

April 2024

English literacy as a barrier to participation in clinical trials

MAPLE REND Project

Introduction

The MAPLE project led by the Bristol Biomedical Research Centre, aims to co-produce an accessible patient information leaflet (PIL) that will aim to improve diversity in those who choose to take part in clinical research.

The first stage of this work is to understand the barriers preventing people taking part in clinical research and gain views on how existing, accessible PILs may address these barriers.

National Voices was commissioned to work with relevant charities and the people they advocate for to understand barriers to participation in clinical research, including, but not limited to literacy.

Participants

- 18 people attended a National Voices online workshop – a mixture of professionals working in health charities and people with lived experience of long-term health conditions and / or disability.
- A further five individuals were consulted individually in follow-up conversations.
- Of the discussion participants, five had been involved in a clinical trial; 15 had not been involved in a clinical trial; one had been involved as a researcher but not as a participant and two did not know or did not provide information.
- Of those who offered more information about their participation:
 - One had been involved in a clinical trial with diabetes and cardiovascular disease
 - One had been involved in clinical trials around HIV
 - One had been involved in an implementation trial

Direct feedback on the sample leaflets

Copies of two sample patient information leaflets were shared in advance of the event and again during the event. Leaflet A looked at medication aimed at people with autism. Leaflet B looked at food allergies. We asked participants for their thoughts on the sample leaflets, and recognised in advance that written leaflets may not be the preferred method to help some people engage with researchers.

We asked participants to share their own perspective or that of the community they work with when considering the questions:

- What did you think when you looked at these leaflets?
- Do you feel they were easy to understand?
- Do they have all the information you need?
- What would make them better?

Through a roundtable discussion we identified six common themes across both leaflet designs.

These were:

1. Many participants felt that the leaflets were better than others they had previously seen, in being simpler and shorter and in including pictures. Many were supportive of the idea of providing a more accessible leaflet.

“I completely agree with that approach of easy read being the right way forward.”

“The first time I read these leaflets I thought ‘oh brilliant, no one’s forced them to talk about GDPR’ because, as somebody who’s gone through the ethics process, there’s so many things that you’re told you have to include that aren’t necessarily what the person who’s reading the leaflet wants to hear. And so, in that way I felt that they’d done quite good work making it accessible.”

2. Several participants raised concerns about long words being used in the leaflets without explanation.

“As someone that doesn't have a learning disability and is not dyslexic, I found them easy to read and appealing. However [...], there's some really long words in there and putting them in bold doesn't mean that they're any shorter.”

3. Participants highlighted a failure to explicitly signal some aspects of inclusion.

“They don't do anything to address any of the barriers that trans or LGBTQ+ people would face.”

4. Participants told us that they thought the leaflets assumed a prior understanding of the nature of clinical trials. Some felt that this should be included in the leaflets, but others cautioned against including too much information in one leaflet.

“There was... an assumption that the people reading it would understand why you would have a placebo group and a non-placebo group. I could imagine [potential participants] might think... what's the benefit of taking part? Particularly if they don't have access to particular treatments that they would really want to.”

“[A] little bit more explanation of why having this design contributes to better quality of research [is needed] and why this means that more people can receive the treatment that they really need.”

5. Some participants felt that there were gaps in the information provided in the leaflets, especially around consent, value of the research and ongoing support. One felt that the leaflets did not recognise that many people are already experts in their own conditions.

“I didn't like either leaflet at all. Not easy to understand. Information on privacy, side effects missing etc. etc.”

“So, what's the ask in the first place? [Need to be] really upfront what's on the tin sort of thing? Not spoon-feeding but being really clear.”

“Before you get into the steps [of what is involved] being really, really clear, much more about consent as well. Is it obvious why would somebody want to do this?”

“Something about what the support offer is, there is no phone number... no email. I want to get in contact with someone.”

“[Patients need to know] where the information's coming from because some of us are kind of light years ahead in scientific research and comparing that around the world and they might actually know more than the leaflet that they're given and then obviously then I could see a loss of trust being formed.”

