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

PILOT STUDY PROTOCOL & MAIN STUDY OUTLINE PROTOCOL

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Pilot study to evaluate staff views of undertaking observational research in patients in the last hours and days of life in the Intensive Care and Nursing Home environments

Protocol

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Introduction
The National Institute for Health Research, under the auspices of the Service Delivery and Organisation Programme, has awarded research funding to the University of Liverpool to undertake a study of the impact of the Liverpool Care Pathway for the Dying Patient (LCP). The study is funded for three years and will be conducted in two diverse care settings: Nursing Homes and Intensive Care Units (ICUs) in England.

This research is a matched case study design that involves direct observation of the interactions between patients in the last hours or days of their lives, their relatives and healthcare staff (see page 7 of this document for an outline proposal for the main study). This work is ethically and practically challenging and in order to maximise the potential for success, a pilot phase is planned. This phase is intended to be a formalised engagement of interested parties to inform the construction of the final protocol for the main study. The guidelines for the completion of ethics submissions strongly urge this type of endeavour as it is important, both for determining the focus and executing the research, that the views of stakeholders (patients, relatives and staff) are sought and taken into consideration.

Ethical Challenges in undertaking the main study

It is recognised that there are complex practical, moral and ethical challenges involved in successfully undertaking this study. The research team has a track record in studies relating to care of the dying and is ideally placed to conduct this work. However, it is recognised that this study has some particular issues which require very careful consideration before the study is launched. Three main ethical and design challenges that need to be addressed are:

1. Recruiting patients who are dying and their family and friends to the planned study (eg timing and consent)
2. Recruiting staff to the study
3. Observations of the care of dying patients

There is some limited research literature on the ethical and practical challenges inherent in carrying out research at the end of life. For example, Seymour (2001) highlights issues and challenges regarding gaining the informed consent of relatives and companions of dying patients in the intensive care setting. She suggests that 'process' consent, where the contract between researcher and researched is renewed at regular interviews, and being as candid as possible about what one is trying to achieve are potential solutions. Lawton (2001) highlights how methods such as participant observation enable the researcher to keep the focus on the dying patients eliciting important data without the need to involve patients in long-winded and potentially tiring and distressing interviews. However, she also acknowledged the practical and logistical challenges of giving information and gaining informed consent from patients and/or their relatives in environments with a high throughput of patients.

Proposed Pilot Study

In view of these ethical and practical challenges, the need for a pilot study has been established to enable the sensitive translation of the proposed research into practice.

Pilot Study Methodology

The pilot study will involve focus groups of staff in nursing homes and intensive care units along with interviews with representatives of relevant patient groups.

Two focus groups will be convened with a purposive sample of up to 10 members of staff working in ICU and 10 members of staff working in care homes in the North West of England. In addition, interviews will be conducted with a representative of up to 4 key patient groups such as Patient Concern, INVOLVE, CRUSE and the National Council for Palliative Care (NCPC). Ethical approval is being sought for the focus groups with staff, as such approval is not deemed necessary for consultation with national voluntary patient/relative groups.

The purpose of the focus groups is: firstly, to elicit views on the main study design; secondly, to explore ways in which the data collection methods may be tailored to meet the needs of the participants as well as the researchers and thirdly, to identify ways in which recruitment to the study could be maximised. The focus groups will be audio-taped (with the permission of

participants) and transcribed verbatim. The transcripts will be thematically analysed to highlight the potential challenges, barriers, and levers for successfully engaging in such research. The information that is gained from this pilot study is likely to be of interest to other researchers and the group may wish to publish the findings.

Accessing the Sample – ICU and Nursing Home

Members of the project team from the Marie Curie Palliative Care Institute (MCPCIL), University of Liverpool, already have established working relationships with a range of teams from ICU and nursing homes nationally. MCPIL currently have a database of organizations that have in principle indicated a willingness to be approached to participate in research studies. A convenience sample of 1 Intensive Care Unit and 2 nursing homes have been identified for inclusion in this pilot stage of the research and they have agreed in principle to receive further information about this study pending ethics committee approval.

Once the sites have agreed to participate and ethical approval has been gained, a meeting will be arranged with staff within the sample sites (in liaison with the head/manager) to explain the aims of the main study and the pilot and to provide written information about participation for further consideration. Those who wish to participate will be asked to contact the researcher directly. A purposive sample of up to 10 individuals from each setting (5 from each participating nursing home) who have expressed a wish to participate will be recruited. The sample will then be sent details of the venue and time of the group and a copy of the consent form. Written informed consent will be sought on the day of the focus group. Participants will be made aware that they may withdraw from the research at any time without giving a reason (see information leaflet and consent forms).

