Full/long title of study	OPTICAL: Optimising Paediatric Transition to Intensive Care for AduLts
Short title	OPTICAL
Version and date of protocol	Version 4, 23rd April 2025
Sponsor:	University College London (UCL)
Sponsor reference number:	EDGE 164521
Funder (s):	National Institute for Health and Care Research
IRAS Number:	338748
UCL Data Protection Number:	Z6364106/2023/12/44 health research
	Sponsor Representative:
Chief investigator/Academic Supervisor: Professor Sonya Crowe PhD, Professor of Operational Research Clinical Operational Research Unit, 3rd Floor, 4 Taviton Street, London Co-PI: Dr Padmanabhan Ramnarayan, Reader in Paediatric Critical Care Surgery and Cancer, Imperial College London.	UCLH/UCL Joint Research Office, 4th Floor, West 250 Euston Road London NW1 2PG

PROTOCOL VERSION HISTORY

Version Stage	**Versions Number**	**Version Date**	**Protocol updated & finalised by;**	**Reasons for Update**
Original	1.0	30/01/2024	Julie Taylor, Sonya Crowe, Christina Pagel, Jo Wray, Padmanabhan Ramnarayan, Roshaye Poleon	N/A
Previous	2.0	24th June 2024	Julie Taylor, Sonya Crowe, Christina Pagel, Roshaye Poleon	NIHR requested changes for funder contact and study duration. Clarifications for ethics/CAG on inclusion criteria.
Previous	3.0	24th November 2024	Julie Taylor, Sonya Crowe, Christina Pagel, Carol McDonald	Updated to change the screening time since admission, for the PICs to use when searching for potential participants. Also to add that we will provide a cover letter.
Current	4.0	23rd April 2025	Julie Taylor, Sonya Crowe, Christina Pagel, Jo Wray, Charmaine Kohn, Qi Huang	Updated to include the supplement to include mental health research, and to add recruitment pathways.

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor SOPs and applicable Trust policies and legal frameworks.

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

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor green light confirmed.

I (investigator) 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. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

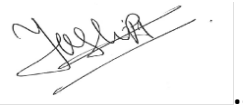
Chief Investigator:

Signature: .....  **..... Date 23/04/2025**

Print Name (in full): .SONYA CROWE

Position: Professor of Operational Research

On behalf of the Study Sponsor:

Signature: .....  **..... Date 02/07/2025**

Print Name (in full): Pushpsen Joshi

Position: Research Governance Manager

STUDY SUMMARY

IDENTIFIERS	
IRAS Number	338748
REC Reference No.	24/EE/0108
Sponsor Reference No.	EDGE 164521
Other research reference number(s) (if applicable)	CAG Reference No: 24/CAG/0068 ICNARC Reference: 241434 PICANet Reference: P115; HQIP 495 NHSE Reference: DARS NIC 772633
Full (Scientific) title	OPTICAL: Optimising Paediatric Transition to Intensive Care for AduLts
Health condition(s) or problem(s) studied	Children admitted to paediatric intensive care units (ICUs) with chronic conditions and complex needs later admitted to adult ICUs.
Study Type i.e. Cohort etc.	Retrospective analysis of linked datasets and qualitative research.
Target sample size	Approximately 200,000 patients for the study. This includes approximately 725 participants for work package 2 (semi structured 1:1 interviews, surveys, and online forums).
STUDY TIMELINES	
Study Duration/length	33 months funded study duration
Expected Start Date	1st August 2024 (project set up began with funding on 1st November 2023).
End of Study definition and anticipated date	31st July 2026 defined by the end of funding. Data retention will be for a further 3 years for WP1, and 15 years for WP2.
Key Study milestones	Collaborator contracts; Protocol; Ethics approval; CAG approval; Dataset applications; Oversight group membership; PPI group membership; NHS Site uptake; Recruit research fellow; Interview recruitment and data collection; Receive linked data; Prepare linked data; Complete interview data analysis; Commence problem structuring; Workshops 1 to 5; Commence linked data analysis; Complete online forum data collection; Complete online forum data analysis. Complete survey data collection; Complete survey data analysis.
FUNDING & OTHER	
Funding	National Institute for Health Research (NIHR)
Other support	
STORAGE of SAMPLES / DATA (if applicable)	
Human tissue samples	N/A
Data collected / Storage	Work package 1: Data will be received from PICANet (data controller HQIP), ICNARC, and NHS England (Critical Care Data Set, HES, Civil Registrations Mortality (ONS)). Data will be stored on the UCL data safe haven. Work package 2: Data will be collected from interviews held at multiple NHS sites and stored on GOSH servers, and the UCL data safe haven.

	Anonymised transcripts from online forums will be received from the charities Mencap, Wellchild, and ICUSteps, and stored on GOSH servers and the UCL data safe haven. Anonymised surveys from participants will be received and stored on GOSH servers and the UCL data safe haven. Work package 3: Contact details will be received from stakeholders who consent to involvement in workshops and held on GOSH servers and the UCL data safe haven.
KEY STUDY CONTACTS	
Chief Investigator	Professor Sonya Crowe sonya.crowe@ucl.ac.uk 02076794953
Co-PI	Dr Padmanabhan Ramnarayan p.ramnarayan@imperial.ac.uk
Senior Research Coordinator	Julie Taylor julie.a.taylor@ucl.ac.uk
Research Coordinator	Carol McDonald carol.m.mcdonald@ucl.ac.uk
Funder(s)	National Institute for Health and Care Research
Committees	**Steering Committee:** PPIE representatives Statistician Qualitative Health Services Research academic Clinical academics Role: Advise and monitor project progress. **Data Monitoring and Ethics Committee (DMEC):** Data linkage expert Qualitative researcher AICU clinician Role: Oversee, monitor, and advise on primary data collected from participants **PPI group:** 9-12 members comprising Teenagers and young adults (TYA) (N=3-4) Family members (n=3-4) Charity representatives (n=3-4) Role: Co-design patient information, topic guides, surveys and questions for the discussion forums, and ensure that the project remains patient and family focused and accessible to all; Lead the dissemination of findings to patients and families (including summaries, blogs/vlogs and infographics) and they will be offered the opportunity to contribute to journal publications and conference presentations
Other relevant study personnel	WP1 lead: Professor Christina Pagel c.pagel@ucl.ac.uk WP2 lead: Professor Jo Wray jo.wray@gosh.nhs.uk

