UNIVERSITY OF LIVERPOOL

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

PILOT STUDY REPORT 2010

Contents

1 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.

The planned research is a matched case study design that includes direct observation of the interactions between patients in the last days or hours of their lives, their relatives and healthcare staff, and interviews with staff and bereaved relatives. It is important to make sure that the ethical and practical challenges, particularly in terms of the recruitment of dying patients, their family and friends and staff members to the study, and observing patients in the last days and hours of their lives, are carefully considered. This is vital to ensure that the study results in both meaningful outcomes whilst at the same time it protects the safety of the people who participate.

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. These authors, however, did emphasise various ethical and practical challenges that she felt were inherent in undertaking 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 for observation 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), also acknowledges the practical and logistical challenges of giving information and gaining informed consent from patients and/or their relatives, particularly in environments with a high throughput of patients.

2 PILOT STUDY AIM

The pilot study was designed to involve key professionals and lay people in shaping the main study. It specifically set out to explore the views of a range of staff working in ICU and Nursing Homes and those of patient/carer representatives regarding the proposed research. The findings will be used to inform the construction of the final protocol for the main study.

3 PILOT STUDY METHODOLOGY

The pilot study (REC Ref: 10/WNo01/26) was reviewed by the North West Wales Research Ethics Committee and was granted a favourable ethical opinion in April 2010. A qualitative, interview based approach was used involving focus groups of staff in nursing homes and intensive care units and telephone interviews with representatives of relevant patient groups. In addition, more

informal feedback was sought from members of the research community who had relevant experience in undertaking similarly challenging work. These informal observations have been used to supplement the findings from the focus groups and interviews where relevant and appropriate.

A convenience sample of 1 local Intensive Care Unit (13 bedded, General/Renal ICU) and 2 local Nursing Homes (1 with 24 beds; 1 with 41 beds; both caring primarily for patients with dementia) were recruited to participate in the pilot study. All used the Liverpool Care Pathway for the Dying Patient. The managers in each setting were telephoned, emailed and given information about the main study and the pilot study and asked to consider the participation of their unit. Once unit consent was given verbally, information about the main study, the pilot study and a copy of the consent form for the pilot study was given out to potential focus group participants by the nurse manager, the LCP/ICU co-ordinator and the medical director in ICU and the Manager/Deputy Manager of the homes. Dates were set up for the focus group. Information leaflets were again circulated and supported with a verbal explanation of the pilot project and all those still interested in participating were invited to sign a consent form.

A sample of patient/carer representatives were identified through contact with several national and regional organizations (including INVOLVE, National Council for Palliative Care, Locality Groups within North West SHA, CRUSE). A contact in each of the groups was approached, given information about the main study and the pilot study and asked to disseminate this information to colleagues who may be interested in taking part in telephone interviews. Once identified, their contact numbers were given to the researcher (with the permission of the potential participant) and they were contacted to arrange a suitable time for interview and to answer any questions or queries arising from their reading of the information sheet. Consent forms were posted to the individuals and prior to the telephone interview participants were asked about their understanding of the process and whether they had any questions.

The following formal interviews were undertaken:

- Intensive Care – 2 focus groups in 1 ICU, 1 with nursing staff (n=4) and with medical staff (n=4)
- Nursing Home – 3 focus groups in 2 Nursing Homes – 1 with nursing and non-clinical staff (n=6); 1 with health care assistants (n=4) and 1 with nurse managers (n=2)
- Individual telephone interviews with patient/carer representatives – 4 recorded telephone interviews; 1 person was sent the topic guide, gave answers to each question in a written format and talked through her answers informally later with the researcher.

The main purpose of the interviews was to elicit views on the main study design, to explore ways in which the data collection methods could be tailored to meet the needs of the participants as well as the researchers, and to identify ways in which appropriate recruitment to the study could be enhanced. A topic guide was used to support the conduct of the interviews which were audio-taped (with the permission of participants) and transcribed verbatim. The transcripts were thematically analysed to highlight the potential challenges, barriers, and levers for successfully engaging in such research. For the purposes of this summary report, only those findings pertinent to the design/operationalisation of the main study have been analysed and included. A more in-depth analysis of the transcripts is planned from which an article will be developed for publication in the research literature.

Contact (primarily by telephone and email) was also made with a range of researchers who had undertaken research in similarly challenging areas. They were given information about the planned study and asked for their thoughts on the inherent challenges in light of their own experiences. Information gained from this exercise was summarized by the researcher and used to supplement and inform the proposed approach to the main study.

4 PILOT STUDY RESULTS AND RECOMMENDATIONS FOR MAIN STUDY PROTOCOL

SAMPLE DEMOGRAPHICS

Focus Groups (n=20*)

	Intensive Care Unit		**Nursing Homes**		
	Interview 1 (n=4)	**Interview 2 (n=4)**	**Interview 1 (n=6*)**	**Interview 2 (n=4)**	**Interview 3 (n=2)**
Gender (F/M)	**3/1**	**0/4**	**4/1**	**4/0**	**2/0**
Mean Age (Range)	**38 yrs (29 – 40)**	**43.5 yrs (33 – 50)**	**43.8 yrs (24 – 55)**	**48.5 yrs (36 – 65)**	**60.5 yrs**
Profession	**Nursing**	**Medical**	**3 Nursing/2 Non Clinical**	**Health Care Assistants**	**Nursing / Managerial**
Mean Years qualified (Range)	**12.5 yrs (7 – 16)**	**20 yrs (11 – 26)**	**Nursing 14.3 yrs (4 – 35) Non Clinical 10.5 yrs (6 – 15)**	**-**	**35 yrs (30 – 40)**
Mean Years in current unit/home (Range)	**8.2 yrs (4 – 12)**	**10.2 yrs (1 – 18)**	**1.07 yrs (2 wks – 2 yrs)**	**8.2 yrs (4 – 15)**	**8 yrs (6 – 10)**

**** one person did not complete a demographic form***

Seventeen participants described themselves as being White British, one Caucasian and one English and the vast majority described their religious affiliation as either Roman Catholic or Church of England (one was agnostic, one Jewish and one who was asked did not answer the question).

Patient/Carer Representatives (n=5)

All of the participants in the telephone interviews were female with a median age of 62.4 years (Range 49 – 75). All described themselves as being White British and 4 of the 5 described themselves as being affiliated to the Church of England (the other had no particular religious affiliation). All had relevant experience of being a carer of at least one relative who had died, mainly either in the Nursing Home setting, the Hospital setting or both. Three of the 5 participants have a diagnosis of cancer themselves and all participants were representatives on either advisory groups of National charities or Regional Forums/Groups striving for better services.

5 PILOT STUDY MAIN THEMES

Two main themes emerged from the analysis of the data: General Attitudes to the Research and Recruitment to the Study. The latter theme is made up of a series of sub-themes: Importance of patient characteristics/expectations of the family; Researcher visibility/familiarity; Importance of providing general information about the research in the environment; The recruitment process; Written and verbal consent; When to approach/interview bereaved relatives.