Patient groups/forums such as Patient Concern, INVOLVE, CRUSE and the NCPC will initially receive an introductory email or telephone call which will be followed by a letter outlining the purpose of the main study and the pilot study. Staff within each organisation will be asked to identify an appropriate representative to take part in a short interview. Although not subject to ethics committee approval the informing and consenting of these national voluntary sector representatives will follow standard research practice. They will receive written information, they will have as much time to consider their participation as they require, and at the minimum this will be 24 hours, they will be required to provide written informed consent to participate and they will have the right to withdraw from the study at any point. Their data will remain anonymous and confidential.

Data Collection and Analysis

The two focus groups will be facilitated by the research fellow and the interviews will be based on the areas within the topic guide (see attached). Focus group interviews are facilitated group discussions where the interviewer asks open-ended questions which are discussed through group interaction. The main concern is with depth of opinion, rather than level of agreement. Using this method, multiple views can be gathered at the same time, dialogue and new ideas can be stimulated, and the format allows for flexibility. The process outlined above will be used to introduce the study and invite participation in the groups.

The focus group interviews will last, on average, one and a half hours. The group interaction will be facilitated by the researcher, Maureen Gambles, and will be audio-taped (with the permission of all involved). The audio tapes will be transcribed verbatim.

A simple thematic analysis will be undertaken on the transcripts to identify issues raised by staff and patient representatives that are pertinent to the focus of the main questions:

1. Recruiting patients who are dying and their family and friends to the planned study (eg timing and consent)
2. Recruiting staff to the study
3. Observing the care of people who are in the last hours or days of life

The pilot will be used to refine elements of the planned design and execution of the study. The findings may also be of interest to other researchers who are undertaking observational work in sensitive areas, and for this reason, the findings may be written up for publication in relevant peer reviewed journals.

References

Lawton J (2001) Pearls, Pith, and Provocation. Gaining and Maintaining Consent: Ethical Concerns Raised in a Study of Dying Patients. *Qual Health Res* 2001; 11; 693-705
Seymour J (2001) Critical Moments – Death and Dying in Intensive Care. OUP. Buckingham

FOR INFORMATION ONLY

Main Study – Outline Protocol
The Impact of the Liverpool Care Pathway on Care at the End of Life

Proposed duration (in months) 36
Proposed start date 01 August 2010

Summary

The Liverpool Care Pathway (LCP) provides a step-by-step approach to care of the dying based on some key principles of hospice care. It aims to provide a structure for the delivery of care in the dying phase and to ensure that patients and their families receive good symptom control, psychosocial support and bereavement care. Although the LCP is cited as good practice there is, however, very little research evidence on exactly how the LCP is used and the impact it has on the care of people who are dying. This study is designed to produce evidence to fill this gap by examining the impact of the LCP on care in two different settings; Intensive Care Units and Nursing Homes in England.

The study will explore the impact of the LCP on: patients, carers, bereaved relatives and clinicians including nurses, doctors and other members of the multidisciplinary team involved in the care of patients at the end of their lives.

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A sample of 24 ICU and Nursing Homes in England will be included in the study - half of the sample will be using the LCP, the other half will not. The following research methods will be used in each case study site:

- Interviews with staff
- Observation of interactions with dying patients
- Case note analysis
- Interviews with bereaved relatives
- Retrospective analysis of deaths in each location
- Analysis of the Strategic Health Authority plans for End of life Care
- Economic Analysis

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Main Study Research Outline

Introduction, aims and objectives

The literature on end of life care suggests that the LCP is a 'best practice' model of care for dying patients and at the same time supports education of generalists (Higginson et al 2006). There is, however, little empirical work exploring exactly how the LCP is used and the impact it has on the care of people who are dying. This study seeks to examine the impact of the LCP on care in two different settings; Intensive Care Units and Nursing Homes in England.

The research builds on the scoping review of generalist End of Life Care undertaken by Higginson et al (2007) and focuses on providing evidence on the impact of the Liverpool Care Pathway on care at the end of life in two generalist settings: Nursing Homes and Intensive Care Units. The study will provide evidence on costs and outcomes to enable the comparative cost-effectiveness underlying the implementation of LCP in different sub-groups of patients and in different contexts to be evaluated. Importantly, this study involves the views of bereaved relatives as well as those of staff and other key stakeholders. The project will generate evidence relevant for the commissioning, development, implementation and management of generalist end of life care services in the NHS and wider health and social care system.

