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Participant Information Sheet (PIS)

Part 1

Study title: Facilitating catch-up vaccination in adolescent and adult migrants and Black, Asian and Minority Ethnic (BAME) communities in UK general practice

Chief Investigator: Dr Sally Hargreaves

*We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it will involve for you. Please take time to read the following carefully and discuss it with others if you wish. **We will go through the information sheet with you and answer any questions you have.** We'd suggest this should take about 10 minutes.*

Part 1 of the PIS tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The purpose of this study is to offer catch-up vaccination to anybody who may not be fully immunised, and to explore people's views on vaccination, primary care and their experiences of COVID-19. Catch-up vaccination is any vaccination given after the recommended age, in the case that a vaccination was missed or is no longer protective. Evidence suggests that in the UK, adults and adolescents who were born overseas are less likely to have had all of their recommended vaccinations. This may also be the case for people of non-White ethnicities, but evidence is currently limited.

We are conducting this study to test whether, by prompting the primary care team to check a patient's vaccination status, we can help identify individuals who have not received all of their recommended vaccinations and refer them on to routine care, helping to bring them in line with the UK schedule and reduce their risk of contracting vaccine-preventable diseases. If you are missing any vaccinations you will be offered catch-up vaccinations by staff at your GP Practice. However, you don't need to participate in the study to receive these vaccinations if you don't want to.

We are also running a subsequent sub-study to understand views on catch-up vaccinations from people who have recently moved to the UK and Black and Minority Ethnic (BAME) communities. We're exploring general opinions on vaccination, experiences in primary care and strategies to increase the accessibility of vaccines to people who need them. We would also like to explore how certain members of the UK population have been affected by COVID-19.

Why have I been invited?

We are interested in learning about the experiences of, people over the age of 16 who were born overseas and recently moved to the UK or who were born in the UK and identify as BAME. You have been invited because you may be part of one of these groups.

Do I have to take part?

Participation is voluntary and it is up to you to decide whether or not to take part. You can participate in the first part of the study without participating in the follow-up interview, and vice-versa. You can also receive the catch-up vaccinations you need without taking part in the study, if you wish. We will describe the study and go through this information sheet. If you do participate, you will be given this information sheet to keep and asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or not take part will not affect the standard of care you receive. As an alternative to signing and returning a consent form you can give consent over the telephone. If you would like to do this, the consent form will be read aloud to you. To join the study you will need to verbally confirm that you consent to each of the items on the consent form. With your agreement the person interviewing you will sign the Consent Form on your behalf and a copy of the completed form will be sent to you by email or post.

What will happen to me if I take part?

Taking part will involve answering a few questions about yourself and your vaccination history, which might take place during your new patient health check or another appointment at the GP practice. You can pick a date and time that is convenient for you. First, we'll ask you a couple of standardised questions about your ethnicity, nationality, vaccination history and any history of vaccine-preventable diseases that you may have had. Depending on your answers, the nurse may offer you catch-up vaccination. It is up to you whether you accept these vaccinations and if it is your wish the nurse will refer you to make an appointment. We plan to collect follow-up data relating to whether you went on to receive the vaccine(s), and how many doses, for up to 18 months after you give consent.

Practice staff will also ask you if you wish to take part in our sub-study that will involve a telephone or online discussion with SGUL Research staff regarding your experience of primary care and opinions on vaccinations, among other things. If you are interested in taking part in the sub-study please indicate on the consent form that you are happy for your personal contact details to be provided to the SGUL research team. They will then contact you with further information to confirm your consent and interest in taking part.

Expenses and payments

There will be no reimbursements for taking part in the first study, as this is an extension of routine care. If you choose to take part in the optional sub-study (follow-up interview), you will be eligible to receive a £20 voucher, as a thank-you for your participation and to compensate you for your time. We will also cover any necessary childcare/support costs.

What do I have to do?

If you agree to participate in the first part of the study, you will be required to answer a short series of questions about your migration history, ethnicity and vaccination history during your appointment with the nurse/healthcare assistant. All of this information will be kept strictly confidential.

What are the possible disadvantages and risks of taking part?

We do not anticipate any major disadvantages or risks of taking part. Discussing your personal history or experiences might be uncomfortable, but we can stop at any point to take a break, or you can leave if you feel you can't continue.

What are the possible benefits of taking part?

