

Full title **IneQUlty in end of life care for children: Investigating experiences and families' Needs after sudden and unexpectEd deaTh in children and young people – the QUINTET study**

Short title The QUINTET Study

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Protocol Version History

Version Number	Date	Update finalised by	Reason for update
1.2	03/Mar/2025	Dr Seilin Uhm	Removal of NIHR Journals Library (page 25) WP3 age range: adjusted to 0-17 (page 16)
1.1	22/Jan/2025	Professor Anne-Sophie Darlington & Professor Katherine Hunt (co-CIs)	Additional details have been included as requested by the funder
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Programme Protocol

SIGNATURE PAGE

The undersigned confirm that the following plan has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved plan 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 document will be explained.

Co-Chief Investigator:

Signature: 

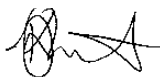
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Abbreviations and glossary of terms:

CDOP – Child Death Overview Panel

CI – Chief Investigator

CoP – Community of Practice

FTE – Full-Time Equivalent

GDPR – General Data Protection Regulation

HRA – Health Research Authority

HSDR – Health and Social Care Delivery Research

HRQoL – Health-Related Quality of Life

JAR – Joint Agency Response

NCMD – National Child Mortality Database

NIHR – National Institute for Health and Care Research

OSC – Oversight Steering Committee

PAG – Parent Advisory Group

PGD – Prolonged Grief Disorder

PPI – Public and Patient Involvement

PSG – Programme Steering Group

PTSD – Post-Traumatic Stress Disorder

QUINTET – Inequity in end-of-life care for children: Investigating experiences and families' needs after sudden and unexpected death

SUDIC – Sudden Unexpected Death in Infancy and Children

WP – Work Package

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1. Lay summary

Background

Each year in England and Wales, around 3,000 children die, with 30% of these deaths happening unexpectedly or suddenly due to accidents, suicide, or unexplained causes. While there is robust guidance and palliative care for children with life-limiting conditions, similar structured care and support for families experiencing sudden child deaths are lacking, despite the often tragic and traumatic nature of these incidents. The study aims to fill these gaps by understanding the needs and experiences of these families and the professionals supporting them.

Plan

The study is organised into four Work Packages (WPs) to investigate various aspects of support for families who experience sudden child deaths:

- WP1: Identifies available care and bereavement support around the time of death, along with a review of child mortality data to understand where and how these deaths occur.
- WP2: Assesses services provided to bereaved families, focusing on professional roles and the experiences and support needs of those involved in child death investigations and care provision.
- WP3: Examines family experiences and long-term outcomes for bereaved parents, including emotional and physical health impacts.
- WP4: Develops and recommends improvements for care and support around sudden child deaths, including guidelines for professional training and family support.

Involving Families

Bereaved parents are integral to the study, with involvement through a Parent Advisory Group and the participation of parent investigators to guide study design, shape the questions asked, help collect and analyse data and ensure effective dissemination and impact.

Dissemination

We will generate varied knowledge products tailored to diverse audiences to ensure meaningful impact.

- **For parents and family members**, findings will be shared through newsletters, results updates, and a public launch event. Lay summaries, co-designed with

bereaved parents, will be made available via partner charities, social media, and online platforms to ensure accessibility.

- **For professionals**, we will develop guidance for practice, educational resources, and deliver presentations to key professional bodies, including Royal Colleges and bereavement support organisations.
- **For policymakers**, recommendations will be integrated into an addendum to the *Ambitions for Palliative and End-of-Life Care* framework, supporting policy development and service improvements.
- **For the research community**, findings will be disseminated through peer-reviewed publications, an NIHR Health and Social Care Delivery Research (HSDR) report, and conference presentations to advance scientific understanding of bereavement care following sudden child deaths.

2. Scientific Abstract

Background:

Approximately 3,000 children die each year in England and Wales, with 30% of these deaths occurring unexpectedly, often due to accidents, sudden illnesses, suicide, or unexplained causes. While comprehensive end-of-life care services are available for children with life-limiting conditions, families experiencing sudden child loss have access to limited structured support, despite the unique and profound impact of these deaths. The QUINTET programme aims to address this gap by investigating the experiences and needs of bereaved families and the professionals involved, to develop evidence-based recommendations for enhancing end-of-life and bereavement care in these cases.

Methods:

The QUINTET programme is a mixed-methods study, organised into four interconnected work packages (WPs):

- **WP1:** Conducts an integrative review of existing care models and analyses data from the National Child Mortality Database (NCMD) to understand the location and context of sudden child deaths, mapping the care resources available to families.
- **WP2:** Engages professionals, including Child Death Overview Panel (CDOP) members and other relevant practitioners, through qualitative interviews to explore their roles, support needs, and experiences in providing care for families after a sudden child death.
- **WP3:** Investigates the experiences and long-term outcomes of bereaved families through semi-structured interviews with 50 parents and a national survey assessing grief, mental health, socioeconomic impact, and satisfaction with care received.

- **WP4:** Synthesises findings across WPs to co-create an addendum to the national Ambitions for Palliative and End-of-Life Care document. A consensus-building workshop using the Nominal Group Technique will bring together stakeholders, including bereaved parents and professionals, to finalise recommendations.

Patient and Public Involvement (PPI):

The study includes substantial PPI, with a Parent Advisory Group, parent investigators, and parent co-applicants actively contributing to the design, implementation, and dissemination phases, ensuring the research remains sensitive and relevant to family needs.

Expected Outcomes:

This study will deliver evidence-based recommendations to improve care standards and support for families experiencing sudden child deaths, including guidance on professional training and family support needs. The programme aims to influence policy and practice, enhancing bereavement care for these families and supporting professionals.

Dissemination:

Findings will be disseminated through peer-reviewed publications, policy briefs, community networks, and social media. Lay summaries and family-friendly materials will ensure accessibility of results for bereaved families and stakeholders.

