**Ethnicity Inclusion in Health Research Workshop for Researchers March 2024: Q and As with Professor Shaun Treweek**

**Question:** What can we do to change the mindsets of people that it doesn't matter if a researcher is from your background – will they still respect confidentiality?

*I think there's a lot of insecurity around what if they disclose my personal details of somebody in the community that they know. I remember in the 80s there was almost kind of this racism that if you were white, you were more professional than somebody who was Asian. So, they wanted to see a white doctor, which was very bizarre, but we have moved away from that.*

**Answer:** We suggest engaging with the target community to understand their worries. An example is a trial involving Asian women, who preferred a non-Asian woman to introduce the trial due to fears about confidentiality. The importance of building trust by ensuring confidentiality and possibly using a neutral, trusted individual to communicate this.

We’d have those conversations as it often throws up things which, for me, coming from a different community was unexpected and then we would do what we can to respect that. We would think we may have a challenge here and we will have to emphasise in a way that is likely to be trusted that the information you give us and that this discussion would be completely confidential, here are the guarantees we can give you, this is why and how it will not find its way into the local community, for example.

You have every reason to feel reassured and we must find somebody who would provide that reassurance. Possibly have an alternative, central point where people could have those recruitment discussions in a way that they felt was safer and felt confident, and their confidentiality was being upheld. Who would they trust when being told this is confidential? This what you can expect from us.

We also suggest having a safe, central location for recruitment discussions to reassure participants about their privacy.

**Question:** What sort of motivations and drivers of change work in the research community?

And are there examples where a process has been built into a research system or setting that has made a meaningful change? E.g. go to an ethics review committee or have people peer reviewing grant applications.

*I am interested in the adoption of INCLUE and frustrated by the number of conversations that that I have where it just hasn't been thought about at all.*

**Answer:** There is stuff out there, what we obviously want is for it to be used and there must be a sort of carrot and stick approach. It's important to highlight why we need to think about inclusion. The examples I gave show we can easily make mistakes if we don't think about it explicitly. And it's important to provide some tools that can help and we're moving in that direction. There are some things that can help.

There are two initiatives that I can think of immediately, e.g.

1. We are having conversations with the National Institute of Health and Care Research to make consideration of inclusion more systematic within the grant review process, that's both peer reviews and panel review.
2. There must be something within that approvals process at the funder end to try and make it less likely that inclusion will not be considered. Another initiative is linked to work being done by the Health Research Authority and the Medicines and Healthcare Products Regulatory agency. As part of their approvals process, are developing something called a diversity plan. The intention is that applicants for approval from either the Health Research Authority alone or HRA plus MHRA would have to submit a diversity plan. The diversity plan asks questions which are broadly like those four questions that I mentioned in the include framework.
* Who's in the trial?
* What are you doing to try and involve them?
* What measures are you taking?
* How are you monitoring it?
* How do you know it works?

It would be possible you would have your application to the Health Research Authority rejected, and not have your submission approved if your diversity plan was inadequate. The HRA and MHRA are going to have a soft release of that.

**Question:** Is there any work being done about the systematic approach to look at how it coordinates across the piece and how researchers can be more incentivized to have that approach and build a relationship? Do you have any thoughts about a systematic approach that looks at the context communities are living within?

*I work across the university trying to coordinate the ways in which people work with different communities, engaging in research. Something that we've heard from communities whilst developing a public engagement strategy across the university is, that if you are of a community from a particular group that researchers are often trying to reach, that you can be very, very saturated with requests. And the researchers tend not to know anything about any of the other researchers that have reached that community and research teams don't tend to have a sense of the broader context for that community. In part that is because in their literature review, they must review the data around the health condition or around the science, but they don't have to review the context for that specific community. They don't have to look at has that community engaged with similar research five years ago and there's been no result from that research. What we see is that funding applications for participatory research tend to go straight into, we'll have a PPI group, and we say, it's going to take you a few months to build the relationships to enable the trust to do that. In the university strategy that we're creating, one of the things we're trying to do to improve this is to have kind of structures where that exists beyond individual researchers that people researchers can kind of come in and out of, but the relationship continues.*

**Answer:** Trial Forge works on the trust side of things and goes through a third party, and we have not gone direct to community organisations and my own personal work has been mostly around ethnicity. We have involved another group, **Egality Health**, which is small company focused on working with ethnic community organisations. They have that relationship that's ongoing and they navigate the relationship, if you like, between the researchers, us and the community organisation. It's much less transactional than the researchers bouncing in - a year apart - asking questions that somebody else asked last year. It’s an approach which has worked well, from our perspective, I don't get the impression that we are wasting community members time in that way.