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

KEY WORDS

Paediatric intensive care; Adult intensive care; Data linkage; Transition from child to adult services

LIST OF ABBREVIATIONS

CAG	Confidentiality Advisory Group
CI	Chief Investigator
DARS	Data Access Request Service
DMEC	Data Monitoring and Ethics Committee
GOSH	Great Ormond Street Hospital
HES	Hospital Episode Statistics
HES CC	Critical Care Dataset
HQIP	Healthcare Quality Improvement Partnership
ICNARC	Intensive Care National Audit and Research Centre
ICNARC CMP	ICNARC Case Mix Programme (a dataset for adult critical care admissions)
ICU	Intensive Care Unit
MH	Mental Health
NHSE	NHS England
ONS	Office for National Statistics
PIC	Participant Identification Centre
PI	Principle Investigator
PPI	Patient and Public Involvement
PICANet	Paediatric Intensive Care Audit Network
REC	Research Ethics committee
TYA	Teenagers and young adults
UCL	University College London
WP	Work Package

CONTENTS

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1 INTRODUCTION

A growing number of children admitted to paediatric intensive care units (ICUs) with chronic conditions and complex needs are later admitted to adult ICUs that often do not know them and are unprepared, compromising care and patient experience at a time of heightened vulnerability.

One parent powerfully described to us the rapid physical and mental deterioration of her young adult daughter when first admitted to adult ICU where the team were unprepared for, and struggled to accommodate, her learning disability and specific communication needs. She recounted a lack of awareness and understanding that made a very distressing situation even more difficult, compromising her daughter's recovery and undermining her trust in health professionals on decisions about resuscitation and end of life care.

Recent guidelines by the UK Paediatric Critical Care Society (PCCS) and Intensive Care Society (ICS) highlight the importance and urgency of improving ICU transition but they are not evidence based due to a scarcity of evidence. In particular, aspects of transition specific to intensive care, such as advanced care plans, resuscitation and medical escalation status, airway and ventilation management, have been neglected in the transition literature. It is not clear how intensive care can be better incorporated into overall transition planning and there are very few established pathways for ICU transition in practice.

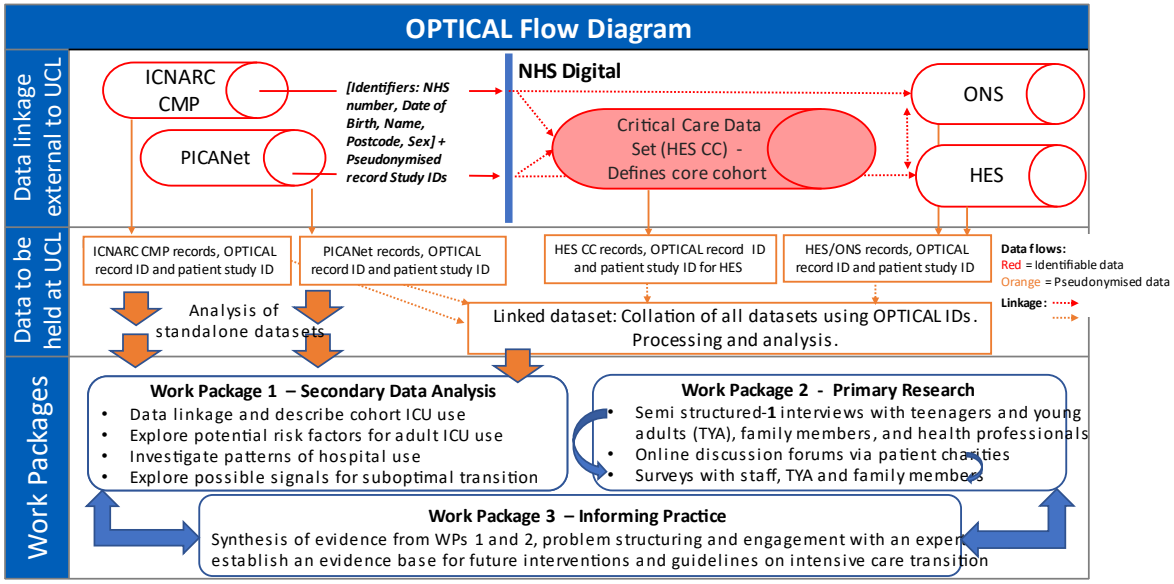
This study will generate evidence to underpin national policy on transition from child to adult intensive care to improve clinical care and patient experience. To do this the research team will:

• Link and analyse national data on child and adult ICU admissions, hospital inpatient, outpatient and A&E visits, and life status, to determine the clinical characteristics and healthcare resource utilisation from teenage years to early adulthood of people who used intensive care as a young person, and how these relate to intensive care use after age 16.

• Conduct semi-structured interviews, online forums and surveys with patients, carers and health professionals to understand their experience of ICU transition, including barriers they face, examples of good practice and suggestions for improving support.

• Synthesise these strands of evidence and establish, in a structured process of stakeholder engagement, evidence-based potential improvements in the processes and support for transitioning to adult ICU services, targeted among patient groups as appropriate.

Importantly, the voice of patients and families is central to the work, including through the Patient and Public Involvement (PPI) co-investigator, dedicated PPI group and charity partners. Evidence will be disseminated in the academic literature, conferences, directly to national professional societies and policy makers, and to patients and families.