3. Background

Each year, approximately 3,000 children die in England and Wales, with 30% of these deaths occurring unexpectedly. These unexpected incidents include sudden illnesses, accidents, suicides, or unexplained causes, often leaving families in profound shock and grief (Office for National Statistics, 2020). Compared to families facing anticipated losses, families experiencing the sudden and unexpected death of a child encounter significant barriers in receiving support and may suffer considerable psychological and social impacts.

Existing guidance and palliative care frameworks primarily address end-of-life support for children with life-limiting conditions (NHS England, 2022). However, these frameworks provide little structured support for families facing unexpected child deaths, resulting in an unmet need within the healthcare system (Garstang, Griffiths, & Sidebotham, 2017). For families, the immediate aftermath is often characterised by trauma, with lasting impacts that include psychological disorders, complicated grief, and

disrupted family dynamics (Gibson-Smith, Jarvis, & Fraser, 2020). Studies show that bereaved parents in such circumstances experience significantly higher levels of prolonged grief disorder (PGD), depression, and post-traumatic stress symptoms, placing them at increased risk for hospitalisation and mental health issues compared to parents who lose children to expected conditions (Li et al., 2005; Wilcox et al., 2015).

Sudden child loss also affects family health outcomes. Bereavement, especially when unexpected, has been shown to correlate with increased mortality rates among parents and siblings (Li et al., 2005). Studies indicate a sevenfold increase in prolonged grief disorder symptoms among these parents who have lost a child suddenly and unexpectedly (Stroebe, Schut, & Stroebe, 2007; Prior et al., 2018). Social factors, including reduced social support and functional impairment, further contribute to the psychological burden of bereavement (Kristensen et al., 2016).

For professionals, investigating and managing unexpected deaths presents unique emotional and logistical challenges. Child Death Overview Panels (CDOPs) and other professionals, including healthcare providers and emergency responders, are often responsible for supporting families in their immediate grief. However, many professionals report feeling inadequately trained or equipped to offer effective support in cases of traumatic child loss, which can contribute to occupational stress and impact the quality of care they provide (Garstang, Griffiths, & Sidebotham, 2017).

The QUINTET programme aims to fill this gap in care and understanding by examining family and professional perspectives, identifying the barriers in current bereavement frameworks, and developing recommendations to improve end-of-life and bereavement support for families experiencing sudden child deaths. Findings will contribute to an evidence-based addendum to the national *Ambitions for Palliative and End-of-Life Care* document, targeting both the needs of bereaved families and the training requirements for professionals to ensure sensitive and effective support in these cases.

This programme aligns with the National Institute for Health and Care Research (NIHR) commissioning priorities on bereavement support, healthcare inequities, and paediatric end-of-life care (Royal College of Paediatric and Child Health, 2021). By addressing these issues, the study seeks to provide actionable insights that will improve the quality of life for bereaved families and enhance professional preparedness in traumatic care situations.

4. Aims and objectives

4.1. Study aims

The primary aim of the QUINTET programme is to investigate the experiences, support needs, and inequities in end-of-life and bereavement care for families who experience the sudden and unexpected death of a child. By identifying gaps and challenges within current care practices, the programme seeks to develop evidence-based recommendations to improve service delivery, enhance professional training, and reduce disparities in support.

4.2. Objectives

Investigation of Care Pathways and Professional Responses

- To review and identify existing components of end-of-life and bereavement care provided to families following sudden child deaths.
- To analyse data from the National Child Mortality Database (NCMD) and other relevant sources to map out where and how care is delivered across different settings, such as hospitals, homes, and community care facilities.

Professional Experience and Support Needs

- To explore the roles, challenges, and support needs of professionals involved in end-of-life and post-death care for children.
- To assess the preparedness, emotional impact, and training requirements of healthcare providers, social workers, emergency responders, and Child Death Overview Panel (CDOP) members, aiming to improve professional resources and training.

Family Experience and Long-term Impact Assessment

- To assess the immediate and long-term emotional, psychological, and practical needs of bereaved families following sudden child deaths.
- To examine how the loss impacts family members' mental health, grief experiences, and socioeconomic outcomes, and identify what support would be most beneficial in both the short and long term.

Guidance and Policy Recommendations

- To develop a set of recommendations and guidelines aimed at improving bereavement care for families, with a focus on trauma-informed approaches to support.

- To create a nationally applicable addendum to the Ambitions for Palliative and End-of-Life Care document, detailing evidence-based standards for professional training and family care in cases of sudden child death.

Stakeholder Engagement and Consensus Building

- To conduct a consensus workshop with stakeholders, including bereaved parents, healthcare providers, social care professionals, and policy-makers, to review findings and finalise recommendations.
- To engage with the Parent Advisory Group (PAG), parent investigators and other public representatives throughout the programme, ensuring that the research is responsive to the needs and perspectives of affected families.

4.3. Research questions

- WP1: What care is available for families grieving the sudden and unexpected death of their child around the time of the death and into bereavement, and where do children die?
- WP2: Which investigations, support and services are available to families and who provides that care, and what are the experiences and needs of the professionals providing that care?
- WP3: What are the experiences of families, what care helped and what do they need? What are the long-term consequences for parents, such as grief and depression and physical health?
- WP4: What recommendations around care and support should we make?

5. Research Methods

The QUINTET programme adopts a mixed-methods approach to explore the experiences, needs, and outcomes of families and professionals involved in end-of-life and bereavement care following the sudden and unexpected death of a child. The study is organised into four interconnected work packages (WPs), each employing a combination of qualitative and quantitative methods to provide a comprehensive understanding of current care practices and inform actionable recommendations.

5.1 Study Design

This programme uses a sequential mixed-methods design, combining qualitative and quantitative data collection and analysis (Fig 1). The findings from each work package

will inform and build upon one another to provide a holistic view of care experiences, needs and models for all involved, as well as identify service strengths, gaps and costs.

