviously, I wanted to support you! But I was also really interested in the topic of ethics and patient-oriented research. I found that the panel provided a really good starting point. And I appreciated hearing a variety of different perspectives. It definitely spanned a

lot of ground. The panelists touched on everything from ethical issues and patient partnerships, to a potential role for Research Ethics Boards, or REBs, in overseeing aspects of patient partnership. And they even talked about patient involvement in REBs.

03:05

Jennifer: Yes, as I was moderating, I was so focused on keeping it rolling that I didn't always hear opportunities to take the discussion in particular directions. So it was great to listen again and then debrief with you. I think we picked up on a few of the same things. In particular, we both really wanted to talk more about the role of REBs.

03:26

Emily: Yeah, for sure. We know that their role is to protect research subjects and ensure that aspects of the research project meets certain ethical criteria. And, though by definition patient partners are not research subjects - and so their involvement doesn't require IRB approval - there are certainly a lot of considerations about how to engage ethically. Not only that, it's actually thought of as an inherently ethical act to include patients as partners. And so it totally makes sense to bring REBs and patient partnership into the same discussion space and to see if it makes sense.

04:02

Jennifer: CIHR, or the Canadian Institutes of Health Research does provide some Ethics Guidance when it comes to patient partnership in research. The guide has a slew of questions and considerations for both patient partners and researchers to consider. We've put a link in the show notes. Now, some of it is helpful, but some of it leaves a lot of room for interpretation! I mean, for example, one of the guidelines for institutions is to "ensure the participation of patients makes a difference to them, ensure their voices are meaningfully considered among all other voices on the committee". So yes, good idea. But because this document is intended as an educational resource and not as policy with compliance requirements, it's just not terribly concrete. And it all sounds kind of optional.

04:54

Emily: Right. And, as I mentioned before, you don't need REB approval for patient partnership. But the lines between patient partner and patient subject are sometimes not totally clear and sometimes a person can be both. This dual role is even acknowledged in CIHR's Ethics Guidance. It says here, "Research Ethics Boards need to ensure that participants will be respected and protected..." Okay, fair, then it says "...with the added complexity that these participants are also involved in the research effort as part of the research team". That's not much to go on. So, I mean, it's not surprising that researchers are often confused about whether they need ethics approval for their engagement plans or not. So this topic is very pertinent and it's likely to interest a lot of people.

05:43

Jennifer: Alright, so let's carry on then. And by the way, each of the panelists gave us permission to use their recordings for our episode, but none of them were involved in the writing and production. And in fact, Child-Bright wasn't either. Just know as we carry on that the opinions expressed in this episode are solely ours.

06:06

Jennifer: So here's who was on the panel. First, there was Elizabeth Stephenson. She's the Chair of the REB at the Hospital for Sick Children in Toronto. Franco Carnevale is a nurse, psychologist and clinical ethicist with research interests in pediatric ethics. Gillian Backlin is a technical writer, and an active member of Child-Bright's National Youth Advisory Panel, and a Patient and Family Ambassador Liaison at Sunny Hill Health Center at BC Children's Hospital. We also had Thierry Lacaze - he's a neonatologist and Scientific Director of MICYRN, which is the Maternal Infant Child Youth Research Network. And finally, Antonia Palmer, a very experienced patient partner, actively involved in the realm of pediatric oncology.

06:53

Emily: Also, Antonia and Thierry are both involved in a project called CHEER, which aims to streamline and improve the research ethics review process to enhance and expedite child health research across Canada. Antonia chairs the Patient and Family Advisory Committee, and Thierry is a Co-Principal Investigator.

07:12

Jennifer: Great, I think that covers it. And by the way, those are all really condensed credentials. This is a very experienced panel of researchers, clinicians and patient partners. Now, this was a funny session to get a handle on because as you can see, there was such a diversity of people and interests. And at first, when I looked at the transcripts and the outlines, I just didn't quite know where to begin and wasn't sure how this would fit within our framework for this podcast. But after we talked a bit, I think we pretty quickly saw some of the same things. And it has to do with some of the underlying and often unexamined assumptions about patient partnership that we keep stumbling on.

07:51

Emily: Yep. And just so this episode doesn't run on for hours, will mostly focus on the questions of REBs, and whether they might have a role in how patient partnership operates. So this would be a good moment to hear from Elizabeth Stephenson, about what generally it is that REBs do. And just a reminder, she chairs the Sick Kids Research Ethics Board.