2 BACKGROUND AND RATIONALE

Advances in medical care have contributed to the increased life expectancy of children with conditions such as prematurity, cystic fibrosis, type 1 diabetes, epilepsy, cancer, and congenital heart disease.[1–3] Consequently there is a growing population who require regular follow up and treatment in adult healthcare services as they leave childhood. In this context, transition is defined as a 'purposeful and planned process of supporting young people to move from children's to adults' services'.[4] The need to optimise this transition for teenagers and young adults (TYA) is well recognised and the subject of several reports, including guidelines from the National Institute for Health and Care Excellence (NICE).[4–7]

Healthcare services have however not fully adapted to this changing reality – other than for specific conditions such as congenital heart disease and cystic fibrosis, transition practices vary nationally.[8] In particular, there are few established transition pathways for TYA with intellectual disability and neurodevelopmental disorders.[9] The importance of high-quality transition has been emphasized previously, both in general terms, and for specific conditions such as diabetes, sickle cell disease, mental health disorders, learning disabilities, autism and congenital heart disease.[10–14] There is evidence that many TYA with complex conditions and their families find transition an anxiety-provoking time as it can be associated with dislocation of care and deterioration in health and wellbeing.[15] Transferring from paediatric to adult services is also associated with worsening adherence to medication and advice about health behaviours, and disengagement with services.[16–18] Despite variability in practice nationally, successful local transition programmes have been described (e.g. Ready-Steady-Go in Southampton, 10 steps to transition in Liverpool, and the Oxford kidney transplant programme).[19–21]

<u>Intensive care</u>

Intensive care is a high-cost, high-impact, specialised NHS service for seriously ill patients who need support for one or more vital organs, including breathing support.[22] Intensive care survivors are at high risk of potentially life-long physical, developmental and psychosocial impairments.[23,24] In general, patients older than 16 years are cared for in adult intensive care units (AICUs), and those

younger than 16 years are cared for in paediatric intensive care units (PICUs).[25] Almost all UK hospitals have an AICU (there are just over 200 general AICUs), but PICUs are only available in 28 hospitals due to the centralised model of children's intensive care services.[26] This means that critically ill children presenting to hospitals without a PICU are transferred to another hospital whereas critically ill adults stay in the same hospital.[27]

Over the past 30 years, the case-mix and outcomes of children admitted to PICU have changed dramatically.[28] In the past, most admissions to PICU were for predominantly healthy children requiring single, short admissions for life-threatening infections or trauma. Encouragingly, immunisation for serious childhood infections and improvements in road safety have reduced the need for intensive care in healthy children.[29,30] In recent years, an increasing proportion of children admitted to PICU have underlying conditions – over 60% of admissions have a chronic complex condition.[31] Many have complex health problems such as learning disabilities and/or mental health issues, some are dependent on medical technology such as long-term home ventilation (LTV), and others have life-limiting conditions such as genetic syndromes or severe congenital anomalies. [31–34] Some require frequent, prolonged and repeated PICU admissions for recurrent acute health deteriorations.[35,36] Improvement in PICU survival over the years means that many children with previously lethal chronic complex conditions are now living longer and may require intensive care as adults. Yet, there has been little focus on paediatric to adult intensive care transition in this population.

Intensive care transition

Teenagers with chronic conditions who require PICU admission(s) during their childhood years, particularly between 14-16, may continue to require one or more intensive care admissions as they grow older. These may be repeated emergency admissions for acute health deterioration or planned admissions after major surgery. In general, once children have turned 16 years old (in some cases 18), these admissions are to an AICU rather than to a PICU.[37] For this vulnerable and high-risk cohort of TYA, coordinated transfer of care from paediatric to adult intensive care services is crucial to maintain high-quality clinical care and patient experience.

The reality, however, is that there are a distinct lack of clear, established processes for intensive care transition, other than where TYA have certain underlying conditions such as congenital heart disease.[14] This means that AICU teams, TYA and their caregivers are frequently unprepared for the first few AICU admissions, which can occur abruptly and often in an emergency – this can compromise patient care and experience. Many TYA, their families, and carers will also have established trusting relationships over the years with their specialist paediatric clinical teams as well as multi-professional hospital and community teams. As soon as they turn 16, TYA may be admitted to an AICU whose teams have little or no knowledge of them or their families. As part of this transition, TYA and their families also have to contend with important differences between paediatric and adult ICUs, including changes to the consent process (the Mental Capacity Act 2005, Deprivation of Liberty Safeguards)[38], the physical environment of intensive care, and different family visiting and overnight stay arrangements.

Differences in the organisation of PICUs and AICUs pose additional challenges for TYA and their families during transition from childhood. The average age of PICU patients is 1-2 years, while the average adult ICU patient is nearly 60 years old.[26,39] Individually, each AICU may not admit sufficient numbers of TYA to be able to plan and provide personalised care: between 2007 and 2014,there were ~2,000 admissions per year aged 16-19 to 212 AICUs in England, Wales and Northern Ireland.[37] The centralised model of paediatric intensive care also means that the PICU in which children with complex needs will have received the majority of their care is most often in a different hospital from where they will be admitted to AICU when they turn 16.

Sharing of information across different hospitals and communication across geographical and organisational boundaries can be significant barriers to the smooth transfer of intensive care. Despite the importance of high-quality transition for this small but significant and vulnerable cohort of TYA as they grow into adulthood, the intensive care aspects of transition (e.g., advanced care plans, resuscitation and medical escalation status, airway and ventilation management) have been neglected, and it is not clear how intensive care can be incorporated into overall transition planning better. In particular, intensive care transition is poorly addressed in TYA with learning disabilities, where adult services including ICUs are often ill prepared.[40]

