

# Insight Report: Online public involvement session on the views of parents with experience of preterm birth in relation to a personalised medicine approach to the treatment of preterm birth using amniocentesis.

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## Background

The National Institute for Health Research (NIHR) currently funds 20 Biomedical Research Centres (BRC) across England. These are collaborations between world-leading universities and NHS organisations that bring together academics and clinicians to translate lab-based scientific breakthroughs into potential new treatments, diagnostics, and medical technologies. The Imperial BRC is a collaboration between Imperial College London and Imperial College Healthcare NHS Trust. It has twelve research themes, of which Pregnancy and Prematurity is one.

To assist with a project being undertaken by this theme, the Imperial College Patient Experience Research Centre (PERC), a core facility of the Imperial College BRC, facilitated an online discussion session to gain the perspectives of people with experience of preterm birth (both women and their partners).

Public Involvement is defined by the NIHR as “research being carried out **‘with’** or **‘by’** members of the public rather than **‘to’**, **‘about’**, or **‘for’** them.

‘Public’ includes patients, potential patients, carers and people who use health and social care services as well as people from specific communities and from organisations that represent people who use services. Also included are people with lived experience of one or more health conditions, whether they are current patients or not.

### Approach and purpose

Public involvement is considered a crucial component of the development of this research.

The aim of the session was to understand their views on research being undertaken by Dr Daniel Short, Dr Nishel Shah, and Professor Mark Johnson as part of a project to assess the feasibility of using a bedside precision-medicine based approach to identify and treat bacterial pathogens in women with threatened preterm labour. This research is funded by the preterm birth research charity ‘Borne’, The Joint Research Committee of Chelsea and Westminster Hospital, the CW+ Charity, and the Westminster Medical School Research Trust.

As part of this online session we particularly wanted to understand the following from individuals with lived experience of preterm birth:

- a) thoughts on proposed research on preterm birth?
- b) barriers or attractions to taking part in this type of research
- c) their thoughts on the use of amniocentesis in the setting of threatened preterm labour, and particularly if they would consent to amniocentesis if they were offered it as part of the investigation and management of threatened preterm labour.

### Call overview and agenda

An online discussion was hosted on 2 August 2023 from 1:00pm to 2:30pm via Zoom Pro and was attended by 6 members of the public (see **Appendix 1** for demographics).

The agenda of this session was as follows:

- Provide an overview of the research project. An introduction was provided to the project and attendees were given the opportunity to ask questions (see **Appendix 2**).
- Give attendees an opportunity to ask questions
- Facilitate group discussion about the following questions. All attendees joined the same conversation hosted by one of the researchers and a public involvement facilitator from PERC

- a. What information would you like to know to help you make the decision about whether to take part in this research study or not?
- b. What questions would you have for the research team about the procedure, about what happens next, about yourself or your baby?
- c. Is there anything that could be put in place to support people to take part in research like this?
- d. Is the outline of the research project presented today acceptable to you as people with experience of preterm birth?

### Feedback

Following the session, attendees were sent an online feedback form to comment anonymously on ways the session could be improved and to give any additional views on the topics covered in the session. Comments received relating to the questions posed in the discussion session were integrated into the Key Insights Summary. Attendees were also given the opportunity to sign up for future public involvement, engagement, and participation opportunities. General feedback on the session is summarised at **Appendix 3**.

### Payment

In accordance with NIHR payment guidance, participants were paid £42.50 for their time including a £5 contribution to Wi-Fi/data for accessing a virtual meeting.



### Attendee recruitment

An email invite and flyer was disseminated through the following routes:

- Pregnancy and Prematurity Community Partners
- To relevant sign-ups to Patient Experience Research Centre mailing list (expressing an interest in this research area)
- Through Experience Research Centre Twitter and Instagram

## Key Insights Summary

Attendees of the discussion session on 2 August 2023 provided responses to the following questions posed and their insights have been themed under the questions below.

### ***What information would you like to know to help you make the decision about whether to take part in this research study or not?***

Attendees wanted to know:

- About the **safety** of amniocentesis in relation to **miscarriage, bleeding, or injury to the baby**.
- If amniocentesis might **hasten the onset of labour**.
- If information from the **neonatology staff** would be available to help them make decisions.

### ***What questions would you have for the research team about the procedure, about what happens next for you or your baby?***

Attendees wanted to ask about:

- the **side effects of antibiotics and medications** in general on the baby, including whether **guidelines** for antibiotic use were available.
- the **pain associated with amniocentesis** being performed, and the **rating of severity of the pain**.