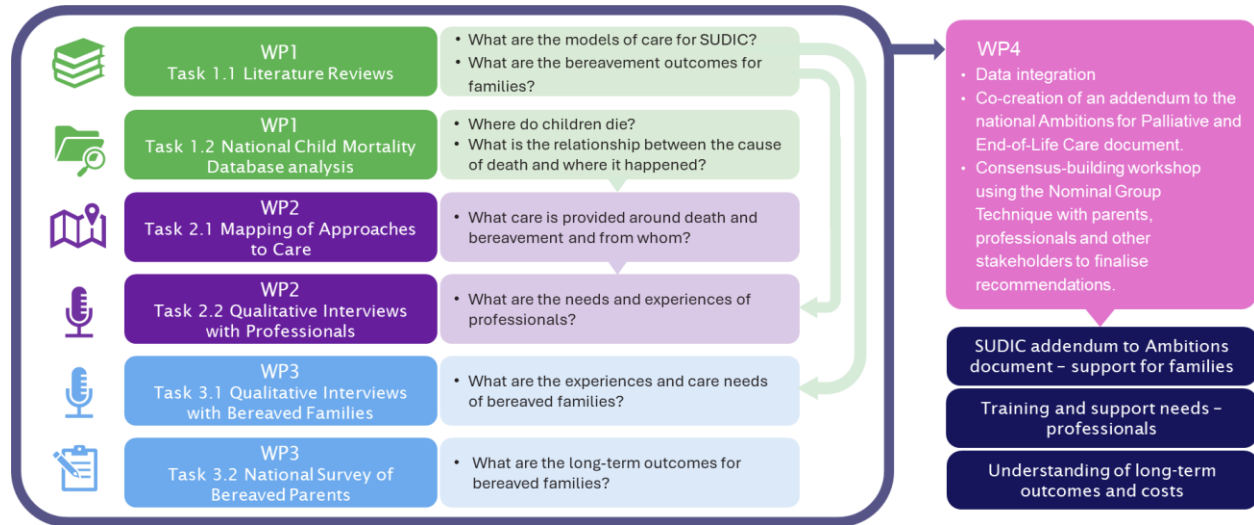


Figure 1 QUINTET Study Overview: Work Packages, Key Questions, and Output

Work Packages (WPs)

WP1: Care Mapping and Data Analysis

Objective: To identify existing models of care and understand the geographic, clinical, and social contexts of sudden child deaths.

Methodology:

- **Integrative Literature Review:** A comprehensive review of academic and grey literature will examine current care practices, support models, and family needs following sudden and unexpected child deaths.
- **Data Analysis:** Analysis of data from the National Child Mortality Database (NCMD) will map out the locations and contexts of sudden deaths, detailing when and where these deaths most commonly occur and what services are available to families at the time. The NCMD data for analysis will be selected from the period **1st April 2018 to 30th June 2024**, focusing on children whose deaths were subject to a Joint Agency Response (JAR) investigation. This analysis will explore the frequency and circumstances of such deaths, including their geographic distribution and relation to cause of death, ethnicity, and socio-economic status.

- **Assessment of economic evidence**

The health economics research fellow will contribute to the literature review to identify and synthesise evidence on the resource implications, costs, or cost-effectiveness of care approaches for families experiencing SUDIC. This will include collaborating with the lead reviewer to design the search strategy, screen abstracts and papers, conduct quality assessments, extract data, and analyse findings. The process will be informed by input from the PPIE group, parent investigators, and Community of Practice to ensure the search strategy and synthesis approach aligns with their expertise and needs.

Subject to data availability, findings will be categorised by age and cause of death, as well as perspectives from health and social care providers, voluntary sector organisations, and families. Resource implications, costs, and outcomes will be compared across these groups.

WP2: Professional Experiences, Roles and Support Needs Analysis

Objective: To investigate the professional response to sudden and unexpected child deaths, examining the care and support provided to families, variations in practice, challenges faced, and the support needs of professionals involved in end-of-life and bereavement care.

WP2.1: Investigations, Care, and Support for Families

Objective

To explore the investigations, care, and bereavement support provided to families following an unexpected child death. This task will identify variations in practice across regions and examine barriers and facilitators to providing effective support through Child Death Overview Panels (CDOPs).

Methodology:

- **Qualitative Interviews:**

In-depth, semi-structured interviews will be conducted with representatives from each of the 52 CDOPs across England. Eligible participants will have a minimum of two years of relevant experience and may include CDR specialist nurses, Designated Doctors for Child Death, Consultant Paediatricians, or CDOP coordinators. We anticipate a response rate of at least 60%, based on previous survey data from Child Bereavement UK.

- **Inclusion Criteria:** Professionals directly involved in end-of-life and bereavement care following sudden child deaths. And >24m experience.
- **Exclusion Criteria:** Professionals with no direct experience in bereavement care for families. And <24m experience.

- **Thematic Analysis:** Transcripts will be analysed using a thematic framework to identify variations in support structures, service provision, and the role of keyworkers. Special focus will be given to the timing of support (first 48 hours, first two weeks, six months, and beyond) and regional disparities in access to care. Findings will inform WP4, providing evidence to develop recommendations for improving consistency and equity in bereavement care.
- **Analysis of Resource Use and Costs of Professional Roles**

In collaboration with our PAG, parent investigators, and Community of Practice, we will design a framework for evaluating the resource implications of professional roles and support needs. This will ensure that data collection reflects key areas of concern for professionals and captures the economic dimensions of their work in end-of-life and bereavement care.

Economic data will be collected in parallel with qualitative interviews and will focus on the following: roles, grades, and working hours of professionals directly involved in bereavement and end-of-life care; additional staffing needs for training, debriefing, or other support initiatives; duration of professional involvement per case (e.g. family meetings, administrative tasks, investigations); resource needs for emergency responders, healthcare providers, and CDOP panel members; costs of training programs, mental health support, and infrastructure improvements.

