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The Impact of the Liverpool Care Pathway on care at the end of life

Chief investigator: Professor John Ellershaw

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1. Introduction/Aims/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 the 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.

2. 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

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 and treatment; 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 delivered in the last hours or days of a person's life.

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 MCPCIL and a report fed back to the participating organisation. To date 503 Nursing Homes and 66 Intensive Care Units have registered to use the LCP.

3. Need

The Liverpool Care Pathway for the Dying Patient (LCP) is cited as an example of good practice specifically for care in the last hours or days of life (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 such 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 patients in the last hours or days of life 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 imminently 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.

4. Methods

a. Setting - Case Study Sites

The study will in essence comprise 24 case study sites – 12 Nursing Homes and 12 Intensive Care Units. 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 that 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

b. Study Design

Study design

The aim of this study is to assess the impact of the LCP on care of the patient in the last days or hours of their life 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 very 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.

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. A pilot phase was undertaken specifically to explore the perspectives of relevant stakeholders regarding undertaking this research. This involved 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 explored their perspectives on:

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 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. Consent in this study will be negotiated at different levels - institutional consent, staff consent, patient and bereaved relatives consent. All the participants in this study (patients and staff) will be dealing with the distress of death and dying which will affect them differently. 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. 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. 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).

In designing the recruitment and consent process for all participants at all stages of data collection, we have tried to adhere to the same fundamental principles which arose from the pilot phase of the study:

1. The study should be discussed and presented in each participating site in advance of the consent process
2. Any individual who feels uncomfortable about the research should be given the earliest opportunity to opt out of the research and not to be approached again.
3. The need to inform people about the study and the need to achieve informed written consent should allow individuals to provide a considered, thoughtful response, but should not be recorded too far in advance of involvement in a period of data collection. The standard 24 hour period prior to informed consent should remain the guiding principle

Observation in the context of this study represents not just methodological challenges, but ethical considerations. The research team feels that observational data is justified in this context because there is so little research on how tools such as the LCP are used in practice. Analysis of the LCP documentation alone would, at best, only reveal whether or not a particular activity had been considered or had been undertaken or rejected. It would not reflect care that had not been given and would not provide any information about how care had been delivered. For these reasons, the research team feels strongly that the value of the observational data outweighs the issues raised by using this method.

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

c. Data Collection

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. This mapping exercise will build on the work already undertaken to explore the views of key stakeholders on how to deal with the practical and ethical challenges that this project presents.

It is planned that in each case study site there will several phases of data collection. These will include interviews with staff, observation of care, interviews with bereaved relatives, case note analysis and documentary analysis. All of these will be discussed in more detail within this protocol. Before any of the above methods are employed, there will be a short period of piloting. The purpose of the pilot is to:

- Refine tools
- Determine the acceptability of the research
- Assess the sensitivity of the approach
- Pilot observational methods

Recruitment of Sites

The Marie Curie Palliative Care Institute Liverpool (MCPCIL) has developed a database of sites registered as using the LCP. MCPCIL staff will identify those organizations which meet the inclusion/matching criteria and will write to the organization informing them of the study. Those organizations that agree in principle to participate at this point will then be matched against the stated criteria (level of provision, size, staffing, type of speciality) with other units/homes that meet the inclusion criteria for the study but are not registered as using the LCP. Information about homes and units not registered as using the LCP will be accessed through appropriate directories of services in England.

Recruitment of Participants within sites

The method for recruiting participants within sites has been devised in line with the findings of the preliminary focus group and interview study (see above). Once all organizational/managerial agreements have been gained, the researcher enter each site to give information about the study to individual members of staff. At this stage any member of staff can opt out of the research. Their details will be recorded on an institution specific data sheet. These members of staff will not be approached again to consider participation. Each organisation participating in the study will develop, in conjunction with the research team, a way of alerting all new patients to the study. This may involve displaying information sheets in prominent places or a verbal report by staff to patients and their relatives informing them of the study. These approaches will be locally determined to fit with current practice. At this stage the purpose is simply to alert patients and families to the existence of the research study. If on hearing about the study patients and/or their family express a desire not to be approached about the study when the time comes, these individuals will be identified on the data sheet relating to that institution and will not be approached to consider participation in the future.

When the clinical team make their decision that a patient is in the last days and hours of life they will alert the researcher who will check whether the patient and/or their family have previously declined to participate. If they have not previously declined, the researcher will check whether any member of staff caring for the patient has declined future participation. The researcher will then approach those members of staff currently caring for the patient, who have not previously declined, to gain their informed, written consent to participate in the study. Once the consent of all staff concerned has been gained, the clinical team will then approach the patient and his/her family to see whether they would be interested in talking to the researcher about participating in the study. The researcher will be responsible for giving study specific information and consenting patients and relatives to the study as appropriate. is likely that a maximum of 4 or 5 patients/families will be recruited in each Intensive Care Unit and only 1 or 2 in each Nursing Home.

