Helping Optimise Primary Care Support During Transition From Children's Hospice Care

SHORT STUDY TITLE: HOPSCOTCH

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Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: Date:

01/07/25

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Name: (please print):

Professor Lucy Ziegler.

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Sponsor	University of Leeds
Funder(s)	NIHR Health and Social Care Delivery Research (HSDR) Programme.
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Study summary

Study Title	Helping Optimise Primary Care Support During Transition From Children's Hospice Care
Internal ref. no. (or short title)	HOPSCOTCH
Study Design	Qualitative interview study with key stakeholders Documentary Review Intervention co-design
Study Participants	Young people with life limiting conditions and their families. Healthcare professionals
Planned Size of Sample (if applicable)	WS1 – Young people and families (n = 18) WS2 – Healthcare professionals (n = 18)
Follow up duration (if applicable)	
Planned Study Period	24 months

Research Question/Aim(s)	Aims: To (1) understand and identify opportunities to enhance engagement of general practice in the coordination and delivery of care to young people as they transition from children's hospices to adult services, and (2) co-design and develop a complex intervention (the HOPSCOTCH tool) to facilitate this enhanced engagement. Research Questions: 1. What are the views and perspectives of key stakeholders on the engagement of general practice in the care of young people as they transition from children's hospices to adult services? Key stakeholders are: i) young people with LLC transitioning from children's to adult services and their families. ii) adult palliative care specialists iii) paediatric palliative care specialists iv) primary care staff 2. What are the key elements of a complex intervention to enhance this engagement

1.0 Background

There are more than 86,000 children and young people living with a life-limiting condition (LLC) in England. Life-limiting conditions are those for which there is no reasonable hope of cure and from which children or young people are expected to die (1). The numbers of young people (aged 14-25 years) with a LLC in England has risen by 40% between 2009 and 2018, and the number of young people with a LLC eligible for transition from children's to adult services rose from 16,107 to 24,773 over the same period.(1, 2) This is a rapidly growing population with increasingly complex healthcare needs, more of whom are surviving into adulthood.(3) General Practitioners (GPs) have a role to play in the care of children and young people with LLCs and their family members particularly at the point of transition to adult services. Their involvement has been shown to reduce emergency secondary care use and facilitate person centred continuity of care for this population. (4-6) Despite this, care during childhood is typically led by specialist services with limited involvement of GPs.(4-9)

This study aims to improve engagement of primary care services in the care of young people with LLC with a specific focus on the point of transition to adult services. In 2022 an amendment to the Human Rights Bill made access to palliative care an explicit human right.(10) This amendment has the power to drive transformative change in the delivery of palliative care. In the National Health Service (NHS) in England, Integrated Care Boards (ICBs) now have a legal responsibility to commission palliative care services that meet their population need and to provide comprehensive equitable palliative care to all. Young people with LLC are a population with complex palliative care needs many of whom are not having these needs adequately met.(4-6, 8-10) This is in part due to a change in how palliative care services are delivered for this population. For over 30 years UK children's hospices have delivered a model of care aligned with the World Health Organisation recommendations for paediatric palliative care. Involvement commenced at the time of diagnosis with a life limiting condition and continued until death. Care often extended from infancy well into adulthood and young people were not discharged from children's palliative care services irrespective of age. This model has become unsustainable due to the rapidly growing population of young people with LLCs and their increased life expectancy.(1-3) This has necessitated transitioning young people from children's palliative care delivered by hospices, to adult palliative care services as they approach young adulthood - a process families and young people have described as 'falling off a cliff'. [11] Adult palliative care services are configured differently to children's services and are often orientated to the last days and weeks of life, rather than the longer term care including short breaks that children's hospices offer. The average duration between referral to an adult hospice and death is 37 days. Adult palliative care services for young people with LLC do not currently provide the continuity of care so critical to coping, effective symptom management, respite for families, and sustaining a reasonable quality of life. Furthermore, children with complex LLCs often receive care from a range of specialist paediatric teams, all of which will have a transition process independent from the transition from children's hospices to adult palliative care. (https://www.nice.org.uk/guidance/ng43). Children with LLCs do not necessarily fit the referral criteria for adult palliative care or hospice services.

Access to appropriate palliative care for young people with LLCs has become precarious and highly inequitable.(7, 11) compounding other inequalities experienced by this population. Prevalence of LLCs is highest amongst young people of Pakistani origin and in areas of higher deprivation, with the highest prevalence of LLCs in young people being in the North East of England.(1) There is growing evidence that primary care involvement is critical to the provision of quality palliative and end of life care for this population and that the GP has a key role. However GPs are infrequently engaged in the care of the young person with a LLC or in any aspect of transition planning from children's to adult services.(7) The 2023 NCEPOD study 'The Inbetweeners' found that 100% of young people peri