A proforma will be developed to guide the economic data collection and will be piloted with a subset of interviewees to ensure its relevance and usability. This tool will capture inputs such as time spent by professionals, costs of attending meetings, and resources allocated for bereavement care. Outputs will also be captured, such as the quality and reach of professional support provided to families.

Economic data will be analysed descriptively to compare the costs and resource allocation across different professional roles and contexts: costs will be categorised by professional type (e.g., healthcare providers, emergency responders) and geographic region; patterns in resource use will be examined to identify high-resource versus low-resource cases and any associated outcomes.

WP2.2: Roles, Experiences, and Support Needs of Professionals

Objective

To explore the experiences, roles, and support needs of professionals directly involved in providing care and support to families following a sudden child death. This task aims to understand emotional impacts, professional challenges, and potential gaps in training and support.

Methodology

• Qualitative Interviews

- A sample of approximately 30 professionals will be recruited, including emergency responders, healthcare providers, and social workers.
- Interviews will explore their experiences in providing care, the emotional and professional challenges they encounter, and their perceptions of available training and support.
- Specific attention will be given to the preparedness of professionals, their emotional resilience, and any gaps in institutional support mechanisms.

• Data Analysis

- Thematic analysis will be used to identify key patterns in professional experiences and support needs.

• Health Economic Analysis

For the interviews with professionals (WP2.2), the health economist will work with the research team to develop structured interview questions that will elicit data on the resources available to the various professional groups that might provide services to families after SUDIC (e.g. Royal College of Emergency Medicine, the College of Policing, Fire Officers, Paediatricians). Although the services are very different, the questions will be standardised and will ask about: the nature and extent of support on offer; budgets available; time allowed per family and any constraints; the role and grade of the staff members involved; training provided; support systems (e.g. debriefing sessions) available to the professionals. These questions will be added, as a third section, to the main qualitative interview schedules explained above. The information gathered will be organised for analysis by service and professional and is expected to be qualitative in nature, descriptive and specific to each service. Costs for personnel involved in service delivery will be attributed using local tariffs if the level of detail and certainty in the data allow. With small numbers of participants representing each service, recruited using convenience methods, it is recognised that the data may not be representative and scope for meaningful comparisons will be limited.

Findings from the health economic analysis will provide an evidence base for identifying cost-effective ways to address professionals' unmet needs, improve support systems, and inform policy on workforce planning and resource allocation. The results will also contribute to the overall recommendations developed in WP4.

WP3: Family Experiences and Long-term Outcomes

Objective: To assess bereaved families' immediate and long-term experiences, mental health outcomes, and support needs following the sudden death of a child.

Methodology:

- **Semi-Structured Interviews:** Families who experienced the sudden, unexpected death of a child (aged 0–17) within the last three years will be invited to participate. Interviews will be conducted with approximately 50 bereaved families (participation of parents, grandparents, siblings based on family preferences) to capture their personal experiences with end-of-life care, bereavement support, and ongoing needs. Up to two interviews will be conducted with members of each family. Interviews will address themes such as emotional and practical support, perceived gaps in care, and suggestions for improvement.
 - **Inclusion Criteria:** Bereaved families within the specified timeframe and geographic region who consent to participate.
 - **Exclusion Criteria:** Families experiencing expected deaths or deaths from life-limiting conditions.

- **National Survey:** A survey will be distributed to bereaved families across the UK to quantify key outcomes, such as mental health, grief responses, and the socioeconomic impact of the death. The survey will use validated instruments to measure grief, depression, post-traumatic stress, quality of care, and other relevant variables. To estimate the prevalence of prolonged grief and depression of clinical concern, a sample size of 264 will be pursued as per calculations. However, to achieve robust and valid results across subgroups (e.g., causes of death, socio-economic factors), we will target 2,265 bereaved parents with an anticipated 35% response rate. These are conservative estimates, ensuring sufficient data for subgroup analyses. Participants will also be recruited through key networks, such as the charity 2wish, which has supported over 1,000 families.

- **Quantitative Data Analysis and Statistical Analysis Plan:**

Survey responses will be analysed using descriptive and inferential statistics to address the following sub-research questions of WP3.2.

 1. **What is the prevalence of complicated/prolonged grief and depression of clinical concern among bereaved parents who meet the inclusion/study criteria?**
 - Descriptive statistics (frequencies, percentages) will be calculated to characterise health outcomes.

- This includes identifying the prevalence of complicated/prolonged grief, depression of clinical concern, and PTSD symptoms among bereaved parents.
 - 2. **How do different causes of sudden and unexpected child death impact the mental and physical health outcomes of bereaved parents?**
 - Subgroup analyses will be conducted to identify differences in health outcomes based on specific causes of death (e.g. accidental, unexplained, or suicide).
 - These analyses will adjust for confounding variables, such as the child's age at death, to uncover any significant patterns or disparities.
 - 3. **How do experiences of care around the time of death and psychological support in bereavement influence grief and physical and mental health outcomes in bereaved parents?**
 - Regression analyses will examine associations between experiences of care, psychological support, and health outcomes.
 - The analysis will control for potential confounders, including time since the child's death, socio-economic factors, and family circumstances.
- **Analysis of resource use and costs of families following SUDIC (WP3.1)**

The health economist will work with the research team and PAG representatives and parent investigators in the development of structured interview questions that seek to elicit data of a descriptive analysis of services received by families after SUDIC and costs incurred by families. This will include: health effects and associated health, social or voluntary sector services accessed by family members; time off work or out of education (for siblings); out-of-pocket expenditures. The objective is to construct a longitudinal account of health and employment outcomes and services utilised for individual families, displayed visually on time-line charts to show event sequence chronologically.

We adopt this approach because the circumstances, experiences and sequelae of SUDIC is likely to be very varied and we do not believe it can be meaningfully combined. The time since SUDIC will vary across participating families. Data provided by different members of the same family will be considered together and cross checked to remove duplication. The research team aims to gather up to 50 individual family stories. Each family will be an individual data point. The time-line charts for each family will be analysed separately with contextual information added from other sections of the interviews, such as social deprivation, household characteristics (e.g. siblings and age).

