

Uganda Virus Research Institute

The Urban Survey of Allergies and Metabolic Outcomes

Information for parents/ guardians of child household members

We are inviting your child to take part in a health-related survey among people living in an urban setting. The Urban Survey is investigating the various types, prevalence and risk factors for allergy-related diseases and for diseases like diabetes in the urban communities of Entebbe, Uganda.

Allergic conditions represent a serious global health problem especially in urban settings. Asthma now affects about 300 million people and eczema 5-20% of all children. The prevalence of asthma and other allergic conditions is increasing more rapidly, and the severity of asthma is greater in low and middle income countries. Similarly, diabetes is increasing in many countries, including countries like Uganda. Little is known about the burden of these diseases in our region.

Worm infections are believed to somehow protect against allergies and related diseases such as asthma and against diabetes. This might help to explain why asthma, eczema and allergies are often commoner in cities than in rural communities.

What are asthma, eczema and allergies?

Asthma is a disease that affects the lungs. People with asthma have attacks of difficulty in breathing which come and go. Different things can trigger asthma attacks – such as exercise, cold weather, and “flu”. When someone has an asthma attack their breathing makes a whistling noise called wheezing.

Eczema is an itchy skin rash which comes and goes. Usually the rash occurs around the eyes, around the neck, inside the elbows or behind the knees.

Allergies are a reaction to substances in the environment which should not normally cause any problem. Allergic reactions are sometimes triggered by foods or insect bites, and sometimes by substances in dusts and in the environment. When the person gets into contact with the substance they are allergic to, they may have diarrhoea (if it is a food) or may start itching, sneezing or wheezing.

Allergy-related conditions are becoming commoner in countries like Uganda. It is thought that living in clean, modern environments may increase the risk of allergies and related conditions.

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What is diabetes?

Diabetes is a disease in which the blood sugar levels are poorly controlled and a person develops high blood sugar. This can lead to complications such as poor resistance to infections, eye disease and heart disease. Diabetes is often associated with abnormal levels of fats (lipids) in the blood. Blood tests can detect diabetes, or a tendency towards diabetes, by measuring blood sugar levels, and the levels of insulin, which controls blood sugar.

What are worms?

Worms are parasites such as hookworm and round worm which infect humans through eating food contaminated with faeces, or walking on bare-foot in places contaminated with faeces. Worms live in the human gut and eggs are passed out in faeces.

Why is this study being done?

We want to find out the different types of asthma, eczema and allergies in Entebbe, and about blood sugar and related abnormalities among people in Entebbe. We also want to find out about risk factors that may be associated with these conditions.

We also want to find out how worms and other infections protect against these conditions. If we can find this out, we may be able to develop better ways of preventing or of treating such diseases.

The study will help the Ministry of Health to plan their worm treatment campaigns, and to plan for improved services to sufferers from asthma, eczema and allergies and diabetes.

Why has my child been chosen to take part in this study?

Your child's household is among the 420 households in Entebbe that have been selected to part in the study. People living in the selected households (altogether 1500 people) will provide information and samples in order to find out what the different types of allergic conditions and about blood sugar levels, and whether worms protect against them. Households to give samples are chosen using a computer. To make it fair, the process of choosing households is like the choice of a number in a lottery.

What will happen if I take part?

If you agree that your child takes part in this study, this is what will happen:

- You will be asked to sign or thumb-print the consent form that accompanies this information sheet
- The researchers will ask some questions about the health of your child



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- You will undergo a physical examination including measurement of height, weight, waist circumference, blood pressure and for visible skin allergies.
- Your child's lung function will be tested. For this your child will be asked to blow into a small, hand-held instrument called a spirometer
- Your child will be tested for his/her reaction to substances that commonly cause allergies, by skin prick testing
- A blood sample (20 ml, four teaspoons, if the child is aged 13 to 17; 12 ml, two-and-a-half teaspoons if the child is aged 5-12 years; 10ml, two teaspoons, if the child is aged one to four years) will be taken from your child
- Your child will be asked to provide one stool sample and one urine sample
- The researchers will map the location of your home, and take note of the type of environment in which your child lives

What will the stool, urine and blood samples be used for?

Stool samples will be used to test for worms and other intestinal infections. Urine samples will also be used to test for worm infections, as well as for sugar levels and protein levels. For girls who have started having periods urine will also be used for a pregnancy test. Blood samples will be used for tests for anaemia, malaria, and other infections, and for allergy tests, tests of blood sugar and insulin and of fat levels. Among infections, counselling and testing for HIV infection will be included if you wish it. Some blood will be used for tests of immunity (the body's defence system against infections). Part of each sample may be stored for other tests in future. Some of the stored samples may be used for genetic studies. All the information collected, and the results of tests, will be completely confidential. We will contact you about the child's results if they will be useful for his/her health. For example, the results of tests for malaria will be given to you if your child has a fever and needs immediate treatment, and the blood sugar results will be explained to you if there is any evidence that your child might have diabetes. We will also contact you with results from the child's stool samples if he/she is found to have worm parasites, and he/she will be given treatment.