transition were registered with a GP and 79.9% had been previously encouraged to access their GP for healthcare however only 4 out of 69 parents said their young person's GP was involved in any aspect of the transition process.(11) In preparing this application the applicant team undertook a survey of UK children's hospices, only one hospice involved the GP in any aspect of transition. This project is grounded in research evidence and is timely from a policy perspective; there is an urgent need for more proactive, personalised care for those with complex healthcare needs. National Health Service (NHS) Integrated Care Boards (ICBs) in England have a statutory duty to commission integrated palliative care for all people with progressive illness or nearing the end of life, to live and die well. It is widely recognised that there is variation in the level of engagement with palliative care in primary care, with barriers identified including inconsistent skills and training, limited workforce, time, and resources.(11-13) The formation of new Integrated Neighbourhood Teams (INTs), which aim to improve access, experience, and outcomes for communities, particularly Core20PLUS5 populations will include co-located generalist and specialist multi-disciplinary teams, community engagement, and workforce development and training. (13) A core function is proactive identification of patients who could benefit from personalised care and continuity, both key characteristics of good palliative and end of life care. A programme of ten projects on transition undertaken by Together for Short Lives found the engagement of GPs is vital to the success of young people transitioning from children's palliative care services.[11] This work informed the 2023 Transitions Pathway Quality Standards which states 'Every young person must be supported in adult services by a multi-agency team fully engaged in their care.' [11](14) The GP holds overall responsibility for the young person and is the key health care professional for the entire family. Regular GP involvement and continuity of care is associated with reduced emergency secondary care use and better coordination of services.(8) GPs have the potential to provide many vital aspects of palliative care, including the coordination of care from community and specialist teams, provision of prescriptions and holistic support for family members (including during bereavement). Consistent poor experiences of general practice cause children and families to feel isolated. Young people and families report fostering a relationship with their general practice enables them to access important aspects of care, including the assessment and management of acute illness, chronic disease, medication reviews, and holistic support. (4-9) There is an urgent need to drive improvements in the care and experiences of young people with life-limiting conditions. The NICE quality standard for transition from children to adult services (14), TFSL Report [11], CQC report 'From the Pond into the Sea' (7) and The 2023 National Confidential Enquiry into Patient Outcome and Death (11) all state GPs need to be included at an earlier stage in the care of young people with LLC and need to develop their skills particularly in relation to communication with young people with LLCs and their families. Barriers to primary care involvement GPs have expressed concerns about having an active role in palliative care for young people including a lack of time, lack of specialist knowledge particularly with rare conditions and understanding of their role alongside specialist colleagues. Barriers can be classified according to three levels: personal: barriers related to knowledge, skills, emotions; relational: barriers concerning communication and collaboration; organisational: barriers related to the organisation of care and compartmentalisation in healthcare.(4, 5, 7-9) The proposed study will identify solutions to help address these barriers and facilitate better engagement of the GP in the care of young adults with life limiting conditions.

The applicants (LF, LZ) involvement in a NIHR funded palliative care partnership Yorkshire 22/561 HSDR Palliative and End of Life Care facilitated access to five commissioners who provided feedback and helped shape the proposal. Two completed NIHR funded projects undertaken/supervised by the project team; DRF-2018-11-ST2-013 "Transitioning from paediatric to adult healthcare with a life limiting condition; does this lead to increased healthcare usage, cost and worse patient outcomes?

and NIHR129213 “End of Life Care for Infants, Children and Young People: a mixed methods evaluation of current practice in the United Kingdom” also underpin this proposal.

2. 0 Rationale, aims and objectives

2.1 Rationale

The research to date has articulated the challenges and evidenced unmet needs in relation to the care of young people with life limiting conditions at the time of transition to adult services. HOPSCOTCH is solution focused and builds on this evidence base to drive much needed improvements in care. The timing is critical to enable us to inform and shape the rapidly evolving policy and commissioning landscape in primary palliative care. The need to address inequities in access to palliative and end of life care through a personalised approach is emphasised in the 2023 Department of Health and Social Care Major Conditions Strategy.(15) The new vision for primary care outlined in the 2022 Fuller Stocktake will result in the development of new integrated teams to provide care in the community, with a blended generalist and specialist workforce.(13) It is critical that young people at transition are considered in processes and procedures including identification of need, care-coordination and continuity. We have identified a selection of relevant read and SNOMED codes that exist for transition, there are no tools or templates to support reviews of care in primary care settings. The timely alignment of these service level innovations alongside HOPSCOTCH will help facilitate its successful implementation and maximise its impact.

2.2 Aim

The study aims are to

(1) understand and identify opportunities to enhance engagement of general practice in the coordination and delivery of care to young people as they transition from children’s hospices to adult services

(2) co-design a complex intervention (the HOPSCOTCH tool) to facilitate this enhanced engagement. Use of the tool in clinical practice will be examined in a subsequent feasibility and acceptability trial.

2.3 Objectives

1. To identify opportunities to enhance engagement between children’s hospices and primary care. We will do this through reviewing information currently shared between hospices and GPs and by undertaking interviews with primary care staff, hospice staff and young people with LLC and their families to understand what GPs really want/need to know and in what format (Workstreams 1 & 2).

2. Identify opportunities for primary care staff to engage with YP with LLC and their family that is feasible and fits within service constraints. Utilising opportunities related to existing service requirements for Primary Care Networks (‘identify patients with complex and problematic polypharmacy for medication review’) may be one such approach (Workstream 2).