How to capture what lots of researchers are doing in that more systematic way so that we don’t either, or don't have to go back at all because we've actually answered it, is more ad hoc. The STRIDE project is trying to collate information we found in the INCLUDE frameworks, so we know from those frameworks about things that we would need to think about when designing a trial that has identified, for example, African Caribbean individuals as being important. Stride, but we won't do what you entirely what you want by any means.

Some effort to aggregate information and maintain relationships with organisations that goes beyond individual researchers is important, plus that there’s some infrastructure around it. The NIHR to their credit, have funded a piece of work that is looking at ethnicity how to what, what, what's the blueprint for doing that? Not, not to develop it, but what, what would you like is to develop? That is working with diverse ethnic community organisations and that will address in the blueprint I hope some of the problems or highlight some of the problems you highlight, but lack of a systematic approach to collecting that information so that we don't keep going back asking the same thing over and over again and we and that we don't record what we already know. Individual researchers can be ‘transactional’, and it annoys people. The ongoing relationship need not be with individual researchers, but with some other part of let's say the university or the research National Research infrastructure. I think your approach is very sensible.

**Question:** What do we do about excluding people who cannot speak English from trials?

*I review a lot of undergraduate research and the number one thing that I find there is we will exclude people who cannot speak English. This is something that is approved by departments, by supervisors. That's the standard.*

**Answer:** You are right. It's very common to throw in that you must speak English and that has consequences, which are not good for some groups who have great potential to benefit from some of the things that have been tested.

Things which might help stop that. We would want funders to ask why there’s that criterion must speak English and push back during the review process and say why? Given what you've told us about who has the condition. If it gets past the funder, then ethics needs to say, but why? Or the Health Research Authority or MHRA needs to say, but why? There are multiple points at which it can be stopped so that it becomes much harder for it to just be waved through, which I think has largely been the case, That particular criterion is very common and we do need to stop and really put people on the spot about that.

**Question:** Do we train undergraduates to become ethical and people inclusive researchers?

*We're training them at 23 to say, if you can't speak English, you can't be part of my study, then we expect them at 46 to now include everybody! With undergraduates, these are the same people that we’ve been encountering years later down the line. Some of these things should happen right from the beginning of, training a person in how to become a researcher. From the HRA, from the NIHR perspective, they are trying to groom researchers right from the bottom because they catch them most of the time as fellows and masters at the upper levels.*

**Answer:** Training undergraduates - a group called the **Trial Methodology Research Partnership**, **Inclusivity Subgroup**, over two years ago, said was we need to develop some sort of curriculum, for training undergraduate medical students or health professionals & biomedical students in inclusive research design. That led to a project which has now been funded by the EU, which has just started, to develop an undergraduate curriculum on inclusive research design, plus some professional training, all of which will be made freely available when it's finished.

**Question:** Do you think there should be PPI involvement in the completion of the INCLUDE questionnaires?

*I'm a PPI contributor, I'm a co-applicant for a trial but I was brought in at rather a late stage. I sit on the grants panel for a major charity that commissions and gives grants for research and the quality of PPI at the design stage is very much a key consideration on which applications can stand or fall.*

**Answer:** Yes, very much so, and on the question is it says who we think should be doing it and that should involve public contributors and other people who have a role to play in the trial. It's very, very hard to do the job well without involving people who represent the people you're trying to include in your trial or think you need to include so PPI.

**Question:** What are your thoughts on addressing equalities in the recruitment method to trials in psychosis?

*The trials that I work on involve people who have psychosis and the route for recruiting participants is relying on referrals from secondary mental health care teams. We have tried to seek self-referrals to that to try to get around the issue of people not being told about opportunities. It hasn't been very effective, and we've hardly recruited anyone via that method.*

**Answer:** The first thing which is a significant step forward would be to recognise the potential for it being a problem. At the at the very least, it puts us in a position to do so at the end of the trial. So even if you do, you only use referrals from the mental health service, for example, that at the end of the trial when interpreting the findings, you can bring out the applicability implications of having used that referral route and then only having the option of using that referral route. That is still progress because one of our great fears within Trial Forge, is that we think we have sorted something when we haven't, we've got something that is effective, but it's effective for whom?