Why this research is needed now

There has been limited research in this area to date, making it imperative that evidence is generated urgently before variations in care become embedded in practice. As part of this proposal, we performed a scoping literature review by searching the databases Turning Research into Practice (TRIP), Cochrane library and PubMed using the following search terms in the Title and/or Abstract: transition AND (intensive care OR critical care) AND (pediatric OR paediatric). Nine of the papers returned related to transition between neonatal and paediatric intensive care, none related to transition from paediatric to adult intensive care. An extended search using the terms transition AND (pediatric OR paediatric) AND adult in the Title and/or Abstract returned over 1000 results, of which 44 were systematic reviews, which covered transition of children with various conditions including epilepsy, cancer, dental problems, intellectual disabilities, human immunodeficiency virus and inflammatory bowel disease. Other systematic reviews had a more general focus on interventions during transition. One systematic review found that common barriers to transition from paediatric to adult care fell within the "Relationships" domain (e.g., difficulties letting go of long-standing relationships with paediatric providers) followed by "Access/Insurance" (e.g., difficulty accessing/finding qualified practitioners, insurance issues), and "Beliefs/Expectations" (e.g., negative beliefs about adult care).[41] In another, a structured transition process was shown to improve adherence to care, disease-specific outcomes, quality of life, self-care skills, satisfaction with care and health care utilisation.[42] The impact of age at transfer on transition outcomes was assessed in a systematic review, which found that models of transition which transfer teenagers in late adolescence or early adulthood can improve transition outcomes and patient satisfaction.[43] The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) is currently conducting a survey of young people and clinicians, and case notes reviews, to explore the barriers and facilitators in the process of transitioning young people with complex chronic conditions from child to adult services.[44]

Intensive care transition is recognised as an area of unmet need. Given the growing population of TYA requiring intensive care in childhood and in adult life, and the importance of intensive care transition, a joint working group of the UK Paediatric Critical Care Society (PCCS) and the Intensive Care Society (ICS) recently published guidance for paediatric to adult ICU transition, with 11 key recommendations.[45] However, none of the recommendations were evidence based due to the scarcity of published evidence on the topic. For example, the first of their standards states that “all young persons who are likely to require future input from adult critical care services must be identified in a timely manner”, yet clinicians lack the evidence and tools needed to identify these young people. Currently, there are no established pathways for ICU transition in practice, other than in Yorkshire.

Implementation of any guidance, either from the ICS/PCCS or the forthcoming NCEPOD report, is hampered by the many unanswered questions in this area: what is the size of the population that requires transition from paediatric to adult intensive care, which teenagers treated in PICU will need intensive care after 16, do certain conditions make AICU admission more likely, can this population be identified during childhood and how, what are their current outcomes, and how can clinical care and patient experience be improved as part of the transition?

Without this crucial evidence, development of future national guidelines, quality standards and patient-reported outcome measures will be severely compromised. OPTICAL will build, for the first time, the evidence base to improve the care and experience of teenagers transitioning from paediatric to adult ICU services.

Mental Health Research Background

The prevalence of mental health (MH) disorders in children and young people has increased in recent years in England [60], leading to increased demand for MH support across health care, voluntary and local authority sectors [61]. Services have struggled to cope with demand and young people have experienced difficulties accessing services, with lengthy waiting times for treatment [62]. Limited opportunities for the timely support of MH needs are reflected in growing numbers of CYP reaching a point where their problems may endanger themselves or others, resulting in the increased use of emergency care for MH crises [61], which are likely to be traumatic for the young person and their family, and is resource-intensive for services.

MH crises may lead to the hospitalisation of teenagers and young adults (TYA), mainly providing an acute place of safety, and to facilitate interventions such as management of overdose or nutritional rehabilitation. There is emerging evidence that the incidence of hospital admission for MH crises is rising [63], especially following the pandemic. A small but significant minority of TYA are critically ill during an MH crisis and require admission to a paediatric intensive care unit (PICU) or a general adult intensive care unit (AICU) depending on their age. Commonly, TYA under 16 years are admitted to PICU and over 16 years to AICU. During the pandemic, there was a significant increase in the incidence of admissions of TYA with deliberate self-harm to PICUs in Australia [64] and in the United States [65]. There is however little evidence relating to MH admissions to UK PICUs or AICUs, particularly focusing on the outcomes of TYA admitted to PICUs and their need for subsequent AICU admissions. This is an important gap in the evidence, since it is likely that TYA admitted to PICUs with MH crises are at high risk of admission to adult critical care as they grow into adulthood. This may be for deliberate self-harm episodes or a life-threatening complication of mental health diagnoses such as anorexia. It is also likely that MH crises requiring critical care are more common among deprived and disadvantaged populations, however this is not well explored in the literature.

A different but related aspect pertains to the impact of transition of care from childhood to adulthood, especially critical care transition, on the mental health of TYA with complex problems, and their families. These TYA who require adult critical care admission may require this for physical health problems as well as MH issues. The implication of this is that the cohorts of TYA that we will be examining in the OPTICAL study are likely to have significant MH issues associated with critical care transition, the burden and impact of which are unclear, especially as they grow into adulthood.

Finally, moral distress amongst staff caring for TYA with complex chronic conditions, including life-limiting conditions, in intensive care is a growing problem. In a national questionnaire of PICU staff, over a third of nurses and 18% of physicians reported high levels of moral distress, with more junior nurses at highest risk [66]. Moral distress has been linked to burnout [66] and intention to leave their job [67]. Understanding the impact of critical care transition on staff mental health is key to developing strategies to support staff and indirectly patients and families during the process of transfer of care from paediatric to adult services.

3 AIM(S) AND OBJECTIVES

3.1 Primary Objective

To generate the evidence base for improving the care received and patient/family experience for teenagers transitioning from paediatric to adult ICU services

3.2 Secondary Objectives

1. Determine the clinical characteristics and healthcare resource utilisation from teenage years to early adulthood of people who used intensive care as a young person, and how these relate to intensive care use after the age of 16.
2. Understand the experience of patients, carers and health professionals of ICU transition, including barriers they face, examples of good practice and suggestions for improving support provided.
3. Establish evidence-based potential improvements in the processes and support for transitioning to adult ICU services, targeted among patient groups as appropriate.
4. Explore the outcomes of TYA admitted to PICUs for mental health (MH) crises in terms of their future need for adult critical care admission.
5. Understand the mental health implications of critical care transition from childhood to adulthood on the individual, their families, and healthcare professionals involved in their management.

4 STUDY DESIGN & METHODS OF DATA COLLECTION

Study Design: This is a mixed methods study with secondary data analysis (Work Package (WP) 1), primary research (WP2) and problem structuring/stakeholder engagement (WP3).