3. We will develop an intervention ‘toolbox’ to support effective engagement using a method adapted from the principles of experience-based co-design with YP with LLC and their families alongside primary care staff and hospice care staff (Workstream 2)

3.0 Study design, methods of data collection and data analysis

Ethical approval was obtained from Wales REC3 ethics board 00/00/2025 (IRAS ID 334486).

The origin of this study and its aims and objectives were born from directly engaging with parents of young people with life limiting conditions and health professionals who care for this population. scoping activity undertaken as part of the Collaborative Paediatric Palliative Care Research (CoPPAR) network (NIHR135304) identified transition to adult services as a priority for research. As such, the rationale for the study was directly grounded in the needs and perspectives of the population the study aims to benefit. Drawing on the views and expertise of young people with life limiting or threatening conditions who have experienced transition to adult services has been critical to the development of the proposal, have informed decisions about recruitment and have given us clear guidance on feasibility of the study design. PPI co-applicants contributed to and reviewed the lay summary.
The project team have a strong track record in engaging in meaningful and impactful patient public involvement and engagement specific to paediatric palliative care. SM will coordinate PPI alongside co-applicant GP. We are committed to ensuring the voice of young people continues throughout the lifespan of the project, a young person advisory group will be established at project setup. Co-applicants with lived experience will support and be part of the group, alongside a further 4-6 members. Recruitment to the advisory group will be supported through links with established groups and organisations such as the 'Leeds Deepend Research Network' that represents the views of people from socioeconomically deprived areas in Yorkshire and user-led organisations such as Pathfinder's Neuromuscular Alliance. To maintain a strong link between the young person advisory group and study steering committee, BM and JW will attend steering committee meetings on behalf of the advisory group.
To complement the expertise of young people, we will also draw on the views of parents of young people who have transitioned to adult services. Studies suggest parents continue to play a key role in coordinating their child's transition to adult services. Relatedly, previous studies have highlighted the consistent barriers parents face in attempting to coordinate transition. Consequently, it is vital that parents play a role in advising the study. To support recruitment to the group, we will utilise existing contacts with organisations who support parents of children with life limiting conditions, such as Together For Short Lives (HD), alongside the project hospice partners.

The study design has been guided by the UK Medical Research Council (MRC) complex intervention framework. The intervention development draws upon the principles of Experience Based Co-Design (EBCD) and is theoretically driven by the Behaviour Change Wheel (BCW).

This study includes ongoing dissemination to key audiences (young people, parents, service providers, commissioners) via knowledge exchange events, web-based platforms, social media and clinical/academic forums. It is anticipated that intervention development will be competed at month 24. An associated feasibility and acceptability study is planned for months 24-36. This will be described in its own protocol and subject to an additional application for HRA ethical review.

Ultimately, we aim to improve the experiences of young people as they transition from children's hospices, their families, and healthcare professionals.

<u>Research plan</u>

<u>Young person and family perspectives on the transition process and the role of primary care within it</u>

Sampling

Young people and family interviews (n=18): six young people and/ or family members who have transitioned to adult services, six that are currently transitioning and six that are approaching transition will be recruited from our partner hospices.

Inclusion criteria (Young people):

- Young person with a life limiting condition.
- Minimum 14 years of age.
- Previous or current user of children's hospice services
- The young person must be approaching transition to adult services, in the process of transitioning to adult services or have transitioned to adult services within the previous 5 years.
- Capacity (with support if required) to understand young person information and consent either in written or verbal form
- Capacity and willingness to take part in a discussion about their experience.

Exclusion criteria

- Transition to adult services occurred > 5 years ago.
- Unable to provide informed consent (family members can participate in addition to or instead of the young person if they are unable to provide informed consent).
- Under 14 years of age.
- Young people who are too unwell (as judged by healthcare professional making initial contact) will not be approached for interview, but their family members may still participate if they wish to.
- Young people who are unable to participate in a conversational interview for any reason related to their condition will not be approached for interview, but their family members may participate if they wish to.

Inclusion criteria (Parent or carer):

- Parent/carer from the same household of a young person with a life limiting condition who is approaching transition to adult services, in the process of transitioning to adult services or have transitioned to adult services within the previous 5 years.
- Minimum 18 years of age.
- Parent or carer of a young person who is a previous or current user of children's hospice services.
- Family/carers may still participate in the study if their young person has died within the previous 5 years and experienced any of the above stages of transition prior to death.
- Capacity to understand information and consent either in written or verbal form
- Capacity and willingness to take part in a discussion about their experience.

Exclusion criteria

- Transition to adult services occurred > 5 years ago.
- Unable to provide informed consent.

Recruitment

We will recruit participants via our children's hospice partners and the corresponding adult hospices (if the young person has recently transitioned to adult services). We will approach the transition co-ordinators/ transition lead at each children's hospice to identify potential participants who meet the eligibility criteria. The transition co-ordinator will share a participant information sheet (PIS) and a consent-to-contact form with potential participants. Those who are interested in participating and/or hearing more about the study and agree to be contacted by the study team, will be contacted directly by the researcher based at the University of Leeds or Kings College London. Contact will take place by telephone or email. The researcher will provide further information, confirm eligibility to participate. To recruit young people and their parent/carer who have already transitioned to adult services, we will liaise via the children's hospices to share the study information with the transition coordinators at the respective adult hospice. We will then follow the same recruitment process with the adult hospice as detailed above.