Background

End of life care has been defined by the National Council for Palliative Care as: 'care that helps all those with advanced, progressive, incurable illness to live as well as possible until they die' (NCPC, 2007). The National Council go on to state that end of life care 'enables the supportive and palliative care needs of both patient and family to be identified and met throughout the last phase of life and into bereavement. It includes the management of pain and other symptoms and provision of psychological, social, spiritual and practical support' (op cit, 2007). The care of people who are dying, however, takes place in a number of settings not all of them specialist in nature, leading to huge variation in understanding end of life care and its relationship to palliative and terminal care (Higginson et al 2006).

Generalist services are those which deal with all conditions on a day to day basis including long term and acute care such as GPs, District Nurses and Geriatricians. The extent to which generalist services offer specialised care at the end of life is not known although it is commonly accepted that care for people at the end of life has not, in the past, been a high priority for all health and social care services. In order to improve the quality of care across the country the Government has published a number of policy documents. The NHS Next Stage Review, (DH, 2008), focused on end of life care as one of eight principal care pathways, and in July 2008 the End of Life Care Strategy was published (DH, 2008). The Liverpool Care Pathway for the Dying Patient (LCP) is cited as an example of good practice in end of life care (Recommendation 14 of the NICE Guidance on Supportive and Palliative care (NICE 2004) and is being disseminated nationally as part of the End of Life Care Initiative to improve care for dying patients in the UK (2008). In a scoping study of the literature on end of life care conducted by Higginson et al (2006) the LCP was reported to be a good model of care which put a process of care into place for dying patients and at the same time enabled generalists to be educated (Higginson et al

2006). There is, however, little empirical work exploring exactly how the LCP is used and the impact it has on the care of people who are dying. This study seeks to examine the impact of the LCP on care in two different settings; Intensive Care Units and Nursing Homes in England.

The Liverpool Care Pathway for the Dying Patient

The Liverpool Care Pathway for the Dying Patient (LCP) provides generic health care workers with a comprehensive template for evidence based multidisciplinary care specifically to support care in the final days or hours of life. Its focus is on the physical, psychological, social, spiritual/religious and information/communication needs of patients and carers. The LCP document forms part of a continuous quality improvement framework that also includes the local provision of tailored ongoing education and training in end of life care generally and in the appropriate use of the document to support the delivery of care. It is designed to replace all other documentation in this specific phase (Ellershaw and Wilkinson 2003).

The LCP provides a structure to support the delivery of care in this phase and to ensure that patients and their families receive good symptom control, psychosocial support and bereavement care. The document itself is structured into three distinct sections:

1. Initial assessment - completed when the multidisciplinary team makes the decision that the patient has entered the dying phase. This stage of the document largely focuses on the rationalisation of medication; spiritual needs and communication.
2. Ongoing assessment – minimum of 4 hourly assessment of important indices of comfort for the dying patients and their families.
3. Care after death – completed in the hours immediately after the death of the patient.

Care goals are identified as either achieved or not achieved or where appropriate not applicable. Whenever a goal is not achieved, staff are required to provide reasons. The care goals clearly describe aspects of patient comfort and in theory form the starting point for continuous monitoring and potential adjustment of care until the death of the patient. One of the most important aims of the LCP is to facilitate good documentation of symptoms, problems and care during the dying phase.

Organisations wishing to use the LCP are encouraged to register with the Marie Curie Palliative Care Institute Liverpool (MCPIL). It is also expected that organisations wishing to register first have the support of the Palliative Care Service supporting the organization and written endorsement from the Organisation /Executive Team. Registration involves providing some basic organisational data and agreeing to complete documentation pertaining to the use of the LCP. This documentation includes a baseline review of current practice and post implementation a review of 20 pathways. In each case, analysis is undertaken by MCPILand a report fed back to the participating organisation. To date 503 Nursing Homes and 66 Intensive Care Units have registered to use the LCP.

Plan of investigation
In essence this is a matched case study design taking place with Nursing Homes and Intensive Care Units in England. Half the sample will have registered to use the Liverpool Care Pathway and half will not. The study involves the collection of data using; interviews, observations, case note analysis and documentary analysis of the SHA's plans for end of life care and end of life care policies in place within individual sites.

Methods

Study design
The aim of this study is to assess the impact of the LCP on care of the dying patient in two different settings: Nursing Homes and ICUs. This will be achieved through a matched case study design. The study will explore the impact on: patients, carers, bereaved relatives and clinicians including nurses, doctors and other members of the multidisciplinary team involved in the care of patients at the end of their lives. The impacts to be studied include: the physical care of the patient; the psychological needs of the patient; the social, spiritual and religious needs of the patient; the information/communication needs of carers, and; the economic costs of care - including the costs associated with education and training as well as the use of specialist care.