6. Several participants said that the samples appeared not to have been co-produced with potential users.

“My first point is ‘Who designed it?’ ‘Who decided what needed to be used?’ and certainly one of them has maybe fallen into the trap of putting some pictures against some still very complicated text, which I think happens a lot in information that's called ‘easy read’.”

Feedback on leaflet A

Leaflet A was based on the use of an anxiety medication in adults with a diagnosis of autism. It included photographic stock images alongside bullet-pointed sentences. It was broken down into three headings: ‘Summary’; ‘If you want to take part you need to’; ‘If you want to take part this is what would happen’. Four clear themes on this leaflet came through in discussions.

Use of images

Some participants were positive about the leaflet and liked the inclusion of photographs and simplified language. However, others raised concerns about the pictures, including whether they were suitable for the target audience and effective in communicating the meaning of the leaflet. It was

also raised that not all parts of the leaflet used pictures and that the large number of logos included seemed unnecessary.

"In my opinion, this looks good. It has quite a few photos, it doesn't have a lot of texts. The words are not very complicated, not very sort of professional, and they do explain things."

"The pictures I think are okay. Making sure you don't use too many pictures for every sentence, but it's [about] right. It's always best to have photos, symbols on the left side and writing on the right side. That's how we read."

"Oh yeah, that bit there [part of A leaflet with text only]. That does need to have some photos, symbols, I think."

"Why would you have so many logos? Is there a need for all of those logos on this information".

"There's no visual literacy at all to it. I mean [the pictures used] don't even make sense in terms of the sentences."

Co-production

There were clear concerns that the leaflet hadn't been co-produced with autistic people. Participants commented that the leaflet felt "patronising" and suggested that may have been an unintended side effect of being aimed at autistic people. There was also concern about using pictures at all, as often this can make information harder to read for autistic people. Finally, one person commented that the information was not tailored to the questions and concerns that people reading it may have, and the overall document had "no humanity...no narrative".

"I've kind of read it and I thought everything is there that you would want to see there, but also very, very long still. And maybe this is just me, I felt like really it was a little bit patronising and I was that thinking, is it because it's centered around adults diagnosed with autism?"

"If the trial is aimed at autistic people for example, then we hear a lot that autistic people don't find the pictures helpful always. So actually, they can make the page harder to read and confusing."

"They clearly didn't co-produce it, I assume."

“There’s no humanity, there’s no narrative as well. And people are very narrative. We think in stories we want to experience. And it feels like you are just going through a list of bullet points, if I’m honest, and people are patronising you whilst you’re going through them.”

Missing information

Several participants raised concerns about missing information, particularly around side effects, as well as the use of unexplained technical language which meant people may not understand what is being told to them.

“Reading it as somebody thinking about taking that medication [...] there's no talk about side effects or concerns and there's no real detail about what care you'll get. They're going to check in on you, but if you start getting chronic diarrhoea from your sertraline within the first two days, who are you meant to be calling? Who's looking after you? It's quite a big choice, isn't it? And there's no independent advocate that you can talk to about your concerns. So, I think they've really missed that personal aspect of it regardless of layout and information.”

“The [A] leaflet I think needs to be explained a little more. One example being when you write placebo you put the word ‘inactive’ in brackets but I think that need to be explain more what placebo/inactive means. Second example is what a ‘fair’ test means but ‘fair’ in what way could be explained more”

“Some of the words would need to be explained in easy read because there is medical jargon that needs to be explained.”

Inclusion criteria

Some participants highlighted the need to offer support to understand the leaflet if required, such as by offering alternative formats or translators. Concerns around the payment offered was also raised, with one participant saying that while payment is a useful incentive, the value stated doesn’t reflect the value to the researcher of participation and may unintentionally result in people choosing not to take part.

"I don't see if the leafleting includes options for people to add if they need, I dunno, interpreters if they need support and if they have any needs to participate."

