The Impact of the Liverpool Care Pathway on Care at the End of Life
INFORMATION ABOUT THE RESEARCH FOR PATIENTS

Introduction

We would like to invite you to consider taking part in our research study and in order for you to do this, it is important that we provide you with information to help you to understand why the research is being done and what it would involve. Please feel free to talk to anyone you feel comfortable with about the research before making your decision.

What is the purpose of the study?

The government's National End of Life Care Strategy (2008) emphasizes the importance of care at the end of life by promoting the use of the Liverpool Care Pathway for the Dying Patient (LCP) to support the delivery of quality care. The LCP is a 'good practice' template, underpinned by education and training, that staff caring for patients in the last hours or days of life can use to help them to deliver appropriate care. This study has been designed to understand whether the tool makes a difference to the quality of care provided. We have chosen to undertake this study in Intensive Care and Nursing Homes because these are two settings in which care should take into account the end of life.

We plan to collect information from a variety of sources (policy documents, patient notes, by observing care as it is delivered to patients, interviewing staff and interviewing bereaved relatives) to help us to understand what care looks like in Intensive Care and Nursing Home settings that use the LCP to support care and those that do not. By comparing the care delivered with and without the support of the LCP we will be able to identify the impact of the LCP.

Why have I been approached?

The people caring for you will have explained that there has been a change in your condition and that they believe that you are now in the last days of life. An important part of the research study involves observing care as it is delivered at this time. We would like you to consider allowing us to observe the care that is provided for you and to have access to your medical records to assess the information that is recorded by staff about that care.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part in this research study. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. We will then approach a named relative/friend to give their consent to take part also. They will be asked if they are happy to be part of the observation of your care and to take part in an interview with the researcher to give their views on the care that was delivered. Only when we have written informed consent from you and your relative/friend will the study begin. However, if at any time you decide that you no longer wish to participate, you are free to withdraw from the study without giving a reason or an explanation. The care that you receive will not be affected by whether or not you decide to participate.

What will happen to me if I take part?

We would like to observe the care that you receive at this time and to have access to your medical notes to review the description of the care recorded by staff. The observation will involve a researcher sitting in the room with you and any relatives/friends as care is delivered. The researcher will do this in 4 hour blocks of time and they will note down information about the care that staff deliver. The researcher will sit at a suitable distance from your bedside so as to avoid any interruption to your time with your relatives/friends or to the care that you receive from staff. At the end of the 4 hour block of time, the researcher will leave the room in order to interview the member of staff who has been most involved in delivering your care and to review the record of care reported in your medical notes. The researcher may then wish to re-enter the room to undertake a further 4 hour block of observation. The researcher will gain the verbal consent yourself and from those at the bedside before resuming the observation period. If at any time you or anyone at the bedside does not wish the observation to continue (temporarily or at all), the researcher can be asked to leave the room.

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

If you change your mind about your taking part in the study you can withdraw your consent at any time without giving a reason and without your care and that of your relative/friend being affected in any way. If you do decide to withdraw from the study, any information already collected will be destroyed and will not form part of the final results.

What are the possible disadvantages and risks of taking part?

We do not think that there are any major risks involved for you in being part of this study. The research does not involve making any changes to your 'normal' care at this time nor does it require you to take part in any invasive tests or treatments. However, maintaining your dignity and privacy is very important to us. For this reason, should you or others at the bedside wish the researcher not to be present whilst certain elements of care are being undertaken, or for any other reason, the researcher can be asked to leave without the need for explanation. In these circumstances, the researcher will not re-enter the room until and unless invited to do so by you, your relative/friend and/or others at the bedside.

What are the possible benefits of taking part?

There is unlikely to be any direct benefit to you, but your participation in this study will help us find out more about the impact that the LCP has on care at the very end of life. It may be comforting to know that someone is sitting with you and observing the care delivered, especially at times when other relatives/friends may be unable to be at the bedside themselves. Should you become distressed at all during the observation period, the researcher will leave the room and alert a member of staff if there is no one else at the bedside.

Will my taking part in the research be kept confidential?

Yes. We will follow current ethical and legal practice and all information collected will be handled in confidence. However, we may need to breach confidentiality for any issues that may arise where we have a statutory duty to disclose. For example, if during the course of the period of observation issues of malpractice, sub-optimal care or abuse are identified, the researcher will report the 'incident' immediately in line with risk and governance arrangements operating within the organization. No audio or audio/visual recording equipment will be used to record information during the blocks of observation.

The researcher will make a written record of important elements of care delivery and communication and only members of the project team will have access to this data in order to undertake an analysis of the results. Numeric identifiers will be used rather than names in order to protect the anonymity of those taking part. These data will be stored in a locked filing cabinet in the University of Liverpool for 3 years after the publication of the results of the study, after which they will be securely destroyed.

What will happen to the results of this study?

All of the information that we collect from the various elements of the project will be brought together to help us to understand the impact of the LCP on care at the very end of life. The findings of this study will be useful in highlighting where services and the delivery of care can be improved in the future. The results will be written up as a final report for the funding body and will include recommendations for future practice. We also intend to publish the findings in peer reviewed journals and make presentations to national and international research conferences in order to make sure that the messages from this study are shared widely and appropriately.

Who is organising and funding the research?

The Principal Investigator for the study is Professor John Ellershaw, Director, Marie Curie Palliative Care Institute Liverpool, University of Liverpool. The study is sponsored by the University of Liverpool and funded by the National Institute for Health Research, Service Delivery and Organisation Programme.

Who has reviewed the study?

This proposal has been reviewed and approved by "North West Wales Research Ethics Committee", which is a committee whose task it is to make sure that research participants are protected from harm. You can find out more about the work of Research Ethics Committees by visiting the National Research Ethics Service website at http://www.nres.npsa.nhs.uk.

Please note

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see contact information below). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure (or Private Institution). Details can be obtained from the hospital/nursing home.

Further Information

If you would like any further information about this study please contact:

Jacqueline Jones
PA to Professor John Ellershaw
Director, Marie Curie Palliative Care Institute, Liverpool
XXXX

UNIVERSITY OF LIVERPOOL

Centre number:

Study number: REC Ref:

Participant identification number for this study

CONSENT FORM

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Name of Researcher: Professor John Ellershaw

	Please initial box
I confirm that I have read and understand the information sheet dated August 2010 (Version 2) for the above study.	
I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I agree to the researcher observing my care and to the researcher having access to my medical notes.	
I understand that I am free to withdraw my consent at any time without giving any reason, and without my care or legal rights being affected.	
I agree to take part in the above study.	

Name of patient : Date

Signature

Name of person taking consent: Date

Signature

When completed: 1 copy for participant; 1 copy for researcher