In order to understand fully the impact of the LCP on patient care, the study will adopt a matched case design. Each Nursing Home/ICU which has adopted the LCP and has agreed to participate in the study will be matched with another Nursing Home/ICU in the same geographical area which has not adopted the LCP. Matching will take place on the basis of a few key variables. Nursing Homes will be matched on independent sector status, size and type of nursing care offered. ICUs will include units which have over 400 admissions per year, with over 80% of admissions mechanically ventilated. ICUs will be matched according to the number of beds and specialist care offered. The idea behind the matching is to gain similar ICU and Nursing Home sites in most respects with the exception of LCP implementation.

The current emphasis on end of life care is expected to encourage commissioners and service providers to think more clearly about the configuration, design and nature of generalist palliative care services. It is therefore likely that over the course of this study the environment for end of life care will change, with new services and ways of working being introduced. The study design being adopted will allow for the impact of these changes to be captured without undermining the central aim of assessing the impact of the LCP on end of life care.

Preliminary Mapping exercise
Given the current policy emphasis on end of life care we are aware of pockets of research which are ongoing but not yet completed. To avoid the unnecessary duplication of data collection, it is our intention to establish what data is currently being collected. This search will involve local intelligence, web based searches as well as discussions with relevant agencies such as the director of the National Programme on End of Life Care; voluntary sector providers; representatives of the private care home sector, patient and carer groups and national charities

such as Marie Curie cancer care, Help the Hospices and the National Council for Palliative Care. This will be achieved through telephone calls, emails and letters.

Case Study Sites

The study will in essence comprise 24 case study sites. Data will be collected in the same way from each of the sites. The study will take place in two geographical areas: the North West, and London. The areas that have been chosen currently have a range of Nursing Homes and ICUs some of which have registered to use the LCP and some have not. Clustering the sites in this way will make data collection more cost effective. The sample will be derived as Table 1. below shows.

Table 1.

	North West	London	Total
Nursing Home with LCP	3	3	6
Nursing Home without LCP	3	3	6
ICU with LCP	3	3	6
ICU without LCP	3	3	6
Total	12	12	24

Interviews with staff

Semi-structured interviews with key clinical and administrative staff will be undertaken at two time points.

Time Point 1

Once a site has been selected for inclusion in the study and has agreed to take part, interviews will be arranged with up to six individuals involved in the management and provision of clinical care. All interviews will be tape recorded and transcribed. These initial interviews will be undertaken to ascertain:

- How care of the dying is organised and managed in each location, including symptom control, ethical issues, spiritual and psychosocial care and relevant policies and documentation (including the use of documents other than the LCP such as the Gold Standards Framework).
- The barriers and levers for LCP implementation in those organisations using the LCP.
- How staff feel about care at the end of life, both in general and with respect to the organisation within which they work.
- How staff define and assess the dying phase.
- How patients' needs and preferences are assessed.

- How relatives are involved in the care of a dying patient.
- Training in end of life issues ranging from communication to the Palliative Care drug formulary.

Time point 2
As identified below, observations of patients in the dying phase will be undertaken. Key staff involved in the care of patients observed in this stage of the research will be interviewed at a time and in a location convenient for them. These interviews will be semi-structured and will allow staff members to talk about the care provided, the things that worked well and the things that might have been done better. They will also be asked to assess how typical this death was of the way in which patients die in their particular setting. It is envisaged that the key staff groupings will vary between Nursing Home and ICU settings. For instance, the role of GPs, District Nurses and palliative care outreach services may be central to discussions around the care of the dying in Nursing Homes. In ICU's, decision making may involve other clinical specialists within the hospital. The study is designed to capture interactions between all these individuals.

Observation of interactions with dying patients
Observational methods have been chosen for the insight into the reality of end of life care that will be provided. In particular, this study will adopt overt non-participant observation of patients who are in the dying phase. This will involve the planned gathering, analysis, and interpretation of mostly empirical data carried out with the consent of all the subjects being studied. In this study the researcher will act in the capacity of complete observer (Gold 1958). The purpose of these observations is to record the nature and content of interactions between patients relatives and staff and in particular to record interventions both those involving the administration of drugs, fluid and food as well as their withdrawal.

The literature often assumes that the observer will take a certain role and maintain it throughout the period of observation. However, it is recognised that in relation to a study of end of life care it may not always be possible to maintain a completely detached status. Protocols will be developed to guide researchers in the unlikely event that unsafe patient care is observed or should staff try to involve them in the clinical care of patients. While not wishing to influence the provision of care at the end of life it is possible that the presence of an observer may alter practice. Bowling (1997) suggests that any effect awareness of observation has on participants reduces with time. For this reason researchers will undertake blocks of observation.