"Would take a bit of time to take it all in and to read it all... [and] I'm normally good at reading, but for other people it'll take them maybe several [rereads]. And maybe for those who can't read, there needs to be an alternative like audio."

"Clearly the thing around the payment just made me see red [...] The fact of it, the way it's expressed... all get is a £10 gift voucher for answering these questions... It's very clinical actually. It's very cold. You could say, 'we recognize that your time and effort and as a thank you...'"

Feedback on leaflet B

Leaflet B was based on the use of food allergy tests for a skin condition. It used cartoon drawings to illustrate numbered sentences and broke the leaflet into three headings: 'What is the study about and what does taking part involve?'; 'Tell me more about taking part'; 'Tell me more about the food allergy tests and advice'. Three clear themes on this leaflet came through in discussions.

Preferred leaflet B to leaflet A

Most participants preferred the leaflet B to leaflet A and were generally positive about it, especially as the pictures used appeared custom-made for the leaflet's content.

"I thought [B] was really great as it very easy to read and I know the leaflet is primarily for the parent/carer but as it has so many good pictures it would be easy for a parent/carer to help to explain to the child."

"Think that's nicely laid out and colourful and it's like a story."

"I think the second one [B] was better, more easy, I think, easy read than the first one [A]."

Inclusion

Some participants flagged that the leaflet could do more to directly signal inclusion to families, especially diverse ones.

“LGBTQ+ people are parents and carers and how they're going to be treated by clinicians as the parent and carer if their child is part of a trial is a real consideration as well. And having assumptions made about them, about their child is a big barrier. Where the pictures show representation of people with different skin colours, there was no representation of different types of families.”

“I didn't like the words about parents in the [B] form, as parents are bound to wonder or notice a cause when eating certain foods. It may alienate parents.”

Overly simplified

Several participants felt that the leaflet was oversimplified, resulting in missing information and the risk it patronises readers.

“I think they've tried to.... Do some visual literacy around it. I personally wouldn't be drawn to this. I think it's very aimed at, I would say, children.”

“I think it's stuck between an adult world and a child's world.”

“I'm not sure there's enough information in here. It seems to be, yeah, I think they tried to really simplify it, which is great in some aspects. But, so for instance, number eight, [which said] ‘we'll follow up everyone for nine months’. What does that really mean?”

“Is there anything about harm and risk? I just don't think there's enough information that would make me feel confident.”

Wider learnings on patient information leaflets

In a wider discussion, participants raised a number of broader points around improving patient information leaflets and the wider provision of information to people to support inclusion in clinical and research trials. Five key learning points were taken from this.

1. General support for written leaflets

Participants were clear that inaccessible patient information leaflets could be a barrier to participation in clinical and research trials, and there was consensus that written leaflets need to be as accessible as possible. However, notwithstanding the limitations of some leaflets, many participants felt that leaflets **were** important in encouraging and enabling people to participate in clinical research and trials, especially because they gave people a source of information which they could refer back to.

“People did like being able to have information that they could take away and read. And I think a lot of people do still like that [...] Because then they've got time to really think about it and reflect on it.”

“I think there's lots of virtues of leaflets. I think there's something really, really tangible about having something to hold and something to look at, something to refer back to. But that needs to be the right thing. That needs to be something that's going to give them the right level of information to make that decision.”

“When we're thinking about writing things, actually the national reading age is nine years old.”

“I think the shorter and more accessible they can be the higher the chance of success.”

“A video is good for that initial kind of discussion and so on at leaflet is also helpful because people can confirm what they've heard, what they've seen in the video, they can then later on stay and look at it and process the information more.”

2. Layered approach to information recommended

There was a recognition that a “layered” approach to information provision would be welcome. For example, Learning Disability England is working on a process called “staged consent”. The representative from this charity explained it as providing a “kind of summary of the study in the first leaflet, but you make it clear that there's more to come and there are places you can look for more information.”