The costs of health and social services accessed, and the extent of lost earnings and out-of-pocket expenditures reported by families will be estimated as data allow. Costs to formal services will be based on national tariffs. Family level data will be grouped by NCMD categories, and variability within and between NCMD categories will be explored and reported in narrative form focussing on types of services

accessed, which family members received services and for how long and in what intensity. With recruitment based on charity membership and use of social media, and participants who are volunteers, the self-reported data by family members may be subject to selection and recall biases. Moreover, small sample bias within individual NCMD categories would render the results from formal analysis unreliable so ranges (maximum and minimum) of service use costs (where available), employment effects and out-of-pocket expenses will be presented with narrative interpretation.

- **Modelling the association between health outcomes and service utilisation (WP3.2)**

The resource implications and costs for health and social services, the voluntary sector, and parents/families experiencing complicated grief will be examined. Costs of formal and informal care will be estimated using validated national tariffs, while private expenditures will be derived from participant-reported data. Family costs will be interpreted with respect to the time since bereavement to account for temporal variations.

Regression analyses (four separate models) will be conducted to explore the associations between services received (summarised as costs) and health outcomes, including prolonged grief, depression, PTSD, and health-related quality of life (HRQoL). These models will adjust for potential confounding variables, such as time since the child's death, socio-economic status, and family circumstances.

Health-related quality of life (measured using EQ-5D-5L) within the bereaved sample will be compared to UK population norms to highlight disparities and inform targeted interventions.

WP4: Consensus Workshop and Development of Recommendations

Objective: To synthesise findings from WP1–WP3, engage stakeholders, and develop evidence-based recommendations to improve end-of-life care and bereavement support for families.

Methodology:

- **Triangulation and Integration:** Data from qualitative and quantitative analyses will be integrated to identify common themes and unique insights across professional and family experiences. The Triangulation Method and a convergence coding matrix will facilitate this process.

The literature review and qualitative data from families will help explain the “how” and “why” behind NCMD and survey findings, providing broader context to the needs and experiences of families. Data from CDOP representatives, professionals, and economic analyses will contextualise and expand on family

interviews, highlighting the personal and economic impact of care approaches. Integration will address the underrepresentation of certain groups by combining data from diverse sources, offering a more nuanced understanding of SUDIC's effects, particularly on disadvantaged or minority groups. The triangulation method of data integration will be applied, specifically the triangulation protocol, to combine qualitative and quantitative data systematically. A convergence coding matrix will guide this process, identifying intersections between experiences, needs, and systemic factors.

- **Consensus Workshop:** A one-day workshop will be conducted with six groups of stakeholders, including:
 - Bereaved parents and family members
 - Professionals supporting families during sudden child deaths (e.g., police, ambulance staff, Designated Paediatricians)
 - Professionals providing bereavement support (e.g., charities, hospices, SUDC nurses)
 - Policy-makers and commissioners
 - A second group of bereaved parents
 - A second group of professionals supporting families around the time of death

Each group will consist of approximately seven participants, resulting in a total of 42 participants for the workshop. Stakeholders who participated in WP2 and WP3 will be invited to take part, and members of the Community of Practice (CoP) will also be included. Using the Nominal Group Technique, participants will review study findings, discuss practical implications, and work collaboratively to reach consensus on a set of actionable recommendations.

Economic insights from all WPs will be integrated into the workshop discussions. Key areas include:

- The resource implications and costs associated with professional roles and support systems (WP2).
 - The economic burden on families (WP3), including direct costs (e.g., funeral expenses) and indirect costs (e.g., lost income).
 - Cost-effectiveness of recommended care pathways and systemic interventions.
- **Guideline Development:** The workshop outcomes will inform the creation of a nationally applicable addendum to the *Ambitions for Palliative and End-of-Life Care* document, with specific guidance for professional training and family support after sudden child deaths.

5.2 Data Collection and Analysis

Qualitative Data: Interviews with professionals and families will be audio-recorded, transcribed verbatim, and analysed using thematic analysis to identify recurrent themes and unique challenges. Coding and analysis will follow a structured framework to ensure consistency and reliability in interpretation.

Quantitative Data: Survey data will be analysed using descriptive and inferential statistics to examine relationships between bereavement care experiences and health outcomes. Statistical tests will be chosen based on data distribution and study aims, allowing for insights into the impact of support services on family well-being.

Data Integration: Findings from both qualitative and quantitative components will be integrated using the triangulation method and a convergence coding matrix, with common themes highlighted across datasets to inform the consensus workshop and final recommendations.

5.3 Patient and Public Involvement

PPI is integral to the QUINTET study to ensure that the perspectives of bereaved families and the wider community are embedded throughout the research process. Their contributions will help shape research questions, refine parent-facing materials, address recruitment challenges, and ensure meaningful dissemination.

Implementation:

- A formal Parent Advisory Group (PAG) will oversee PPI activities, supported by a dedicated PPI lead.
- Bereaved parents, recruited through charities such as SUDC UK and 2wish, will play key roles as parent investigators and advisory members.
- PPI representatives will be actively involved in co-designing recruitment strategies, evaluating study findings, and advising on stakeholder engagement.

Training and Support:

We will provide training in research for PPI representatives to enhance their ability to contribute effectively. Individual support will also be available, including opportunities for debriefs after meetings discussing sensitive topics. This approach aligns with our commitment to ensuring the research is co-produced with bereaved families, whose lived experiences provide valuable insights into care needs and gaps following sudden child deaths. To ensure diversity in the experiences captured, we will adopt a range of targeted recruitment strategies:

Demographic Representation: We will include families across diverse ethnic, socio-economic, and cultural backgrounds. Particular focus will be given to underrepresented groups, including minority ethnic families and those from areas with higher indices of deprivation. The sample will reflect a broad range of sudden child deaths, including accidents, suicides, and unexplained deaths, ensuring all experiences are accounted for.