Please note that WP3 does not involve a study population or recruitment. WP3 involves establishing an expert group to review evidence relating to the management of ICU transition, with representatives from four stakeholder groups:

- Children and teenagers who have been through PICU and AICU, and their carers (2-3 each)
- Our partner charity organisations (1 each)
- Healthcare professionals (3 from AICU, 3 from PICU, including nurses, AHPs, doctors and transition nurses)
- Commissioners (2 from Integrated Care Boards (which are responsible for AICUs), 1 from NHSE (responsible for PICUs)

No members of the independent steering committee, PPI group or research team will be on the expert group.

Five stakeholder workshops will be held, with one person from each stakeholder group in attendance (where possible the same person for consistency) and additional group members invited to specific workshops based on the content and perspectives / expertise sought.

WP3 will run alongside WPs 1 and 2 as an overarching strand focused on establishing the evidence base for future interventions and guidelines for ICU transition services. Activity in WP3 will initially focus on informing the design and conduct of WPs 1 and 2 to ensure that the evidence generated in

those WPs is relevant to informing practice. Later activity will utilise that evidence in the development of guidance to inform practice for which we will seek endorsement from relevant professional societies. The research team will adopt the approach of Crowe et al. [54] for robustly synthesising diverse forms of knowledge to address challenges in delivering care for patients who use or move between multiple services and organisations.

Activity will be centred on 5 workshops with the expert group:

Workshop 1 [Month 22]. Present study overview (aims, workstreams, timelines); Review emerging insights from the WP2 interviews, incl. identifying any gaps in perspectives sought / issues to explore further; Review plans for identifying patient groups in WP1.

Workshop 2 [Month 25]. Review findings from WP2 interviews, in particular examples of best practice and suggestions that address identified service problems/gaps in support; Review draft questions for WP2 online forums (incorporating learning from interviews); Review preliminary patient groups identified in WP1 for any prioritisation or customisation of support in transition.

Workshop 3 [Month 28]. Finalise the characterisation of patient groups that might benefit from different types of support or prioritisation in transition services (drawing on WP1 analysis); Review findings from WP2 online forums; Review draft survey questions and recruitment plans (WP2) in light of the finalised patient groups and learning from the interviews and forums.

Workshop 4 [Month 30]. Review findings from the surveys (WP2); Review findings from the quantitative data analysis (WP1); Use the final findings from WP1 and WP2 to establish initial evidence-informed potential improvements to the transition process.

Workshop 5 [Month 32]. Assess the feasibility and acceptability of each potential improvement identified in the study and any customisation or prioritisation for certain patient groups given their particular needs and any resource constraints; Finalise for wider endorsement (via our dissemination workshop, see section 6) and evaluation in future work of a set of targeted evidence-informed potential improvements to the transition process.

Study population:

Work Package 1

The research team will create three datasets: two standalone ICU audit datasets from the Paediatric Intensive Care Audit Network (PICANet) and the Intensive Care National Audit & Research Centre Case Mix Programme (ICNARC CMP), and a linked dataset of the Hospital Episode Statistics Critical Care dataset (HES CC), Hospital Episode Statistics Inpatient admissions (HES APC), Outpatients (HES OP), Accident and Emergency attendances (HES A&E), Civil registrations mortality data, ICNARC CMP, and PICANet data.

Study population for the linked dataset: Includes all patients with at least one critical care admission in England aged 14-15 years between January 2017 and one year prior to the date of data extraction (giving at least one year of follow up), captured in the Hospital Episode Statistics Critical Care (HES CC) dataset.

Study population for the standalone PICANet dataset: Includes all patients from dataset inception in 2003 who had at least one PICU admission between 14 and 21 years of age.

Study population for the standalone ICNARC-CMP dataset: Includes all patients from dataset inception in 1994 who had at least one AICU admission between 14 and 21 years of age.

Work package 2

WP2 comprises interviews, online discussion forums and surveys.

Study population for semi-structured 1-1 interviews: Health professionals providing care to teenagers and young adults (TYA); TYA aged 16-21 years who have had at least one PICU admission >14 years and one AICU admission; family members/carers of TYA meeting the above criteria.

Subgroup of the study population for semi-structured 1-1 interviews for objective 4:

Health professionals providing care to TYA in AICU admitted with a MH crisis or working in hospital or community settings (e.g. child and adolescent/adult MH services) or charities supporting TYA admitted to PICU or AICU with MH crises.

Teenagers and young adults (TYA) aged 16-21 years with at least one PICU admission >14 years and one AICU admission where a MH crisis has been a contributory factor to either their PICU and/or AICU admission.

Family members/carers of TYA meeting the above criteria. Participants do not have to be from the same family as the TYA interviewees.

Study population for online discussion forums: TYA who have had a PICU admission, and their family members.

Study population for surveys: Health professionals in AICUs nationally and in paediatric centres involved in preparing teenagers for transition in clinical specialties where patients are likely to require AICU admission; TYA aged 16-21 who have had at least one PICU admission > 14 years and at least one admission to AICU; family members of TYA who meet the above criteria.

The study population for surveys will also now include: Staff in AICUs and in community and paediatric settings who prepare young people for transition, and MH professionals who support staff when TYA are admitted with a MH crisis; TYA who meet the survey criteria outlined above where a MH crisis has been a contributory factor to their admission; Parents/carers of TYA who meet this criteria.

Work package 3

Not Applicable.

Sample size:

Work Package 1

The main linked dataset (based on HES CC) is expected to have approximately 140,000 patients. However, the final number of patients and records will not be clear until final linkage and cleaning of the data at UCL.

The standalone PICANet dataset will have approximately 15,000 patients included some of whom will have more than one admission recorded.

The standalone ICNARC CMP dataset will have approximately 120,000 patients included some of whom will have more than one admission recorded.

The datasets will comprise the entire relevant critical care population. As such, there were no sample size calculations necessary (since in effect, we are looking at the largest available sample).

Work Package 2

Semi-structured 1:1 Interviews for original and new objective 5: The research team anticipate interviews will be undertaken with approximately 120 participants over the three participant groups: Health professionals providing care (n=35-40); TYA aged 16-21 years (n=35-40); Family members/carers of TYA (n=35-40).