08:13

Elizabeth Stephenson: We are an independent body at these institutions that review research and make sure that it is moving forward in the most ethical way possible. Our primary goal is around protection of participants, make sure that people understand exactly what they're agreeing to, and that what they're being asked to do is a reasonable and ethical thing. We also consider the ethics of the community at large. One of the things that we would look at in a given research project, for example, would be whether or not the research appears to have bias in it, whether that's racial bias - something we've been talking a lot about in research lately - or gender bias or population bias, for example, by only including or only excluding certain populations.

09:08

Jennifer: I found this description really informative. Although it is their main stated focus, REBs are not solely just about the protection of research subjects. They also look at research methodology and methods. And they

look at the scientific basis for what's being proposed and whether the proposed research itself is serving a public good.

09:28
Elizabeth Stephenson: We look to make sure that the research is based on informed consent as one of the sort of fundamental principles, certainly for any direct participant research, that there is justice and beneficence, saying that it is being done for good reasons, that it's founded in good science, that it's adequately funded so that the research can actually be completed in the way that it's been been proposed. And that ultimately, it's serving a public good.

10:01
Jennifer: So just reflecting on this, I think most patient partners we know would take exception to any idea that, despite inherent power imbalance between patients and researchers, that patient partners need protection in some way, or in the same way as research subjects. But when I hear Elizabeth say things like "informed consent" or "founded in good science", or is it "serving a public good", I think there could be an argument made in support of expanding REB involvement into patient partnership. I think it is worth asking whether patient partnership is indeed good science, and in what ways it's serving the public good.

10:40
Emily: So I find that there's an interesting tension there. We describe patient partners as equal members of the research team. But then, when we ask questions about engaging them ethically, in a way that we don't with other research team members, we're acknowledging the power imbalance and that there is something different or unique about this position. Regardless, I still think we'd hit the same roadblock we always encounter - which is...what is the underlying reason we're so committed to patient partnership and health research in the first place? If REBs were involved, what would they be looking for, or monitoring? We're hearing more and more that outcomes and impact aren't the point. But it's about meaningfulness and patient voice and diversity of perspectives. There could be a kind of affirmative action approach that could be taken where there's quotas and guidelines and so forth. But that still doesn't guarantee in any way that there will be meaningfulness. How do you regulate that? Who decides what counts as meaningful?

11:46
Jennifer: Yeah, these are good questions. It could also be argued that by creating yet more checkboxes, we may actually be circumventing or avoiding doing things that would be experienced as meaningful. We could consider the impact of the current REB approval process to get a glimpse of how this might play out. Now, before I go on, I do have to say I have virtually no insight into whether REBs actually accomplish the things they say they do, like protecting research subjects. I just don't know. But I do know that I've encountered a lot of researchers who think of the REB process more as an administrative hurdle. They have to "get through ethics" so that they can carry on. I can't say I've ever heard a researcher say that the REB really helped them make sure they didn't harm their subjects. I mean, maybe the REB process is a preventative measure? Research is often designed to make sure it passes the REB threshold for acceptance. So over time practice has been refined to meet those standards. Fair enough. Although I do wonder to what extent this gatekeeping mechanism might suppress innovation or present unnecessary roadblocks. Anyway, back to patient partnership.... If there was to be any sort of

monitoring or oversight of patient partnership by an REB, it may actually have the net effect of relegating it to nothing more than a checkbox exercise. And just like REB requirements now, there's a risk that they may be seen as sufficient in addressing ethical issues, or, in the case of patient partnership, questions of meaningfulness.

13:26

Emily: Actually, this is a good moment to hear from Franco, a clinical ethicist and ethics researcher. And his work enters this discussion at exactly this point. REB standards are one thing - they establish minimum requirements and try to ensure that projects meet them. Jen, I think on the panel, you call this "big-e Ethics". But Franco's work is more concerned with the human and interpersonal aspects of bringing patient voices into shape research, which you called "small-e ethics".

