Participant Information Sheet

Study title: Maternal vaccination uptake in socially and ethnically diverse communities: a qualitative study among pregnant/post-partum women and service providers in London to inform the co-production of future health interventions

Short title/acronym: **V**accination **i**n **p**regnancy - **id**eas, **e**xperiences and **a**ttitudes, **L**ondon (VIP-IDEAL)

Dear potential participant,

We would like to invite you to take part in a research study. Before you decide whether you would like to take part, it is important for you to understand why the study is being done and what is involved in participation. Please take some time to read the information below carefully and discuss with others if you wish.

If you have received this letter following a miscarriage, please accept our sincere apologies. If receiving this letter has distressed you in any way, please contact the Miscarriage Association helpline on 01924 200799.

What is the purpose of the study?

Our research team from the London School of Hygiene and Tropical Medicine at the University of London is conducting research in South London. We would like to find out what types of vaccines women have been offered during pregnancy and what they think about these different vaccines, including vaccines against whooping cough, flu and Covid-19.

In some areas uptake of one or all of these vaccines has been low, and we would like to find out what the reasons are and if people have any suggestions on things that could be improved in the future, such as the way these vaccines are offered to pregnant women. We particularly want to make sure that we get the views of people from a range of social and ethnic backgrounds to ensure that the experiences and concerns of a wide range of people living in South London are understood and considered in the future. The information from this study could help researchers to think of ways to develop or improve health interventions and programmes together with different service providers and members of the public. The research may also influence future decisions regarding new vaccines that are currently being developed.

Why have I been asked to take part?

You have been invited, because you are either currently pregnant or have recently given birth to a baby (any time after April 2021) and live in South London, where uptake of vaccines during pregnancy has been low.

Do I have to take part?

No. It is entirely up to you to decide whether to take part. If you do not want to take part, that is ok. If you decide you want to take part but then change your mind, you can withdraw at any time without giving a reason. Whatever you decide, your medical care will not be affected in any way.

What will happen to me if I take part?

After you have had all your questions answered and have agreed to take part, we will contact you by your preferred method (e.g., phone, email, post, or text) to arrange an interview with a member of the research team (Dr Sima Berendes or another qualified and experienced research team member). Alternatively, you could also join a focus group discussion (please see info below).

The interview can be conducted either over the phone, via secure video conferencing (e.g. Zoom, Skype or WhatsApp video call), or in person at a mutually convenient venue (e.g. in a private room at a local community centre, or another safe, quiet public place, where one cannot be easily overheard, or at your home if possible), whichever you prefer.

What will happen during the interview or focus group discussion?

If you are meeting the researcher in person for the interview or group discussion, we will ask you to sign a consent form stating that you understand what is involved in your participation and that you are willing to take part. If the interview or group discussion is done via telephone or video conferencing the researcher will read the consent form to you and ask if you would like to take part. (You will also be able to read the consent form yourself beforehand, and we will give or send you a copy of the form signed by the researcher if you wish.)

With your permission, the interview or group discussion will be audio-recorded. Everything you say in the interview will remain confidential unless there are immediate safety concerns , as explained in detail below. We will also take notes during the interview.

As mentioned above, you have the choice between participating either in an interview or in a group discussion.

The confidential interview will last about 45 to 60 min. It will be a relaxed and informal chat about you, your current or recent pregnancy, your attitudes towards different vaccines, your experiences with the healthcare you received and possible ways to improve it in the future.

Instead of participating in an interview, you could also join a focus group discussion which gathers about six to eight pregnant or recently pregnant women together. The group of participants will be guided by a group facilitator (Dr Sima Berendes and/or possibly another qualified and experienced research team member) who will introduce the topics for discussion and help the group to participate in a discussion amongst themselves about their attitudes towards different vaccines during pregnancy. During the discussion women will also have the opportunity to share their experiences with the healthcare they received and make suggestions on possible ways to improve it in the future. The discussions will be confidential, nothing discussed should be repeated outside the group, and participants will be asked to allow everyone to express their opinions without being judged.

Will you compensate me for the time this takes?

We will give you £20 (either in cash or as a gift voucher) for completing the interview or focus group discussion as a thank you for helping us. If you prefer to participate in person rather than over the phone or video conferencing, we will compensate you for your travel costs.

What will I have to do?

If you agree to take part you will need to provide consent and complete the interview.

What are the alternatives? You do not have to take part.

What are the disadvantages in taking part?
Completing the interview will take up some of your time. (We do not offer advice on vaccinations, but can refer you to other organisations for advice and support)

What are the possible benefits of taking part?
Your interview will help us find out more about the experiences and opinions of pregnant and recently pregnant women regarding vaccinations during pregnancy, what the reasons for low vaccination uptake in South London are, and on how things could be improved in the future. It will also be an opportunity for you to talk about your experiences and views to an attentive listener. At the same time, you will be contributing to a research study.

Will my partner, a family member or friend be able to join?
Interviews are usually conducted with the participant alone, but if you want to attend with another person, or if you are in need of support for any reasons you are free to bring another person. If so, please let us know beforehand, if possible.