The observer's role is to record group interactions and behaviours as objectively as possible using various qualitative inquiry tools. It is recognised that non-participant observation techniques bring with them a range of methodological and analytical problems which are well recorded in the research methods literature (see for example, Hammersley and Atkinson, 1983; Hammersley, 1989; Silverman, 1993). The observations of interactions between staff and between staff and patients and their relatives will be focused on care in the dying phase. Non-participant observation techniques are accompanied by a well recorded set of methodological

and analytical problems, the most frequently cited being those of subjectivity, selectivity and an introduction of bias similar to the experimental effect known as the Hawthorne effect. On the basis that researchers observing any activity begin to influence what is being researched, we anticipate recording a higher standard of care than that which might exist in unobserved settings.

We will not be able to take any type of recording instrument into the clinical settings. We therefore have to decide how to capture the dynamics, content and interactions between the staff, patients and family members while accurately recording the proceedings but changing the observed world as little as possible. There are several different approaches to observational research and in order to assess which of these approaches best suits the study we will pilot different methods with a view to selecting one method which delivers rigorous, high quality data.

Piloting of methods
In order to select the most appropriate observational technique there will be an initial stage in which 3 observational techniques will be pilot tested. This stage of the research will draw heavily on the experience and skills of Professor Perkins who was trained in observational research methods by Dr Martin Bauer at the Methodology Institute London School of Economics. One of the following three techniques will be selected for use in this study following pilot testing:

1. Grid technique
2. Focused observation
3. Contemporaneous narrative record

1. Grid technique
The grid technique for recording information to some extent reduces or removes the subjectivity and selectivity of the researcher by gathering data in predefined categories. These categories will be based on activities of care identified in the three sections of the LCP.

- Initial assessment - completed when the multidisciplinary team makes the decision that the patient has entered the dying phase. This section deals with anticipatory prescription of medication, discontinuation of inappropriate interventions, spiritual /religious assessment and appropriate information giving and communication with patients, relatives and other agencies.
- Ongoing assessment - 4 and 12 hourly assessment of important indices of comfort for dying patients and their families including symptom control and maintaining the ongoing physical, psychological and spiritual/religious comfort of patients and relatives.
- Care after death - assessment of important practical issues and appropriate support for relatives after the death of the patient.

At set time intervals during a period of observation the presence or absence of key pieces of information will be recorded.

2. Focused observation
Work previously carried out by other researchers (Adler and Adler, 1994; Fasschnach, 1982) suggests that adopting a narrow focus to the field of observation improves the accuracy of the data recorded. Focused observation allows the researcher to record observations in a narrative manner within a structure. For the purposes of this study the three sections of the LCP will provide the structure. The researcher will record not just whether something happens (as outlined in the grid format) but how it happens and with what consequences.

3. Contemporaneous narrative accounts
Contemporaneous narrative accounts sit at the opposite end of the observational spectrum to grids. These techniques are well established in the field of anthropology and ethnographic research. They require the researcher to record, usually in a field diary, their observations as they occur. In relation to this study the observer would be recording all of the activity and interactions relating to the care of the dying person as it occurs. The account is not predetermined or prestructured in any way.

Following pilot testing of the 3 observational methods outlined above a decision will be taken about the observational approach to be adopted.

Location
Observations will be recorded from a convenient and unobtrusive seat in the patient's room/environment.

Timing
All observations will be undertaken when the clinical team assess the patient is in the dying phase which on average will be the last 72 hours. Observation will be undertaken in blocks of time to include during the day as well as at night.

Case note analysis
The case notes/records of each patient observed will be examined and analysed. Data will be extracted from these notes using a structured proforma. Some preliminary research has already been undertaken at MCPCIL on extracting information regarding care at the end of life from case notes. Particular attention will be paid to the nature of clinical and nursing interventions, referral to specialists, communication over needs and preferences.

Interviews with bereaved relatives
It is recognised that after-death interviews with bereaved respondents add an important dimension to studies examining the quality of end-of-life care (Addington Hall and McPherson 2001). An attempt will be made to interview a relative of all patients observed in the dying phase. Clearly the timing of these interviews is important with the need to balance ethical concerns about intruding upon grieving relatives too soon after the death with the need to facilitate recall. The interviews will provide an important insight into how the care of a dying relative is viewed. The interviews are not designed to provide proxy data about how the patient might have felt about the quality and timing of care received. They will focus on the

perceptions and experiences of bereaved relatives on the care of the dying patient. These will be in-depth interviews tape recorded and transcribed.

Retrospective analysis of deaths in each location

It is possible that by chance there will not be enough deaths to observe in each location sampled during the period of data collection. We therefore propose to include a retrospective analysis of case notes relating to deaths experienced in each of the locations. We propose to analyse up to 30 sets of case notes drawn from the case study sites. The aim of this stage of the research is to try and establish what kind of factors are reported by staff in the documents to influence the nature and content of care provided at the end of life. Particular attention will be paid to the administration and withdrawal of interventions and the recording of any preferences expressed by patients and their relatives. In addition, the records will be examined to discover the level of contact patients had with specialist palliative care providers at the end of life. Place of death will also be recorded.