Attendees would have also taken the opportunity to ask questions about **risks of amniocentesis** again, even if written information had been provided. Some said it would help to **contextualise the process**.

### ***Is there anything that could be put in place to support people to take part in research like this?***

Attendees wanted to know:

- If there were any videos or similar, to help **visualise what an amniocentesis looks like**
- What the **continuity of care** would be for someone who agreed to take part, and if there would be a **specific point of contact**.
- If they would get **feedback** about their participation with an **exit consultation or debrief**, which could make participation a more positive experience. Feedback was a recurring theme during the discussion.
- If **appointments would be long enough to discuss all their concerns** during their follow up.
- If they would have **access to the research team between appointments** to clarify any points by phone call.
- If there was a way of **speaking to someone who had undergone amniocentesis in order to better understand the process**.

Attendees were concerned that:

- The anxiety surrounding the whole situation of **possible preterm birth might be too stressful to consider participating in research**.
- **Additional time commitments when participating in research** might make it unattractive to some people, however a **clear pathway of appointments** might be helpful.

- One attendee said ***“Just the idea of research makes you think, ‘oh, I’m gonna have to do a lot more here”***.
- **Family and partners may not be on board with the idea of research in pregnancy** which could change someone’s mind about taking part.
- They might wish to **withdraw from the trial, but that would mean not completing the course of antibiotics.**

***Is the outline of the research project presented to you today acceptable to you as people with experience of preterm birth?***

Attendees who answered this question said the following:

- *“I definitely think so. I don’t see any big red flags that would make me concerned.”*
- *“It’s really well put together and makes sense.”*
- *“I think the project is very important, beneficial, and very straightforward.”*
- *“I think people will be very cooperative and willing to help.”*
- *“I would agree to take part if there were enough information and reassurance around antibiotics”*

### How we will use the insights

The insights gained from this public involvement session have highlighted the following which we will address as follows

- **The importance of the safety of amniocentesis being paramount to patients**
  - To address this, we have performed a systematic review of the literature to assess the safety profile of amniocentesis in the context of preterm birth prevention. The results are reassuring and will inform the counselling of patients. This information will also be included in the patient information document, and the study consent form.
- **The need for information about the practicalities of the amniocentesis procedure**
  - Time will be given for adequate discussion with clinicians experienced in conducting amniocentesis to ensure that the patient is making the correct decision for them.
  - We will provide useful, usable information at the time we approach people in order to assess if they would be willing to take part in the study.
- **The need for continuity of care**
  - Follow up during the trial will be with the research team. This will provide continuity of care. The Research Midwives will act as a specific point of contact.
- **The need for feedback about the research**
  - We will be following every patient from the time they present to hospital with suspected preterm labour to the birth of their child, and they will be offered a full debrief appointment at a time convenient to them to discuss their experience and birth. We will work with Borne (our charity funder) to disseminate the results of the research via their experienced communications team. It was discussed that results of research can often take years to complete.

- **The need for the involvement of the neonatal team from the beginning**
  - It is standard of care in our unit for neonatologists to engage in discussions with patients who attend hospital at high risk of preterm birth. This will be no different during our trial – all patients will have the opportunity to speak to a member of the neonatal team.
- **Reassurance about the impact of follow up during the trial.**
  - Follow up will be at a time convenient to the patient. We expect some patients will have their baby shortly following their presentation, and others may find that the reason they attend hospital in the first instance, rather than the trial itself, keeps them in hospital for a period of time.

## Appendix 1: Demographic of public attendees

**Table 1: Demographic characteristics provided during event registration for discussion group (N=6)**

| Characteristics                               | n (%)    |
|-----------------------------------------------|----------|
| <b>Age groups (in years)</b>                  |          |
| 18-24                                         | 0        |
| 25-34                                         | 3 (50)   |
| 35-44                                         | 0        |
| 45-54                                         | 3 (50)   |
| 55-64                                         | 0        |
| 65 – 74                                       | 0        |
| 75+                                           | 0        |
| Prefer not to say                             | 0        |
| <b>Gender</b>                                 |          |
| Female                                        | 5 (83.3) |
| Male                                          | 1 (16.7) |
| Prefer not to say                             | 0        |
| <b>Ethnic group</b>                           |          |
| <b>White</b>                                  |          |
| English/Welsh/Scottish/Northern Irish/British | 3 (50)   |
| Irish                                         | 0        |
| Gypsy or Irish Traveller                      | 0        |
| Other White background                        | 0        |
| <b>Mixed/Multiple Ethnicity</b>               |          |
| White and Black African                       | 0        |
| White and Black Caribbean                     | 0        |
| White and Asian                               | 0        |
| Other Mixed/Multiple background               | 0        |
| <b>Asian/Asian British</b>                    |          |
| Indian                                        | 0        |
| Pakistani                                     | 0        |
| Bangladeshi                                   | 1 (16.6) |
| Chinese                                       | 0        |
| Other Asian background                        | 0        |
| <b>Black/African/Caribbean/Black British</b>  |          |
| African                                       | 1 (16.6) |
| Caribbean                                     | 0        |
| Other Black/African/Caribbean background      | 0        |
| <b>Other</b>                                  |          |
| Arab                                          | 1 (16.6) |
| Any other ethnic group                        | 0        |
| Prefer not to say                             | 0        |
|                                               |          |
|                                               |          |