5.1 GENERAL ATTITUDES TO THE RESEARCH

5.1.1 **ICU -** Staff in ICU, described their environment as research active and were generally very positive about the idea of undertaking research into care delivered to patients in the last days or hours of life. It was acknowledged that many people die within this environment and therefore it was important to explore whether care was as good as it was perceived to be.

> "its a lot of what we do cos we have a very high proportion of patients who die so it makes sense to actually study whether we do it properly and that's from a scientific point of view and also from quality point of view .. we already do research with patients who are critically ill so we do already approach families who are perhaps particularly stressed and I think it has to be handled sensitively and there has to be an acceptance that a lot of families won't wish to be involved but . with those caveats aside I think that its important that we do do this type of thing"
>
> (ICU Focus Group 2)

Whilst supportive of the need to evaluate the LCP, they did acknowledge that a study involving direct observation of patients in the last days of hours of life could be challenging. Thinking about their practice, ICU staff reported that when they withdrew treatment following a conversation with a family, they would generally leave the bedside:

> " having somebody sat in there watching the patient as they were dying .. cos we're [nursing staff] not actually even in there .. and that's as a nurse who's been working with them and maybe has known them for a couple of days .. so you'd have complete stranger sat in the corner I think that would be quite difficult for the family"
>
> (ICU Focus Group 1)

Others, however, felt differently:

> "I think once you'd got consent from the family the actual sitting in because you're not actually doing anything to the patient you're just there observing. I think once they fully understood and you'd go consent that would be fine .."
>
> (ICU Focus Group 1)

It was generally agreed that recruitment to the study needed to be handled very sensitively and the differing needs of patients and families would have to be considered.

> "I just think its about being sensitive isn't it to what the family needs. Its not unethical what you're doing you know what you're doing is really good but its just that it needs to be done with certain categories of patients and different circumstances .."

(ICU Focus Group 1)

Certain cultural barriers may also exist (eg specific religious rituals dictated at the end of life) that could affect recruitment and similarly environmental issues such as the lack of space and privacy may also cause some difficulties.

> " .. so muslims and jewish people they have very specific rituals at the end of life don't they that they need carried out .. so they might not want .. a non muslim .. person sitting in there with the family ..." – participant 3
>
> " .. its just very cramped you'd have to literally sit right at the bedside" – participant 2
>
> (ICU Focus Group 1)

5.1.2 **Nursing Home -** Nursing Home staff were generally in favour of research per se in order to build the evidence base, but they did acknowledge the vulnerability of patients who were in the last days or hours of life, and that of their relatives.

> " I think its very important for getting the views of yes the staff but also the families .. and overall looking at every aspect I think is very, very important and is beneficial because everything is evidence based and if you have that evidence you can prove what works and what doesn't work"
>
> (NH Focus Group 1)

In general, the staff in nursing homes expressed greater misgivings about the observational element of the research than staff in ICU. Some staff felt that this element could be viewed as intrusive, "an invasion of privacy" (NH Focus Group 2) because this was such a 'personal time':

> "I think relatives ... like to have their moments with their loved ones and even if you have to do some sort of care for that person it's very difficult to do that care because the relatives want to have that every second with that person especially at the very end .. I mean I've been in one where you're physically told to very politely to get out of the room syringes and everything in your hand .."
>
> NH Focus Group 1

One person felt very strongly were they to be asked to take part in the study if they were a dying patient or relative of a dying patient:

> " I don't like the sound of it myself .. for a researcher to be sat in the room if I was dying no it wouldn't be for me ... you see as a member of staff I wouldn't mind whatsoever but if that was my mother I would not want you sitting at the bedside when she's in her last days" – participant 1

Others recognised that there are likely to be various opinions:

> ". its down to personal choice" – participant 2

(NH Focus Group 2)

Some Nursing Home staff felt that there might be positive outcomes from having an observer present at the bedside.

> " and its going to be like days or hours I think it would be nice even if they [the patient] didn't know that .. there is going to be somebody there all the time .. so that could be seen as a positive .."
>
> (NH Focus Group 3)

Nursing Home staff felt strongly that their role was to protect vulnerable patients and ensure that their dignity is preserved. A clear understanding of the research approach, having confidence that the findings would have a positive impact on future care, and being familiar with the researcher undertaking the study when 'handing over' the care of patients and relatives, were in their minds, likely to be very important aspects in ensuring the successful completion of such a research study.

> "You'd always be a bit wary with such vulnerable people, but once you saw the approach you got to know a bit more about it a bit more of the people and what it entailed you'd say well that's OK"
> (NH Focus Group 3)
>
> ".. I'd just like to know that whatever gets said that whatever's found in the findings of all this is taken serious ..
>
> (NH Focus Group 1)
>
> ".. we have that many people in here who don't really .. see that many people so you take them on as your family for want of a better word .. if someone's going to sit there [researcher observing] you'd want to know exactly who it is you know and meet them before "
>
> (NH Focus Group 2)

5.1.3 **Patient/carer representatives -** As with the staff interviews, patient/carer representatives had a range of views on the research. One patient/carer representative held a very positive attitude to the need for research with dying patients and suggested that more research like this should be undertaken:

> "Its brilliant what you're doing .. I think it would be lovely to take it even further and do you know death at home .. but I think end of life needs to be looked at from all aspects"
>
> (Individual Interview 4),

Other representatives were more cautious about the research and one was completely opposed to the observational element of the proposed research 'intruding' into this very personal time. Whilst acknowledging the fact that others she had spoken to held more positive views towards it and could see ways in which it might lead to positive outcomes for some, this participant acknowledged that her views differed:

> "..from my own experience and from talking to others I think some things are just too personal too private and should remain so and I understand why you are doing this to study the Liverpool pathway but I know personally I would not want anybody around very, very definitely .. I can't help feeling that however well something was done I just think its too far I just think its just certain things that we sort of shouldn't do .. and having read about your retrospective analysis I just feel we ought to be able to learn enough from how things are done to inform good practice"
>
> (Individual Interview 5)

Participant 5 was particularly concerned that people did not feel coerced into participating. In her view people generally wanted to be helpful and had concerns that people might feel more inclined to help when approached personally by staff with whom they have developed a trusting relationship.

> "on the whole people like to co-operate with things .. if people ask them to do something on the whole they'll cooperate.. it probably should be [a member of the clinical team who introduces the research] but this is part of the problem for me because they would probably be trusted by whoever it was given to and I think that's where you've got this real sort of difficulty that would possibly make people more erm willing inclined to feel they should cooperate and yet you probably need it to be for any sort of trust at all .. I have some confusion about that myself .."
>
> (Individual Interview 5)

On the other hand:

> "others who might be quite pleased to be asked because they'd have a they'd feel that they maybe they would get extra care or whatever .. the fact that someone's taking a bit more interest in them looking at them more closely whatever I think some people would appreciate that rather than feeling that it was intrusive .."
>
> (Individual Interview 5)

Another participant was unsure as to whether she and her family would have wanted someone observing in the final few minutes of life, though she did speculate that the presence of a person placed unobtrusively within the room may make very little difference to family members. This participant also acknowledged that the presence of an observer would have provided an important 'external eye' on the process of care delivery that would have supported their work for the improvement of future care.