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 a maximum of 6 key individuals per participating organisation (a minimum of 24 across all the sites) involved in the management and provision of care of the dying. The actual

number of interviews undertaken within each site will be dependent on the nature and organisation of the particular unit/home. This purposive sample will be constructed to represent a cross-section of members of staff wherever possible, including administrators, managers, nurses, doctors, allied health professionals, and healthcare assistants. Inclusion criteria include: being employed within the unit/home for 6 months or more; for clinical staff – recent experience of caring for a patient who died in the unit/home (ie at least one patient in the last 3 months). 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 the care of patients in the dying phase will be undertaken. Staff involved in providing this care (who have not previously opted out) will be recruited and consented once the patient has been identified. They will then 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 patients in the last days or hours of life

Observational methods have been chosen for the insight into the reality of end of life care that will be provided. The use of the observational method with 'vulnerable' groups, including people who are dying is not unprecedented (Lawton 2001, Seymour 2001, Mills et al 1994, Buckingham et al 1976). 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. Indeed, many patients who are in the final days or hours of life may be comatose and unable to participate in research that requires their active participation. Using observational techniques can be useful to highlight important issues for such patients, and to allow consideration of their needs based on empirical data. 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. During the course of the observational work researchers may observe instances of unsafe or unethical practice. If they arise, they will be dealt with on a case-by-case basis in accordance with professional guidelines and facility procedures. A Protocol has been developed to guide researchers in the unlikely event that sub optimal 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 observational 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. Draft Case Note Analysis Date Extraction Tool – to be developed during pilot phase.

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). A relative of all patients observed in the dying phase will be interviewed. These interviews will take place at a time and in a venue that is most convenient for bereaved relatives. On occasion it is likely that the interviews will take place in the homes of bereaved relatives and a Fieldwork Code of Practice has been developed to ensure the safety of research staff in these circumstances. 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 findings of the pilot study suggest that the most appropriate time is likely to be dependent on the individual circumstances of bereaved relatives. Wherever possible, an appropriate time to contact the relative after the death of the patient should be negotiated as part of the initial consent process, though sensitivity to changing circumstances will be required. However, unless otherwise agreed, an approach will not take place earlier than one month after the death of the patient. 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. The subject matter of these interviews will necessarily involve the discussion of emotive issues and it is possible that participants may become distressed during the interview. A procedure for dealing with distress identified during interview or observation sessions has been developed to guide good practice in these instances.

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. Retrospective Analysis of Deaths Data Extraction Tool – to be developed during Pilot Phase.

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. Documentary Analysis Data Extraction Tool – to be developed during Pilot Phase.

d. Data 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. Economic Evaluation Data Extraction Tool – to be developed during Pilot Phase.

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 have consulted 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. 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, have commented as part of the pilot phase and are committed to the development of the research.

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.

Project Management

The project will be managed by the Project Team (see below) who will meet monthly throughout the project to oversee the day to day running of the project, to advise and support the Research Associates working in the North West of England and in London and to track and monitor progress to ensure that the project meets its designated milestones and deliverables. In addition, an Advisory Group of around 20 personnel is currently being formed, which will have representation from nationally and internationally renowned 'experts' (both professional and lay) in end of life care and research. This group will meet face to face on 3 occasions over the course of the project, but will be called upon to offer specific advice and support to the project team via electronic media as and when required.

Project Team

Chief Investigators

Professor John Ellershaw
Director, Marie Curie Palliative Care Institute
University of Liverpool

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 for the Dying Patient 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 Elizabeth Perkins
Director, HaCCRU
University of Liverpool

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 patients with prostate cancer.

Co-Investigators

Dr Alan Haycox
Reader in Health Economics
University of Liverpool

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

Maureen Gambles
Research Fellow, MCPCIL & HaCCRU
University of Liverpool

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

2 Research Associates to be appointed

Advisory Group List – Confirmed Membership

CHAIR: Professor Sheila Payne, Help the Hospices Professor of Hospice Studies, Observatory of End of Life Care, University of Lancaster

Professor Jane Seymour, Sue Ryder Care Professor of Palliative and End of Life Studies, University of Nottingham

Dr Maureen Coombs (MBE), Consultant Nurse, Intensive Care Unit, Southampton University NHS Hospitals Trust

Dr Jayne Brown, Senior Research Fellow, University of Nottingham

Professor Julia Addington-Hall, Professor of End of Life Care, School of Health Sciences, University of Southampton

Dr Katherine Froggatt, Senior Lecturer, Observatory of End of Life Care, University of Lancaster

Dr Louise Jones, Head of Unit, Marie Curie Palliative Care Research Unit, UCL, London

Dame Barbara Monroe, Chief Executive, St Christopher's Hospice, London

Ms Chris Haywood, Head of Hospice Services, Willowbrook Hospice, Liverpool

Dr Joy Duxbury, Reader in Mental Health Nursing, Divisional Leader for Mental Health, University of Central Lancashire

Mrs Barbara Burkey, Lay Representative, Liverpool

Professor Kathy Rowan, Director, ICNARC, London

Dr Massimo Costantini, Head, Regional Palliative Care Network, National Cancer Research Institute, Genova, Italy

Dr Rebecca Bancroft, Consultant Geriatrician, Royal Liverpool and Broadgreen University Hospitals NHS Trust, Liverpool

Dr Jane Harper, Consultant, Intensive Care Unit, Royal Liverpool and Broadgreen University Hospitals NHS Trust, Liverpool

Eleanor Sherwen, End of Life Care Programme, Department of Health, London

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