PATIENT INFORMATION

The Stroke in Sierra Leone (SISLE) Stroke Register

We are inviting you to take part in a research study. The study collects information to help plan services for people with stroke, prevent strokes and improve the quality of stroke care.

This information booklet explains why we are carrying out the research, why we are asking you to take part and what is involved.

Please read the booklet and discuss it with others if you wish. We will be happy to give you any more information or explain anything that is not clear.

Thank you for reading this booklet

What is the purpose of the study?

The Stroke in Sierra Leone Stroke Register (**SISLE)**

We set up SISLE to find out how many people in our area have a stroke and how stroke affects them and their families. This information is important. We use it to:

- Increase our knowledge about stroke
- Help improve quality of care at the hospital
- Publish scientific articles about stroke

This information is useful to help improve the quality of care people receive while they are in hospital and in the years to come.

Who runs the SISLE Stroke Register?

The Register is run by an international stroke research team, including researchers from College Of Medicine and Allied Health Sciences and King's College London. We are based at the research office at Connaught Hospital and the 34th Military Hospital.

We work closely with the doctors, nurses and therapists at Connaught Hospital and 34th Military Hospital.

A member of the research team, most often a research nurse, will have contact with you regarding the study. They will not be involved with your routine clinical care.

Why are you asking me to take part?

We ask everyone who has had a stroke who comes to Connaught Hospital and 34th Military Hospital to take part. We are in contact with all

hospital wards and departments where stroke patients might be seen.

Who can take part?

Anyone presenting with suspected stroke at USLTHC-Connaught Hospital or 34th Military Hospital with suspected stroke as per WHO definition: “Rapidly developing clinical signs of focal (or global) neurological deficit lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin”.

- Adults 18 years or over
- Ischaemic stroke
- Intracerebral haemorrhage
- Sub Arachnoid Haemorrhage

The following people will not be able to take part:

- Under 18 years
- No consent

- Transient Ischaemic Attack (focal neurological signs recovering within 24 hours)
- Known neurological disease with infectious etiology; meningitis, brain abcess, encephalitis

Do I have to take part?

The decision to take part is yours alone. If you decide not to take part or to withdraw, this will not affect your care in any way. Even if you agree to take part today, you can withdraw at any time without giving a reason. The final date you can withdraw by is 31/12/2021.

You do not have to make a decision today. If you wish, take time to discuss this with your family and friends.

What happens once I agree to take part?

We will ask you to sign a consent form to show that you have agreed to take part in this study.

A researcher from our team will ask you for information at the time of your stroke, then 3 months and 12 months after that. Then we will contact you again once every year. So we would like to follow your progress for many years to come.

The first time we see you we will ask you about:

- Your age, sex, ethnic group.
- Your health, including blood pressure, cholesterol, diabetes, medication.
- The care you received in hospital and any care you received before coming to the hospital.
- Your ability to do certain tasks, like getting washed and dressed.
- Any problems you have had with swallowing food, water or medicines in the past.

For example, “Have you ever been told by a health worker that you have high blood pressure?”

“Did you visit any health workers or institutions for your current health problem before coming to Hospital?”

The researcher may also like to do a brief physical examination, to find out more about how the stroke has affected you. A research nurse will examine you to check if you are safe to take food, water, and medicines by mouth, this should take less than five minutes. The nurse will check that you can sit up, stay awake for at least five minutes, can breathe comfortably, and have a clean mouth. Next the nurse will

- Check to see how well you can move your tongue
- Ask you to cough as loud as you can
- Ask you to say ‘ha, ha, ha, ha’
- Examine your throat.

Next the nurse will ask you to take sips of water from a teaspoon. Then a ½ cup of water. The nurse will tell you and members of the clinical team the results of your swallow screen.

The research team will support you to access investigations that should be part of your normal recommended hospital care these include:

- CT- brain scan
- Chest X ray
- ECG
- Blood tests

These research team will help you access these investigations, whether you choose to participate in the research or not.

The research team can explain each of these investigations to you in greater depth.

In later visits we will ask you about:

- Your current health, including your medications.
- How the stroke affects you now.
- Any medical and social care you received.

Each interview lasts between 40 – 60 minutes. The researcher will arrange to come to you, at a time that suits you.

Are there any risks involved?

There are no known major risks in participating in the study, however there may be aspects of the research which involve risks that are currently unforeseeable.

The main disadvantage to taking part is that you will have to spend a short amount of time whilst in hospital answering questions. If any uncomfortable or distressing topics arise, you can refuse to answer, withdraw from the discussion or ask the specific topic to be excluded from the final report.

The research team will provide access to the routine investigations you should receive from the hospital. These include a head CT scan and a Chest X-ray.

CT scans are quick, painless and generally safe. But there's a small risk you could have an allergic reaction to the contrast dye used and you'll be exposed to X-ray radiation. CT scanners are designed to make sure you're not exposed to unnecessarily high levels.

Generally, the amount of radiation you're exposed to during each scan is the equivalent to between a few months and a few years of exposure to natural radiation from the environment. The benefits and risks of having a CT scan will always be weighed up before it's recommended.

There are no additional costs that should result from participation in the research, and you will be reimbursed for the travel fees associated with returning for any follow up surveys.

How will my information be kept private and confidential?

The information you give is anonymous. We give your form a unique number so that when

we have entered the information on the database, no-one (apart from the SISLE researchers) will be able to identify which form belongs to which patient. The forms are stored without any identifying information (such as your name or address) in a secure place that only we have access to.

We will not ask you to undertake any invasive medical procedure other than those your doctor has already requested for you.

We cannot promise the stroke register will help you personally, but the information we get will help to improve care for people who have a stroke in the future.

The SISLE Stroke Register will keep identifiable information about you from this study for 5 years after the study has finished.
From time to time we might also contact you to ask if you are interested in taking part in other studies we carry out.

How will the research findings be shared?

The research team will shared anonymised research findings through scientific journals, conferences and internal reports to ensure that professionals and the public can learn the latest stroke evidence from Sierra Leone. A summary of the results of the research will be shared with participants once the data has been analysed.

Contact Details

If you have any other questions about the research, please get in touch with any of the research team:

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This proposal has been reviewed and approved by King's College London Research Ethics office and Sierra Leone's Ethics and Scientific Review Committee, whose task it is to make sure that research participants are protected from harm. You have the right to contact the Committee, if you have any issues with the study or feel you have suffered harm as a result of the study:

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