## Appendix 2: Questions/comments asked by attendees during the session.

### Questions answered during call:

- Is there a risk of miscarriage with amniocentesis in this setting?

Thank you for your question. Yes, as I kind of alluded to in the, in the presentation at the 15 weeks mark we quote kind of 1-2% increase in the background risk of miscarriage. Which is, you know, a very concerning thing for someone to read about, because as you say, the first thing that anyone will do when they're asked if they want to consent to amniocentesis is have a quick look up, do some reading and that jumps out. But with the research that we've done having a look at amniocentesis in the third trimester and looking at amniocentesis particularly in the context of preterm labour we have identified that there was no lasting harm to any mums or babies. So, we're not expecting miscarriage or, any harm to come to the babies in these circumstances.

- Might amniocentesis worsen the clinical picture, such as causing labour?

With regards to the question about hastening labour, that is also a concern that some care providers have. One of the things that's been very difficult to extract from the data that's published out there is that we're doing these in people who already have a really high risk of having a preterm birth. Your waters going somewhere in the region of about half of people will have their baby within 7 days after the waters going. And the people presenting with contractions before their due date as well. Many will go on to have a baby. So, it's very difficult to delineate. But that said from the 1,000 cases that we've looked at we don't think that there is a big cause for concern that we would hasten labour or make labour happen quicker.

- Will the amniocentesis be performed more than once during the research?

We are just proposing that we do it once at the time that people present. So just once at the time of the first presentation to the hospital with either the waters going or the first presentation with the signs and symptoms of preterm labor. There are studies out there that do, that have done repeated amniocenteses over many weeks to, as you say, mainly to try and identify the eradication of the infection that they've identified the first time round. We're not proposing to do that, we'll do one and one only.

### Appendix 3: Post-session Feedback from attendees (n=4/6)

In the post-session anonymous online feedback form emailed to attendees they were asked questions about how they rated the session, its clarity, what they enjoyed the most, and their motivations for joining the session. Respondents were also asked about their thoughts of the project, the questions they would have if they were approached to be part of the study, and the barriers to joining.

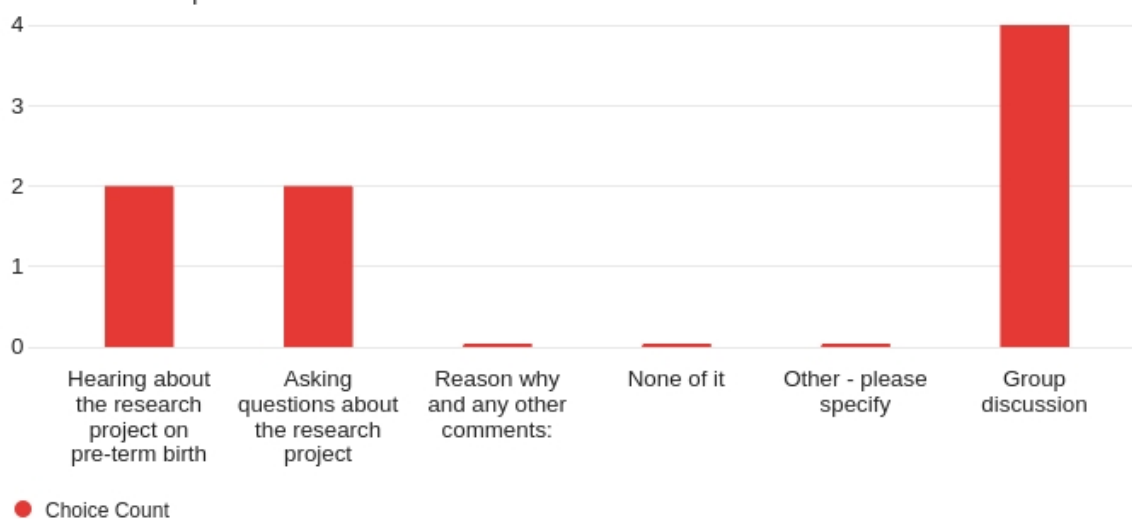
Q1 - On a scale of 1-5, how would you rate the session?



