The Impact of the Liverpool Care Pathway on Care at the End of Life
INFORMATION ABOUT THE RESEARCH FOR STAFF (2)

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, your patients and their relatives and friends. 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?

An important part of this research study involves a researcher being present to observe care as it is delivered to patients (in the last days or hours of their lives) and their relatives and friends. It is likely that during the course of the study, patients for whom you are providing care will enter the dying phase and will wish to consent to participate in this study. We are approaching you to gain your consent to the observation of any patients you are caring for (for whom written, informed consent is also gained). In addition, we may wish to undertake an interview with you about the care that we have observed.

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 in principle to the observation of the care of patients in your care, we will then ask you to sign a consent form. Only when you have given informed written consent for this will we approach any of those patients (where appropriate) and/or their relatives/consultees for their specific consent when appropriate. We may approach you to consider taking part in a post observation interview and to gain your verbal consent. If at any time you change your mind you can withdraw your consent for a specific patient, and/or you can decline the offer to take

part in a post observation interview without giving a reason or an explanation. The choice that you make will have no bearing on your job or on any work-related evaluations or reports.

What will happen if I take part?

We would like to observe the care that you deliver to patients in the last hours or days of life for whom we have specific informed, written consent (from patients themselves, their consultees and/or from their friends/relatives) for participation in this study. If you do consent to being part of the study, we will check verbally with you each time an observation block is commenced.

The observation will involve a researcher sitting in the room in 4 hour blocks of time and noting down information about the care delivered. The researcher will sit at a suitable distance from the bedside so as to minimise any interruption to your work and to the environment in general.

The researcher may also like to interview you, on occasion, after you have delivered care to an 'observed' patient to understand your views on the delivery of that care. On each occasion, they will approach you to consider whether or not you wish to take part in this interview and to arrange a suitable venue and time if you give verbal consent at this time. The researcher may then wish to re-enter the patient's room to undertake a further 4 hour block of observation. They will gain the verbal consent of those at the bedside (including staff) before resuming the observation period. If at any time the patient or 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 taking part in the study you can withdraw your consent at any time without giving a reason and without this decision having any bearing on your job or on any work-related evaluations or reports. You may also decline verbally at any time to be part of specific periods of observation or to undertake post care delivery interviews.

Expenses and Payments

No expenses or payments will be paid to you for taking part in this study.

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 delivery at this time. However, you may feel uncomfortable at first being 'watched' by an external observer as you go about your day to day business. As you become more used to their presence this feeling should abate. In addition, you may feel that the dignity and privacy of your patient is compromised during certain procedures/elements of care you are carrying out on their behalf. For this or any other reason, should you or anyone else at the bedside wish the researcher not to be in attendance at such times 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 the patient (where appropriate), and/or their relatives/friends at the bedside and yourself.

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. Other studies which have involved observational techniques have reported that staff and relatives may find it comforting to know

that someone is sitting with the patient when you or others are unable to be at the bedside. Should the patient 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 or the subsequent interview 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. Only in exceptional circumstances (for example witnessing the delivery of dangerous or poor quality care) will the researcher be duty bound break this confidence and to alert the person in charge of the patient's care. You will be informed should this course of action be necessitated.

We would like to audio record (with your permission) any interview(s) that we undertake with you after the observation period. No individual will 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. These recordings will be stored in two ways: as an audio file and, as a transcript. The audio recordings 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, they will be securely destroyed. The transcripts of the interviews will be analysed by the researcher and other members of the project team. No-one will be identified by name in the transcripts – only numeric identifiers will be used. The transcripts 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 agree to the researcher observing the care that I deliver to patients for whom specific informed, written consent has been gained for participation in this study	
I agree to being approached to consider taking part in a post observation interview with the researcher.	
I understand that I am free to withdraw my consent at any time without giving any reason and that this will have no bearing on my job or any work-related evaluations or reports.	
I agree to take part in the above study.	

Name of Patient:

Name of staff member : Date:

Signature

Name of person taking consent: Date:

Signature

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