> "[in the final minutes of his life] we were so focused on him at that point whether somebody say in the corner of the room just sort of away from it would have made a difference because if he died in the general ward which is where he was we would have been surrounded by people but then we would have had no choice in the matter . anyhow"
>
> (Individual Interview 2)

"if someone else had been there to see what was going on then that would have added grist to our mill if you like .. so in that sense it would have helped us really"

(Individual Interview 2)

This participant also felt that participation could be positively viewed by some patients as the opportunity to give something back:

"its a legacy for that person as well you know that they're doing something .. that they're not going to be there anymore at least something will come from it and they've left something behind"

(Individual Participant 2)

The timing of the invitation to participate was seen as very important patient representatives. It was recognised that patients and families would need to be fully aware of the prognosis of the patient before being approached to participate. Hearing about the research for the first time only when relatives were told that the patient was imminently dying should be avoided and would give little time for consideration (see *'the research process'*). Understanding the purpose of the research fully and being assured that confidentiality would be maintained were deemed essential, as was ensuring that patients and relatives are aware of the purpose of the research:

"I would like an answer to WHAT, WHY, outcome etc, assurance of confidentiality & when completed a copy of results. My initial response would be to give me a little time to think before giving an answer. I most probably would have agreed."

(Individual Interview 4 – written response)

"I think people might think its intrusive you know .. so you would need to sensitively tell them that this work is vitally important to get things right for the next generation of patients .. and that's the only way you can learn by doing the research and I think that if you sensitively speak to them about the necessity of it then you might break down the barriers"

(Individual interview 1)

5.1.4 **Attitudes of staff to participating in the research**

It was felt by some patient/carer representatives that staff may be reluctant to participate because their care would be under scrutiny. However, staff in both environments stated that they would be generally happy to be personally involved in the study. They felt that research in the healthcare environment is now accepted and well established in both nursing and medical professions, and they are often 'observed' as they deliver care in the environment by other members of staff and relatives. However, nursing staff in ICU did suggest that more junior members of the team may be nervous about being observed when withdrawing treatment/interventions and therefore potentially less inclined to participate.

" .. withdrawing treatment on a patient is extremely frightening and its certainly not a pleasant thing to do .. [as] a junior member of staff .. you would be petrified"

ICU Focus Group 1

It was also recognised that staff who had been recently bereaved or those who may have been upset by the imminent death of a particular patient may be more reluctant to participate in the study.

5.2 RECRUITING TO THE STUDY

Several important elements were highlighted by participants to minimise the potential for distress at a sensitive time. The views of participants are summarised separately for ICU, Nursing Homes and Patient/Carer Representatives and recommendations for the main study are made, where appropriate.

5.2.1 **Importance of patient characteristics/expectations of the family**

ICU Medical staff were of the opinion that deciding who to approach for participation in the study should be done as 'scientifically' as possible (ie every eligible patient should be considered regardless of their characteristics or circumstances) in order to ensure that there is no systematic bias in recruitment. However, others suggested that, it might be easier to approach the families of patients who are elderly, on the basis that as one grows older, death becomes more of a possibility:

> "an elderly person although its sad you know they've had a life whereas when its a young person its a bit more raw isn't it?"
>
> "they [family] were very accepting of the fact that their mother was dying and she'd been off sedation for several days and it had been discussed several days in a row and ... they were very, very accepting .. because they'd done their grieving and sat with her at the bedside so .. I think they'd have been quite happy [to be approached]
>
> (ICU Focus Group 1)

Staff explained that their relationship with older patients in ICU was often very different from their relationship with other patients:

> "patients that we've had for a long time you get to know the relatives but .. also the relatives are exposed to like a rollercoaster of one minute the patient will be doing well the next they could deteriorate then they do well .. and you have this pattern and during this time you have numerous conversations about the care .. and .. you know if they do deteriorate again we're not going to do that and our focus of care will change so that the family has had a run in and been exposed to some end of life issues before .. and they have a little chance to sit and think and discuss amongst themselves"
>
> (ICU Focus Group 1)

Younger patients who are dying unexpectedly as a result of an accident/trauma, on the other hand may be more difficult to approach because of the likelihood of increased stress on the family:

> "whereas a young person or somebody that's come in with trauma families don't have that .. one minute they've just waved their son off haven't they at the bus stop and the next he's in an ITU bed so you know they haven't had that run in or thought about any end of life issues .. and its the grief process isn't it you know it's the denial, the anger ... you know you

can't accept what's happened so the thought of introducing the research with that category of patient is a lot more difficult I would imagine .."

(ICU Focus Group 1)

However, the same participant later suggested that taking part in research may offer similar benefits (eg solace) to such families as gained by those who had decided to donate their loved ones organs.

"we were talking before with the unexpected or the sudden traumatic deaths I don't really want to rule those kind of patients out because I know in terms of organ donation .. the families are told the worst possible thing aren't they .. and to have their relatives' organs donated . might give them some comfort and I don't know whether it's similar for research if they think that they perhaps might be helping future families or you know it might give them a little bit of comfort in a terrible . time mightn't it . so I don't really want to think oh no you can't approach them .."

(ICU Focus Group 1)

Nursing Home In the nursing home environment patients are generally elderly and death is often an expected outcome. Staff felt that this would be likely to make recruitment easier as families would probably be more accepting. Staff felt that death in this environment brings relief as well as sadness particularly in patients with dementia where relatives have experienced 'the long goodbye' (NH Focus Group 1).

Some people may be happy to help with research because they feel it will benefit others in the future, but all are individuals and some may view the research as an opportunity to improve care in the future whilst others may feel that death does not afford the opportunity to participate in research. A really important aspect to consider for these Nursing Home staff, specifically for those who lack capacity, is that the person's dignity is not compromised:

"throughout my training and being here relatives and residents who have got the capacity are always happy to give to a research project or give to something because like they say no its going to benefit them or it will benefit people in the future but that just would be one of my concerns if I was doing that [acting as a consultee] I would be thinking dignity wise would that person really want someone observing in the room"

(NH Focus Group 1)

Patient/Carer Representatives felt that it would be difficult if not impossible to recruit patients with dementia to the study. In part this was predicated on the notion that the lack of capacity precluded participation in research. Certain other patient characteristics may also affect the potential for recruitment. For example:

"if somebody is dying wracked with pain or something I mean .. it might be difficult for someone else to be there .."

(Individual Interview 2)

The theme raised by ICU staff of the participation of older patients in the study was reiterated by patient/carer representatives. Older patients were seen as easier to recruit as an 'expected' death can be both "a relief and a blessing" whereas, families who have lost a young person unexpectedly to injury/trauma are more likely to be too distressed. Cultural issues such as a person's background, upbringing and/or religion may have a negative effect on recruitment (Individual Interview 4).

