Participant Information Sheet

Exploring perceptions on the proposed cystic fibrosis (CF) screening protocol incorporating next generation sequencing (NGS)

IRAS: 307623

Thank you for taking the time to read this information document.

PART 1: Taking part in the research

We (the Sponsor, King's College London and King's College Hospital NHS Foundation Trust) are approaching you as a parent of a child who has either (i) been diagnosed with cystic fibrosis (CF) (ii) been told they are a carrier of CF (iii) been given a designation of CF screen positive, inconclusive diagnosis (CFSPID), (iv) have received a false positive screening result for CF or (v) have received a false negative screening result for CF - collectively referred to as parents with experience of CF screening from now on.

We would like to invite you to take part in a research study to explore your perceptions on the proposed CF screening protocol incorporating next generation sequencing (NGS).

Before you decide whether to take part, you need to understand why the research is being done and what it will involve. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. You may also like to look at the following website https://www.hra.nhs.uk/about-us/what-we-do/taking-part-or-getting-involved-research/. If you would like to take part once you have understood what the project is about, we will ask you to sign a consent form. You will be given a copy of the consent form to keep.

What is the purpose of this study?

Newborn bloodspot screening, which we will refer to as just 'screening', is well established and has lots of advantages. Screening for CF became part of the national screening programme in 2007. This works well but has some disadvantages including carrier reporting - which is not the intention of CF screening in the UK (~200 each year); the need for repeat samples which can be costly and contribute to parental worry (~300 each year); mutation panels not fully reflecting the ethnic diversity of the birth population; and identification of children designated as CF screen positive, inconclusive diagnosis (CFSPID) which can cause uncertainty (~20-30 each year).

A trial of NGS in one centre for one year found that it would be possible to perform at a reasonable cost and with an acceptable turnaround time. In addition, this trial determined that using NGS could lessen some of the disadvantages described above.

The main purpose of this project is to gather, compare and analyse the views of a range of people with experience of CF screening as well as those who care for or support people with experience of CF, on the proposed CF screening protocol incorporating NGS.

Do I have to take part in this study?
No. This information sheet gives you more information about the whole project so that you can take it away and think about whether you would like to be involved; you can decide to be involved in all or some of the activities listed below. If you are interested in participating, you can provide your name and telephone number/email address to a member of the research team (contact details are at the end of this information sheet). We will then contact you shortly after to ask if you have had time to think about the project and whether or not you would like to be involved. Before you can be involved in the project, you will need to sign a consent form. Even if you agree to be involved now, you are free to withdraw your consent at any time, without giving a reason.

What will I have to do if I take part?
If you decide to be involved, we will invite you to take part in the following activities over a maximum period of 12 months:

a) A questionnaire (via email) collecting demographic information that should take about 5 minutes to complete
b) An online focus group (group interview) lasting 60-90 minutes with other parents with experience of CF screening
c) An online workshop lasting 90-120 mins with adults with experience of CF and/or other parents of children with experience of CF screening and/or professionals involved in caring for or supporting those with experience of CF
d) Online evaluation surveys following the focus group and workshop that should take 10 mins to complete each.

The purpose of the online focus group (group interview) is to explore your views of incorporating NGS in CF screening. The purpose of the online workshop is to explore how any perceived harms/benefits identified in the online focus group are balanced by participants, and any variations in viewpoints. The purpose of the evaluation surveys is to learn about how to best engage different groups of people in research such as this to inform future studies. You will receive a one off £20 voucher on completion of the activities (demographic questionnaire, online focus group, online workshop) above.

The focus group (group interview) and workshop will be audio recorded (using an encrypted recorder) so we can ensure your comments are accurately reported. These recordings will be upload onto computer servers, transcribed, the transcription checked and then the original recording deleted. The electronic record (the transcript) of the interview, will be stored securely on a server for up to 5 years. You will not be identifiable from the record as all records will be given a code and will therefore not contain any personal identifiable data. After 5 years, records will be destroyed as confidential waste as per relevant local policies. Findings from the data collected may be used for conference presentations and/or articles in medical/nursing journals.

Are there any risks or discomfort anticipated?

No risks are anticipated. You will be given the name and telephone number of a member of the research team whom you can contact at any time should you have any concerns following your participation.

PART 2: Additional Information to be read before you decide whether to participate or not.

Why is this study important?
Before NGS can be incorporated into screening for CF, it is important to know that it does not cause any excessive or unexpected worries or concerns to those with experience of CF screening and/or professionals. This study will explore this by gathering, comparing and analysing the views of a range of different people including those who have experience of CF screening and those who care for or support people with experience of CF.