13:58

Franco Carnevale: I might just tweak that a little bit in sort of what you're referring to is big-E ethics is what we might call deontological ethics - sort of formal norms, standards and rules, the do's and the don'ts that may be linked in law and maybe linked in widely accepted standards that define some very clear thresholds that have to be respected. Then as we work with those, or as young people and families navigate those, they encounter their own questions about good and bad, right or wrong, just/unjust. And I think that more sort of lived experience in navigating right and wrong, might be what I would refer to as a "smaller-e ethics". So the moral realm of everyday experiences involved in trying to operationalize these "big-E" standards.

14:57

Emily: Franco also does a nice job of explaining how protected can go too far. Franco's work and research is particularly focused on children and youth. But I think what he's saying here has relevance to all patient partnership. He starts out explaining the importance of protecting against exploitation and harm, and that there are potential risks with that.

15:18

Franco Carnevale: We are using people as a means for the ends of others the idea here, except for people participating in clinical trials, where they may derive benefit as well - may or may not! - the aim of the research study is to advance knowledge that can then be used to the benefit of others. And so that is always going to raise a potential risk of maltreatment and exploitation, or commodification, even if people, when we are using them as means for the interests and benefits of others, and therefore protections are necessary. So you've got that one layer protection that's necessary. Now, when we're talking about young people, we've got a whole bunch of other layers of protection, because young people have been widely recognized as vulnerable. And we have actual, as well as potential, risks of exploitation of their vulnerabilities in all kinds of ways. And so we have all kinds of additional measures, both in research ethics, as well as youth protection types of standards that ensure that young people are particularly protected. A very, very serious... I won't even call it a gray zone, because I because I think it's not, as far as I'm concerned, there's nothing gray about it... a serious problem that results from all this protection is the risk of really suppressing a real authentic recognition of the personhood of the people in question, is that you can protect people so much that they become voiceless, and really just become objects that others are making important decisions about. Within the field of Childhood Studies very

broadly, and the work that we're doing within the field of Childhood Ethics, we're trying to bring forth a greater and clearer recognition of young people as active moral agents, who have particular aspirations, ethical concerns, and capacities to participate meaningfully in matters that affect them.

17:28

Jennifer: We actually had a young person on the panel, Gillian Macklin, who is an experienced patient advisor. She mentioned that sometimes when youth are accompanied by a caregiver, or maybe are participating as partners along with a parent, others on the team might conflate them, as though they think as one, or maybe they defer to the adult. And this may be a degree of overprotection, but more likely, this would be a symptom, I think, of tokenism. Which, again, brings the idea of meaningfulness back into the spotlight. And this would be very hard to teach or oversee. Here's Gillian:

18:06

Gillian Backlin: Well, we want all perspectives, but when we're specifically looking for the patient or youth perspective, it can be hard to get that without the influence of others around us, especially when it comes to caregivers or parents. It runs the risk of kind of merging into one voice instead of two very different voices with two very different perspectives. So I think that that's important to recognize - is that I might have a different goal than somebody else. And that goes the same for, you know, people of the same family or caregivers. So being able to find a way where they're all heard, but their voices can be distinguished instead of just grouped together. Because I think that that can lead to a number of different biases and results.

19:17

Emily: The kind of dynamic Gillian is describing can be obvious, but it can also be really subtle and hard to see. I imagine these types of biases could be addressed through things like best practice guidelines, or maybe through training courses? Something akin to sensitivity training? It's hard to say how effective that would be. Making sure that we value particular voices isn't something that's easily mandated or supervised, because it's so rooted in interpersonal communications and relationships.

19:51

Jennifer: Yeah, I agree. But the fact remains, that it's exactly in the realm of interpersonal dynamics where serious questions get raised about how partnership is handled. Here's Antonia. In the panel discussion, she had a lot of thoughtful contribution about patient or lay person involvement in REBs, which was kind of outside the scope of what we wanted to talk about here. But she did have this to say about patient partnership outside of any consideration about REBs.

20:22

Antonia Palmer: You know, it's about creating an effective and positive ethical engagement between the two parties. And that's all about issues of respect and concern and justice. And, you know, it's about being a valued member of the research team, being a respected member of the research team, making sure that there is that multi-dimensional information sharing. You know, I think far too often patient partners, their voices aren't heard in an equitable way. But it is about being able to create a solid understanding from the beginning of how these partnerships can move forward and how we do that in an ethical way.