This approach would also support concerns whether information, even if presented in alternative media, is in itself enough to reduce participation barriers. A layered approach could ensure better signposting to other areas of support people may need to hear from before agreeing to take part. This could include opportunities such as conversations with people from similar backgrounds already involved in trials and an ability to ask questions to their own care team about how their care would be affected or managed if side effects were to develop. It would also provide an opportunity to uncover additional support needs, such as the availability of translators.

“Obviously leaflets are good, but you could also maybe offer up a follow-up phone call or a follow-up video call if they have any more questions or stuff like that.”

“Perhaps link to patient groups as well, so they've got a community that they can join rather than feeling left alone with a diagnosis or research or, I know obviously they can't talk to other participants, but I think they need a point of call.”

“Leaflets should be a starting point for a conversation with people around you to support you to make decisions.”

“So I think I would say 30% of written information supports people making a decision. The rest of it is, I suppose, the exposure to the opportunity. People in those settings, advocating, supporting, conversation around [it].”

3. Need for alternative formats

It's clear that information needs to be provided in alternative formats – including audio and video options - and there is a need for ongoing work to encourage the adoption of these formats in clinical research. It was also recognised there is a wider context to better accessibility with participants

recognising that the lack of widespread adoption of the Accessible Information Standard and the Reasonable Adjustment Flag act as other barriers to participation.

“With the INCLUDE study I was involved in, we took the patient information sheet and information produced five video podcasts in different South Asian languages as a way to make it more accessible to reach those communities.”

“So, my experience in the clinical trial was I had to ask for my information to be emailed to me. They were not able to do videos and get them past the clinical [guidance] or whatever they needed to do. [...] That would've helped the process for me in a massively different way.”

4. Research must address real lives

Participants highlighted the need for patient information leaflets to address people's real concerns and support their real lives rather than reflect issues that researchers are most interested in. For example, participants highlighted a concern that leaflets are not produced with the needs of the people participating in trials at the centre, but rather for researchers to meet legal requirements.

This links into concerns that go beyond PIL co-production and reflect the need for the whole process, from research idea to trial initiation, to be co-produced with targeted communities to improve sign-up and research outcomes. For example, queries were raised that related more to the design process than the leaflet itself, such as how carers would be involved in the process and whether the NHS had capacity to help if side effects arose.

“Does it need to start from the perspective of what questions they might have? And is that then again, does that then go back to having good PPI [Public and Patient Involvement] involvement in the design.”

“Often the leaflets feel like they're written to protect the researcher or the trial not to properly inform the people who might take part... it's often written to pass somebody else's test.”

“The leaflets fail to reflect how people lead their lives, make choices and interact. How often do you make a choice around a leaflet as compared with social media groups, YouTube etc.”

“It's got to be a much more sophisticated process led by and informed by the people who were involved and really thinking about who you're writing it for rather than to just tick a box and go, we did an easy read version.”

“I think actually thinking about it as you say from a dementia perspective, [...] and then there is something about what does it mean [or them] as well in terms of how can we support... because it feels like kind of an additional responsibility on them.”

“What information does the GP need to support that conversation when they're handing that leaflet out, or when that leaflet is being made available in their practice?”

“I think the key word for me coming out is co-production because of the subtleties that you might not pick up on. [...] And that's got to be budgeted for and compensated for and recognised that it is work and it takes people's time and energy.”

“Actually, go visit the people themselves, the groups, self-advocacy groups, and get an idea, their own opinion about these things.”

5. Wider research barriers need considering

Many other barriers to participating in research were raised during the whole session, many of which fell outside of the scope of this inquiry. Attitudinal barriers were significant, with fear and mistrust, often due to historical legacies, raised as a concern for participating, alongside a lack of awareness that trials were happening or knowing other people who took part in trials. These barriers were compounded by financial, geographical and digital exclusion concerns.

Attitudinal quotes

“There's a lack of information and awareness about clinical trials, particularly in the [South Asian community] groups I work with.”