Targeted Recruitment Channels: Collaborate with community organisations, bereavement charities (e.g. SUDC UK, 2wish, Lullaby Trust), and local networks to engage with diverse groups. Translate recruitment materials into multiple languages and ensure they are culturally appropriate to maximise accessibility. Use social media platforms and targeted campaigns to reach families in hard-to-reach communities.

Monitoring and Adaptation: Participant demographics will be monitored throughout recruitment to assess representation and address any gaps in diversity.

5.4. Ethical Considerations

The study involves sensitive research on bereavement and trauma; therefore, a Distress Protocol will be implemented to support participants. This includes access to emotional support and a clear pathway for managing distress during interviews. Our charity partners will work together to triage and provide individualised support (2Wish, Shooting Star Hospice, SUDC UK, Forget Me Not Child Hospice). Ethical approval will be sought from the University of Southampton Ethics Committee and HRA with all data management adhering to GDPR guidelines.

6. Project Management and Data Quality Assurance

6.1 Project Management Structure

Programme Management Group (PMG)

The PMG, consisting of Chief Investigators, Co-Investigators, and key team members, will oversee all aspects of the programme's execution. This group will meet monthly to monitor progress, review milestones, and address any issues that may arise.

Responsibilities include:

- Overseeing the WP leads to ensure alignment with overall objectives and timelines.
- Monitoring the budget, resources, and staffing needs to ensure project sustainability.
- Reviewing regular reports and addressing any delays or risks to project delivery.
- Ensuring that ethical, regulatory, and safety standards are consistently met.

Advisory Committees

The programme will also involve two key advisory bodies:

- **Oversight Steering Committee (OSC):** Comprised of external experts in paediatric palliative care, health policy, and bereavement research, the board will provide annual strategic guidance and independent oversight of

project quality. The committee will also have oversight of the project budget, ensuring financial accountability and alignment with the study's objectives.

- **Programme Steering Group (PSG):** A separate committee from the broader stakeholder groups, the PSG consists of independent experts who are not part of the research team but provide practical guidance on study implementation. The PSG will support decision-making on operational aspects, troubleshooting challenges, and ensuring methodological rigour. Decisions made by the PSG will be reported to the OSC via the research team.
- **Parent Advisory Group (PAG):** The PAG, including bereaved parents, will offer ongoing input to ensure the programme remains sensitive and responsive to the experiences of affected families. The PAG will provide feedback on study materials, interview protocols, and dissemination plans, meeting quarterly with the project team.
- **Community of Practice:** The CoP is comprised of national charity, professional and non-governmental representatives. Using transformative research to create collective action, the CoP will have a direct and democratic contribution to research decisions, planning, design and analysis.

Operational Team Meetings

Regular operational meetings, led by the Chief Investigators, will facilitate detailed planning and coordination. These meetings will involve WP leads and research staff to discuss day-to-day tasks, assess progress, and troubleshoot any logistical issues. Task lists and action points will be recorded and reviewed to ensure accountability and timely completion.

6.2 Data Quality Assurance

The QUINTET programme incorporates robust quality assurance measures to ensure data accuracy, integrity, and reliability across all work packages.

Standardised Data Collection Protocols

- **Interview and Survey Protocols:** Standard operating procedures (SOPs) will guide all qualitative and quantitative data collection activities, ensuring consistency in data gathering across research sites and WPs. SOPs will

include detailed instructions on conducting interviews, using consent forms, recording data, and managing participant confidentiality.

- **Training:** All research staff will receive training in data collection, interview techniques, and ethical handling of sensitive topics. This training will reinforce adherence to study protocols and equip team members to manage participant distress.

Data Entry and Monitoring

- **Data Entry Validation:** Quantitative survey data will undergo double entry and validation checks to identify any discrepancies, minimising the risk of data entry errors.
- **Qualitative Data Transcription:** All interview recordings will be transcribed verbatim and cross-checked by research staff to ensure accuracy. A sample of transcripts will be reviewed by the WP leads to maintain consistency in transcription and coding practices.
- **Data Management System:** Data will be stored securely on a password-protected, encrypted platform managed by the University of Southampton. Access will be restricted to authorised team members only, and all data management practices will adhere to GDPR guidelines.

Regular Data Audits

- **Internal Audits:** WP leads will conduct monthly data audits to check for completeness, consistency, and quality of data. Any anomalies or missing data will be promptly addressed to prevent delays in analysis.
- **External Review:** An independent data quality review will be conducted annually by a third-party auditor to verify data integrity and adherence to the project's quality assurance protocols.

Data Analysis Quality Control

- **Thematic Coding Validation:** Qualitative data coding will be validated through independent coding by multiple researchers to ensure reliability and consistency in theme identification.
- **Statistical Analysis Checks:** All statistical analyses will be peer-reviewed by a statistician who is part of the project team to confirm the appropriateness of methods and the accuracy of results.

Documented Change Management Process

A change management process will be in place to document any adjustments to data collection procedures, SOPs, or project timelines. This ensures transparency in project

modifications and allows the PMG to review and approve all changes that may impact data quality.

6.3 Risk Management and Contingency Planning

To ensure the project remains on track and within scope, a risk management plan will be employed with the following components:

Risk Assessment

The PMG will conduct a risk assessment during the project initiation phase, identifying potential risks related to recruitment challenges, data collection, ethical considerations, and resource availability. Risks will be categorised by likelihood and impact.

Mitigation Strategies

- **Recruitment Support:** Collaborations with clinical networks, bereavement organisations, and community groups will support participant recruitment, especially for bereaved families.
- **Contingency Planning:** In the event of delays, such as low recruitment rates, the PMG will activate a contingency plan to adjust timelines or extend recruitment windows as needed.

