

Patient Information Sheet for **Parents of Children**: Severe Atopic Disease in the Bangladeshi population, Version 2, ReDA 011978, IRAS Project ID: 227153, REC 18/LO/0018, 24/01/2018

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Severe Atopic Disease in the Bangladeshi Population:

For parents of children participating in this project

We would like to invite you to take part in a research project. Before you make a decision, we would like to explain what the project is and what will be involved if your child participates. Please feel free to ask the research team any questions you have about this project.

Why are we studying eczema in East London?

Eczema is a long term itchy skin condition and is very common. We know that eczema in people from Bangladesh or in people with parents from Bangladesh is usually severe. This means that creams are not usually strong enough to control the skin rash and that powerful tablets may be needed to make things better. We also find that Bangladeshi people in East London with eczema have to be admitted into hospital more than other people in different parts of the country. We want to find out why there is a difference in eczema in Bangladeshi people.

- We would like to look at your child's genetic code (DNA).
- We would like to look at your child's skin and see how bad it is.
- We would like to check the link between your child's eczema and allergy, asthma and pollution near your home.

If we can find an answer to why eczema is very bad in Bangladeshi people, we hope to find better treatment and solutions for people with eczema in East London and hopefully elsewhere too!

Why are we asking you to join?

We have asked your child to join as they have eczema, live in the local community and they are from Bangladesh or both of you (Mum and Dad) are from Bangladesh.

Do I have to join?

No. It is entirely up to you if you would like to join. This information sheet will give you information to help answer this question. If you do join the study and at a later date choose to leave/withdraw the study, you can do so at any time, without giving a reason. Your decision will not change the care your child receives from the dermatology department.

What will happen if I take part?

If you decide to take part in the study, we will ask you to sign a consent form on behalf of your child. We would ask you to keep a copy of this for your own records. This consent will be for your child's involvement in this project. If you agree, you will also consent for us to store and use any samples in possible future projects/research. Prior to use of these samples in future projects, we will obtain ethical approval to do so.

Once you have joined the study we will perform a few harmless tests on your child's skin. This can be performed on the day you sign the consent form or at a time that suits you. We

will also examine your child's skin and ask you to fill in a series of questionnaires regarding their skin. This visit is likely to take 30-60 minutes in total. We would like to take photographs of your child's palms/arms/legs and lips – these photos will not show anything identifiable and will be kept for the duration of the study. If your child is over 12 years old, we may ask you to come back at a later date to arrange for a sample of skin to be taken for testing. We will only take a sample of skin if you and your child agree to this. If your child is not over 12, you will not be required to come back to see us.

Will the care I receive for my child's skin change?

No. We would ask for you to continue your child's treatment as recommended by your dermatologist. If your child's skin worsens, do not attempt to contact us but contact your regular dermatology team.

What procedures are involved?

We will perform several harmless tests on everyone:

- 1) Questionnaires. We will complete several questionnaires with you. These will ask for basic information on your child's skin and their eczema. We will also ask how much the eczema affects your child and your entire family
- 2) Examination. We will perform an examination of your child. We will look at all of their skin and record where the eczema is and how severe it is.
- 3) Saliva ('spit sample) sample or mouth swab. We will ask your child to 'spit' into a collection tube. If they are unable to do this we will rub the inside of their cheek with a small brush. This will take about 10 seconds. This sample will be used to test your child's genes (DNA) – we will look at specific genes related to eczema to see if they are present.
- 4) Nitric Oxide testing. If your child is over 4.5 years old, our nurses will perform a test on their breathing. Your child will need to breathe out (blow) into a machine to assess their breathing/airway. This will take place in the same room as the other tests.
- 5) Nitrogen dioxide monitoring. For children with asthma, we may ask for your child to carry a small badge (in their pocket, their pram or your baby bag) for two weeks to measure levels of pollution near you.
- 6) Skin moisture tests. We will place two probes on your child's skin for about 60 seconds each to assess how much moisture there is in the skin and how leaky the skin is. This tests looks at how good the skin is as a barrier.
- 7) Superficial skin sample. We will take samples of the very top layers of skin by placing sticky plastic discs on your child's forearm. These will be placed on the skin and then removed. This procedure is painless and does not leave a mark. These samples will be stored in our laboratory (Barts and the London School of Medicine and Dentistry) for use in future research.