Semi-structured 1-1 interviews (for original and new objectives): The research team anticipate interviews will be undertaken with an additional 18-24 participants identified as a subset of the current inclusion criteria over the three participant groups: Health professionals providing care to TYA with MH crises (n=6-8). TYA aged 16-21 years where a MH crisis has been a contributory factor to admission (n=6-8). Family members/carers of TYA meeting the above criteria (n=6-8).

If recruitment targets for any participant group cannot be met, additional participants may be recruited from other groups.

Online forums: The research team anticipate that >200 TYA/family members will participate across the six forums.

Surveys: The research team anticipate approximately 375 participants will undertake the surveys.

Work Package 3

Not applicable.

Data collection:

Work Package 1

The research team will seek approval from Health Research Authority (HRA) NHS Research Ethics Committee (REC) and Confidential Advisory Group (CAG) for permission to use unconsented, routinely collected national data. They will submit applications to NHSE, ICNARC and PICANet / HQIP to access and link data (see flow diagram for linkage process). All study datasets will be securely held within the University College London (UCL) Data Safe Haven.

Standalone datasets: ICNARC and PICANet will send to UCL Data Safe Haven standalone datasets of all records pertaining to patients who had at least one ICU admission recorded aged 14 to 21 years. ICNARC and PICANet will include pseudonymised record study ID and patient study ID. These standalone datasets are useful because they began several years earlier than HES CC, and from experience they are quicker to access than the HES data so analysis using the standalone data can start before receiving the linked dataset, if necessary.

Linked dataset: NHS England will identify the cohort in HES CC and identify all records in HES APC, OP and A&E relating to that cohort from 2017-2023 (at least one year follow up). NHS Digital will send a pseudonymised clinical dataset and latest life status data from HES/ONS to the UCL Data Safe Haven. PICANet and ICNARC will send all identifiers of patients who had at least one PICU / AICU admission aged 14 and 15 from Jan 2017 to one year prior to the date of data extraction to NHSE for linkage to HES CC. They will include the same pseudonymised record study IDs already sent to UCL for the standalone datasets. NHS England will then send the pseudonymised ICNARC CMP record IDs and pseudonymised PICANet record IDs for successfully linked records to UCL. UCL analysts will then incorporate the linked ICNARC CMP and PICANet records, using the record study IDs from the standalone datasets already held, to the linked HES/ONS dataset provided by NHS England.

Work Package 2

Semi-structured 1:1 Interviews:

Interview topic guides will be developed for each participant group, informed by transition literature, expert opinion and the PPI co-applicant and will include questions related to: participants' experience of transition, barriers, expectations, concerns, information requirements, perceptions of change in how care is delivered (e.g. family centered care to person centered care) and any associated challenges, examples of good practice, requirements for support and experiences of receiving it, advance care planning and associated pathways, goals of care and suggestions for improvements (including an idea of priority for these). Additional questions focused particularly on MH impacts of transition will be added to the planned interviews for the main OPTICAL study.

The same topic guides will be used for the additional participants for the mental health research.

Participants will also be asked to provide some basic demographic details.

The team will conduct 1-1 interviews with place, mode and time of interview organised to suit the participant, ensuring accessibility of interviews for TYA with a learning disability/autism (e.g. with signing interpreter, other communication aids). Interviews will be face to face for TYA/family members but the majority of staff interviews will be by telephone or Zoom/Teams, and will last 45-90 minutes. At the start of the interviews all participants will be asked to provide verbal (for virtual interviews) or written (for face to face interviews) consent for their participation and for the interviews to be audio-recorded. They will have the opportunity to ask any questions. The researcher will reassure all participants about confidentiality and the fact that they will not be identifiable from any dissemination. The researcher will also ensure that all participants are aware that they can stop the interview at any time and a stop sign will be negotiated prior to the interviews commencing, particularly for the TYA. If appropriate, TYA and family members will be provided with information about support services at the end of the interview. The same approach will be followed for objectives 4 and 5.

Online Forums:

Following a proven approach [49–51], the team will run online discussion forums with three patient charities (WellChild, ICUSteps, Mencap) to elicit experiences and perceptions from a wider group of TYA and their family members including TYA whose needs have previously been met through PICU admission but where they were not admitted to AICU, or AICU admission does not happen due to patient preferences or resource constraints. In conjunction with the charities and our PPI group, the team will develop a series of questions based on findings from the initial interviews with TYA and family members, together with the wider transition literature. The team will undertake this in a one-

day co-design event, co-facilitated by the parent co-applicant. The charities will then moderate an asynchronous discussion forum for each participant group (TYA and family members) via their closed social media platform. The charities will be responsible for moderating the forum, ensuring appropriate online behaviour, and posting prompts and new questions depending on participant responses.

Surveys:

Recognising the workforce pressures that NHS staff are experiencing, the team will run the survey for 3 months and ensure that it is not overly burdensome. They will liaise with professional groups to ensure content and burden are acceptable and that the purpose of the survey is clear. The team will also draw on previous experience of conducting national staff surveys, where they received 2200 completed surveys about providing care to children with and without learning disabilities from staff working in children's hospitals in England [53].

All surveys will be anonymous with basic demographic details collected to check eligibility. Consent will be inferred from completion. Surveys will be developed in SmartSurvey including an easy-read format and an audio option. Questions will include forced choice, Likert scales and free text and will cover topics identified in the interviews and online forums, providing 'sensechecking' of both information already gathered and about possible toolkits, guidelines or recommendations that might be developed in relation to transition for TYA who will require adult intensive care and their families. Questions will be developed during the one-day face to face co-design event (see above); any further additions to incorporate new findings from the online forums will be made in conjunction with the study PPI group. Staff surveys will also include questions related to confidence, competence, and capacity to deliver care to TYA who require AICU (to inform any recommendations for staff training/support/resources for wider discussion in the final two WP3 workshops to inform practice).

Questions specifically focused on MH experiences and impact, informed by preliminary analysis of interview findings and existing evidence, will be added to the surveys.