5.2.1 **Recommendations:**

> ***Recommendation****: Although it is likely that it will be 'easier' to approach elderly patients where death is an expected outcome, all eligible patients should be considered for the study and the decision to offer participation judged on a case by case basis in liaison with care, nursing and medical staff looking after the patient and family.*

5.2.2 **Researcher Visibility/Familiarity**

ICU Staff felt that it would be very important for the researcher to become embedded within the unit for the whole of the data collection period. Being around in the unit to give information/explanations to staff and to almost become part of the team, joining ward rounds, MDT's and making contact with influential people such as charge nurses and organ donation co-ordinator. This would help to sow the seeds of the research and make the researcher a familiar face on the unit – to engender trust.

> "I think its a good idea for you to be around on the unit before any research . even just to instil the idea ..I mean join the ward rounds and introduce yourself .. just so people get to know who you are and why you're here and just sort of integrate become part of our team .. there's that much information and different things going on all the time .. and you know in a busy environment its difficult for .. busy people to retain the information but I think if they just see you .. and recognise your face and know who you are .."
>
> (ICU Focus Group 1)

Nursing Home Staff felt that it was important that the researcher is familiar to them as this would help both staff and relatives to get used to someone being in the room observing. Also, being viewed as 'part of the team' would help the researcher to become an accepted part of the environment:

> "I think that once the families were aware of what was going on then the researcher would be part of the team .. and they would be accepted as such once you know they're part of here .. and of course if it's the researcher doing it [taking consent] you've got more answers so you know if they [patients/relatives] came up with a question you'd be able to answer it"
>
> (NH Focus Group 3)

Patient/Carer Representatives felt that it would be important that the researcher lays the 'groundwork' with staff in each site to introduce the study and themselves and to engender the development of a trusting relationship as the health care professionals are in effect handing over their patients and families. Ideally, the researcher should become known as part of the 'team' –

joining MDTs in ICU and talking with groups of staff in NH. However, the nature of the NH environment probably means that the researcher will necessarily act in a more isolated manner.

They also stressed the importance of staff feeling comfortable about the research and about being observed. The felt that it should be made clear that the emphasis of the research is on the utility of the LCP and not about 'marking' their performance. Another reason why the researcher needs to be in the environment for some time prior to data collection, is that this will allow them to better understand the site and enable them to make more appropriate and 'accurate' interpretations about what is going on.

> "[having the researcher embedded in the environment] I think that's a quite a good idea .. because hopefully somebody would be professional enough that they would be able to judge .. they're .. handling it [recruitment] in such a way that there genuinely is not the slightest pressure .. you get past that sort of assumption of co-operation and people would feel able to genuinely say what they really felt about it ."
>
> (Individual Interview 5)
>
> "laying the groundwork with them first before you are actually planning to do anything .. just so people start to feel comfortable and the nurses too because .. [they] are going to be there most of the time [and] they would need to feel comfortable with it and understand that they're not being you know having time management done on them"
>
> (Individual Interview 2)
>
> " and to make sure that you're also interpreting what you're seeing in the right way and that you're not jumping to a conclusion .. acclimatising I think would be good"
>
> (Individual Interview 2)

Patient/carer representatives emphasised the need to employ only researchers with experience in end of life care, good preparation and training and the opportunity for debriefing, as otherwise they may become unduly distressed.

> "in my view the researchers have to have some sort of knowledge about what things are like .. I would like to see that they have some sort of preparation for this and some sort of debrief .. I think that's very important because you can think you're hardened to these things and you go in but sometimes you see things that you just .. don't expect and if you're not prepared for them then that's difficult for you"
>
> (Individual Interview 1)

5.2.2 **Recommendations:**

Recommendation: *The researcher should spend as much time as possible in each site prior to and during the data collection period – giving information about the research to staff (and, where appropriate patients and relatives) attending multi-disciplinary team meetings and being part of the ward rounds/handover and 'life' of the environment wherever possible.*

When the decision has been made that the patient is felt to be in the last hours or days of life and communicated to patients and families, the researcher should be introduced by staff as 'part of the team' and then offer information about the research.

Recommendation: *The researcher should have a background in and experience of research in end of life care, should receive any specific training felt to be appropriate to the role and a robust support system for researchers should be provided and maintained throughout the study period.*

5.2.3 **The recruitment process**

ICU Staff highlighted that background information about other studies that are currently being carried out in the ICU and the fact that people may be approached to participate is made available routinely in this environment. Some felt that generic information about this study could also be included:

> "we've got a kind of thing that says there are various studies and research are going on in the unit and you may be approached about one of these thats kind of out there so for people to be approached about any research shouldn't come as a major surprise .. I mean I think if were slightly woolly on the subject and say there are studies out there" (ICU Focus Group 2)

Although all recognised that providing any general written information for a study on death and dying feels more challenging – ie it is more difficult to put such information into 'black and white' in a sensitive way

> "trying to say things about death and dying in a leaflet is very different to saying it to you or how you speak to a relative isn't it because you can talk to a relative you use other forms of communication . you can say some terrible things still some very upsetting things but the way you say it and the way you are as a person would make that easier for them.."
>
> (ICU Focus Group 1)

Some felt that the optimum time for the study to be introduced was when the idea of withdrawal of treatment is first broached with relatives (often begun by doctors and followed up by nurses) as these conversations be protracted over a period of days or longer:

> " I think it would almost have to be in the conversation where the doctors are saying to the family about withdrawing treatment and then kind of say we are you know as part of the unit we are doing research would you like some information and almost kind of simple as that just we're looking at patients doing some research on patients who are at this point of their lives would you be interested in more information and if they say no then you just shut the conversation off"
>
> (ICU Focus Group 1)

The medics pointed out the parallels between consideration for research and consideration for organ donation. Some clinicians felt that even introducing the study and/or organ donation might endanger the trust that had been built up between them and the family and would prefer to hand

over to the organ donation co-ordinator/researcher at that point. The fear that relatives might feel coerced into participating if asked by their consultant was also raised and it was decided that keeping the two roles completely separate was probably the best route. The general consensus amongst these medics at the end of the debate was that, in general, they would prefer to alert the researcher to potential families, introduce the researcher as a member of the team (which is likely to be important to the relatives) during the conversations about withdrawal of treatment and then leave the researcher to give more information about participation and to gain consent.

> "[alerting the researcher to a family] no problem with that at all, that would be my preference . we should do what we do normally and then there's that curtain if you like comes down .. we would have to introduce you to them at that point as .. a member of the team"
>
> (ICU Focus Group 2)

In addition, the information leaflets would need to make it clear that patients/relatives could withdraw from the study at any time:

> " I think you'd almost need a get out clause for relatives so that if at any point they said actually we don't want you here anymore .. you'd need that kind of thing that they could change their minds if they felt that it was too intrusive for whatever reason"
>
> (ICU Focus Group 1)

A 'debate' about the utility of retrospective consent emerged in one of the ICU focus groups. Staff suggested that if it was important to 'observe' the communication between staff and families and patients that took place during the deliberations regarding the withdrawal of treatment, but it was difficult to decide whether the family should be approached for consent to participate, in principle, retrospective consent could be sought for the use of data collected during these conversations. An 'observer' – (the researcher or a clinical fellow?) could be present at these meetings with families to record information about the conversations – then, once the decision to withdraw has been made, and patients/relatives had been recruited into the study, retrospective consent could be gained from the relatives for use of that information. For those who decline to participate, previously collected data would be destroyed. They highlighted precedents that have been set in other research where the 'data' (sometimes including blood samples) has to be gained as soon as a patient enters the environment. However, it was acknowledged that this may lead to 'wasted time' for the researcher and that the point at which the decision to withdraw has been finalised represents a specific time-point (even though this may mean that potential participants only have a limited time to decide) that is more easily marked which means that it can be replicated across other sites. Information about communication prior to this point in time could be gathered from what has been routinely recorded in the patient notes (case note analysis) if required.