21:04

Emily: Yeah, I don't disagree... but I wonder where should the "solid understanding" come from? This is maybe where capacity building and training comes in. Antonia talked about guidelines like the Tri Council Policy Statement, or TCPS 2, providing a good foundation. Not just for conducting research ethically, but also engaging with each other ethically. Like she says here, she's expressing not so much a need for formal oversight, but more for building people's understanding and skills.

21:37

Antonia Palmer: This is outside of being an REB member... but if it's a patient partner involved in a project, doing that type of training to make sure that they understand ethical issues and research and how to serve their community ethically... I think that the core principles of the TCPS 2 are really important ones that teams need to abide by - the respect for persons, the concern for welfare, and issues around justice. I think if the entire research team has that foundation and has that training, they can act on those three pillars to move the research forward, and move them forward with potentially not with a formal oversight, but at least with a strong foundation.

22:27

Emily: Yeah, I can see how it might be helpful to draw on existing ethical training to inform how teams can work together. Just thinking though... both Antonia and Gillian raise the concern that patient partner voices may not be heard in an equitable way... which, I don't know, may not be properly addressed with training designed for other purposes. I think just overall, it's very difficult to create specific frameworks and course content to address concepts that are either vaguely defined or that might mean different things to different people. We heard throughout the conversation that the development of standards should be collaborative and specific to the particular context. So even borrowing ideas developed with other communities or populations is tricky, as you'd need to ensure alignment with the community you're working with.

23:18

Jennifer: Mm hmm. And I was really interested to hear from Thierry about all of this. He's a neonatologist, and a Co-Investigator on the CHEER project. CHEER stands for Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research. Basically, their mission is to streamline research ethics review for child health research as it pertains to multi-site research, which is usually subject to review by multiple REBs, maybe with different requirements. I didn't really think of this at the time of the panel, but now, I find it kind of telling that a project like CHEER is required. It's a multi-year multi-million-dollar CIHR-funded project. And it exists primarily because the REB process, in this context, is too unwieldy. Their goal is to simplify the process, not make it more complicated. So I wondered what Thierry thought about this idea of whether patient partnership needed oversight and if so, who should do it?

24:20

Thierry Lacaze: So the funder, CIHR, apart from SPOR networks and SPOR projects, actually do not require any kind of... you know, at least at the minimum, descriptions of how patients are going to be engaged in the project. And of course reviewers sitting on the panel of CIHR have absolutely no education around that as well.

So that might be one way of looking at whether the public money is distributed by CIHR for a selection and review process, maybe we would want to have CIHR developing some guidelines for the review process to ensure. Now for the REB, I think there is room and you know... I'm thinking of the INVOLVE initiative in the UK that actually lists a few items that could be part of the REB evaluations in regards to process of patients who have been engaged and showing, you know, lack of conflict of interest, ensuring that their participation is appropriately rewarded, and that they are involved at each step. So that could be developed. I don't think it actually exists formally, but it could be something we may want to do with the REB members and share as part of the CHEER project.

25:47

Emily: Yeah, so that's interesting. Thierry does see a potential role for REBs in patient partnership. But it seems mostly in the realm of technical questions and implementation, such as considering conflicts of interest, compensation, maybe stages of involvement. That's make sense from a researcher's perspective - they would want to know what the minimum requirements are and how to fulfill them. But honestly, this kind of administrative oversight wouldn't put much of a dent in the "small-e" ethical questions we discussed earlier, which include questions of meaningfulness - which kind of means we're no further ahead than when we started.

26:28

Jennifer: Yeah, maybe. But we could look at it another way. Maybe there's something kind of inevitable about how elusive this all is. The growing popularity of patient partnership in research I think says a few things about people's confidence in our health research industry. Now, I know people don't like this word... but I think that inserting patients into research, in the way that we're doing it, does have populist undertones. The implication is that health research isn't relevant enough. It's not in tune with patient needs. And it needs to show that it's incorporating the voices of patients. And these are just not things that an REB typically catches and its dragnet. These are emergent demands or needs that kind of defy an ability to rein them in through checklists and regulations. And maybe that's the point. Maybe patient partnership is seen as an antidote, or maybe at least a disruption, to what are seen as rigid scientific methods. And it's done by infusing a somewhat unpredictable and chaotic human element. I say chaotic, not to suggest that it's some random free for all. But the lack of oversight? Or even authoritative guidelines? It's caused not a small degree of confusion and disorder. And so here we are. Now there are aspects of this that are getting uncomfortable. Researchers and patient partners alike are really keen for some kind of standardization, or at least a common reference point for how to go about it meaningfully.

