When Cure Is Not Likely - Methodology Protocol

Interviews and Workshops

[REC Ref: 13/LO/1098]

Rationale

This mini protocol outlines the approach to be implemented for the data collection phase (interviews, workshops and analysis). This will be informed by a realist approach which aims to understand the causal mechanisms which generate outcomes, consideration of context and a desire to improve practice and service delivery. Its iterative approach assists the capture of multidimensional aspects of the evaluation of End of Life Care and explores links between context, mechanism and outcome. It will increase our understanding of 'what works, for whom, in what circumstances, in what respects and why?'

WCINL: Aims and Objectives

Methods

Interviews

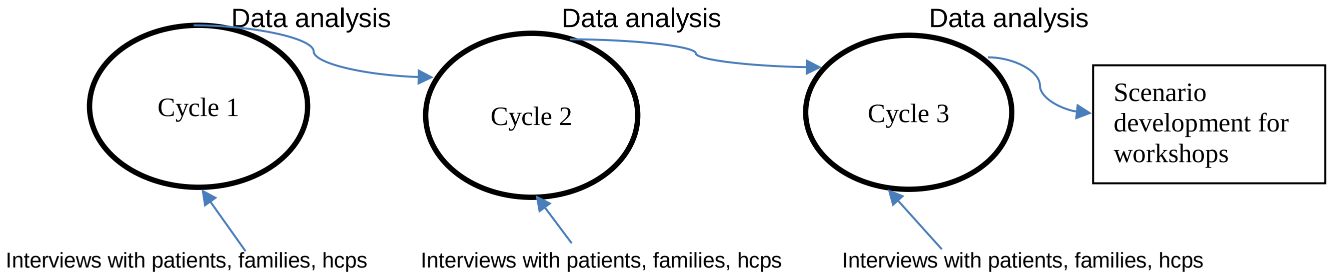
Realistic evaluation will be used as a guiding framework in exploring participants' experiences on the following outcomes;

Good patient centered care
Good family centered care
Responsive clinical care

Our understanding of what is implied by the term 'good care' will develop as our interviews take place and are analysed. For example, emotional spiritual physical; communication, information giving, management of symptoms; promotion of health family systems; social situation; quality of life; supporting finding meaning finding balance between acceptance and hope.

We plan a set of iterative cycles of interviews conducted with 3 groups in each cycle: patients, nominated family members and nominated health care professionals. We shall sample a maximum of 5 patients within each of the two age ranges (16-25 and 25-40) in each cycle, thus a maximum of 15 interviews per age group. Analyses of data will occur after each cycle and findings will be used to inform the conduct of the next cycle of interviews. Once data saturation is reached, the findings will be used to develop scenarios for use in the workshops in the next phase of our work.

Schema of iterative approach for interviews at Time 1:



The interviews will be explorative in their approach due to a significant lack of available evidence about the experiences of this population when cure is not likely and death approaches. This includes a lack of evidence on the availability and appropriateness of palliative approaches to care either alongside treatment or in the dying phase. Through the interviews we aim to explore and understand past and present experiences leading to how the future is viewed and conceptualized. We shall consider the internal, external and reflexive processes of the individual's experience. This will involve the different levels that impact on care: individual, group (family and within healthcare professional teams), systemic and organizational (Ferlie and Shortell, 2001). We shall also explore the situational and contextual attributes for the individual.

