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

CONSULTEE INFORMATION SHEET

Introduction

We would like to invite your relative/friend to participate in our research study. As they are unable to make an informed decision about taking part at this time, we are approaching you to give your opinion as to whether or not you think they would wish to be involved in this 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 your relative/friend. 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 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 at this time and we would like to invite your relative/friend to participate by allowing us to observe the care provided to them. As they are unable to make an informed decision about taking part in this study at the current time, we would like you to consider whether or not you think that they would wish to take part (had they been able to make a decision on their own behalf) and whether you feel able to make that decision on their behalf.

Does my relative/friend 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 think your relative/friend would have wished to take part in this research study and whether they should take part. If you do decide that they would have wished to take part in the study, we will then ask you to sign a consultee form to confirm your view. However, if at any time you change your mind about your friend/relative's wishes or you think that they wouldn't wish to continue to have their care observed, you can withdraw them from the study without giving a reason or an explanation. The care that your relative/friend receives will not be affected by whether they take part or not.

What will happen if they 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.

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

If you change your mind about your relative/friend's wishes or you think that they wouldn't wish to continue to have their care observed, you can withdraw them from the study without giving a reason and without the care 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.

What are the possible disadvantages and risks of taking part?

We do not think that there are any major risks involved for your relative/friend 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 to take part in any invasive tests, treatments or data collection activities. However, maintaining the dignity and privacy of your relative/friend 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.

What are the possible benefits of taking part?

There is unlikely to be any direct benefit to your relative/friend, but their 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 their 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 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

Study number: REC Ref: Centre number:

CONSULTEE FORM

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Name of Researcher: Professor John Ellershaw Please initial box

Name of Patient/Client:	
I confirm that the patient/client lacks capacity to give or withhold consent to take part in this research study because:	
I have no connection with the Research Project	
I have read and understood the Consultee 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 believe that ..... would not object to being involved in this research study	
I understand that their medical notes will be looked at by responsible members of the research team	
I understand that I am free to withdraw ..... at any time if I feel that it is not in their best interests.	

Name: .....

Relationship to patient/client .....

Address .....

.....

Signature: ..... Date: .....

Name of person taking consent: ..... Date: .....

Signature: .....