And what you'll be able to do if you recognise the referral route has implications, is say this works for those individuals who are referred through that referral route. What we know about that referral route is that the people who come to us look like this. Other data suggests that the people who have the condition look like this and there's a difference. This is these are the implications for that difference.

Filling the gap while designing the trial, I think is then tricky. That brings us back to trust, what is it that means that some individuals who have the condition are not being referred? And why is it that that is the case? What's happening? And that might be a larger challenge or a different challenge to running that trial. And what is it about the referral service that is we think bringing some inequality about referrals that we would not expect given the disease itself and that that might be worth investigation. If there were options for other referral routes, as you say, you can explore those, but I imagine without that sort of working with organisations who have trust already, that is likely to be tricky but possible. So, you'd think, OK, this is a problem. These individuals for whatever reason, are for example, not engaging with mental health services and therefore cannot get referred because they're not engaging. Why is that? Who else could we work with? Which other organisations do they work with, if any? And could we therefore tap into them as a way of being able to engage individuals and we would benefit from the trust that individuals, potential participants have with those organisations, even though they're not using the health service that many of us do. I don't think that reflects badly on you at all., this is hard. This is a quite different way of working to how we have in the past and we don't have easy solutions. Even if it was completely impossible within the context of a particular trial to change to a range of recruitment routes, for example, it would at the very least enable you to say something at the end with regard to applicability and more measured interpretation as to whom these results apply. And I think that's in itself an important step forward.

**Question:** How do we apply the same standards or values to other researcher types, do we adjust the standard slightly? How do we get around the kind of problems when there is a smaller resource available?

*I wanted to open the conversation to other types of research because a lot of the research in our group is at a slightly earlier stage than identifying or understanding treatments. And all of this feels equally important there, but it feels slightly more challenging because it's often smaller studies. There are researchers, a PhD student on their own doing a study with not much funding over quite a brief time pressure. Avoiding those language restrictions feels equally important for all this research. I feel very stuck on how I would recommend that a PhD student on their own could make the research more inclusive.*

**Answer:** They are related to the last question. It would be progress to be explicit about the limitations of not being able to do something. So that by not being able to do X or Y with the with the funding that's available or the time that's available resources that we have made a decision to do this. A careful use of that information in the interpretation so that the consequences of that on interpretation are clear.

This is progress in the sense that it may say that we have found that this looks promising, but we have only been able to involve individuals who have a high proficiency in English. What that means is that given that the disease area has 22% of individuals who come from immigrant populations and have language issues, it means we are unable to say with any confidence whether this would be useful for them, and that requires further work. So, you put limits I think on the interpretation of your findings, and I think that is very important because we that isn't something we see I don't think very often.

Another type of research we working on is **evidence synthesis** where we would look across bunches of trials and try and say something about equity, diversity, inclusion and the limits on applicability that there may need to be or may need to be highlighted because of who is in the trials included within that systematic review. So, the interpretation is better. At the systematic review stage, we're not doing anything about the design. We're not changing the designs, we're interpreting the results more appropriately so that decision makers can use those results more carefully or it's more obvious to them that OK, there are some limitations. This is a step forward, even if it's not possible to make the changes that you'd like to. It's important to go into it knowing that by making that design decision where, for example, the one you highlighted, we're only going to engage individuals who have high proficiency in English by making that design decision. These are the consequences. This is what limits how our interpretation will be limited and that is progress.

**Question:** Is the INCLUDE toolkit is applicable to a lone PhD researcher who doesn’t have a wider team?

*I work at the Oxford BRC, in PPIE, and do training around patient public involvement which includes PhD students, who are very much on their own. I think that even the four questions are a good starting point, even if you're not able to fully fill them out? There are good, worked examples within the on the Trial Forge website.*

**Answer:** Any way in which they can be used to improve design decision making about inclusion is worth doing and if it's looking at the four questions, as a PhD student and they otherwise would not have considered those questions, that's a win. It is great that you're using it in the way that you suggest. I think that will bring benefits, but we need evaluation.