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- 8) Skin swab. Using a swab, that looks like a 'Q-tip' we will rub your child's skin to look for normal bacteria found on the skin. These samples will also be stored for future research.

If your child is over 12 years old:

- 9) Skin biopsy (optional). To test what is happening with the natural chemicals deep inside the skin we would like to take a sample of skin if you and your child agree to this. We will bring your child back to our department at a later date for this test. Your child will be brought to our Dermatology procedure room and we will talk through the procedure with you and them. If you are all happy to go ahead we will ask your child to lie down on a flat couch. For this test, we will make an area of skin (eg forearm) numb with an anaesthetic cream. Once this is working, we will use a very small needle to inject more local anaesthetic into the skin to make it completely numb. This injection can sting a little bit but afterwards there should be no pain at all. We will then clean your child's skin and use a device to cut out a circle/cylinder of skin – 2-3mm wide and 2-3mm deep. We will close the wound with 'steri-strips'. Stitches will not be required. Your child will be left with a small permanent mark (scar) about 3 mm long. There may be some minimal bleeding during or after the procedure – this can be stopped with 10 minutes of pressure on the skin. The risk of infection of this clean procedure is less than 3% - this can be treated with antibiotic cream or antibiotic tablets. If your child has pain after the procedure it is usually very mild and paracetamol is enough to control it. The whole procedure should take around 10 minutes.

Will you need access to my child's hospital record?

Yes. We would like to have access to your child's hospital record to gather information on their past medical history and family history, previous allergy tests and record the nature of any hospital visits, particularly relating to their eczema

Will my child benefit from this study?

There are no immediate benefits from joining this study. By joining the study we hope that your participation will help us to better understand eczema in Bangladeshi patients in East London. In the future, this will hopefully lead to better treatment of eczema, improved prevention strategies and possibly improved pollution measures locally.

Are there any risks to my child?

We don't anticipate any risks to your children as the tests performed do not cause harm. If your child is over 12 years of age and consents for a skin biopsy to be performed, the risks including bleeding (this can be stopped with pressure), infection (<3%; treated with antibiotics) and a permanent mark (scar) will be discussed prior to the procedure.

What happens to the samples that your child gives to the study?

We would view your donation as a gift for the purposes of scientific research. Samples will be stored in locked freezers located in approved locations in the Blizard Institute, Barts and the London School of Medicine and Dentistry and access will be restricted to responsible individuals within the Blizard Institute.

Samples collected as part of the present research project may be used by Barts and the London School of Medicine and Dentistry for future medical research.

If at any time, you or your child would like to withdraw from the study, your child's samples would be destroyed.

At the end of any project, we will publish the results of our experiments and present them at meetings to other scientists. Samples used for research will be anonymous which means no one will know they were your child's. All staff using your samples either now or in future studies will abide by the Data Protection Act 1998. All tissue will be disposed of lawfully when it is no longer required.

We do not expect any commercial gain from this research, but it does mean that you would have no right to a share of any profits that might arise in future from studies that use your skin, for example, if in collaboration with industry, a scientific idea was patented.

Will my child's data be confidential?

Yes. We will follow ethical and legal practice and all information about your child will be kept strictly confidential. Information on your child that leaves the hospital will have all identifiable information deleted. This will happen to data transmitted electronically as well. Your child will be allocated a unique study number, which will be used for recording data. For example, the questionnaire we fill out, the mouth swab/sample, skin swab, tape stripping and skin biopsy will only have your child's study number, sex and age as an identifier. We will not include your child's name, date of birth, hospital or NHS number. All data will be stored on a secure computer at the Blizard Institute, Barts and the London School of Medicine and Dentistry. Personal identifiable details linking your child to the study will be recorded separately on paper and stored in a locked filing cabinet in a locked research office. Only the clinical members of the research team will have access to you or your child's identifiable data.

What happens if there is a problem?

Queen Mary University of London has agreed that if your child is harmed as a result of their participation in the study, you will be compensated, as long as the 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 study. These arrangements do not affect your right to pursue a claim through legal action.

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Please contact Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. Please telephone 020 3594 2040, or email pals@bartshealth.nhs.uk, you can also visit PALS by asking at any hospital reception.

If you have any specific questions regarding this project please contact Dr Bjorn Thomas. Telephone 020 7882 2341 or e-mail b.r.thomas@qmul.ac.uk.