Documentary analysis

As part of Lord Darzi's review of the NHS, each strategic health authority (SHA) outside London was commissioned to produce a report outlining their 'vision' for care in their region over the coming decade. The nine SHAs were instructed to establish eight 'clinical pathway groups' made up of clinicians and stakeholders. These groups were asked to develop plans for 'world quality care' in their respective clinical areas one of which is end of life care. These documents, published in June 2008 reflect local demographic factors, priorities and targets. Information on the end of life care strategies contained in the documents produced by the relevant SHAs for the sites participating in this study will be analysed. For example, the North West Team has set three main goals for the twelve months to March 2009. They are to reduce hospital deaths by 10%; to provide 24 hour, seven day access to specialist palliative care services and finally to increase the number to provide 24 hour, seven day access to specialist palliative care services and finally to increase the number of organisations using the recognised end of life care tools. Analysis of the data generated in this study will provide a useful benchmark by which the plans of the SHAs can be realistically assessed.

In addition, current policies on end of life care in use within each of the sites will also be subject to documentary analysis.

Analysis

This study is designed to elicit both quantitative and qualitative data. The quantitative data will principally be used for the economic modelling, while the qualitative data will be used to understand the perspectives of those involved in end of life care whether guided by the use of the LCP or not.

Qualitative data analysis

The aim of the analysis will be to explore the perceived impact of the LCP on care in two different settings -the Nursing Home and the Intensive Care Unit. The findings will establish whether the experience of providing care at the end of life and the experience of bereaved

relatives is associated with whether or not the Liverpool Care Pathway was used. The qualitative analysis will also examine the use of the LCP in Nursing Homes and in ICUs as well as between Nursing Homes and ICUs. This will provide important insights into the transferability of the LCP into diverse generalist settings. Comparisons between those sites using the LCP and those not using the LCP will provide detailed evidence on information transfer, appropriateness of response, availability of drugs, good channels of communication between providers, clear role remits, collaborative and co-ordinated working, as well as gaps in provision. The qualitative data will be analysed using the grounded theory approach proposed by Charmaz (2006). This approach is based on the idea that 'knowledge' is constructed and embedded in human perception and social experience. Issues such as race and gender are individually experienced and embedded within agreed social norms or standards. As the theoretical concepts emerge from the data, these will offer an interpretive portrayal of the 'studied world', where participant's meanings and experiences are placed in their relevant situational and social contexts (Charmaz 2006).

As previously stated, data collection and analysis will overlap. Incidents and sections of the data will be continually compared and similarities and differences across the data explored. As the data is coded and compared, concepts and categories will be produced and patterns established which will help explain the development of core categories (a central phenomenon, occurring frequently which explains variations, discovered towards the end of analysis). Theoretical saturation will occur when no new relevant concepts can be found that are important for the development of the emerging theory.

Quantitative data analysis

The fundamental aim of the economic analysis is to evaluate the effectiveness with which inputs, processes and outcomes are combined in different structures of care provision to improve care for patients during the final days or hours of life. At all stages, the extent to which the LCP contributes to either the cost or benefits associated with care provision will be evaluated in detail. The economic evaluation will also generate evidence on costs and outcomes to enable the comparative cost-effectiveness underlying the implementation of LCP in different sub-groups of patients and in different contexts to be evaluated.

Undertaking such an evaluation requires a detailed analysis of the comparative quality of care provision for patients, comparative therapeutic outcomes and comparative resource use that arises from Nursing Homes which use or do not use the LCP and from ICUs which use or do not use the LCP. It is important that all resource and quality of care implications arising from the comparative structures of service provision are appropriately identified, valued and measured. In order to achieve this, the analysis will evaluate in as great a detail as possible the costs and benefits arising from the implementation of the LCP.

It is important to recognise that any analysis undertaken of a new service will inevitably be evaluating costs and outcomes identified in the initial stages of a process of change. During these initial stages, the service will be evolving and developing in a manner that may make it difficult to generate accurate estimates of the level of costs and outcomes that would arise

once the service has ‘settled down' into a steady state environment. Where Nursing Homes or ICUs have only recently implemented LCP they may still be on a ‘learning curve' with regard to its use in improving patient experience at the end of life. In such circumstances, economic modelling will be employed to extrapolate away from transitional costs and benefits in order to estimate the levels of costs and outcomes that would arise in steady state. Economic modeling can also be used to analyse factors that generate or limit the success underlying the implementation of LCP through development of an ‘impact model'. Such a model enables the analysis to identify individual factors contributing to the success of LCP and dichotomise between ‘location specific' and ‘generalisable' elements.