Ongoing Risk Monitoring

Risks will be monitored continuously, with a risk register updated monthly. Emerging risks will be promptly reported to the PMG, allowing for swift intervention if necessary.

7. Dissemination, outputs and anticipated impact

The QUINTET programme prioritises wide-reaching dissemination and meaningful impact, aiming to influence end-of-life and bereavement care policies, improve professional support systems, and enhance service delivery for families who experience the sudden and unexpected death of a child. The dissemination strategy targets healthcare providers, policymakers, bereavement support organisations, and bereaved families, ensuring that the findings are accessible and actionable.

7.1 Dissemination Strategy

Academic and Professional Publications

- Findings from each work package will be published in high-impact, peer-reviewed journals covering paediatric palliative care, mental health, healthcare inequities, and bereavement research. Planned journals include Palliative Medicine, Journal of Palliative Medicine, BMC Palliative Care,

Archives of Disease in Childhood, BMJ Paediatrics, and Journal of Child Psychology and Psychiatry, and Cochrane Collaborations .

- Study protocols and key outputs will be made available via the NIHR Open Research platform, facilitating early sharing of findings and engagement with the wider research community.
- Articles will be tailored to share insights on family support needs, professional experiences, and care recommendations, contributing to the scientific literature on traumatic bereavement and healthcare service gaps.

Policy Briefs and Practice Guidelines

- **Policy Briefs:** Targeted briefs will be developed for healthcare policymakers, summarising key findings and practical recommendations. These briefs will highlight specific, evidence-based improvements for service design, professional training, and family support in cases of sudden child death.
- **Practice Guidelines:** An addendum to the national Ambitions for Palliative and End-of-Life Care framework will be created, providing clear guidance for professionals in managing unexpected child deaths. This will support the adoption of trauma-informed, culturally sensitive approaches in end-of-life and bereavement care.

Engagement with Bereavement and Healthcare Organisations

- Partnerships with bereavement charities, healthcare networks, and child support organisations will support dissemination to frontline practitioners.
- Stakeholder workshops and webinars will share findings directly with practitioners, allowing them to integrate evidence-based practices into their work and providing opportunities for feedback.

Lay Summaries and Public Engagement

- Lay summaries will be developed in collaboration with the Parent Advisory Group (PAG) and distributed to bereaved families, community groups, and through digital platforms. These summaries will present findings in accessible language to ensure families can understand and use the information.
- Public engagement activities, such as community presentations, webinars, and updates via social media, will raise awareness of the study and its implications, particularly among families, caregivers, and local health practitioners.

Conference Presentations

- Findings will be presented at leading national and international conferences.

7.2 Expected Outputs

Research Publications: Peer-reviewed journal articles plus additional papers focusing on specific findings such as family mental health outcomes, professional training needs, and recommendations for systemic changes.

Policy and Practice Toolkit: An addendum to the *Ambitions for Palliative and End-of-Life Care* framework, designed for use by healthcare organisations, commissioners, and bereavement support agencies.

Lay Reports and Digital Content: Lay summaries and digital updates created with PAG input, designed for widespread distribution via websites, social media, and community groups.

7.3 Anticipated Impact

The anticipated impact of the QUINTET programme spans several key areas:

Improved Bereavement Support for Families

Findings from the programme will provide evidence-based recommendations to enhance bereavement services, particularly for families experiencing sudden child deaths. Improved guidance for family support will aim to reduce the psychological burden on bereaved families, providing timely and culturally sensitive care that meets their unique needs.

Enhanced Training and Support for Professionals

By identifying the support needs and challenges faced by professionals, QUINTET will inform the development of targeted training materials and resources for healthcare providers, social workers, and first responders. This will contribute to improved professional resilience and confidence when working with families affected by sudden child death.

Policy Influence and Systemic Change

The recommendations and framework addendum produced by QUINTET will support policy advocacy efforts to address service gaps in bereavement care. Policymakers and healthcare commissioners will be equipped with actionable insights to create equitable and comprehensive end-of-life care policies that include sudden and unexpected child deaths.

Long-term Research Impact

As one of the few studies focusing on the needs and experiences of families after sudden child deaths, QUINTET will contribute to a critical area of bereavement

