

What will happen to the results of the studies using data from the database?

The results from all studies using data from the database will be available on the PCN Database website (www.medscinet.net/ UKPCN). They will also be published in health care journals and presented at medical and midwifery conferences.

What if there is a problem?

If you have a concern about any aspect of this project, you should ask to speak to the Local Project Lead (see contact details overleaf). If you have a complaint, you should talk to your doctor who will do their best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. Details can be obtained through the Trust's Patient Advisory Liaison Service (PALS) on 020 7188 7188 or KIC, Ground Floor, North Wing, St Thomas' Hospital, London, SE1 7EH.

This project is co-sponsored by King's College London and Guy's and St Thomas' NHS Foundation Trust. The sponsors will at all times maintain adequate insurance in relation to the study independently. Kings College London, through its own professional indemnity (Clinical Trials) and no fault compensation and the Trust having a duty of care to patients via NHS indemnity cover, in respect of any claims arising as a result of clinical negligence by its employees, brought by or on behalf of a study patient but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who has reviewed this project?

The East of Scotland Research Ethics Service REC 2, which has responsibility for scrutinising all proposals for research on humans, has examined the proposal and has raised no objections from the point of view of research ethics (REC Ref.16/ES/0093).

It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from King's College, London and Guy's & St Thomas' NHS Foundation Trust whose role is to check that research is properly conducted and the interests of those taking part are adequately protected. The Guy's & St Thomas' NHS Foundation Trust Information Governance Department has approved the involvement of the company (Medscinet) to undertake the development and security of the database.

What do I do if I have further questions?

For further information please contact:

Local and Overall Project Lead

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Thank you

for taking time to read this leaflet



Preterm Clinical Network Database

Information Sheet

About the PCN database

We are members of the UK Preterm Clinical Network (UKPCN), which is a network of doctors, midwives and researchers who are working to prevent the problems that occur when babies are born too soon. We use the Preterm Clinical Network (PCN) Database for storing information about the care of women at risk of preterm birth. This includes information about why they may be at risk of preterm birth, including information about their physical and mental wellbeing, any treatments they have had, and whether they had their babies early or not. The information (data) is already collected in maternity notes, but this database makes it much easier for us to review our records and helps us to understand which treatments are the most effective.

Advantages of the PCN database

Other members of the UK Preterm Clinical Network also use this database to store information about the care they give women at risk of preterm birth. Although members can only access records about their own patients, because the same information is collected in the same way, it is possible to put data from all the hospitals together. This means we can learn much more about preterm birth and what we can do to reduce the risks because the more information we have, the more certain we are. Members of the UKPCN, or other researchers, wanting to look at data from other hospitals will have to apply for special permission.

Who gives this permission?

Applications for the release of data are considered by the PCN Database Access Committee, which is made up from members of the UKPCN, the Royal College of Obstetricians and Gynaecologist Preterm Clinical Study Group and the KCL Department of Women and Children's Health Preterm Birth Studies Patient and Public Involvement Panel.

What do I have to do?

As you may be at risk of preterm birth, we would like to include information about you and your pregnancy on this database. This information (up to when you and your baby leave hospital) will be collected from hospital and/or GP records. If you are happy to be included we will ask you to sign a consent form. Your maternity care will be exactly the same whether or not you agree to your information being stored on this database.

Following your baby as he or she grows up

Being born early could have long term, as well as short term effects on the child. The PCN Database will also offer researchers the possibility of investigating longer term effects of preterm birth, monitoring and interventions. If you are happy for further information about your child's health and

development to be collected as they grow up please indicate this on the consent form. This information may be sought directly from you (we would write to you about any questionnaire or follow up studies that included appointments) or from routinely collected health and educational records. Your child would be asked to consent themselves to any follow up studies once they had reached 16 years of age. A letter asking them to consider taking part would be sent to them directly at the most current address held by NHS care records.

Your health in the future

We would also like to follow up women for longer than just after their babies are born. This will help us to understand longer term consequences of any conditions they experienced during pregnancy, for example, infection, or treatments they received to reduce the risks associated with preterm birth. Again, this information may be sought directly from you, or from your routinely collected health records. Please indicate if you would be happy about this on the consent form.

Future research opportunities

You may be eligible, now or in the future, for other research studies about preterm birth. If you would be happy for us to keep a record of your name and contact details, and for us to contact you with further information please indicate this on the consent form.

Do I have to agree?

Whether you agree to your information being stored on this database or not is entirely up to you. Your decision will not affect the care you receive in any way.

What if I change my mind later?

If you agree now, but change your mind later, you are free to withdraw, without giving a reason, and your data will be deleted. Just contact the Project Team (details overleaf).

What are the benefits of taking part?

You may not benefit personally from taking part, but what we learn about preterm birth and what we can do to prevent it will benefit women and babies at risk of preterm birth in the future.

Who has funded this project?

The project has been funded by an NHS Innovations Challenge Prize and Tommy's charity.

Will my taking part be kept confidential?

The information we store on this database is anonymous, that is to say, there are no details that may make it possible to identify individuals (such as their initials and date of birth). However, it will be linked by a special ID number to another special database called the PCN Patient Details Database, so it is possible for us to identify you to add details about the birth of your baby later, and, if you have consented, to longer term follow up.

All data released for research will be anonymous, and strict security measures will be followed for any transfer of data to researchers within, and outside the UK.

Guy's and St Thomas' NHS Foundation Trust and King's College London is the sponsor for this project based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this project and will act as the data controller for this project. This means that we are responsible for looking after your information and using it properly. Guy's and St Thomas' NHS Foundation Trust and King's College London will keep identifiable information about you for 25 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information www.kcl.ac.uk/innovation/research/support/ethics/how-does-gdpr-affect-ethics/king's-college-london-statement-on-use-of-personal-data-in-research.aspx and <https://www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx>.

Guy's and St Thomas' NHS Foundation Trust and King's College London will use your name, date of birth and contact details to contact you (and where applicable those of your baby) about the project, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Guy's and St Thomas' NHS Foundation Trust and King's College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in Guy's and St Thomas' NHS Foundation Trust and King's College London who will have access to information that identifies you will be people who need to contact you to follow up or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. Guy's and St Thomas' NHS Foundation Trust and King's College London will keep identifiable information about you from this study for 25 years after the project has finished.