Location specific elements (factors such as a uniquely gifted or motivated team leader) are fundamental to the success of the service but are unlikely to be automatically transferable to other locations. In contrast, generalisable factors arise as a consequence of having identified improved organisational structures and processes and are therefore likely to be replicable throughout the NHS. In addition, a feedback loop will be used to highlight areas in which the LCP appears to be performing sub-optimally, either in patient care or resource terms to identify areas for further improvement. The economic evaluation will also therefore identify efficiency improvements that would enable the NHS to enhance the quantity and quality of care that it is able to provide from the available resources that are currently being devoted to the implementation of LCP.

Critically important to the success of the implementation of LCP will be the appropriateness and adequacy of training provided to health professionals with patients during the final stages of their life.

The design of the economic evaluation

The economic evaluation draws on data collected during each stage outlined above. A structured tool will be developed with which to capture data in a routine and standardized way. This will be embedded within each of the stages of the research. Considerable attention will be paid to the development of these data collection schedules, as they will form the basis for comparing the outcome and resource implications associated with the LCP. The final stage of the economic support provided to the project consists of data analysis and economic modelling. The exact nature of analysis and modelling required will only become identified towards the end of the data collection phase. This process will identify the comparative clinical and cost-effectiveness of each service and identify the ongoing clinical and economic issues that need to be addressed to improve the quality of care provision at the end of life.

Ethical issues and consent

The ethical issues involved in the conduct of this study are complex but the Marie Curie Palliative Care Institute specialises in research of this nature and has established a reputation for negotiating this complexity in a sensitive and caring manner. In addition, a pilot phase is planned which will involve focus group interviews with members of staff from Nursing Homes and Intensive Care Units and individual interviews with representatives of patient/relative

groups or forums. These interviews will explore the perspectives of relevant stakeholders regarding undertaking such research and specifically:

1. Recruiting patients who are dying and their family and friends to the study
2. Recruiting staff to the study
3. Observing care in a potentially distressing environment

The principles which will guide and underpin this research are respect for the patient's privacy and dignity as well as the wishes of the relatives. This will be achieved through the sensitivity of the researchers and through the concept of process consent. Process consent will ensure that the involvement of all participants is kept under review in an appropriate way so that patients do not feel they are being repeatedly asked if they want to continue to participate but at the same time consent is not a one-off event (Lawton, 2001). Given the nature of this study it is recognised that only providing information and gaining consent from people to participate at the beginning of a study is inappropriate. All the participants (patients and staff) will be dealing with the distress of death and dying which will affect them differently. Lawton (2001) in her ethnographic research in a hospice found that, patients were not always able to state whether they still wanted to participate or not and many had problems remembering that she was a researcher. Consent in this study will be negotiated at different levels - institutional consent, staff consent, patient and bereaved relatives consent. All potential participants will be invited to consider whether or not they wish to take part in the research, will be given time to ask questions and will be invited to complete a consent form prior to participating, a copy of which they will keep. In cases where the research participant becomes concerned or distressed as a result of talking about their experiences, the researcher will follow established protocols which will including pausing or suspending the interview. All participants have the right to withdraw from the study at any stage.

Ethics review

The study will be submitted for approval to the Research Ethics Committee and NHS R&D approval committees.

Benefits of research to NHS

A greater evidence base is needed on the effectiveness and application of current tools such as the Liverpool Care Pathway and about models of palliative care for patients with diseases other than cancer. In particular, more needs to be known about models of end of life care and how these can be integrated into a generalist's workload. Effective management of change in the NHS requires a clear demonstration of the advantages offered by new methods of care provision to both patients and healthcare professionals. The economic evaluation will also generate evidence on costs and outcomes to enable the comparative cost-effectiveness underlying the implementation of LCP in different sub-groups of patients and in different contexts to be evaluated. The economic evaluation will also therefore identify efficiency improvements that would enable the NHS to enhance the quantity and quality of care that it is able to provide from the available resources that are currently being devoted to the implementation of LCP.

Proposals for the involvement of stakeholders

Stakeholders will be involved at all stages of the research process in a number of ways. An advisory group will be convened for the project. Barbara Burkey is currently a user representative for the Merseyside and Cheshire Cancer Network including a) member of taskforce b) vice chair of the patient/healthcare professional partnership group c) member of the End of Life and Palliative Care Clinical Network Group. She has been involved in discussions about this project and the response outlined in this document and is very keen to be the user representative on the advisory group.