What are genetic studies?

Genetic studies are studies that test whether inherited differences between individuals and families, resulting from differences in ancestry, have an effect on resistance to infections or diseases. Genetic studies on the stored samples of blood will test whether inherited differences explain why some people are more resistant to certain infections (such as worm infections), and whether inherited differences explain why some people are more likely to develop diseases like asthma, eczema, allergies and diabetes. These inherited differences can be identified by studying the chemicals (DNA) in your child's blood. It may also be possible to conduct studies on the DNA to find out how worms alter the risk of other diseases, like asthma, eczema and

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allergy, as well as metabolic processes. If you agree we will store your child's blood for future genetic studies.

What will happen to my stored samples?

Stored samples will be used for tests of immunity or for genetic testing. These tests will be conducted at specialised laboratories in Uganda or outside Uganda. Storage could be for many years. We will not contact you with the results of this future genetic testing because the work is for research purposes and not for identifying illnesses. If you allow your child's blood to be used we may be able to find out information that will help to provide better services for people in Uganda and elsewhere in the future.

Are there any risks or disadvantages to me of taking part?

Taking part in the study is not expected to cause any problems for your child, apart from the discomfort of having blood samples taken and the smaller discomfort of skin prick testing. Skin prick testing involves placing about five drops of liquid, containing the substances to be tested, on the skin, and gently scratching through the liquid. In some cases there is an itchy reaction, like the reaction to a mosquito bite. Very rarely a person may over-react to a skin prick test and may need urgent treatment. The research team is ready to treat such a reaction, but it is very unlikely to happen.

Are there any benefits to me of taking part?

There are no direct benefits to your child of taking part, but your child and all the members of your households will benefit from the medical examination and where possible treatment for infections found. If your child is found to have a condition that needs treatment this will be provided whenever possible, or you will be advised as to how to obtain the treatment that he/she needs. Your child will be provided with a soft drink when procedures have been completed and if he/she is invited to the study clinic for any reason a transport refund of 10,000 Ush will be provided.

What happens if I refuse my child to participate?

Taking part is voluntary. You are free to refuse for your child to participate or to withdraw at any time. This will not affect the child's right to health care provided by the government services.

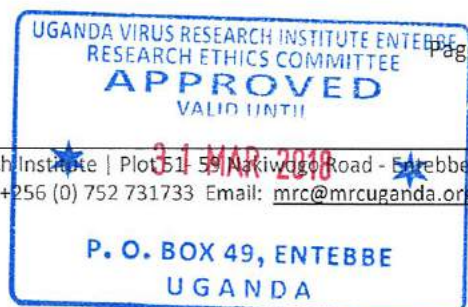
Who will have access to information from this research?

All our research records are stored securely in rooms with restricted access and on password protected computers. Only research staff trained to keep the information confidential will have access to the records. The names of individual participants will not appear on any reports on

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this research. After all your child's samples have been collected, his/her name will be removed from the records, so no-one will be able to find out information about him/her from our records.

Who has allowed this research to take place?

An independent national committee (the Uganda National Council for Science and Technology) and a committee at the Uganda Virus Research Institute have looked carefully at this work and agreed that the research is important, that it will be conducted properly, and that participants' safety and rights have been respected.

What if I have any questions?

If you have any questions about your child's participation in this study, please feel free to ask any member of the research team at any time. If you prefer, you may speak to the principal investigator for this study (Professor Elliott, telephone 0417 704000).

What if we want to ask someone independent anything about this research, or have any questions about our rights as research participants?

You may speak with the Ethics Committee Chairman from Uganda Virus Research Institute on 0414 320631.



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Uganda Virus Research Institute / Entebbe Hospitals
The Urban Survey of Allergies and Metabolic Outcomes

Consent form for parents and guardians

<p>Sub-ward name</p> <p>Child's Name</p> <p>Parent or Guardian</p>	<p>Child's ID number</p>
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*Initial or thumbprint
each box*

1. I have read and/or been fully explained the information sheet concerning my child's participation in this study and I understand what will be required if he or she takes part. I understand that my child's participation is voluntary. My questions concerning this study have been answered. I understand that at any time I may withdraw my child from this study without giving a reason and without affecting his or her entitlement to government health care. I understand that a part of each specimen may also be stored for other tests in future. I agree for my child to take part in this study.
2. I agree for my child to undergo skin prick testing to assess my response to substances that can cause allergy.



.....
 Name of parent or guardian Signature or thumb print Date

Relationship to child (mother, father, guardian).....

Witness:

.....
 Witness name Signature Date

Witness required only for those using a thumb print instead of the final signature, or unable to read the information and consent form, or if the person taking consent does not speak the participant's language. The witness must not be a member of the research staff or a study participant. The witness must be present for the whole consent process.

Person taking the consent:

.....
 Researcher name Signature Date

Form to be completed and signed in duplicate. Give one copy to the participant; retain one copy for the study file.



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