The interviews will be iterative in their style using key questions and prompts to explore the perspectives and experiences of the participant. It is anticipated that each interview will last c. 1 hour. Interview schedules can be found at the end of this document, but in short;

> **Patients** will be asked to discuss their care, and perspectives of support for them, using the broad framework "What has happened, what is happening now, and what do you think will happen next?" Experiences of Internal processes; interpersonal and communication, relationship to others and the situation and context will be explored.
>
> **Family members** (nominated by patients) will be asked about the patient's experiences as well as their experiences and perspectives of support for themselves as a family and/those in a caregiving role. This will include considering the effects on family dynamics, communication between family/ young person and professionals; how families can be supported to enhance their capacity to manage patient care and their perspectives of the past, present and future needs of the patient. Family centered outcomes in loss include experiences in bereavement [could use bereavement risk assessment tools for guidance (Agnew et al., 2010)].
>
> **HCPs** will be asked about their experiences of providing care for the specific patient who nominated them, their more general experiences of caring for patients in this age group when cure is no longer likely leading to discussions to inform our understanding of their internal processes of dealing/coping with younger patients who face death. Here the realist approach will allow both interviewer and interviewee to contribute to discussions of working in an area where sensitive issues are commonplace, thus facilitating opportunities for greater insights.

Patient Age Range: 16-25 years
Cohort 1: BRIGHTLIGHT
Sample size: 15 patients over 3 iterative cycles (maximum 5 patients per cycle)
Sampled from 4 cancer groups – minimum of 3 patients from each group

- leukaemia, lymphoma
- bone and soft tissue sarcoma
- brain and CNS tumours
- carcinomas including germ cell tumours

Interviews in this cohort will take place at time 1, and again after 2-4 months (time 2). The second interviews will explore the current situation and what has changed for the patient since the first interview using the same interview schedule but with a greater focus on what has changed. We anticipate that patients will have experienced both external and internal changes. We shall explore how they have experienced changes in their care, their relationships, and how they now conceptualise the future.

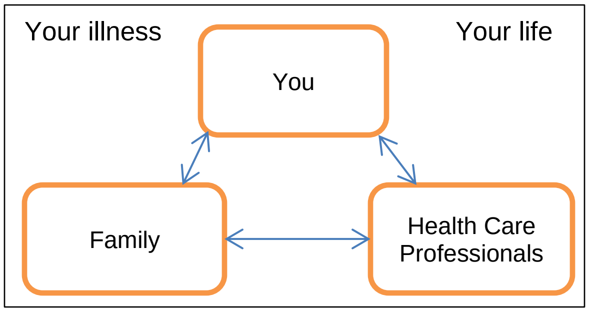
Patient age ranges: 10 16-24 yr olds; 20 25-40 yr olds
Cohort 2: Sites
Sample size: 30: interviews will occur at time 1 only.
Four cancer groups:

- Any carcinomas including breast, colorectal, melanoma, gynaecological and rare tumours – the most frequent diagnoses, so sample to recruit minimum of 21 patients
- Bone and soft tissue sarcoma – minimum 3
- Brain and CNS tumours – minimum 3
- Leukaemia, lymphoma – minimum 3

Conduct of semi-structured realist interviews:
A realist interview allows both interviewer and interviewee to contribute to discussions to facilitate deeper exploration of pertinent issues and allow the possibility of considering innovative issues and solutions.

Interviewers will work to a simple topic guide, allowing free discussion of issues in the past and present and what may occur in the future.

If a patient has difficultly answering questions or conveying their experiences a simple visual prompt may be used (example below) to provide a focus



Simple visual interview prompt

Analysis

All interviews will be audio-taped and transcribed verbatim. Two members of the research team will read in depth each transcript.

A modified grounded theory approach to analysis will be used (Charmaz, 2006). This will take an interpretative approach to identify themes and look for meanings and relationships within the interview data.

Each patient (cohort 2) will generate a set of 3 interviews which will be considered together as case studies which will then be compared and contrasted. In addition, the full set of each category of interviews (patient, family and HCP) will be analysed separately to extract common themes. We shall compare the datasets for the two age groups and look for commonalities and differences. Our findings will be used to inform the development of scenarios to be used in the workshops in the next phase of our research.

