The Impact of the Liverpool Care Pathway on Care at the End of Life

INFORMATION ABOUT THE RESEARCH FOR RELATIVES (1)

Introduction

We would like to invite you to consider taking part in our research study. 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 for you. 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. Here, at (Name of site) clinical care at the end of life follows the palliative care guidelines which are based on the LCP. 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 your relative/friend will have explained to you that there has been a change in your relative/friend's condition. They believe that the person you care about is now in the last days or hours of life. An important part of the research study involves observing care as it is delivered and talking with relevant people about their thoughts and feelings on the care that was delivered. Your relative/friend has agreed to allow us to observe the care that is provided for them and to have access to their medical records to assess the information that is recorded by staff about that care. We would like you to consider whether you are also happy for the observation to take place and whether you would consider taking part in an interview with the researcher.

Do I have to take part?

No. We will describe the study and go through this information sheet with you. It is up to you to decide whether or not you wish to take part. If you agree to take part, we will then ask you to sign a consent form. However, if at any time you change your mind about taking part, you can withdraw from the study without giving a reason or an explanation. The care that your relative/friend receives or that you receive will not be affected by whether or not you decide to participate.

What will happen if I take part?

We would like to observe the care that your relative/friend receives during the last days or hours of their lives and to have access to their medical notes to review the description of the care recorded by staff. The observation will involve a researcher sitting in the room with your relative/friend (and others at the bedside) 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 the bedside so as to avoid any interruption to your time with your relative/friend. 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 the care and to review the record of care reported in your relative/friend's 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 of those at the bedside before resuming the observation period. If at any time anyone at the bedside does not wish the observation to continue (temporarily or at all), they can ask the researcher to leave the room.

We would also like to interview you to gain an understanding of your view of the care that was delivered. This will be a semi-structured interview with the researcher that will last around an hour and will take place at a venue and time that is acceptable to you. You will be approached to consider taking part in the interview no sooner than one month after the death of your relative/friend (unless an earlier time has been agreed with the researcher prior to the start of the study).

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.

Expenses and Payments

No expenses or payments will be made to your relative/friend for their participation in the study. Any travel expenses that you may incur in order to attend the interview with the researcher will be repaid.

What are the possible disadvantages and risks of taking part?

We do not think that there are any major risks involved in being part of this study. The research does not involve making any changes to 'normal' care at this time nor does it require your relative/friend or you to take part in any invasive tests, treatments or data collection activities. However, maintaining the dignity and privacy of your relative/friend and of others at the bedside is very important to us. For this reason, should you, your relative/friend 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 any 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.

It is possible that you may become upset during the interview with the researcher when asked to reflect on the last days or hours of your relative/friend's life. Please remember, you do not have to answer any questions that you find too upsetting and you can ask the researcher to stop the interview at any time, either for a short while or completely. You will be given access to appropriate external support if you would find it helpful.

What are the possible benefits of taking part?

There is unlikely to be any direct benefit, 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 your relative/friend and observing the care delivered at times when you or others are unable to be at the bedside. Should your relative/friend 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 observation or interview (see below) 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.

We would like to audio record (with your permission) the interview with the researcher after the death of your relative/friend. You will not be identified by name on the recording and only the project team and the person transcribing the recording (who has signed a confidentiality agreement and has 10 years experience of undertaking such transcriptions without incident) will have access to the data. The recording will be stored in two ways: as an audio file and, as a transcript. The audio recording will be stored on a password protected data stick which will be kept in a safe in the University of Liverpool for a period of 3 years after publication of the results of the study, after which, it will be securely destroyed. The transcripts of the interviews will be analysed by the researcher and other members of the project team. You will not be identified by name in the transcript – only a numeric identifier will be used. The transcript and the analysed materials will be kept 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

Study number: REC Ref: Centre number:

Participant identification number for this study

CONSENT FORM

The Impact of the Liverpool Care Pathway on Care at the End of Life

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 am happy for the care of my relative/friend to be observed by the researcher.	
I agree to being approached one month after the death of my relative* friend to take part in an interview with the researcher * or alternative date agreed:	
I understand that I am free to withdraw consent for my participation 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 relative/friend:

Name of Participant: Date

Signature

Name of person taking consent: Date

Signature

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