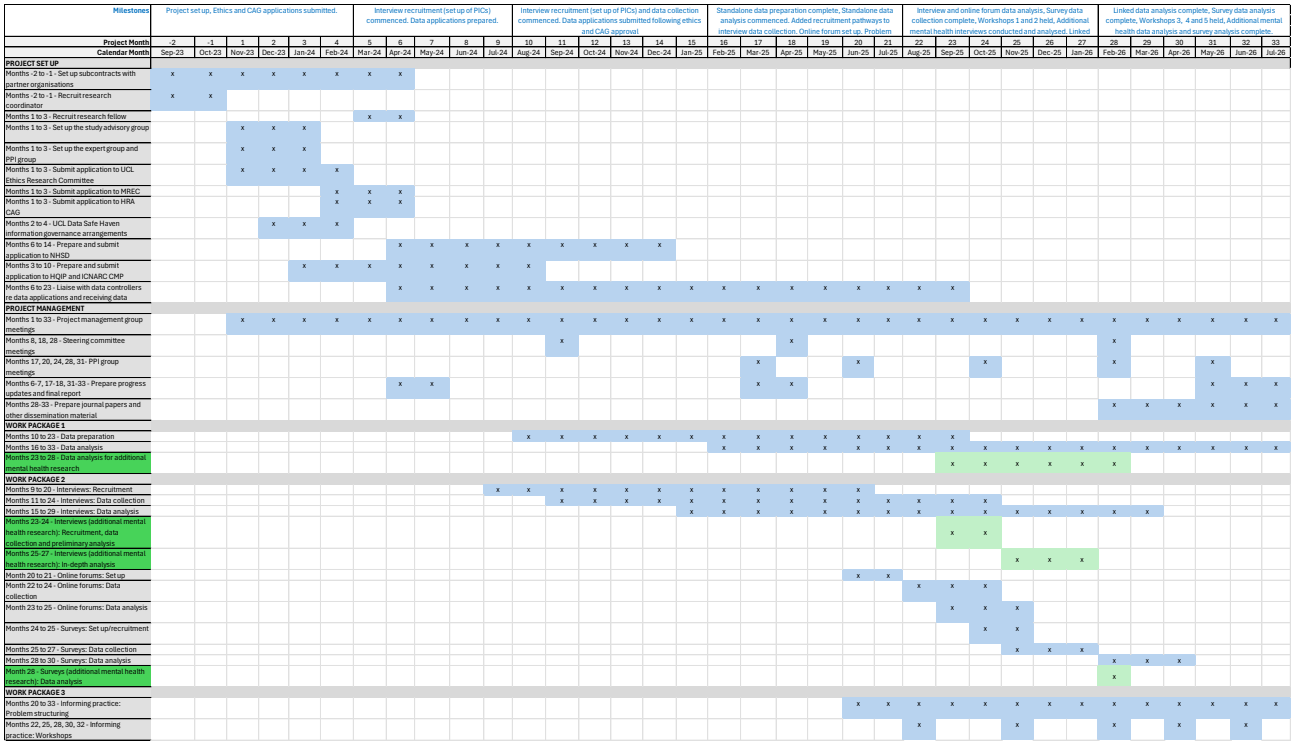
Work Package 3

Not applicable.

5 STUDY SCHEDULE

The schedule is based on target dates for establishing data linkage, collaborator involvement, researcher recruitment, analysis and output for WP1, recruitment and data collection and analysis for WP2 (interviews, online forums, surveys), and workshops for WP3.

The study end date is defined by the end of funding. Data retention will continue for a further three years to complete publications.



6 ELIGIBILITY CRITERIA

6.1 Inclusion Criteria

Work Package 1

For the linked dataset, the Hospital Episode Statistics Critical Care (HES CC) Dataset is the core dataset. HES CC collates all critical care activity data collected for administrative purposes for every patient treated in England.

The inclusion criteria for the linked dataset are all patients in HES CC with at least one critical care admission in England aged 14-15 years between January 2017 (earliest HES CC data for children) and one year prior to the date of data extraction (giving at least one year of follow up).

The inclusion criterion for the standalone PICANet dataset is all records from dataset inception (2003) pertaining to patients who had at least one PICU admission between 14 and 21 years of age.

The inclusion criterion for the standalone ICNARC dataset is all records from dataset inception (1994) pertaining to patients who had at least one AICU admission between 14 and 21 years of age.

Work Package 2

Semi-structured 1-1 interviews will be undertaken with three participant groups with sub groups with the following inclusion criteria:

1a) Health professionals providing care to teenagers and young adults (TYA) in AICU or in paediatric clinical specialities or community settings (e.g., long-term ventilation teams, social workers) where teenagers are prepared for transition and likely to need AICU. Sampled by seniority and profession (nurses, medics, allied health, mental health, key worker, transition co-ordinator).

1b) Health professionals providing care to TYA in AICU admitted with a MH crisis or working in hospital or community settings (e.g. child and adolescent/adult MH services) supporting TYA admitted to PICU or AICU with MH crises. Sampled by profession and location.

2a) Teenagers and young adults (TYA) aged 16-21 years who have had at least one PICU admission >14 years and one AICU admission. Sampled by: whether their AICU admission was emergency/planned; any prior contact (outpatient or inpatient) with the adult centre; type and chronicity of health condition (including receiving palliative care); presence/absence of a learning disability/autism; age group (16-18 vs 19-21 years). To ensure inclusion of TYA who did not wish to transfer and/or their family members, the team will include a sample from this group who are aged 16-21 years who have had at least one PICU admission >14 years and who have chosen not to transfer (e.g. on a palliative care pathway).

2b) Teenagers and young adults (TYA) aged 16-21 years who have had at least one PICU admission >14 years and one AICU admission where a MH crisis has been a contributory factor to either their PICU and/or AICU admission. Sampled by whether MH crisis necessitated admission to PICU, AICU or both; presence/absence of a learning disability/autism; age group (16-18 vs 19-21 years).

3a) Family members/carers of TYA meeting the above criteria. Participants do not have to be from the same family as the TYA interviewees (if for example the TYA does not wish to participate but a family member does) and may include family members of TYA who have died in AICU.