We shall also use our findings to develop further our programme theories. These theories have begun with the underlying hypotheses and enablers and barriers that we have identified at the start of our work from the literature and expert opinion of the research team. By defining our proposed outcomes as the provision of 'good' experiences of care for patients and families, and responsive care from HCPs, we shall use our data to develop a fuller understanding of what constitutes good and responsive care, and good experiences for patients and families. We shall use diagrams, flow charts, maps and memos to develop a full picture.

Outline of next stage of research:

Scenario workshops

Workshops will be held across our three recruitment sites across UK, Leeds, London and Southampton. Three workshops will be held at each site (total of 9) comprising of 1 with family members; 1 with healthcare professionals and 1 mixed family and HCP. The scenarios will be used to facilitate interactive discussion of issues arising for patients, families and HCPs in the experiences of care and illness for people in the age groups 16-25 and 25-40 years. The realist approach allows the opportunity for participant to disclose perspectives, opinions and experiences. The conduct of the workshops will enable the generation of hypotheses on mechanisms by which care in the last year of life for people aged 16-40 years might be delivered to enable 'good' care. We shall use our programme theories to underpin our thinking in the workshops and in the analysis of the data they generate. We shall use the emerging hypotheses to populate in more depth our existing programme theories. The teacher-learner approach by which researchers and participants both contribute to discussions will enable the researchers to use their theories and knowledge from the interviews to interact with workshop participants as well as confirm or falsify theories.

References

Agnew, A., Manktelow, R., Taylor, B. and Jones, L. (2009) Bereavement needs assessment in specialist palliative care: a review of the literature. *Palliative Medicine*, vol. 24:1, pp. 46-59.

Charmaz, K. (2006) *Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis*. Sage, London.

Ferlie E.B, Shortell S.M. (2001) Improving the quality of health care in the United Kingdom and the United States: a framework for change. *The Millbank Quarterly*, vol. 79:2, pp. 281-315.

When Cure Is Not Likely – Interview Topic Guides

We need to collect some background information about each participant, so we can describe who has taken part in the study.
What year were you born?
How would you describe your gender?
Do you recall when you were first diagnosed (date/month/year?)
At the moment are you employed (on sick leave) or in full time education?
How would you describe your ethnicity?

During the interview, we would like to talk about a number of issues relating to your medical care, how this may have affected your social life, how well you think information has been given to you or how this could be improved and how decisions have been made about your care;

BOLD = questions Plain text = prompts

Patient	Past (up to WCINL) **Can you tell me what has happened up to this point?**	Present (WCINL) **What is currently happening?**	Future (Post Interview) **Do you think about things that might happen in the future?**
Medical Management	When did you find out something serious was wrong? [diagnosis] When did this happen, where, who was there, how did you feel What treatment did you have [if prompted by patient] How did you find out/ know things were not going so well [prognosis]	How do you think things are going with your illness /symptoms/ cancer at the moment? **Are you receiving any treatments now? Are you on medications, if so what are they for?** **What/who is helpful about the care you are receiving? What/who is unhelpful??** **How do you feel in yourself now? [feelings about medical aspects/situation]**	If yes, what do you think about / how do you plan?? Has anything been discussed with you about potential future treatment plans/ options [this needs to be dependent on what they say about the present]
Social Management	**How did you tell others (family/friends/colleagues) what was happening and how did they react** (illness, treatment, prognosis) **How did you find telling other people about your situation? If it was difficult, which parts were difficult??**	**Thinking about your day to day life – can you do the things that you want to do? If not, what is the impact on your life** **Does your illness have effects on you financially**?	**Is there anything in particular you want to do or achieve? (day to day; immediate, longer term)** **Do you have any worries/fears**