Nursing Home In the nursing home environment there is the potential to mention the research in general terms when people are first admitted to the environment. Posters about the research were generally not felt to be a good idea, but a general information leaflet could made be available as part of this process in the packs for new residents or more generally in the home. This general

introduction to the research may make it easier to raise the issue later if and when the patient is in the last hours or days of life.

> " [it should be discussed] I would say when people first come in .. to the nursing home although they can be quite well the actual relatives who are putting in like I put my dad in a nursing home know they probably won't be coming out .. so while they're still quite well I think that something like that needs to be brought up .. [nurse in charge] would say and this is what we do as well .. and bring it into it like that .."
>
> "if you have an initial talk that we just said about then you'd probably have a better idea about how people are going to react when it eventually came to the time it would give you a sort of better understanding of how to ... approach it you'd have an idea rather than go in blind really ..."
>
> (NH Focus Group 1)
>
> "its like planting the seed isn't it you know just preparing them in advance"
>
> (NH Focus Group 2)

They suggested that it could be introduced in such general terms as part of the advance care planning that goes on around Gold Standard Framework (GSF)/Preferred Priorities for Care (PPC) and their views and reactions could be noted down. Some suggested that people could be asked if they would be happy to be approached in principle for participation and their response noted on the advance care plan.

> "so everybody who's coming in now is going to have an advance care plan .. all that [information about the research] could go into the place of "what your wishes are" while you're still able to say and while you're not having the trauma of going through this loss .. at least you've put it there in their mind that this may happen .. [you could ask] would you be willing to be approached .."
>
> (NH Focus Group 3)

One patient/carer felt that patients and relatives should only be asked to 'opt in' for further information as 'opting out' would place too much stress on the family to be proactive.

> "[opting out] no you're putting the kind of responsibility on them to do so to opt out no I don't think so . you've got to have people agree to do something not to say no to .. but you might not get much response .. "
>
> (Individual Interview 5)

If an agreement in principle has been gained, most staff felt that it was important that an empathic member of staff (probably the nurse in charge and/or the key worker) with whom the families feel comfortable should raise the issue again when the patient is deemed to be in the final hours or days of life as patients/relatives would probably be more likely to be able to decline further information/consideration if they wished:

".. If they're asked when they first get .. a new resident coming in and its put to them then and then you've got your resident who you think is going to pass away then maybe you could say well remember that thing we talked about .. they might feel different they might say yeah at the time and then when the time comes [they may say no]"

(NH Focus Group 2)

"I think with regards to who discusses it .. from my past experience when I've been asked to do things if its a stranger that I don't know I'm more inclined to go oh yeah I'll do it .. whereas if I've got someone there who I can speak to and go actually I don't know about that because of this that and the other .."

(NH Focus Group 1)

Patient/Carer Representatives Most patient/carer representatives referred to the importance of generic information about the study being made available in the environment. They felt that this might mean that families were better equipped to think about participation if and when specifically asked to do so. Most felt that this information should be in the form of information leaflets. Such literature should be in simple language and avoid the use of jargon.

"rather than gearing the information to me in particular .. having it as a common thing that I might know about [a leaflet] .. and then I would probably have read that then I could have made a decision [beforehand] but somebody actually coming to me and saying .. your [relative] is going to die in the next week .. would you help with this I probably would have freaked and been so upset .. whereas if it had been generic and I'd read it and I was put in this situation I would have felt better equipped to help"

(Individual Interview 1)

"not sure about posters but leaflets in simple language (non-medical jargon) reiterating/supporting the conversation could be helpful to some"

(Individual Interview 3)

However, the difficulty of putting such literature together was acknowledged:

"written information .. for loads of people that's extremely difficult because English may not be the first language you don't know quite what level of understand they have .. I'm aware that if you just have notices about things people just don't respond to it"

(Individual Interview 5)

In terms of who should first approach patients and/or families about their specific participation, patient and carer representatives felt that much would depend on the relationship between the health care professionals and the families. One participant had experienced a negative relationship with staff in the environment in which her father died and she felt that it should *never* be the healthcare professional as they should continue to focus on providing care – a sympathetic researcher with experience of similar recruiting would be better. However, she felt that if a palliative care professional is involved in the care of the patient, the relationship that is likely to have

formed may mean that this person would be the best one to make the first personal introduction to the research.

For other participants it seemed to be important that the person who first introduced the study to the patients was someone with whom the relatives have a relationship and whom they trust. One participant suggested that in ICU nurses may be best placed to identify those who should be approached for participation as they often get a gut feeling about families.

> "nurses they will be able to select relevant families .. you get a gut feeling about somebody .. and they would have a rough idea as to who would be willing to participate and who definitely wouldn't .."
>
> (Individual Interview 3).

Some patient/carer representatives stressed the need for the information leaflets, particularly those written to inform the decision to participate (when dying has been diagnosed) to include explanations of the importance of the research, what will happen and what benefits are expected from the findings.

> "if you have got a leaflet ready as to what the study is in simple terms nothing that's going to be an essay .. I would think a basic leaflet explaining who you are what you're doing and what you hope to achieve from what you are doing ..the nurse if they are willing or yourself if you are there to just hand that leaflet to the *relative* and say if you just have a look at this I will approach you again maybe in an hour
>
> (Individual Interview 3).

One participant suggested stressing that it is a way of giving something back is also important, as people do generally want to help if asked.

> " .. promote the issues as much as possible you know make people thing that they're giving you something don't make it look like a chore make it feel like they're adding .. because people do want to help they really do .. by promoting the god things that will come out of this you know then they'll be more than happy to take part"
>
> (Individual Interview 1)

However, another participant felt very strongly that relatives may already find it difficult to say 'no' to participation, and that information should ideally remain as 'neutral' as possible in order to allow participants the opportunity to express their true wishes.

> "I'd like things to be really neutral that you can say yes or no but sometimes even asking the questions.. there's an assumption that its reasonable to ask and I'm not sure that it is reasonable"
>
> (Individual Interview 5).

Most participants agreed that the researcher should probably be the one who undertakes the actual consent process with the family. This should help to avoid any feelings of coercion (letting down the

care staff by not agreeing to participate). It is also vital that the relatives are fully aware that HCPs think that the patient is going to die imminently before being approached for consent to the study – particularly if it is still possible to consent patients.