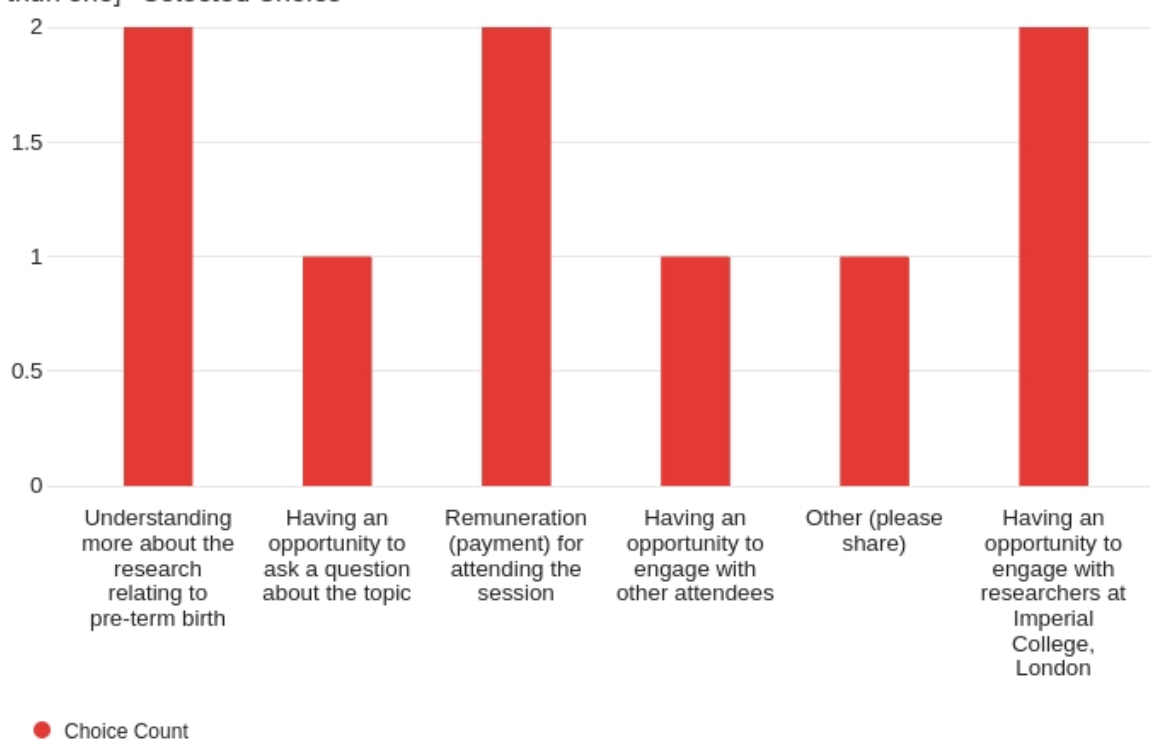
Q2 - Did you find the presentation easy to understand? - Selected Choice



Q3 - What did you like most, if anything, about the session? Feel free to include the reason why in the free text box provided below. - Selected Choice



Q4 - Please tell us your main motivations for attending the session? [Feel free to choose more than one] - Selected Choice



Q5 - Do you have any further comments about the session?

No data found - your filters may be too exclusive!

No answers.

**Q6.1 - Reflecting on your own experiences, if you were approached to take part in this study what would be your initial thoughts be?**

Reflecting on your own experiences, if you were approached to take part in this study what would be your initial thoughts be?

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I would agree to take part if there were enough information and reassurance around antibiotics

**Q6.2 - What questions might you have for the research team before taking part? and/or what information would help you to make the right decision for you?**

What questions might you have for the research team before taking part? and/or what information would help you to make the right decision for you?

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What's the long term side effects for me and baby in taking antibiotics if baby is born will they require antibiotics still, is there a chance these antibiotics would have created a resistance in baby meaning they would be more difficult to treat once born, the risks of the amino and my specific risk for delivering early at that time backed up by evidence like acti prom etc

**Q6.3 - What do you think might be some of the barriers to taking part, and how might the research team overcome these?**

What do you think might be some of the barriers to taking part, and how might the research team overcome these?

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Worry's about amnio it's a well documented procedure lots of people know a little bit about. Fear at a stressful time, lack of understanding

**Q7 - Do you have any further comments you would like to make on what was discussed during the session?**

No data found - your filters may be too exclusive!

No answers.