**Ethnicity Inclusion in Health Research Online Training for Researchers October 2024: Q and As with Professor Shaun Treweek and Dr Carinne Piekema**

**Question:** What are your views on Progress Plus and EDI Pro?

**Answer:** Pro Edi is aimed at systematic reviews, but I think it has much to say about the design of any piece of research, and it is based on progress plus. So what we wanted to do so progress plus is actually really focused on systematic reviews in it. And I think it's come really from equity focus reviews. But what we wanted to do was can we make it easier for systematic reviewers. And that's what we hope we do with the Pro EDI tool. So, but there's a list of characteristics which we consider to be the court, but we again to be project. We've had lots of input.

Things that we think mandatory essentially all systematic reviews should extract all pieces of research or to extract to describe their populations, and then some other pieces of other characteristics that may or may not be relevant to all reviews and potentially.

We’ve tried to balance workload given where we are against our aims of being able to better describe our populations and make more useful findings. So I think it's a very good place to start, I guess plus which is what we did. It is the most used tool in systematic reviews around equity. **Question:** Is there any intention of developing a framework that incorporates more aspects of the wider determinants of health? I'm thinking especially about the intersectionality of ethnicity and socioeconomic factors. You mentioned the separate INCLUDE frameworks, but I am also thinking about gender and climate vulnerability.

**Answer:** Not at the moment. I'm not aware of a framework that does what you're asking for right now. When we started developing the ethnicity framework in 2020, we asked ourselves a similar question. The answer we came up with was that it was too complex to develop a single framework that handled intersectionality. At that time, we felt unprepared to attempt it. So, we decided to focus on ethnicity in isolation, then on socioeconomic disadvantage and impaired capacity to consent. We knew that continuing this approach would result in numerous separate frameworks, which is impractical. We do have a PhD student, Azar, supervised by teams in Aberdeen, Liverpool, and Cardiff, who is exploring how to tackle intersectionality, particularly focusing on ethnicity, gender, and socioeconomic disadvantage. We hope to have something more operational in about a year, but it won't be perfect. There will still be room for improvement in this area.

**Question:** How do you sustain the engagement of underrepresented groups. How have you maintained these relationships moving forward?

**Answe**r: It can be challenging, especially with funding pressures. We keep our groups updated regularly. For example, we received funding in 2023 and again in 2024, allowing us to continue working with the same people who were already familiar with the project. We're also setting up a broader neurological disorders group that meets monthly. This regular engagement helps maintain relationships and keeps our contributors informed. Feel free to ask any follow-up questions.

**Question:** How do you reassure participants of your commitment to ethnicity inclusion. How can you effectively communicate this to build trust?

**Answer:** Building trust is crucial. It's about being transparent and honest, ensuring that your engagement is genuine and not tokenistic. If you need to include certain groups because of funding requirements, find meaningful ways to involve them. Sean, do you have any additional thoughts on this?

Trust is central. For example, in a project about vaccine hesitancy, participants expressed that they were curious and had questions rather than being hesitant. Listening to their perspectives and making changes based on their feedback is vital. It's about showing commitment through actions and being willing to adapt.

**Question:** How do you prepare researchers to engage with ethnically diverse groups without causing unintended harm. How can we be sensitive to the challenges faced by these groups?

**Answer:** Training researchers on respectful communication is essential. It's not just about talking to people from different ethnic backgrounds but about general bedside manners. Making mistakes is okay as long as you learn from them and move forward.

It does also come a bit with experience and it does come a bit with feeling more secure about when you're dealing with those things and it's like I do a lot of helping our researchers to get to that point.

We have to make our research count for everybody. We have to do better and we have to reach these people. So we have to continue trying and and and changing the ways in which we do things in order to get there because otherwise.
Respect is key. Researchers should be prepared to engage respectfully and be open to different perspectives. It's about having meaningful discussions and being willing to learn from each interaction.

**Question:** How can we promote the idea of breaking down aggregated data in trial publications to better reflect diversity?

**Answer:** It's crucial to present data as granularly as possible. Aggregating data into broad categories like "white" and "non-white" is unhelpful and can erode trust. We should aim to describe our populations in detail and avoid unnecessary aggregation.

**Question:** What is thedifference between diversity and inclusion in research. Is there a difference, and which is more important?

**Answer:** Inclusion is the action we take to ensure diverse participation, while diversity is the outcome. Both are important, but inclusion is the process that leads to a diverse research population.