If you decide to join a focus group discussion, and wish a pregnant or recently pregnant friend to attend the same discussion, please let us know beforehand, so we can arrange for you to be in the same group if possible.

What if I need language support?
Please let us know if you need this information sheet to be translated into another language and/or if you need an interpreter for the interview or focus group discussion and we can arrange this. If you think you do not need an interpreter, but cannot speak and understand as well as an average native speaker, the researcher will make sure to speak slowly, repeat questions in different words and/or try to find other ways to communicate and make you feel comfortable.

Can I change my mind about taking part?
Yes. You just need to tell the researcher that you don't want to be in the study anymore and we will no longer contact you. If you change your mind during the interview or focus group discussion, tell the researcher. They will then stop the interview or interrupt the focus group discussion and you can leave at any time. You do not have to give a reason for wanting to end the interview or leave the focus group discussion. If you withdraw from the study after having completed part or all of the interview or focus group discussion, we will need to use the data collected on you up to this point in time. Similarly, if you lose capacity to consent at any point in time, we will need to use the data collected on you up to that point in time. In summary, you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

What if there is a problem?
You can contact a member of the research team if there is a problem (Dr Sima Berendes, tel. 078 9515 3469, or email sima.berendes@lshtm.ac.uk). If you remain unhappy and wish to complain formally, you can do this by contacting: Patricia Henley at rgio@lshtm.ac.uk or +44 (0) 20 7927 2626, who is the head of the Research Governance and Integrity Office at the London School of Hygiene and Tropical Medicine and is independent of the research team.

Will my taking part in this study be kept confidential?
Yes. All information you provide in the interview will remain confidential. We will need to use information from you for this research project. This information will include your name and contact

details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.
No one will be able to trace anything said in the interview back to you as an individual. The researchers will also keep all information provided during the focus group discussion confidential. With your permission, we will audio record the interview/group discussion. The audio-recording will be transcribed by the researchers or a professional transcription service provider, who will be bound by a confidentiality agreement. The transcript from the interview/group discussion will be stored anonymously, that is, your personal details won't be connected to what you say in the interview/group discussion.

If you choose to tell us that you are at risk of harm, for example your partner has kicked, hit, slapped or otherwise physically hurt you or your child, then we would want to help you. We would prioritise your safety. Dr Cari Free (a GP) would contact you and check it is convenient to talk. However, for your own/your baby's / your child's safety we could not promise to keep that information confidential. Everything else you say in the interview or focus group discussion will remain confidential.

What happens when the study stops?

After we have completed interviewing participants, we will analyse what everyone has said to help us better understand people's views, opinions and experiences and think about possible ways to improve how pregnant women are told about and offered different types of vaccinations in the future.

What will happen to the results of the research study?

The results will be published in a scientific journal so that other people know about it. If you would like a copy of the results once they are available you may request a copy via email (sima.berendes@lshtm.ac.uk). We will also include a link to the report on our study website: www.lshtm.ac.uk/vip-ideal
Your personal information will not be included in the study report and there is no way that you can be identified from it.

Who is organising and funding this study?

The London School of Hygiene & Tropical Medicine (LSHTM) is the sponsor for the research and they have full responsibility for the project including the collection, storage and analysis of your data, and will act as the Data Controller for the study. This means that we are responsible for looking after your information and using it properly. The LSHTM ISSF Pump Priming Grant with funding from the Wellcome Trust is funding this study (ref: 204928/Z/16/Z).

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at https://www.lshtm.ac.uk/files/research-participant-privacy-notice.pdf
- at www.hra.nhs.uk/patientdataandresearch
- at https://www.hra.nhs.uk/information-about-patients/
- by asking one of the research team members
- by ringing the LSTHM Data Protection Office, Tel: +44 (0)20 7927 2708
- by sending an email to the LSHTM Data Protection Office: DPO@lshtm.ac.uk

Who has reviewed this study?

All research involving human participants is looked at by an independent group of people, called a

Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The London School of Hygiene and Tropical Medicine Research Ethics Committee. The NHS London - South East Research Ethics Committee has also reviewed the study and have agreed that it is okay for us to ask people to take part.

Further information

Thank you for taking time to read this information sheet. If you think you will take part in the study we will ask you to read the consent form. Prior to participating in the interview you will either need to sign the consent form or (if the interview is conducted remotely) the consent statements will be read to you by the researcher and you will need to agree to them prior to the interview.

If anything you have read is not clear or you would like further information, please contact Dr Sima Berendes (Tel 078 9515 3469 or email sima.berendes@lshtm.ac.uk) or any other study team member (see contact info below) who can answer any questions you may have about the study.

Thank you for taking the time to consider taking part.

If you would like further information please contact the VIP-IDEAL Research Team

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If you would like to take part, please contact Dr Sima Berendes

via text/ WhatsApp/ phone (Tel 078 9515 3469) or email (sima.berendes@lshtm.ac.uk)