“A big barrier that we've noticed is self-selection bias. We run focus groups with people who have lung conditions but it's almost always full of white middle-class women and we believe it's due to ethnic minorities and people

living in deprived communities not feeling that it's something that is relevant to them.”

“The clinical trial units, again, they and the researchers don't reach out into the communities as well as they should do, so they don't have awareness of where to go, how to reach those communities that they need to.”

“There's a real lack of trust of medical professionals and establishments within some parts of the trans community. Hence the need for someone to almost say 'we've vetted [the researchers] and they're ok'.”

“There is a genuine concern about clinical trials and about trials in general from the Roma people because it's still in our kind of living memory of tests being done on us without our consent for various reasons. We've seen, for example, not to be too negativistic here, but we've seen cases as early as 2004, 2007 with Roma women being forcibly sterilised in Czech Republic, Slovakia.”

“Specifying 'we particularly encourage people from [x, y, z groups] to take part; The representation shown in any literature or adverts, do people see them represented; Inclusive forms (would a non-binary person feel able to fill the form?); Sharing requests through trusted organisations within the community; Co-production and PPI - this [all] helps make sure that the research is sensitive to people's needs and information [provided] has FAQs answering the concerns from specific communities”

Wider barriers

“I think coming from the perspective of what it would be like for an individual to make that decision [to take part]... it's not just [concerns] around the clinical perspective or... around the medical side of things. There's a lot of social decisions that need to be made as well.”

“There would be travel and accommodation, there would be things like having to take time off work, particularly affecting those in low social demographics and childcare, all of those kinds of things [will affect someone's decision to take part]. The practical logistics of getting yourself out of your normal day-to-day circumstances to moment be in hospital all day.”

“Not a lot of research is happening in primary and community care settings. Often a lot of research is taking place in hospital settings.”

Conclusion

We saw positive support for the attempt to make patient information leaflets more accessible and that the ability to take away the leaflet to consider the opportunity to take part in clinical research is a strong benefit. It was felt that while the use of images made the leaflets easier to understand, they had to be visually literate to the information provided. The wording in the leaflets also had to strike a better balance between being simple and making people feel patronised.

There was a clear need to ensure the leaflets contained more information, with themes around consent and side effects coming up in discussions multiple times. It was also felt that people needed to know how and who they could contact if they had concerns over side effects or wanted to hear from peers before agreeing to participate.

More information could be provided via a cascading or layering of information approach, with people signposted to additional information or alternative resources after reading the initial leaflet.

A need to consider how to provide information in alternative formats must also be embraced by the clinical research community, with audio and video seen as important ways to bring people on board. Consideration of who presents these may also help improve signup from diverse communities. There must also be a clear commitment to providing alternative formats for those with additional communication needs.

The vast majority of attendees believed the two sample leaflets would be very significantly improved through genuine co-production with the communities the research targets.

Participants also wanted this co-production to go much further and be extended to the entire research process, from initial design to trial initiation. It was felt this could help overcome wider participation barriers that were not within the scope of this project.

Acknowledgements

We would like to thank National Voices' Associate Kate Jopling for her significant contributions on this project.

We would also like to thank our member organisations and people with lived experience for sharing their insights and inputting on this work, including The Nerve of My Multiple Sclerosis, Macular Society, TransActual, Thomas Pocklington Trust, Roma Support Group, South Asian Health Action, BHA For Equality, Blood Cancer UK, British Heart Foundation, Age UK, Rethink Mental Illness, National Voices' Lived Experience Partners, and others.

This activity was funded through the ICS Research Engagement Network (REN) development programme. The views expressed in this publication are those of the author(s) and not necessarily those of NHS England or the Department of Health and Social Care.

National Voices

National Voices is the leading coalition of health and social care charities in England. We work together to strengthen the voice of patients, service users, carers, their families and the voluntary organisations that work for them. We have more than 200 members covering a diverse range of health conditions and communities, connecting us with the experiences of millions of people.

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