> ".. my concern is that do the family or the carers actually know that you're near the end of life .. because its not always apparent you know you think people know and they don't .."
>
> (Individual Interview 1)

5.2.3 Recommendations:

***Recommendation**: In ICU, generic information should be made available within the environment in a sensitive format (see above) so that people are aware that this research is taking place. In order to avoid the potential for coercion and to keep the clinical and research roles separate, the researcher should liaise closely with medical and nursing staff (and organ donation co-ordinator, where appropriate) to identify those who should be approached to consider participation in the study. Once identified, and only when patients/relatives are fully aware that the patient is deemed to be imminently dying, the researcher should be introduced to the potential participant(s) by the medical/nursing team caring for the patient as 'part of the team', should give specific information about the study and seek informed consent. The amount of time available for potential participants to consider the information will then depend on the individual circumstances of the patient (eg whether the discussions around withdrawing treatment have already begun).*

***Recommendation:** In the Nursing Home, generic information leaflets should be made available generally within the home and as part of the information packs about the home given to patients and relatives. This generic introduction to the research should be undertaken by the nurse in charge at the same time as advanced care planning discussions are taking place. The views of patients/relatives on being approached in the future to consider participation could then be assessed and documented. Ongoing discussion between the researcher and the nurse in charge would take place to identify those who should be approached to consider participation in the study. Once identified, and only when patients/relatives are fully aware that the patient is deemed to be imminently dying, the researcher should be introduced to the potential participant(s) as part of the team, should give specific information about the study and seek informed consent. It is likely in this environment that 24 hours consideration time could be given.*

***Recommendation:** Retrospective consent should not be considered because of the particular ethical and moral challenges of this study.*

***Recommendation:** The information leaflets (generic and specific) should be constructed in simple, neutral and jargon free language, should explain in outline terms only the various elements involved in the study and should include the researcher's contact name and details for further information. They should clearly outline the rationale for the study, but not in such a way as to coerce participation.*

5.2.4 Written vs Verbal Consent

ICU Staff pointed out that in this setting, the majority of patients who are eligible for the study are likely to be comatose and therefore they felt that formal written consent for participation in the study needed to be gained only from the named consultee. If the researcher needed to come back into the room to observe further 4 hourly slots of time, they felt that verbal consent only would be required – ie checking that it is still OK to observe though separate written informed consent would be required for the bereaved relative interview.

> "I think its the nearest and dearest [who give informed consent] cos sometimes there's too many people who have a say and then the loved one gets all confused and don't know what to do so it needs to be one person well one or two people.."
>
> (ICU Focus Group 1)

Nursing Home In the nursing home, staff already assess and reassess the capacity of the patient to make decisions and it is important to consider this and allow anyone with capacity to give written informed consent to participate.

> " well you would wouldn't you it would be like asking you or myself .. its your individual choice then cos you're able to make that choice for yourself aren't you and that decision"
>
> (NH Focus Group 2)

In addition, or where the patient lacks capacity, gaining consent from the whole family would be the best option to avoid confusion, and could be done 'in tandem' with the researcher (as part of the team):

> "we'd get consent for the family .. because there's not that many but if there's a big family we'd say check this if this is OK with everybody"
>
> (NH Focus Group 3)
>
> "the whole family would have to be happy with it and then you wouldn't come into that situation [a new relative/friend at the bedside who was unaware of the research] .. because you'd have the consent off everybody"
>
> (NH Focus Group 2)

After initial written consent has been gained, staff felt that verbal consent would be appropriate for subsequent visits. However, if anyone at the bedside is unhappy then the observation must cease. In answer to the question "each time we go back do we have to get signed consent again, one participant said:

> "not if you've already had the consent from the beginning .. but if you came back the next day you'd have to say wouldn't you obviously is it OK if I?.."
>
> (NH Focus Group 2)

Staff consent – this could be gained on 'block' ie they should consent in principle to being observed and interviewed about their care delivery for any patients who will be recruited to the study and specific consent for each individual patient would not be necessary. However, because their care is

being observed, gaining informed consent would have to be done sensitively and managers would also have to have previously given consent for the research to go ahead.

> "you could do that on block I think .. you could generalise that one"

Participants referred to the salience of the consent process they had used when making a DVD about the home:

> "[staff] were given the opportunity to opt in or out when the filming process was on ... and some were very happy to do so and some declined and that was how it had to be"

It was recognised, however, that the care skills of the team would be under scrutiny in this study and some sensitivity would be required when consenting staff:

> "its observing your care skills in that setting .. we might have to approach it more sensitively"
>
> (NH Focus Group 3)

Patient/carer representatives – These participants felt that written informed consent should be gained initially and that verbal consent for follow up observations and for the approach for interview after the death of the patient would then be appropriate as repeated written consent could be burdensome.

> "people might get a bit fed up of having to keep doing it [signing a consent form] .. If I was agreeing to something I'm agreeing to it and that would then cover .. it until such time as its over .. [or] until I said ... I don't want to do this anymore"
>
> (Individual Interview 2)

One participant suggested that gaining joint family consent would be the best option, preferably where one person signs on behalf of the family:

> "so there might be .. say if my sister was to sign the form that would be fine by me because we'd talked about it and agreed"
>
> (Individual Interview 2)

Some felt that written consent should be gained from everyone who enters the room for the first time when the observation is taking place:

> "I would think so because if you're going to use situations that they might be involved in then I would think ethically then you need to have their consent .. I would say written consent for the simple reason that these people are under a lot of stress and strain anyway and after the event could turn and say that they didn't give permission"
>
> (Individual Interview 1)

After this initial written consent has been gained, however, verbal consent only would be required to check that they remain happy with the observation:

"Once you've got it [written consent] you know I think verbal consent in my view would be enough"

(Individual Interview 1)

Several participants suggested that identifying the 'best' person from whom to gain consent might be more complex than initially apparent:

"it depends on what you mean by family as well .. I mean is it sons or daughters or ... maybe a niece or a nephew or grandson even or even nobody who's related to the person actually had been caring for them who would know better than maybe closer family members might .."

(Individual Interview 2)

Only one participant felt that written consent should only be sought from relatives even when the patient had the capacity to consent for themselves.