Consent

We will obtain written and / or verbal consent and agreement from every individual taking part in an interview.

Informed consent will be obtained at the start of the interview. For young people under the age of 16, consent will be obtained from the parent and then verbal or written agreement obtained from the young person. In keeping with the Mental Capacity Act (MCA), there is an assumption of capacity in young people aged 16 years and over, so they will be asked for consent first, followed by agreement from their parent. This parental agreement is not legally required, but conducting an interview with a young person about a potentially difficult subject without the knowledge or agreement of their parents might raise ethical concerns. For young people aged 18 and above, parental agreement will not be sought. Parental consent will be required for any interviews that require a researcher to visit the family home. Parents and carers who take part as research participants themselves either with or without their young person will be asked for verbal or written consent depending on the mode of interview.

Healthcare professionals will give written or verbal consent prior to their interview.

Verbal consent involves the researcher guided by our remote consent script, reading all questions listed on the consent form and audio recording this and the participants yes/no response.

Potential participants will be given at least 48 hours to read the PIS (Appendices 7, 8, 9). Consent will be taken immediately prior to the recorded interview, and can be written or verbal, in the case of remote contact (Appendix 14). Verbal remote consent will be audio/video recorded and stored separately from the rest of the recorded interview. Participants will be informed of their right to withdraw consent at any time during the interview and to withdraw their data for up to 2 weeks after. Any participant withdrawing from the study will have their data and any personal information destroyed.

Data Collection young people and families

In-depth Interviews will be conducted by an experienced researcher under the supervision of programme leads. Participants will choose the venue for their interview, where privacy can be assured, such as the home, University or hospice. Interviews may be carried out by Microsoft Teams or in-person as is the participants preference. Participants will be assigned study identification numbers. Demographic forms will be labelled with the participant identification number only. The code link

document will be stored on secure Teams drive at the University of Leeds in its own password protected document.

The interview schedule will be piloted with at least two members of our young person and family advisory board. A narrative approach followed by semi-structured questions will be used. (16, 17). This approach has the benefit of allowing participants to tell their story regarding their experience of the transition process without imposing a structure or order in the first part of the interview but ensuring that key topics are consistently covered with all participants.

The second substantive section of the interview will use in-depth, semi-structured questions to explore the pathway to transition, the transition process and, if relevant, care beyond transition with a specific focus on the role of the GP within it. Interviews will last around 60 minutes, to allow sufficient exploration of experience whilst minimising participant burden. However, because of the narrative approach it is expected that some interviews may take longer.

Interviews will be audio and video recorded. Recordings will be transcribed. Analysis of young person and family interviews will be undertaken alongside healthcare professional interview data from WS2 (see detailed analysis plan below).

<u>Development of catalyst animation and/or film</u>

A professionally produced catalyst animation will use extracts of pseudo anonymised transcripts of participants interviews to highlight key aspects of the transition process. Participants will have consented to the public dissemination and use of their words in a pseudo anonymised format.

Extracts from film of young people and families' interviews will be combined to make a catalyst film highlighting overarching themes, key experiences and learning for improvement.

Participants will be given the opportunity to decide if any parts of the interview may not be included and will approve the completed version before dissemination.

Our consent process enables participants to choose whether participants wish film and audio of them to:

a) Be used only in workshops during the intervention co-development with other young people, family and healthcare professional participants

or

b) Also be used in a publicly disseminated film to be widely shared.

We will continue to work with YP and family PPI partners in an iterative process to determine the content and dissemination strategy for these.

<u>Feedback workshop 1- YP and families</u>

Following the analysis of the YP and family interviews we will hold a feedback workshop for YP and families. YP and families who took part in the interviews will be invited to the feedback workshop. The purpose of which will be to show the catalyst film and allow the participants to discuss their responses and reactions. The feedback workshop will be facilitated by SM, a GP with at least one PPI co-applicant JW and or BM. The facilitators will run an emotional mapping exercise to help young people identify key points of the transition journey that could benefit from improvement. The meeting will be attended by a professional Illustrator who will in 'real time' create story boards to inform the mapping exercise. From the areas of potential improvement identified by the map, the participants narrow down their list to 4-5 priority issues to be discussed at a joint health care and professional co-design event (see workstream 2).

Healthcare professionals' perspectives on the transition process and their role within it and documentary review:

Months 8- 18

Interviews with healthcare professionals (n=18)

Six primary care staff, six adult palliative care clinicians and six paediatric palliative care clinicians will be recruited to participate in interviews which will focus on the pathway to transition, the transition process, documentation supporting this and care beyond transition with a specific focus on the role of primary care within it.

Inclusion criteria (Healthcare professional)

• Minimum 18 years of age.

• Work in primary care, adult hospice or children's hospice.

• Hospice staff has a role or responsibility in supporting transition.

• Capacity to understand information and consent either in written or verbal form.

• Capacity and willingness to take part in a discussion about their experience.

Exclusion criteria (Healthcare professional)

None.