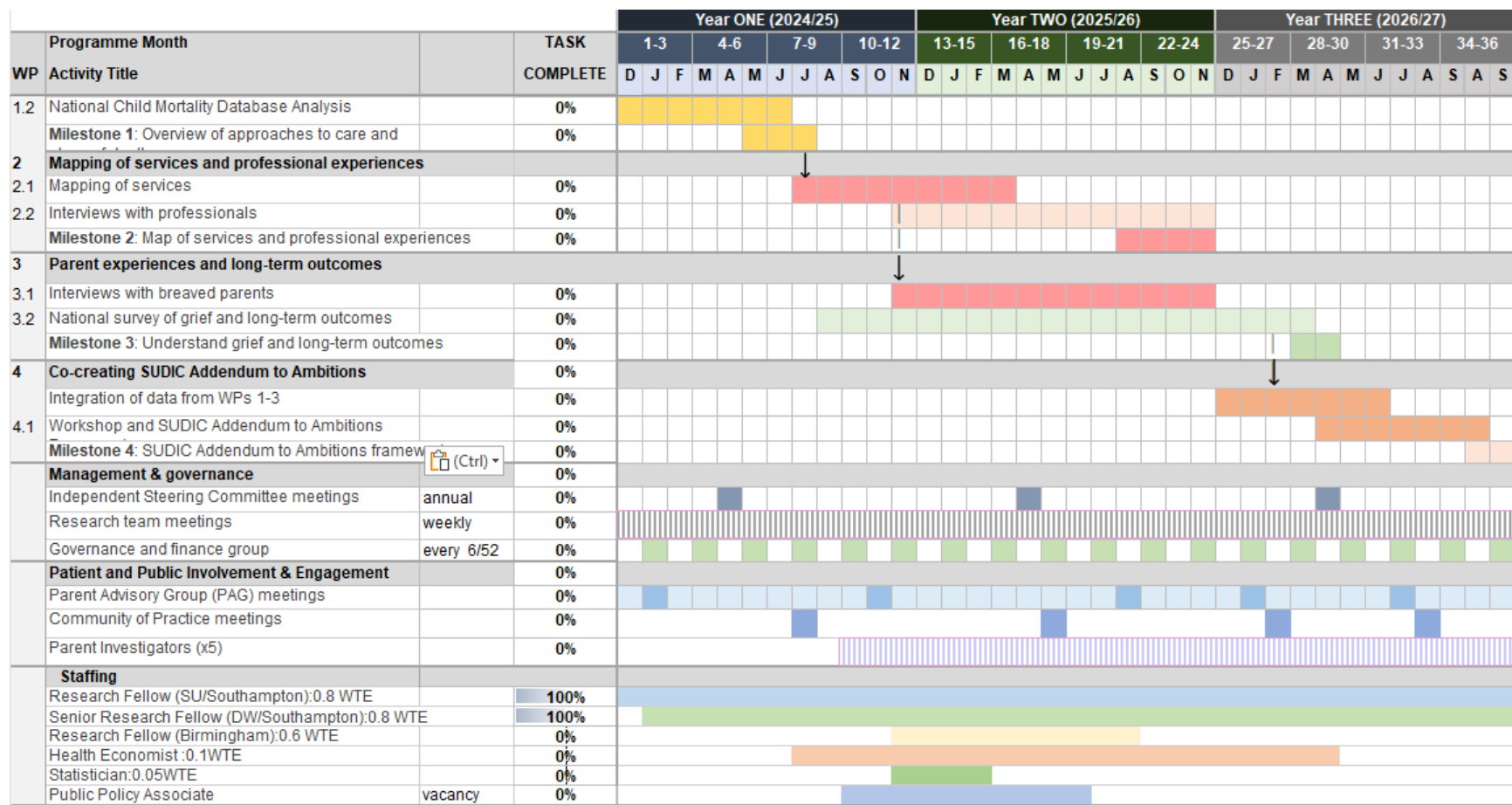
research. The programme's findings will serve as a foundation for further research into traumatic grief and its effects, encouraging continued improvements in bereavement support practices and policies.

8. References

1. Office for National Statistics. (2020). *Child and infant mortality in England and Wales: 2020 Stillbirths, infant and childhood deaths occurring annually in England and Wales, and associated risk factors*. Available at: <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/childhoodinfantandperinatalmortalityenglandandwales/2020>.
2. Gibson-Smith, D., Jarvis, S.W., & Fraser, L.K. (2020). Place of death of children and young adults with a life-limiting condition in England: a retrospective cohort study. *Archives of Disease in Childhood*, 106(8), 780–785. Available at: <https://doi.org/10.1136/archdischild-2020-319700>.
3. Fleming, P., Blair, P., Bacon, C., & Berry, P. (2000). *Sudden unexpected deaths in infancy: The CESDI SUDI studies 1993–1996*. London: Stationery Office.
4. Williams, T., Sleep, V., Pease, A., Fleming, P.S., Stoianova, S., Ward, J., Speed, N., Kerlake, A., Cohen, M., & Luyt, K. (2022). *Sudden and unexpected deaths in infancy and childhood*. National Child Mortality Database Programme Thematic Report.
5. Royal College of Paediatric and Child Health. (2021). *Child Mortality*. Available at: <https://stateofchildhealth.rcpch.ac.uk/evidence/mortality/child-mortality/>.
6. Dyregrov, A., & Dyregrov, K. (1999). Long-term impact of sudden infant death: A twelve to fifteen-year follow-up. *Death Studies*, 23, 635–661.
7. Song, J., Mailick, M.R., Greenberg, J.S., & Floyd, F.J. (2019). Mortality in parents after the death of a child. *Social Science and Medicine*, 239, 112522.
8. Prior, A., Fenger-Grøn, M., Davydow, D.S., Olsen, J., Li, J., Guldin, M.B., & Vestergaard, M. (2018). Bereavement, multimorbidity, and mortality: a population-based study using bereavement as an indicator of mental stress. *Psychological Medicine*, 48, 1437–1443.
9. Stroebe, M., Schut, H., & Stroebe, W. (2007). Health outcomes of bereavement. *The Lancet*, 370(9603), 1960-73.
10. Garstang, J., Griffiths, F., & Sidebotham, P. (2017). Rigour and rapport: a qualitative study of parents' and professionals' experiences of joint agency infant death investigation. *BMC Pediatrics*, 17(1), 48. Available at: <https://doi.org/10.1186/s12887-017-0803-2>.
11. NHS England. (2022). *Specialist palliative and end of life care services: children and young people service specification*. Available at: <https://www.england.nhs.uk/publication/service-specifications-for-palliative-and-end-of-life-care-children-and-young-people-cyp>.
12. Li, J., Laursen, T.M., Precht, D.H., Olsen, J., & Mortensen, P.B. (2005). Hospitalization for mental illness among parents after the death of a child. *New England Journal of Medicine*, 352, 1190–1196.

13. Wilcox, H.C., Mittendorfer-Rutz, E., Kjeldgard, L., Alexanderson, K., & Runeson, B. (2015). Functional impairment due to bereavement after the death of adolescent or young adult offspring in a national population study of 1,051,515 parents. *Social Psychiatry and Psychiatric Epidemiology*, 50(8), 1249-56. Available at: <https://doi.org/10.1007/s00127-014-0997-7>.
14. Kristensen, P., Dyregrov, K., Dyregrov, A., & Heir, T. (2016). Media exposure and prolonged grief: A study of bereaved parents and siblings after the 2011 Utoya Island terror attack. *Psychological Trauma*, 8(6), 661-7. Available at: <https://doi.org/10.1037/tra0000131>.

9. Appendix- Programme Management Plan (Gantt chart)



[End of the Protocol]