"I don't think that the patient should be involved at all . apart from observing them and I think that choice has got to be the relatives not the patients"

(Individual Interview 3)

5.2.4 **Recommendations:**

Recommendation: *Written informed consent for participation should be gained from patients (where applicable and possible) and from the named 'consultee' if not. Ideally, written consent that has been negotiated on behalf of the whole family should be gained wherever possible. Written consent should also include permission to approach the relatives after the death of the patient to arrange an interview. All subsequent times when the researcher wishes to commence a block of observation, or where new people enter the 'research environment' verbal consent should be gained from all present. Whenever anyone at the bedside expresses unhappiness about the researcher being present, the researcher should withdraw.*

Recommendation: *Staff should provide written consent to being observed and interviewed about care delivery in principle, (ie on one occasion rather than individually for each patient recruited). However, they should be asked to re-confirm their consent verbally (and be given the opportunity to change their minds) each time a new patient is recruited to the study and/or a new observation block is commenced.*

Recommendation: *Separate, written informed consent should be sought for Time 1 interviews with staff and bereaved relative interviews.*

5.2.5 **When to approach/interview bereaved relatives**

ICU - Staff in ICU suggested that it would depend what information the bereaved relative interviews were designed to elicit as to when would be the best time to undertake the interviews. If accuracy

and detail about the care delivered in the dying phase was to be sought, then the earlier the better. Some felt that even a day or so later might be appropriate and others that if people were approached too soon they may still be in shock, whereas too late and they may not remember. 7 – 14 days was suggested as a time when the initial busyness (including the funeral) would be over whereas a month seemed to be an appropriate compromise for others. Some felt that after a month, people may be disinclined to revisit the issues or that they might forget the salient elements:

> "after a month they might actually be like .. not that I've got over it but I actually don't want to go back and just think about it and talk about it I've moved on from that .."
>
> (ICU Focus Group 1)

Whilst others felt that giving time for reflection would be a good thing:

> " .. I would rather talk about somebody's death and my experience of their death a way down the line come back and revisit that .. when I'd sort of processed it all in my mind.."
>
> (ICU Focus Group 1)

Giving the participant the opportunity to have some choice over when to be interviewed was another suggestion:

> ".. once they've [been] accepted into the study and you say we would like to speak to you .. when do you think would be the most convenient and give them almost a choice say you know in a couple of days, a week or 2 to 3 weeks and then they could almost choose .. if you decide you want to do it after a couple of days and they say oh we're not ready say well can I speak to you next week and give them that option kind of thing.. "
>
> (ICU Focus Group 1)

Nursing Home - In the nursing home it was felt that the decision is likely to be 'a personal' thing. It is likely that some families would be happy to be contacted sooner than others and some families would not be happy to be contacted at all. After the funeral seemed to be an appropriate time for most – probably not approaching them until around a month after the death of the patient. This would give people some time to grieve but they would probably still remember enough of what had transpired. Some felt that giving relatives complete autonomy over the decision was the most appropriate thing to do with a follow up phone call:

> ".. what's right for one person is definitely not right for another so I think .. the family should have the autonomy .. I'll give you a ring later on .. a nice follow up phone call"
>
> (NH Focus Group 1)
>
> "that's so personal though isn't it you what you could do is when they're giving consent . is say when you want to talk to us you could contact us .."
>
> (NH Focus Group 1)

However, the latter participant also suggested that this may not be something that the relative is likely to do spontaneously. An alternative could be that the researcher could agree to contact the

relative at a pre-determined time to find out if the relative is ready to undertake the interview and to arrange a date/time or another time to follow up.

> " .. but then its not something they might say . well they're not going to make that phone call - they might they ... or just say we will phone you in 2 days to see if you are still willing to give us a date .."
>
> (NH Focus Group 1)

Patient/Carer Representatives – One participant thought that it would be impossible to decide on the best time for all to be approached and that this would depend on the individual circumstances of the bereaved relative. Again, a sensitive and flexible approach would be required, possibly where the decision was left to the relative.

> "that varies quite a bit with individuals .. I don't think there is a fixed appropriate time .. I think it definitely varies with individuals individual circumstances .. but I think again perhaps it's got to remain fairly flexible it's got to be discussed beforehand I think .. you could easily say not before a funeral or something but not necessarily .. somebody might want to .. I really think that has to be kept really flexible .. it isn't really about time it's about circumstances .. it would be when they felt able to do it .. "
>
> (Individual Interview 5)

One participant felt that it would be appropriate to prompt them if they failed to get in touch but that the researcher would need to do this sensitively. Most patient/carer representatives thought that after the funeral (2 weeks to a month for most) would be a good time to contact bereaved relatives. They pointed out that there are lots of things to see to prior to the funeral and people are likely to be more relaxed after the funeral and happier to sit down and talk and be able to give a more considered, reflective view at this point. Leaving it any longer than this may mean that people have moved on and do not wish to revisit the issues. One participant suggested that a list of questions for the interview could be given to relatives before they leave the environment (including researcher contact details) as an aide memoir

> " if we had been left with something to take away like some prompts in the form of questions or something .. may be six or seven questions to think about .. as an aide memoir as well .. so that we wouldn't forget and with contact details on .."
>
> (Individual Interview 2)

One participant suggested, however, that the interviews should not be undertaken until at least 3 months after the patient's death to give time to get over the shock/confusion and to reflect.

> " I tend to think that 3 months sounds a long time but actually its just like the blink of an eye .. I think that's a good time for the simple reason that initially you go into shock .. automatic pilot almost .. and you're mourning and you're sorting out different documents and various things .. and then comes a period where .. you begin to reflect on what happened .. so I think that although you think that things might be forgotten they're well and truly

embedded .. and I think before that you're so confused with everything that's going on .. people don't forget things just become more embedded."

(Individual Interview 1)

5.2.5 **Recommendations*:***

Recommendation: *A sensitive and flexible approach is likely to be the most appropriate way of arranging interviews with bereaved relatives. Information about the fact that people will be approached should be given on the information leaflets and the permission to do so should be part of the written, informed consent process. Informal discussion at that time may highlight when the best time is likely to be, however, no-one should be approached prior to the funeral (a minimum of one month after the patient's death) unless they have been given specific permission by the relative. If the relative has not spontaneously contacted the researcher, (s)he should contact the relative to sensitively assess whether they wish to agree a date and time for interview.*

IMPLICATIONS OF THE FINDINGS FROM THE PILOT STUDY FOR THE DESIGN AND CONDUCT OF THE MAIN STUDY

The pilot study revealed a range of views regarding the proposed study. The main theme to emerge from the data as a whole is the fact that this research needs to be handled very sensitively and that all potential participants (patients, relatives and staff) need to feel as 'comfortable' as possible with all aspects of the research process. This will require the researcher to be very flexible in their interactions with potential participants, acknowledging their individuality and taking into account their unique set of circumstances, views and needs in the process of recruitment and throughout the conduct of the study.

One clearly important element is creating a suitable environment in which trust, sensitivity and comfort can develop, is to 'embed' the researcher within the 'team' to as great a degree as possible so that they become familiar to all – healthcare staff, patients and relatives. In the Intensive Care setting this might include attending ward rounds, multi-disciplinary team meetings, getting to know clinicians and nursing staff and, in some settings, liaising regularly with the organ donation co-ordinator. This level of engagement would also allow some informal opportunities for interaction with patients and relatives. In the nursing home, it might mean the researcher being on hand within each nursing home on regular occasions (perhaps for half a day or a day a week in each home over a period of time), joining in activities, giving information about the study (formally and informally) meeting patients and relatives and liaising with the nurse in charge, in order to become a familiar and trusted face within the organisation. It is important, however, to ensure that the role of researcher and healthcare professional are clearly demarcated within the team in order that patients and relatives can feel free to make informed choices about whether or not to participate without fear of a negative impact on their care or that they have let staff down.