Primary care staff will be recruited from practices across West Yorkshire, London and the Northeast of England. Access to West Yorkshire based practices will be facilitated by the research manager for NHS West Yorkshire Integrated Care Board (co-app PC). Our primary care advisory board members based in the Northeast and Greater London respectively will support recruitment of primary care staff in these areas. Our advisory board will make an initial approach and identify primary care staff who are interested in participating in the study. These will be contacted by the researchers who will share any further information they require and, if appropriate, obtain informed consent to take part in an interview. Research activity will be conducted outside of their NHS working time and by University of Leeds Microsoft Teams or on non-NHS property.

Six adult palliative care clinicians and six paediatric palliative care clinicians with a key role or responsibility relating to transition will be recruited via our adult and children's hospice partners. The adult hospices serve diverse populations and have relevant experience on which to draw having received referrals from the children's hospice sector over the past five years. The children's hospices

are geographically dispersed throughout England and adopt a range of different approaches to transition. Where the hospice has a designated transition lead clinician their participation in the interview will be requested specifically. As with the primary care staff recruitment process, if palliative care clinicians are interested in participating, the research team will share further information about the study, obtain consent and schedule the interview either at their place of work or online depending on their preference.

Interviews may be carried out by Microsoft Teams or in-person as is the participants preference. Participants will be assigned study identification numbers. Interviews will last approximately one hour.

Data collection

Primary care staff interviews will focus on the transition process and explore potential opportunities to engage with YP with LLC and their families at the time of transition, including those that align to existing primary care services such as medication reviews and learning disability checks. Confidence and perceived competence to provide palliative care to young people with LLCs, and training needs, will also be explored. To maximise feasibility of the intervention we will explore perspectives about the potential of the primary care multi-disciplinary team who could have a role in transition and how best to engage with them. Interviews with transition leads and palliative care clinicians will focus on the current transition process within their organisations, including barriers and enablers to successful transition and opportunities to engage primary care in the transition process.

Combined Analysis

Interview data will be analysed using reflexive thematic analysis, to draw out key themes that "capture something important about the data in relation to the research question and represent some level of patterned response or meaning within the data set" (18). Where relevant, young people's family/carer and professionals' data will be analysed together; however, data from both groups will also be compared during the development of themes to identify similarities, differences and disagreements. The analysis will focus on barriers and facilitators to providing quality and equitable care at transition, and how different experiences of transition impact on care and quality of life including opportunities for social interaction, psychological support and family support. Other key themes that offer additional insights and contexts will also be included.

The researchers conducting the fieldwork in WS1 and WS2 will be the primary analysts, working closely with the WS leads and young people co-investigators (BM, JW, analysts 3 and 4), will be involved in the analysis of data to provide a different interpretation from their experience and aid the reflexive process.

They will receive appropriate training and support for the role.

Having four analysts working together will help to ensure rigour and dependability of findings. (18) Analysts 1 and 2 will keep a reflective journal throughout data collection and analysis to record thoughts and reflections on the process and how it may be shaping the responses of participants and interpretation of data. The wider research team and young person and family advisory group will be utilised at key points during the analysis to shape key themes and interpret meaning, to ensure credibility and authenticity of study findings. The five steps of thematic analysis will be applied as follows:

1) familiarising with the data: analysts 1 and 2 will read and re-read all the transcripts, starting with young people and family transcripts and then moving on to the staff transcripts to explore similarities and differences. During this process, the researcher will annotate interesting concepts and ideas

(referred to as 'codes' from herein) informed by the research objectives and theoretical framework. Analysts 3 and 4 will read a proportion of transcripts, selected to represent some of the diversity in experience and note down commonly occurring codes.

Working together, the analysts will discuss the selection, labelling and meaning of codes to inform step 2, and decide whether to generate separate codebooks for young person and professional data.

2) generating initial codes: analysts 1 and 2 will continue to generate codes that represent the data and discuss these regularly with analyst 3 and 4 before applying the agreed codes systematically across the dataset, the purpose of which is to organise the data into meaningful analytical categories. The data will be managed and coded in NVivo software.

3) searching for themes: using the coded data, the analysts will work together to identify themes by combining groups of codes.

Analytical tools such as mind mapping and brainstorming will be used during this step, with constant reference to the raw coded data to ensure the meaning is retained. Similarities, differences and disagreements between the young people/family and professionals' data will also be explored during this step, and a thematic map will be produced to illustrate the links between themes and codes.

4-5) reviewing and defining themes: during these steps the analysts will work with the wider research team and young person and family advisory group to review and refine the themes and the thematic map. The final themes will be defined and described using quotations to illustrate meaning and relationships between themes.

Feedback workshop 2 – Healthcare professionals

Following the interview analyses we will hold a feedback workshop for health care professionals. Health care professionals who took part on the interviews will be invited to the feedback workshop. The purpose of which will be to feedback to attendees the content of the interviews, review the YP catalyst film/animation and allow the participants to discuss their responses and reactions. The feedback workshop will be facilitated by SM, LZ, LF, with at least one PPI co-applicant JW BM. The facilitators will help healthcare professionals identify the priority areas of potential improvement identified by the data presented. The participants will narrow down their list to 4-5 priority issues to be discussed at a joint health care and young person co-design event.