	On a very practical level, what were the biggest things that changed with the illness – e.g. where you were living / work / finance etc. **Have you used the internet to find out information about your illness** (What has been helpful/unhelpful? (illness, treatment) **Do you use social media like Facebook and Twitter? How has your illness affected that??**	**How does your current health affect you your relationships? (sexuality/family/friends/others/dependence/emotional)** **If you have a bad day, who/where do you turn to for support (what do they give you/how do they help? Have you found anything/ anyone particularly supportive)** **How do you feel in yourself now? [emotional wellbeing]** **Have you found a way to make some sense of what's happening at the moment? What has been helpful/unhelpful (spiritual)**	What are your fears (do you worry about) for the future? (parents/children/siblings, increase symptoms, being less able to do things you want to do, decreasing independence, dying process, life after death) **Do you have any hopes, dreams aspirations?**
Communication/information giving	**What was helpful / unhelpful about the conversations you have had with health professionals? How could it have been done better??** (e.g. timings / communication / information)	**Can you tell me about the support you are currently receiving from health care professionals (Cancer CNS, Pall Care, Consultant, GP, District Nurse, Social Worker)** **Can you tell me about the support you are receiving from your family (emotional, practical, financial, care)**	**What have your clinical team said about your future?** **What have you asked your clinical team about your future?** **Who do you think you would contact if you if you have concerns about the future? Why that person?**
Decision making	**Who has been involved in the decisions about your illness / care**?	**Are there any key decisions you are facing at the moment?**	**Are there any key things you think you will need to make decisions about in**

	What input have you had in decisions made about you illness/care?	**(further/stopping treatment; ACP; breaking news to others e.g. small children)** Prompt: If so, is anyone helping you with this? Is there anyone you would like to help you? Are you able to talk to that person / people… if not why not	**the coming weeks and months?** Who do you think might be able to help you with this? Are you able to talk to those people? – if not why not, **Are there questions you want to ask but don't feel able to? What might help to make that easier??** Prompts: (Simple everyday things/activities; Preferred place of care; Preferred place of death; memory boxes, photos, Writing a will; Funeral planning)

Is there anything we haven't mentioned that you would like to talk about today?

Family

We need to collect some background information about each participant, so we can describe who has taken part in the study.

How old are you?
How would you describe your gender?
Do you recall when you were first diagnosed (date/month/year?
At the moment are you employed or in full time education?
How would you describe your ethnicity?

During the interview, we would like to talk about a number of issues relating to x's medical care, how this may have affected their and your social lives and interactions, how well you think information has been given to x or to you and whether this could be improved and how decisions have been made about x's care.

Family	Past **What has happened up to this point**	Present **What is currently happening**	Future **What do you expect to happen in the future…**
Medical Management	When did you find out something serious was wrong with x [diagnosis] When did this happen, where, who was there, how did you feel **How involved have you felt in their treatment and care?** **How would you rate x's experiences of the care (diagnosis, treatment,;** helpful **/ unhelpful –in terms of care delivery / care pathway?** **Were you/other family members offered any support at this time by the clinical team (explain illness, treatment)** What was offered, did this differ by family members what was helpful/unhelpful	What are your views towards the current care that x is receiving How do you feel x is coping at the moment **How do you feel at the moment?** Do you feel supported Is there anyone who is supporting you? Do you have anywhere to go or anyone to talk to if you feel low? **How are the rest of your family coping (explore individual members)** **Is there anything more or different that could be done to help or support you or other family members?**	**Has anyone offered support to think about the future? If yes – was it helpful / unhelpful? If no – would you want some support ? who from? What should it look like?? What would you like?** What do you think might be available to help you and the patient in the future? (Pall Care, CNS, GP) What worries or hopes do you have about this?