By taking part, you may be referred for routine vaccination on the NHS which is free and will help to bring you in line with the UK immunisation schedule and reduce your risk of contracting vaccine-preventable diseases. You may find it fulfilling to take part in research aimed at improving access to vaccination on the NHS for migrant and BAME populations in the UK. You will be able to take an active part in improving your own and your community's health.

What if there is a problem?

If you have any problems, a concern about the research, or how it is conducted, please contact a member of the GP practice staff. The detailed information on this is given in part 2.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with this study?

You can withdraw your consent at any time, even during the appointment. If it was your wish, we would destroy any records or notes we have from your consultation, provided data analysis has not started. Where consent is withdrawn after starting analysis and/or finishing our reports, we will be unable to destroy the research data we've collected up until that point.

What if there is a problem? Complaints: If you wish to complain or have any concerns about any aspect of the way you have been treated during the course of this study then you may speak with the staff at your practice who will do their best to answer your questions or concerns. You can also contact your local Patient Advice and Liaison Service. Their contact details are provided at the end of this form. The normal National Health Service complaints mechanisms are also available to you.

Harm: St George's University of London sponsored research: St Georges, University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. We would not be bound to pay compensation where: -The injury resulted from a drug or procedure outside the trial protocol and/or - The protocol was not followed. These arrangements do not affect your right to pursue a claim through legal action.

Will my taking part in the study be kept confidential? We take your confidentiality seriously, and as such will not use any identifiable information about you in the data that we use for our analysis (for example, your name, address). We may ask for your contact details so that we can keep you up to date with the research and the results and get in touch with you for a follow-up interview (if you agree). However, you don't have to give these details if you don't want to. Throughout our work we will comply with the requirements of the Data Protection Act 2018, and the General Data Protection Regulations (GDPR).Your



individual records/notes will not be shared outside of the GP practice, and your data will be de-identified and made completely anonymous before being shared with the research team.

How will we use information about you?

We will need to use information from you for this research project. This information will include your country of birth, ethnicity, age, time in the UK, reason for migration, history of vaccine-preventable diseases, vaccination history and what vaccines you receive through the study. 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.

What are your choices about how your information is used?

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. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. 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. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

You can find out more about how we use your information: <https://www.sgul.ac.uk/privacy>

For general information on how the NHS uses research data please visit <https://www.hra.nhs.uk/information-about-patients/>

What will happen to the results of the research study? The results will be combined with data from other participants to give a wider picture of vaccine coverage and uptake in migrants and BAME communities in the UK. The results may be published and shared in academic journals and events. This is common practice for how most research is shared. We will also produce a report to give directly to you about what we've found and hold a virtual meeting (remotely, via video-conference) to present and discuss our findings with people who were involved should they wish to join. With your permission we may use your anonymised data in future research or contact you about future research opportunities.

Who is organising and funding the research? The study is organised and sponsored by St George's, University of London. The research is funded by the NIHR (National Institute of Health Research), a government body that funds and supports medical and health research.

Who has reviewed the study? All research in the NHS is looked at by independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favorable opinion by Yorkshire and the Humber - South Yorkshire Research Ethics Committee.

Further Information and Contact Details:

General information: How can I find out more about vaccination in the UK?

- If you are interested to find out more about vaccination in the UK, the NHS guidelines can be found here: <https://www.nhs.uk/conditions/vaccinations/nhs-vaccinations-and-when-to-have-them/>

Contact details: If you have any questions about research or this research project, or you are unhappy with the study at any point, please contact one of the individuals named below.

Local research team contact details: Name: Desiree Fyle; Email: noclor.norththamescrn@nhs.net Please write "Vacc on Track" in the subject line; Tel: 020 3317 5707

Data Transparency Information

St George's University of London is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. St George's University of London may keep information collected for the purpose of the study up to 5 years after the study has finished. This is to ensure integrity of the results. All data will be stored in a secure manner. Additionally,

- St George's University of London will collect information from you for this research study in accordance with our instructions.
- St George's University of London will keep your name, contact details and other identifiers confidential and will not pass this information on.
- St George's University of London will use this information as needed, to contact you about the research study, and to oversee the quality of the study.
- Certain individuals from St George's University of London, St George's University of London and regulatory organisations may look at your research records to check the accuracy of the research study.
- St George's University of London will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, identifying information or contact details.

If you need further help or advice with a data protection issue, please email your query to St George's, University of London Data Protection team.

Data Protection Officer Contact Details: email: dataprotection@sgul.ac.uk