Documentary Review

We will review documentation and map processes currently used by children's hospices and primary care in relation to the transition process. The documentary review will also incorporate information materials and resources and mechanisms used to share information across organisations.

Design:

We will adopt the READ approach to documentary review (19), a systematic procedure for collecting documents and gaining information from them in the context of health studies at any level (global, national, local).

Sampling: The research team will contact hospices who will share blank copies of documentation used within and across organisations and professional groups in relation to the transition process, via the transition co-ordinator and other relevant professionals. Additional public facing information such as that accessible through hospice websites will also be collected.

The documentation will be required to meet the following criteria:

Documentation inclusion criteria:

• Guidelines and policies

• Relates to the planning of the transition process

• Staff training materials relating to transition

• Information materials for staff and young people and their families in relation to transition

• Flow charts, description of transition pathways

• Materials used to support communication within and across healthcare organisations in relation to transition

Exclusion criteria

• Documents that have been populated with any identifiable young person or family information

A digital copy will be saved of every document that meets the inclusion criteria.

Data extraction will be undertaken by the researchers and will include the following fields: Author/organisation, date of publication, document type (e.g., report, guideline, referral template, planning tool, intended user).

Analysis of Documents

Documentation analysis will involve mapping relevant data onto the nine intervention functions (education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling and enablement) of the Capability, Opportunity, Motivation, Behaviour (COM-B) model of behaviour change.(20) This will enable the research team to determine which types of documentation can help support the behaviour change to facilitate an optimal model of transition care and understand where new resources are needed.

Co-design phase: Joint Experience Based Co-Design Workshops

A joint young person, carer and healthcare professional one-day event will be held to co-design the HOPSCOTCH intervention. All young people, families and HCPs that took part in interviews and/or feedback workshops will be invited. This will be held online using University of Leeds Microsoft Teams to facilitate the participation of young people with complex healthcare needs, their family members and healthcare professionals from different regions to come together.

It is intended to move participants from feedback to action. Online workshops may be recorded and stored on Microsoft Teams to facilitate note taking.

Participants will be made aware of the meeting recording at the start.

Methods will draw upon the principles of Experience-based co-design. The event will be facilitated by stakeholder group leads and an EBCD expert from the Point of Care Foundation. The event will be structured so that it focusses on the experiences of young people and families, and how they can be improved.

In the morning session, the themes and findings and film/animation from WS1, and main themes from WS2 will be presented. An interactive process mapping exercise will then be undertaken which will be

solution-focussed, so that participants can discuss shared priorities and feasible ways that these can be addressed at each stage of the transition process. The discussion and process mapping will lead to the development of a logic model.

In the afternoon, structured small group discussions will be held using the logic model to identify and agree key priorities for the HOPSCOTCH toolbox intervention. There will also be opportunity for participants to contribute any examples of existing good practice, and to consider whether these would be further enhanced with the HOPSCOTCH toolbox. Co-design groups will be facilitated by the stakeholder group leads and will include young people, families and clinicians working collectively on creating the HOPSCOTCH intervention with specific focus on the component most relevant to their role in the transition process. The event will close with presentation by the research team to include a clear plan for outputs, followed by a thank you to participants and a celebration of the day.

The first key output from the co-design event is a logic model to outline optimal primary care support at the time of transition from children's hospices to adult care, including the roles and responsibilities of young people, family members, and professionals from primary care and specialist palliative care.

Subsequent co-design online working groups will be facilitated by the stakeholder group leads and will include young people, families and clinicians working collectively on creating aspects of the HOPSCOTCH intervention with specific focus on the component most relevant to their role in the transition process.

This will underpin the development of three 'modules' which will make up the HOPSCOTCH toolbox of resources, for further development in a subsequent feasibility and acceptability study:

• Young person and family module – information for young people and families regarding the role of the GP at transition and how to engage with them.

• Primary care module – a consultation template with embedded links to training and communication resources within existing GP e-learning systems (e.g. RCGP e-learning palliative care) and guidance regarding opportunities for engagement with young people that are feasible and fit within service constraints.

• Specialist Palliative care module – a corresponding template that aligns with the primary care consultation template to improve communication processes and facilitate the flow of information to primary care from the children's hospice.

Study Timeline

A Gantt chart showing the approximate timelines is included in Appendix 15.

4. Ethical and regulatory considerations

We will conduct this study within adult and children's hospices and GP practices. Favourable opinions will be sought from individual hospice regulatory approval processes. NHS ethical approval will be sought via the HRA (Health Research Authority) and REC. Individual GP practices will confirm capacity and capability to undertake this research.

This study involves data collection from young people with life limiting conditions and their families and could raise some ethical considerations.

