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# Why do patients develop severe pressure ulcers? Patient interviews (community based; version 3 (04/02/2010)

*We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with your relatives and your ward nurse or carer if you wish. Ask us if there is anything that is not clear or if you would like more information. Part 1 tells you the purpose of this project and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.*

## Part 1

### What is the purpose of the study?

The development of a severe pressure ulcer (PU), also called a bed sore or pressure sore, has serious consequences for everyone involved. For patients, they cause much suffering and pain. For staff involved in the care of someone with a severe pressure ulcer, they are now seen as what is called a 'serious clinical incident', and require investigation into the causes. For carers they are a major worry, and an obstacle to caring.

This study is about trying to find out the reasons why people develop severe pressure ulcers which may not always be clinical ones. One of the purposes of this study is to see whether the causes may be down to healthcare system weaknesses, rather than to individual weaknesses or blame. The study involves interviewing patients like yourself, and all the people involved in your care throughout the development of your severe pressure ulcer, to see if there are any general underlying patterns which lead to developing a severe pressure ulcer. The study also aims to uncover any other reasons for developing a severe pressure ulcer, which may have not yet been noticed. The final aim of the study is to help produce a risk assessment tool, which will try to help prevent severe pressure ulcers from developing.

**Why have I been invited?**

You have been chosen to take part because we are interested in talking to people who have experience of having severe pressure ulcers. Any person who has, or has had in the past, a severe pressure ulcer, from a sample of either hospitals or within the community, will be asked to participate.

**Do I have to take part?**

You are under no obligation to take part in this study, it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part we will then ask you to sign a consent form to show that you have agreed to take part. You will be given a copy of this information sheet and the consent form for you to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

**What will happen to me if I take part?**

If you agree to take part, you will be introduced to the researcher, who will be accompanied by the tissue viability nurse. This will give you an opportunity to ask questions about the study. If you then still wish to take part, the researcher will arrange an interview with you. It is expected that the interview will take about an hour. We will make sure the interview takes place in as private a place as possible, either in your own home or on the ward where you are admitted, at a time convenient for you. The interview will be informal, in a conversation style, rather than a list of questions.

The researcher will also seek permission to access and analyse your case notes, to look into what possibly led to you developing a severe pressure ulcer. Your nurses and carers/relatives will be approached to participate in the research and provide information relating to your care. No further involvement from you is required.

The discussion that you have with the interviewer, with your permission, will be tape recorded and transcribed to help us analyse it. The tape recording will be used only by

researchers involved in the project and it will be stored in a locked cabinet. As soon as the information on the tapes in analysed, the tapes will be destroyed.

**What are the possible disadvantages and risks of taking part?**

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and you will need to reflect on your personal experience of having a severe pressure ulcer and what your experience of care has been. There is a possibility that you may find this distressing. The interview can be stopped at any point if you feel you do not want to continue. If necessary, a referral can be made to your nurse or other healthcare professionals if you are distressed at all by the interview.

**What are the possible benefits of taking part?**

We hope that being given the opportunity to take part in this study would give you some satisfaction that you are contributing to increasing knowledge about the reasons and risks behind why people develop severe pressure ulcers. We hope that the information we get from the interviews will help to inform healthcare services about patterns in a person's care pathway which may be more likely to lead to the development of a severe pressure ulcer. We also hope to help produce a risk assessment to help prevent severe pressure ulcers from occurring.

**Will my taking part in this study be kept confidential?**

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. In the event that any evidence of poor practice, neglect or abuse is identified during the course of the interview, the researcher might need to disclose details to a third party outside of the interview. This would not be done without discussing it with you first. Details are included in Part 2.

**This completes part 1.**

*If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.*

**Part 2**

**What will happen if I don't want to carry on with the study?**

You are free to change your mind at any point up to, during or following the interview. You will not be able to be identified in the study results but if you wish to withdraw any data already collected prior to publication of the results then arrangements can be made for the interview tape to be destroyed and your discussion excluded from the study.

**Will my taking part in this study be kept confidential?**

The procedures for handling, processing, storage and destruction will be according to the Caldicott principles and the Data Protection Act 1998.

Lisa Pinkney and her supervision team have a duty of confidentiality to you as a research participant and will do their very best to meet this duty. Any information that is collected about you will have your name and address removed so that you cannot be recognised. All information will be kept in locked cupboards and will only be accessible by members of the research team. No names or details that would identify specific people will be included in the outputs from this study. Outputs, including quotations from interviews, may be used in reports, presentations and papers, and for healthcare and/or medical research, but these will not be traceable to specific individuals. All published and unpublished reports will disguise the identity of people.

**What will happen to the results of the research study?**

Participants will not be identified in any report or publication. The study results will be used to inform healthcare provision, and to help produce a risk assessment tool, based on the information gathered from participants. Information from this study will be included in a final report and published in a scientific journal.

**Who is organising and sponsoring the research?**

This study is funded by the National Institute of Health Research, which is part of a larger pressure ulcer research programme aimed to reduce the impact of PUs on patients, and to

produce a risk assessment framework to help prevent pressure sores. This study is also being undertaken as part of a PhD qualification supervised by the University of Leeds.

**Who has reviewed the study?**

This study has been peer reviewed by the National Institute of Health Research before approval for funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by the *Leeds West* Research Ethics Committee.

**What do I do now?**

Once you have read the information and if you would like to take part in the study, please tell your district nurse or tissue viability nurse who provided you with this information leaflet. They will complete the Agree to Researcher Contact Form at the end of this leaflet and send it back to the researcher, Lisa Pinkney, who will contact you upon receiving the form, to discuss this study further (with your tissue viability nurse present) and then arrange a time for the interview.

**Further information and contact details**

Thank you for taking the time to read this leaflet and for considering this study. If you would like to discuss the study further or have any questions about the study at any time, please contact the researcher, Lisa Pinkney on 0113 343 0828 or the study supervisor, Professor Justin Keen on 0113 3436941 or speak to your district nurse or tissue viability nurse who provided you with this information sheet.

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**PATIENT AGREEMENT TO RESEARCHER CONTACT**

**Name of researcher**: Lisa Pinkney
Centre for Health and Social Care
University of Leeds
Leeds Institute of Health Sciences
101 Clarendon Road
Leeds
LS2 9LJ
0113 343 0828

**Name of consultant/nurse:** _____

**Contact number:** _____

## Why do patients get severe pressure ulcers? Patient interviews

Please initial the boxes:

- I have read the information sheet (version 3) and kept a copy. ☐

- I am happy to be contacted by the above named researcher to discuss the study further (with a tissue viability nurse present) ☐

***Please complete your contact details in the space provided***

Patient name _____

Address _____

_____

_____Postcode_____

Telephone Number _____

Preferred contact time _____

**Thank you for completing this form. Please return to Lisa Pinkney at** Centre for Health and Social Care, Room 2.02, LIHS, University of Leeds, 101 Clarendon Road, Leeds, LS2 9LJ or phone 0113 343 0828.