	[if prompted by family member] How did you find out/ know things were not going so well [prognosis]		
Social Management	**What was the impact of x's illness on you/your family's day to day life (changes in relationships; priorities; carry on as 'normal')** In what ways has x's illness changed your family (closer, distant) **Who did you tell that x had cancer; how did they react; how did this make you feel?**	**What is the impact of x's illness on day to day life (financial, emotional)** How do you think this has changed your relationship with a) x b) other family members Have you found a way to make some sense of what's happening at the moment? How has this been? **Is there anything particular that sustains you when things are not going so well? (spiritual)**	**What are your fears/ hopes (do you worry about) for the future?** What support do you think you will need in the future (emotional, financial, care) What support do you think other family members may need
Communication/information giving	**What information were you given after x's diagnosis; who gave you this information; what did they say; what this information sufficient?** Do you think they were the best person to tell you this, if not, who would have been better How was information communicated between a) you and x; and b) between the different members of the family What was helpful/ challenging **Were there any things that you**	**What do you know about x's current situation** **What else would you like to know about their current situation; where/who would you go to find this out?** **Who do you turn to for support? Is it adequate, how could it be improved?? What should change??** Who do you share how you are feeling with (family, friends, counsellor); what do they provide	**Has x or their clinical team discussed with you about what might happen in the next weeks and months?** **Have you been offered any support for now or in the future? Is it adequate, how could it be improved? What should change?**

	couldn’t talk about to some people; any people you could talk openly too?		
Decision making	**How involved were you in any decisions that x had to make about their treatment** Who decided on your level of involvement Would you have liked greater or less involvement?	**How involved are you in decisions that x has to think about or make (what are these decisions; what involvement have you had)**	**Have you thought about what will happen in the future?** Have you discussed the future with x; what have you talked about (Preferred place of care; Preferred place of death; memory boxes, photos, Writing a will; Funeral planning)

Is there anything we haven’t mentioned that you would like to talk about today?

Heath Care Professional

We need to collect some information about each participant.
How old are you?
How would you describe your gender?
Could you tell me what your current job title is please?
How long have you been in this position?
How long have you worked in palliative care?
How long have you worked with the young adult population?
Have you completed any further training for working with young adults with cancer?

During the interview, we would like to discuss the past, present and future dimensions of care for x, and then talk about your wider experience of working with this patient population. With these topics in mind;

With reference to the patient:

- **Past:** How long have you known the patient; What has happened up to this point? (Diagnosis, treatment)

- **Present:** What does the patient/ family understand about what is happening; at what points has communication of significant issues around what is happening taken place, can you tell me more about these. What discussions about this patient have taken place across the MDT

- **Future:** What do you expect to happen in the future? (Prognosis, towards end of life); what has been put in place for the patient – ACP? What support do you think the family will need – has anything been put in place? What is difficult for the patient?

- What do you think would improve the pathway of care for this patient?? How should/could it be done differently?

Wider experiences of working with young adult population

- What are the most important aspects of care for this patient group? (holistic; pain/symptoms; family issues; socio-demographic; financial, Peers, life tasks, support, advocacy, listening, empathy compassion , being there)

- Beyond providing medical care, what other needs do this patient group often have and how do you identify and address these e.g. social, family, educational, financial needs do you think that your system is robust enough, or is there the potential for issues areas to be missed / forgotten?

- At what stage do you know ‘when cure is not likely’; can you give me examples of breaking this news to a patient/their family - where it went well and an example of where it was more challenging. What can make these scenarios more difficult

- How do palliative treatments e.g. chemotherapy affect patients’ desired end of life outcomes (Ref, USA evidence chemo in last months of life associated with CPR ventilation and dying in ICU, Wright et al, 2014)

- How do you negotiate patient/family relationships (e.g. family dynamics)

- What do you enjoy about working with this population?

- What do you find more difficult about working with this population

- How does it affect you when a relatively young cancer patient dies (emotional impact; coping mechanisms; specific patients e.g. those with young children)

- Have any personal or professional experiences affected your practice (e.g. using experiences to improve care; managing emotions; maintain a professional distance)

- Do you have clinical supervision/support available; do you use this or other sources of support? How else do you relax and gain perspective

- Any issues you are aware of generally for professionals, teams, units, places of care, caring for young adults with cancer who may die

- What could be put in place to improve end of life care for this specific patient group?

Are there any other aspects of care for this population that we have not discussed and you feel are important?