In addition to discussions with the advisory group, we will be consulting widely with organisations such as Patient Concern, INVOLVE, Bereavement Support groups, including CRUSE, North West Users Research Advisory Group and the National Council for Palliative Care as well as conducting focus groups with staff from Intensive Care and Nursing homes about the design of our approach and documentation (see pilot protocol above for a comprehensive description of the planned pilot study). Additionally, user advice and involvement will be sought regarding dissemination, accessible media and networks. The LCP National Reference Group which comprises Department of Health representatives, policy makers, healthcare practitioners, commissioners, academics and representatives of the voluntary sector and users and carers have been involved in the progress of this proposal and are committed to its development.

Plans for dissemination of results

The findings of this project will be of interest to policy makers, practitioners, academics, and users and carers in the field of palliative care, the care of older people, and critical care. Peer reviewed articles and conference presentations will provide the main mechanism for dissemination. In addition the research team will make use of the links provided by OPCARE 9 (an EU 7th framework funded project focused on optimising care of the dying) which offers a unique opportunity to share practice with 6 European countries and New Zealand and Argentina.

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Team Expertise

MCPCIL was formed in November 2004 and is a partnership between Marie Curie Cancer Care, the University of Liverpool and The Royal Liverpool and Broadgreen University Hospitals NHS Trust in support of a palliative care research & development and learning & teaching agenda with a portfolio that is directed to making a real and sustained difference to patient care. The MCPCIL is under the academic and clinica lleadership of John Ellershaw, Professor of Palliative Medicine at the University of Liverpool, Medical Director at the Marie Curie Hospice Liverpool and Clinical Director of Specialist Palliative Care at the Royal Liverpool and Broadgreen University Hospital NHS Trust.

The Liverpool Care Pathway is the hallmark of the MCPCIL (Marie Curie Palliative Care Institute Liverpool)As well as continuing research, audit and evaluation of the LCP nationally and internationally, the MCPCIL works closely with other clinical areas such as cardiac, renal, ICU, paediatric, dementia, diabetes and cancer pain to develop best practice in care of the dying.

Professor Liz Perkins is Director of the Health and Community Care Research Unit (HaCCRU). The Health and Community Care Research Unit was established in July 1993 to develop knowledge-based services. Professor Perkins has been working in the field of health and social care research for the last twenty years. After an initial training in survey methods at Policy Studies Institute London, she has specialised in undertaking qualitative research studies. She is an expert in the use of Grounded Theory and is a member of the Grounded Theory Institute. She has used both observational and interview methods extensively in her policy related research. She conducted a large study of Mental Health Review Tribunals for the Department of Health in 1996 which successfully combined observational and interview techniques with documentary analysis. She is currently co- managing a study on men's experiences of prostate cancer which involves developing qualitative research skills in a number of clinical nurse specialists and prostate cancer sufferers.

Dr Suzanne Hodge studied at the University of Bristol where she was awarded an MSc and PhD in Policy Studies. Since joining the Health and Community Care Research Unit in 2003 she has undertaken a range of research projects including an evaluation of the Family Refugee Support Project, a project that combines horticulture with psychotherapy to address the mental health needs of refugee and asylum-seeking families; a study of the experiences of people who use communication aids; and a study of the way in which treatment decisions are made in relation to children with gastro-oesophageal reflux. She is currently working with colleagues on a three year evaluation of therapeutic community day services. Dr Hodge has a long standing interest in Habermas's theory of communicative action and in work that explores the relationship between intersubjectivity and subjectivity. All her research has been qualitative in nature.

Alan Haycox is based in the Management School at the University of Liverpool and has a long track record in health economic research.

Until February 2010, Maureen Gambles was the Research and Development Lead with the Marie Curie Palliative Care Institute, University of Liverpool (MCPCIL) where she has worked since its inception in 2004. She has been involved in several major projects evaluating care in the last days or hours of life – eg: co-ordinator of the National Care of the Dying Audit – Hospitals which (in collaboration with the Clinical Standards Department of the Royal College of Physicians); EU 7th Framework co-ordination and support actions project - 'OPCARE9' – involving 9 countries. Prior to joining the Institute, she was a researcher affiliated to the Marie Curie Palliative Care Research and Development Unit in London. At that time her main research interests were focused into the evaluation of complementary therapies in cancer and palliative care and communication skills training for nursing staff. Prior to this, Maureen was a Research Assistant with the Manchester Metropolitan University working on qualitative research projects to evaluate the personal and societal challenges inherent in combining employment with the care of disabled children

The intention is to appoint one further research assistant, who will have a background in qualitative research methods, will have worked in health and social care research and will have an interest in the development of services for people who are dying and their bereaved relatives.

Gantt Chart

The Gantt chart (attached) summarises the main timelines for execution of the pilot and main study (2010 – 2012).