Becoming comfortable with the research process also involves making the right amount of information, in the most appropriate format available (for patients, relatives and staff) throughout the research process. Written information should use simple, neutral, jargon free language that gives enough information on which to base an informed decision to participate. It is also important

that potential participants are given as much time as possible to consider participation. All participants in the pilot study felt that some generic, verbal and written information should probably be made available in the environment that alerted potential participants to the fact that the research was taking place and that they may be invited to participate. This advance knowledge, it was felt, would mean that potential participants would better informed and prepared for the subsequent approach and may be less likely to become distressed by it. This information should include a general description of the study that includes the intention to observe the last hours and days of life and to interview bereaved relatives at some point in the future. It was acknowledged that compiling such sensitive information in a written format was likely to be challenging.

In the Intensive Care setting (particularly those that are more 'research active') information about all of the studies currently underway could be summarised into a leaflet that is given to all patients who are admitted (and their relatives). Leaflets or posters (though some participants did express some concern about the use of posters) with general information about this specific study could be made available in the environment. Ideally they should be given to patients/relatives as part of the initial conversations around the withdrawal of treatment. It would be possible for people to be invited at this point either to 'opt in' (ie to give permission for an approach to made to them in the future where appropriate) or to 'opt out' of future consideration/approach. One patient/carer representative felt that 'opting out' in this way would be too much to expect the patients/relatives to do and only the 'opt in' option should be considered, though it was accepted that this was less likely to result in high 'take up'.

Something similar could be put in place in the Nursing Home setting, particularly in those homes where the GSF and the PPC are in operation. A general leaflet about the study (similar to that for the ICU above) could be produced that could be given to residents and/or their families by a trusted member of staff at the same time as discussions about advance care planning are introduced/revisited. Again, potential participants could be given the opportunity at this point to opt in' for further consideration/approach and this decision could be noted down as part of the advance care plan. When such patients were deemed to be entering the last hours or days of life, the researcher could then approach them, as by this time they should have become an accepted part of the team and would be both familiar and accepted within the environment. This would effectively demarcate the roles of health care professional and researcher and hopefully minimise the potential for coercion. In the ICU setting, continued liaison with clinicians, nurses, attendance at ward rounds and MDTs and liaison with the organ transplant co-ordinator (where appropriate) will ensure that all potentially eligible participants are considered for participation. In the Nursing Home, liaison with the nurse in charge and attending 'handover' wherever possible, is likely to be the most appropriate way of identifying potential participants.

In both environments, formal, written consent for participation should be gained by the researcher and not the clinical staff, again to minimise the potential for coercion. Formal, written consent should be gained from patients (where appropriate) and their families. Ideally, this would be the consent of the whole family (ie a consensus decision), however, in practice it is very unlikely that this will happen. Where patients lack capacity to consent for themselves a consultee should be approached or identified to make a decision on behalf of the patient. By law this person must be someone who has had direct recent contact with the patient, and so it is likely that they will also be the most appropriate relative/friend to invite to take part in the study. The formal written consent

should explain that they will be approached after the death of the patient to participate in an interview and they should be asked for their consent to do this. When going through the consent process with the relative/friend at this time, it may be appropriate to find out how and when they may wish to be approached after the death of the patient.

Whilst most participants in this pilot study felt that gaining written consent from anyone who enters the bedside for the first time was necessary, the logistical issues surrounding this mean that only verbal consent will be sought from these people once written consent has been gained from the patient or consultee and relative/friend. Wherever possible, this consent should reflect the consensus of the family and friends of the dying patient, though for logistical reasons this may not always be possible. It is important that consent is checked each time a new observation block is begun however, it is also important to remember that too much 'checking' that consent is still valid can become burdensome for relatives/friends.

Staff should receive information about the study and what it would involve for them – being part of the observation and participating in informal post care delivery interviews. They should then be asked to consent in principle to participate if consent has been gained from a patient and/or relative for whom they are providing care. This could take the form of an 'opt out' or an 'opt in' in principle. Separate written consent, however, should be gained for participation in the Point 1 interviews.

Although most people in the pilot phase felt that bereaved relatives should not be approached until after the funeral (probably around a month for most people) it was generally also felt that the best time to approach someone was likely to be influenced by their individual circumstances and also by any 'relationship' that has built up between the researcher and the relative during the observation period. As noted above, it may be useful to discuss with the relative at the time that consent is gained for entry into the study/observations what they feel would be an appropriate time. Of course, any agreement made at this time may change in response to subsequent circumstances and so the researcher would need to be sensitive and flexible when approaching the bereaved relative. Separate , specific information must be made available prior to the post bereavement interview and separate written consent must also be gained.

CONCLUSIONS

The reason for undertaking this pilot study was to explore with key stakeholders how the ethical and practical challenges of undertaking this research could be overcome. Whilst many participants in this pilot study appreciated the need for research to underpin the delivery of high quality of care, the greatest divergence of response came in relation to the observational stage of the research. All participants in some way recognised the sensitive nature of observing care in the last hours or days of life and the need to protect and promote patient dignity at this time. However, only one person felt that there could be no justification for directly observing care and that appropriate information could be gained in much less intrusive ways.

Participants recognised that undertaking this study sensitively would require the researchers to view each potential participant as an individual with different experiences, needs and circumstances and to take a flexible, sensitive and responsive approach to recruitment. In particular, success hinges on the researcher being visible and familiar within each environment - building relationships of trust between themselves, staff, patients and families. In addition, providing appropriate information in

the right format and at the right time, approaching the recruitment of participants with compassion and undertaking the observations with discretion are of paramount importance. It is clear that the researcher needs to be very experienced (both in such research and in end of life care) and that an appropriate support system is provided for them and maintained throughout the study.

These findings have been used to refine the proposed study, both to ensure that the principles of compassion, sensitivity and flexibility underpin the approach as a whole and more specifically to directly guide the process of recruitment and the conduct of the study. A full summary of "The implications of the findings from the pilot study for the design and conduct of the main study" formed Appendix 4 of the Working Protocol. A flow diagram of the consent process and a Gantt Chart for the study were also included as Appendix 5 and Appendix 6 (respectively) of the Working Protocol for the main study.

Dissemination:

The following poster presentations of the findings from this study have been made to National and International audiences:

Gambles, M; Perkins E; Nolan K, Ellershaw J (2011). Researching care in the last days of life: involving professionals and lay people in refining the research approach. Poster presented to the Marie Curie Cancer Care Research Unit Conference, Royal Society of Medicine, London, 25th March 2011

Gambles, M; Perkins E; Ellershaw J (2011) Observing end of life for research purposes: the findings of a pilot study to involve professionals and lay people in key aspects of research design. Poster presented to the European Association for Palliative Care (EAPC) Congress, Lisbon, 18th – 21st May 2011.

REFERENCES

Buckingham R W, Lack S A, Mount B M, MacLean L D, Collins JT (1976) Living with the dying: use of the technique of participant observation. Canadian Medical Association Journal, 115 (2) 1211-1215

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

Mills M, Davies H T O, Macrae W A (1994) Care of dying patients in hospital. BMJ, 309: 583-586

Seymour J (2001) Critical Moments – Death and Dying in Intensive Care. OUP. Buckingham