28:01

Emily: Yeah. And, AGAIN, I'm not sure we can ever really get there if we don't actually understand why we're doing patient partnership and research in the first place. I've been around this long enough to know the talking points and what the arguments are. And I've used them myself. And I do sometimes see that there's value in some contexts and in some situations. But I've really started to feel that a lot of the time that's kind of in spite of how patient partnership is set up, and not because of it.

28:32

Jennifer: Yeah. I think over this podcast series we've started to see much more clearly that the prevailing reason given for patient partnership is this collaboration piece. And the expectation is that if it's done meaningfully, positive impact and outcomes will follow. So that's the real linchpin in all of this. It's the meaningfulness. And I think in this context, the only people who can judge a partnership to be meaningful are the patients themselves. And if we're talking about needing frameworks and approaches? Well, it seems a bit incongruous that institutions would lead the development of that. None of it really makes coherent sense unless patients aren't just included, but actually lead and define the work.

29:16

Emily: Yeah. And so now we're back to that elusive idea of patient advocacy, or a different kind of research model altogether, like one that's community-based and not starting with the institution. I'm just not sure adding the REB into the mix would help anything. I mean, even adding patients to REBs or having patients co-design frameworks... we're still working within the same system with the same power structure. We'd just be doing the same things, but now with more red tape and an easy way to justify decisions "because patients were involved". I mean, I take your point earlier about how researchers can see REBs not necessarily as benevolent protectors of patients, but rather as administrative hurdles. Researchers make sure they say the right things on proposals to improve the chance they get funding. Now, of course, that's NOT to say that researchers then don't fulfill those commitments. But like you said, I do wonder what gets lost when we spend so much energy trying to check boxes that sometimes might have little to do with protecting patients, and more to do with control. I can see why patient partners in particular fear this the most - being seen as checkboxes. There's a precedent.

30:32

Jennifer: Yeah, that's actually a point of critique that has an academic foothold. There's an argument that despite whatever the origin story is said to be, REBs were actually set up to protect institutions, under the guise of protecting patients. I have a couple of papers as examples - I'll link to them in the show notes. And I've actually made this same argument about institutional bioethics and the role of the clinical bioethicist - that even if, individually, bioethicists are providing valuable counsel to patients, there's an inherent conflict because they represent the institution. Part of their job is to minimize risk. And it could be argued that part of the job of the REB, whether explicitly stated or not, is to minimize risk for the institution, and even the funder. Now, of course, like with all of these complex systems, that involve humans and that we talk about on this podcast, this isn't necessarily how it always looks on the ground. I do think most people are sincere and earnest in their desire to carry out their responsibilities. And most people are rightly focused on not harming patients. My question is more about the structure and function specifically of the REB. Is it necessary?

31:48

Emily: Oh boy!

31:50

Jennifer: Yeah I know [laughs]. It was a controversial thing to say. Maybe it's an exploration for a future episode.

31:59

Jennifer: Thanks so much to Child-Bright for inviting me to moderate their event. Hopefully anyone listening to this episode was in attendance for the event or has seen the video. If not, we encourage you to go check it out. Part of the goal of doing this episode was to extend the conversation beyond the event itself and not just summarize what was already said. Hopefully, this has added something useful or at least interesting to the discussion.

32:23

Emily: And thanks to Elizabeth Stephenson, Franco Carnavale, Gillian Backlin, Thierry Lacaze, and Antonia Palmer for giving us permission to bring in their voices. And just to reiterate: none of the panelists nor anyone at Child-Bright was involved in the writing and production of this episode. And thanks for listening! If you have any questions or comments, please get in touch through our website at mattersofengagement.com.

32:51

Jennifer: This episode was written and produced by Jennifer Johannesen and Emily Nicholas Ang, with generous financial contribution from the Ontario SPOR SUPPORT Unit, or OSSU, which is jointly funded by the Government of Ontario and the Canadian Institutes of Health Research, or CIHR. The views and opinions expressed in this episode belong solely to the producers and are not to be considered endorsed by OSSU, the Government of Ontario, CIHR, Child-Bright, or any of the panelists.