- Informed consent: The first approach to the young person and/or family member will be via their own clinical team who will be able to assess capability to participate and ability to give consent and need for parental consent if appropriate. The young person and/or family member will be given adequate time to ask questions and read information about the study before they consent to participation. It will be made clear on the information leaflets that there is no obligation to participate in this study.
- Participating in this study may raise issues or concerns not previously perceived or articulated, and therefore generate needs for support. At the end of the interview, the researcher will ask if the interviewee if they would like to receive a follow-up contact (via telephone call, text of email) three or four days after the interview. This will accommodate interviewees wanting to share further reflections and provides an additional opportunity to articulate the need for support.
- It is possible talking about their experiences may be upsetting for participants. If this is the case, we will make some suggestions who they might like to talk about this with. Signposting will vary according to participant type (parent, young person or HCP), age, transition status and location. Example sources to signpost to are; Parents, Peers, condition-specific charities, Children's hospice, Transition coordinator, GP and mental health support organisations.
- If during an interview or workshop, a participant tells us something that raises a concern for risk of serious harm to themselves or others, an appropriate person would be contacted. The consent form makes it clear that in this case, it will be necessary to share the concern, and the participants contact details for this purpose. Examples of appropriate people may be someone at the children's hospice if the participant is currently supported by them, a parent or guardian for participants under 18 years or a local Adult Safeguarding team.
- All participants will be informed in the information leaflets that they can stop the interview at any point and withdraw from the study for up to 2 weeks after the interview.
- All members of the research team involved in direct data collection will be required to have experience of doing qualitative research on sensitive topics. Staff will be trained in managing distress and the articulation of concerns.
- Supervision (individual and group) of researchers involved in direct data collection and data analysis will pay attention to potential for distress and impact on researchers. The University of Leeds and Kings College London have comprehensive staff well-being services which, if appropriate, staff will be encouraged to access.

Risks and benefits to participants

Possible risks:

- There is a risk of increasing young person and family distress by bringing a focus to their condition and change of support at the point of transition or reflecting upon past experience.
- There is potential burden in the time and energy required to take part in the interview and workshops.

Possible benefits:

- Opportunity for involvement in research to express opinions and share experience to shape future clinical practice and service delivery.
- Opportunity for building social connections with those with similar experiences.

Peer review
This study has been favourably reviewed by the NIHR funding panel.

5.0 Patient & Public Involvement (PPI)

The origin of this study and its aims and objectives were born from directly engaging with parents of young people with life limiting conditions and health professionals who care for this population. Scoping activity undertaken as part of the Collaborative Paediatric Palliative Care Research (CoPPAR) network (NIHR135304) identified transition to adult services as a priority for research. As such, the rationale for the study was directly grounded in the needs and perspectives of the population the study aims to benefit. Drawing on the views and expertise of young people with life limiting or threatening conditions who have experienced transition to adult services has been critical to the development of the proposal, have informed decisions about recruitment and have given us clear guidance on feasibility of the study design. Both contributed to and reviewed the lay summary.
The project team have a strong track record in engaging in meaningful and impactful patient public involvement and engagement specific to paediatric palliative care. SM will coordinate PPI alongside co-applicant GP.
We are committed to ensuring the voice of young people and parents of young people with life-limiting conditions continues throughout the lifespan of the project. The project will utilise the expertise of an established group of parents of children with life-limiting conditions based at the University of York. GP and LZ in particular have established relationships with the group. Group members will have input into the study throughout. This will include attending meetings every 3 months to update the group on the progress of the study. In addition, group members will have the opportunity to engage in specific study related tasks. These include, review and co-development of parent-facing recruitment materials, co-development and piloting of the interview guide, reviewing the animation video (catalyst film), analysis of the parent interviews and supporting the planned co-design workshops. Members will be paid for their involvement.

As co-applicants, BM and JW will play an integral role in the study throughout its duration, engaging in the outlined study activities. This strategy will ensure the project benefits from the continued insight and input of both young people and parents with direct experience of transitioning to adult services.

6.0 Data protection and participant confidentiality

It is recognised that data relating to young people and their family/carer discussing health conditions in detail are particularly sensitive and have been classed as tier 3 data in conversation with the Leeds Institute of Health Science's Information Governance Manager and the Data Analytics Team based in Leeds Institute of Data Analytics. As such, we have put in project application to store the following datasets in LASER. LASER is a cloud-based Trusted Research Environment (TRE)which provides a secure environment for storage, handling, processing and analysis of sensitive and confidential data. The platform is Data Security and Protection Toolkit (DSPT) and International Standard for information security management (ISO27001) accredited. End-to-end support from the in-house Data Analytics Team and an Information Governance Manager is available. Data will be managed by the LASER Data Analytics Team according to the Research Data Management Process.

Type	Format	Category	Type of data	Storage timescale

Consent forms and consent to contact forms for young people and families	Word doc/PDF	Directly identifiable	Names, contact details of young people and families, associated study. Personal contact details. Home address will be required for any face-to-face interviews.	LASER Duration of the study plus 3 years.
Demographic form for young people and families	Word doc/PDF	Indirectly identifiable (only participant number used)	Young people = age, gender, ethnicity, who lives at home, medical conditions, first line of postcode Adults = age, ethnicity, gender, relationship to young person, young person's medical condition, employment status, home postcode	LASER Duration of the study plus 3 years.
Audio recordings of interviews with young people and families.	Recorded via encrypted Dictaphone, mp3	Directly identifiable	Voice, details of health condition, services used and experience.	LASER whilst in raw audio form. 6 months.
Young people and family video recordings of in person interviews	Recorded via University of Leeds Microsoft Teams mp4	Directly identifiable	Voice, image, details of health condition, services used and experience.	LASER. 12 months. Extracts of the film may contribute to a 'catalyst film' for use in workshops and dissemination where explicit, informed consent for this purpose is given.