Who will this study help?
The information will inform discussions and decisions by the fetal, maternal and child health (FMCH) group and UK National Screening Committee (UK NSC) about the inclusion and use of the proposed protocol within CF newborn screening nationally. These advise ministers and the NHS in the 4 UK countries about all aspects of population screening and supports implementation of screening programmes.

Data privacy statement
King's College London and King's College Hospital NHS Foundation Trust are co-sponsors and King's College London, King's College Hospital NHS Foundation Trust are joint data controllers for this study based in the United Kingdom. This means that we are responsible for looking after your information and using it properly. The legal basis under which your data will be processed is King's College London and King's College Hospital NHS Foundation Trust public task.

How will we use information about you?
We will need to use information from you for this research project. This information will include your:

- Name
- Contact details
- Information you provide via the demographic questionnaire

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.

Personal data will be retained for two years after the end of the study in keeping with King's College London and King's College Hospital NHS Foundation Trust research data management policies. Research data that has had all personal identifiable information removed may be shared between members of the research team. Research data will be retained for five years in keeping with King's College London and King's College Hospital NHS Foundation Trust research data management policies.

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.

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

- at www.hra.nhs.uk/information-about-patients/
- via https://www.kch.nhs.uk/research/use-of-data-for-research (For KCH) and www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research (for KCL)
- by asking one of the research team (contact details included below)
- by contacting the Data Protection Officer: (For KCH: Nick Murphy-O'Kane kch-tr.dpo@nhs.net; For KCL: Albert Chan info-compliance@kcl.ac.uk)

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and any information about you will be handled in strictest confidence by the research team only and will only be used in a way that will not allow you to be identified. In the event that disclosures are made during the course of the research which raise concerns of a safeguarding/ legal nature, the relevant clinical care team/ authorities will be informed.

Data collected during the study, may be looked at by individuals from the sponsor (King's College London, and King's College Hospital NHS Foundation Trust NHS Foundation Trust), the research team, the funder and regulatory authorities, where it is relevant to taking part in this research. Relevant information may also be used in scientific publications. Direct quotations from the focus group, workshop or evaluation surveys, that are made available through publications or other academic outlets will be anonymised so that you cannot be identified. Screenshots and photographs of the online focus group and/or workshop may also be used in scientific publications. However, faces will be blurred/redacted to protect the identity of those involved and the original image overwritten.

We will let your GP know that you are taking part in this study so that they are aware should you want to discuss the study with them.

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time without having to explain why.

What will happen when the study stops?
Once the study ends, we will not require you to provide any further information. But if you are interested, you can tell us and we may ask if you can help us with other studies in the future.

How will I learn about the results of this study?

- We can send you a summary of the study once all the results have been analysed.
- We will be giving talks about the results to other doctors and nurses and will provide a summary for all those parents taking part, if they would like that information.

Who is organising and funding the research?

The NHS COMMISSIONING BOARD (also referred to as NHS England).

Who has reviewed this Study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity.

This study has been reviewed and given favourable opinion by Tyne and Wear South Research Ethics Committee who consider that it is addressing an important question and that there will be minimal risk to you if you participate.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Dr Jane Chudleigh, 02078485590, jane.2.chudleigh@kcl.ac.uk). If you remain unhappy and wish to complain formally, you can do this through the King's College Hospital Patients Advice and Liaison Service (PALS) on 020 32993601, kch-tr.palsdh@nhs.net.

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against King's College Hospital NHS Foundation Trust and/or King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

You can also use the NHS Complaints Procedure. Details can be obtained from the hospital PALS service.

Insurance
The study is co-sponsored by King's College London (KCL) and King's College Hospital NHS Foundation Trust. The sponsors will, at all times, maintain adequate insurance in relation to the study. KCL through its' own professional indemnity (Clinical Trials) & no fault compensation and the King's College Hospital having a duty of care to patients via NHS indemnity cover, in respect of any claims arising as a result of negligence by its employees, brought by or on behalf of a study participant.

Who can I talk to about this study?
Any of the research team will be more than happy to talk to you about this study. Their contact details are below:

If you would like further information before this time, you can contact a member of the research team by telephone or email:

Dr Jane Chudleigh: ☏ 02078485590 jane.2.chudleigh@kcl.ac.uk
Pru Holder: ☏ 02078485590 pru.holder@kcl.ac.uk
Professor Felicity Boardman ☏ 02476 151291 Felicity.Boardman@warwick.ac.uk
Corinna Clark: ☏ 02476 150 455 Corinna.Clark@warwick.ac.uk
Professor Louise Moody: ☏ 02476 655601 l.moody@coventry.ac.uk
Jacqueline Cowlard ☏ 020 7377 7000 j.cowlard@nhs.net
Lorna Allen ☏ 020 3795 1555 lorna.allen@cysticfibrosis.org.uk