Development and implementation of Realistic Medicine for severe stroke through Shared Decision Making at The Royal Infirmary of Edinburgh (RIE)

INFORMATION SHEET

Patient Representative

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part**.**

1) Why are we doing this study?

After a stroke, it can be difficult to decide what treatments are suitable for individual patients. Some treatments may not always be helpful, and some (for example, feeding tubes) may be uncomfortable. We want to find out how well the clinical team (doctors, nurses and therapists) have involved *you* in discussions about the care given to your ward/relative.

In this study, shortly after the stroke, then at 2 weeks, 4 weeks, 8 weeks and at 6 months, we will ask you about your communication with the clinical team. This will involve completing a short questionnaire and/or answering some questions.

2) Why have I been invited?

Your ward/relative has had a severe stroke. We want to find out how well the clinical team have involved *you* in decisions about their care

3) Do you have to take part?

No. Participation is voluntary.

Not taking part or withdrawing at any time will not affect the standard of care the your ward/relative will receive.

If you decide to take part, you will be asked to sign a consent form.

4) What happens in the study?

- We will ask you to answer some questions and to complete a short questionnaire as soon as possible
- We will ask you to complete the same questionnaire at 2 weeks, 4 weeks and in 8 weeks time. This questionnaire can be sent you, and returned to us, by post or by email. Whichever you prefer.
- We will ask you to answer some questions in 6 months time over the telephone.
- We may ask to interview you in more detail to find out about the quality of communication you have had with you doctors, nurses and therapists. This is optional and you can opt out of the interviews. Interviews will be transcribed to allow for researchers to analysis the information.
- We will not be asking your ward/relative to complete any questionnaires or interviews. If they regain capacity we will speak to them about the study and if they are willing to continue to have their medical data collected, to sign a consent form.

5) What are the benefits of taking part?

Some people find it helpful to be able to provide feedback about the quality of care that their ward/relative has received. The information you provide will help us improve the way that the clinical team communicates with patients who have had a severe stroke, and their families.

6) What are the possible risks of taking part?

There are no dangers to you or the health of t your ward/relative.

Some of your time will be required to complete the questionnaire and answer questions. Each time should only take up to 10 minutes.

If you take part in the interview, this can take up to an hour.

Some people might find it difficult or upsetting to talk about the care after stroke. If you find that the questions are too difficult or upsetting, you can change your mind about participating.

7) What if I do not want to carry on with the study?

You may change your mind about taking part in the study at any time. This does not affect the care your ward/relative will receive.

We would like to use the information we have collected up until you stop taking part

8) Will information be given to my relatives GP?

We will not be contacting your GP or the GP of your ward/relative with regards to your participation in the study.

9) What am I giving consent to?

- To answer questions regarding your ward/relative's care and the discussions you have had with doctors, nurses and therapists.
- To be contacted again in 2 weeks, 4 weeks, 8 weeks and in 6 months for obtaining follow up information.
- To be interviewed in more detail about the quality of communication *you* have had with your doctors, nurses and therapists. This is optional and you are able to opt out of the interviews on the consent form provided. The interviews will be recorded on an NHS approved Dictaphone, the recordings will be transcribed and destroyed as soon as analysis has taken place.
- To store personal information securely, this allows us to contact you for follow up information and will be stored on a password protected computer and deleted as soon as we have completed analysing the data (up to 12 months after study has ended).
- To anonymise and store your information on a password protected database for seven years after the study has ended.

10) Will the information collected be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard you and your ward/relative's privacy at every stage.

We will collect your contact details in order to contact you in 2 weeks, 4 weeks, 8 weeks and in 6 months time. People who do not need to know who you or your ward/relative are, will not be able to see your name or contact details. The data will have a code number instead.

We will keep all information about you safe and secure.

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.

You can find out more about how we use your information

- by asking one of the research team
- by sending an email sharedstrokedecisions@nhslothian.scot.nhs.uk

11) What will happen to the results of the study?

The study will be written up and papers will be published. Results may also be presented in conferences. You or your relative will not be identifiable in any published results.

12) Who should you contact with questions?

Professor Gillian Mead (Professor of Stroke and Elderly Care Medicine)

Gillian.x.mead@nhslothian.scot.nhs.uk

013124226927

If you wish, you could contact an independent person:

Dr Andrew Coull

Associate medical director

Royal Infirmary of Edinburgh

Andrew.coull@nhslothian.scot.nhs.uk

01312426945

For complaints:

NHS Lothian Patient Experience team

2nd floor Waverley Gate

2-4 Waterloo Place

Edinburgh EH1 3EG

feedback@nhslothian.scot.nhs.uk

01314655709

We would like to thank you for reading this information sheet and considering taking part in this study.