Young people and family verbatim transcriptions of in person and remote interviews	Word doc	Indirectly identifiable	Details of health condition, services used and experience.	LASER 3 months from last data collection.
Pseudonymised transcript	Word doc	Pseudonymised to tier 2 level For example, identifying information such as participant names, staff names or care locations will be redacted	Details of health condition, services used and experience.	University of Leeds Microsoft Teams accessible only to research team. Duration of the study plus 3 years.

Data of Health Care Professionals is considered less sensitive as it will not relate to a HCPs health condition or an identifiable individual's health condition. Demographic and consent forms, audio recorded interviews and pseudoanonymised transcripts of these will be stored on University of Leeds Microsoft Teams.

Storage of personal data - temporary storage of personal data on paper (e.g consent form, demographic form) will be minimised and for the shortest time necessary before scanning and storing electronically on Microsoft Teams or secure LASER storage at University of Leeds as appropriate. After electronic storage, paper copies will be shredded. For temporary storage of a paper documents a dedicated, locked office with restricted access is available on Level 10 of the Worsley Building, University of Leeds.

Data belongs to University of Leeds and will be analysed by the research team from the Academic Unit of Palliative Care, Leeds Institute of Health Sciences, University of Leeds and Kings College, London. The researcher from Kings College London will hold an honorary University of Leeds contract and access data (including secure LASER storage) through a University of Leeds laptop. A collaboration agreement is in place with King College London.

Participants consenting to take part will be allocated a study ID number and the code link document associated with these ID numbers will be stored in a password-protected electronic file. Personal data such as telephone numbers and postal and email addresses will be stored separately from the other study data in a password protected folder and only accessible by the research team.

Audio will be deleted from Dictaphone's as soon as the file is stored and as soon as possible.

Transcription of audio files will be done in house by a member of the research team (Senior academic secretary). . Once strongly pseudoanonymised, transcripts will be stored for analysis in University of Leeds Teams, accessible only to the research team.

Personal data will be stored for 3 years following closure of the study, and all data will be held under the data custodian who will be the Chief Investigator. Access to all electronic files will be limited to the study research team or appropriate University staff for quality control/audit purposes.

7.0 Amendments

The Sponsor (University of Leeds) will decide whether any amendment is substantial or non-substantial. The Chief Investigator or designee, in agreement with the sponsor will submit information to the HRA for them to issue approval for the amendment. For non-NHS sites amendment approvals will be handled in line with the sponsors and site research governance policies. The Chief Investigator or designee will work with sites so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

All amendments should be noted on the protocol and should include the amendment type and date. These should be communicated to the whole study team and participating sites.

Amendments will also be notified to the Research Delivery Network (RDN) national coordinating centre and communicated to the participating NHS organisations to assess whether the amendment affects the NHS permission for that site.

8.0 Protocol deviations

A “serious breach” is defined as a breach of the protocol that is likely to affect to a significant degree the safety or physical or mental integrity of the trial subjects, or the scientific value of the research.

All deviations and serious breaches of protocol will be reported to the sponsor within 1 working day of research team awareness to governance-ethics@leeds.ac.uk and serious breaches will be reported to the REC within 7 days.

9.0 Indemnity

The University, has insurance cover in force, which meets claims arising from death or injury, which are brought against the University and where those claims arise from the Universities own negligence in its role and activities relating to the study (and which is subject to the terms, conditions and exceptions of the relevant policy). Clinical negligence indemnification will rest with the participating NHS Trust under standard NHS arrangements.

10.0 Dissemination policy

We have undertaken a process of key stakeholder mapping and are planning targeted study outputs for each stakeholder audience. The study outputs will be a significant contribution to the evidence base to

understand the need primary care support and processes by which this can happen, that will lead to practical resources and improvements in patient care for the growing population of young people who transition from children’s hospice care into adult services.

Outputs

- The new HOPSCOTCH toolbox of resources and implementation pack with recommendations and guidance, including the three 'modules':
  - Young person and family module – information regarding the role of primary care at transition and how to engage with them.
  - GP module – the GP consultation template suitable for use in existing GP IT systems, including SystmOne and EMIS, with embedded links to training and communication resources, recommendations and guidance.
  - Specialist Palliative care module – a corresponding template that aligns with the GP consultation template.

Expected outputs are manuscripts/conference presentations as follows:

• Development of data collection methods, including barriers, facilitators and learning in the

recruitment of primary care professionals to research. A methodology paper describing the development and adaptation of EBCD-based methodology for this particular population is expected.

• Qualitative findings of WS1 and 2 (documentary analysis and interview findings) and the

logic model

• Catalyst animation/film

• Approaches to PPI in palliative care research for young people

• The project website

• Research and policy briefings and infographics to accompany each output

• Recommendations for future research

• Final project report for the NIHR

Protocol amendments will be submitted to the Sponsor for approval prior to submission to the REC.

The study is considered at is end point when the HOPSCOTCH intervention has been developed and has been agreed by all stakeholders as an acceptable final version to take forward into feasibility testing phase

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