3b) Family members/carers of TYA meeting the above criteria of TYA where a MH crisis has been a contributory factor to their admission. Participants do not have to be from the same family as the TYA interviewees.

The team will include a sample of non-English speaking TYA and family members (interviews facilitated by an interpreter).

Online Forums:

The inclusion criteria are teenagers and young adults who have been admitted to PICU with or without a subsequent AICU admission, their family, friends or careers who volunteer to take part in the online discussion forums through one of the three charities running them.

Surveys:

Inclusion criteria for the three surveys are:

1a) Staff in AICUs nationally and staff in paediatric centres involved in preparing teenagers for transition in clinical specialities where patients are likely to require AICU admission (e.g. transition nurses, hospital transition leads, specialist nurses for patient groups for whom transition to AICU is more likely).

1b) Staff in AICUs and in community and paediatric settings who prepare young people for transition and MH professionals who support ICU staff when TYA are admitted with a MH crisis

2a) TYA aged 16-21 years who have had at least one PICU admission >14 years and at least one admission to AICU.

2b) TYA aged 16-21 years with at least one PICU admission >14 years and one AICU admission where a MH crisis has been a contributory factor to either their PICU and/or AICU admission.

3a) Family members of TYA who have had at least one PICU admission >14 years and at least one admission to AICU.

3b) Family members of TYA aged 16-21 years with at least one PICU admission >14 years and one AICU admission where a MH crisis has been a contributory factor to their PICU and/or AICU admission.

Work Package 3

Not applicable.

6.2 Exclusion Criteria

Work Package 1

Linked dataset: Any patient not represented in the Hospital Episode Statistics Critical Care (HES CC) Dataset with at least one critical care admission in England aged 14-15 years between January 2017 (earliest HES CC data for children) and one year prior to the date of data extraction (giving at least one year of follow up).

Standalone datasets: Patients who did not have an ICU admission between the ages of 14 and 21 recorded in either the PICANet or ICNARC CMP audits.

Work Package 2

Participants for the interviews will not be eligible if they cannot give informed consent for their participation.

Work Package 3

Not applicable.

7 RECRUITMENT

Work Package 1

WP1 does not involve recruiting participants, instead they are identified by the existing HES CC, PICANet, and ICNARC CMP datasets, which cover the critical care population in England.

New data will not be collected for the quantitative part of this study (WP1) so there is no enrolment. The quantitative data will come from routinely collected clinical audit and national datasets.

Follow up of patients included in the linked dataset will extend to date of extraction (or latest date available at data extract) for HES, ICNARC-CMP and PICANet data, and civil registrations mortality data. Follow up of patients included in the standalone PICANet and ICNARC data will extend to 2023 (or latest date available at data extract).

The lawful basis for processing personal data under the UK GDPR is:

Article 6(1)(e) - processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

The lawful basis for processing special category data under the UK GDPR is:

Article 9(2)(j) - processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

UCL is the research sponsor and the controller as the organisation responsible for ensuring that the data will only be processed for the purpose described.

Work Package 2

Semi structured 1-1 interviews (including for objectives 4 and 5):

Participants will be identified in the following ways:

1. By Participant Identification Centres (PICs) appointed in 15-20 AICUs (sample stratified by size, location, type of ICU and whether the hospital has a PICU) and 3-5 paediatric centres that prepare TYA for transition who are likely to require AICU (sample stratified by size, location, whether they are a specialist children's hospital). PICs in the adult and paediatric hospital settings will be asked to identify relevant community teams in their network who provide care to TYA who meet the inclusion criteria to enable recruitment to this group of staff.

The following will also be appointed as PICs for all inclusion groups:

i) Service units within NHS trusts that are specialised for certain diagnoses/treatments.
ii) Departments other than ICU within NHS trusts who provide care to TYA who meet the inclusion criteria (e.g. MH liaisons in A&E, rehabilitation teams).
iii) Establishments outside of the hospital setting (e.g community health teams, hospices, community rehabilitation teams).

2. Dissemination of the study details to allow self-selection by potential participants. Interested participants who believe they may be eligible can contact the study team directly. We will disseminate study information via:

i) Charities. We will ask charities to disseminate study information with contact details for further information and to discuss eligibility with the study team.

ii) Patient and parent networks. We will ask networks to share the study information within their networks which will include the contact details for further information and to discuss eligibility with the study team.

iii) Clinical networks. We will ask for study information to be disseminated within clinical networks. Clinicians that do not consider their units to have enough of the target population and would therefore not be set up as a PIC but who may know of/encounter an eligible participant, will be asked to direct them to a charity website or to the study website.

Participants will be approached in the following ways:

Health professionals: PICs will be asked to distribute emails to eligible health professionals, providing information about the project and asking for completion of a consent to contact form if they are interested in participating, which will then be given to the research team. We will recruit health professionals for 1:1 interviews through our charity partners, the NHS, PIC sites outside of the hospital setting (e.g. hospices, community health teams, MH services), and by self-selection to the study team via disseminated study material.

TYA: PICs (hospital and non-hospital setting) will be asked to identify TYA who meet the inclusion criteria, screening admissions over the previous 2 years. They will provide eligible TYA with written information about the study and ask them to complete a consent to contact form to be given to the research team. Following a similar process, the research team will ask paediatric and community health professionals to identify TYA who have chosen not to transfer and provide them with relevant information. TYA will also be able to approach the study team directly from information on charity and study websites and through networks, for further information and to discuss eligibility.

Family members of TYA: once recruited, TYA will be asked to identify one family member to participate in an interview either with them or separately. If a TYA does not wish to participate they can still identify a family member to participate. For a TYA with profound and multiple learning disabilities where the PIC deems that they do not have capacity to consent to participate, family members only will be approached. Family members of TYA who have died in AICU will be identified and asked for consent to contact via appropriate local clinical staff/bereavement teams, an approach which we have successfully used previously with bereaved parents.[47] On the recommendation of our parent coapplicant, families will not be approached within the first year post-bereavement. Similarly, family members of TYA who did not want to transfer will be identified and asked for consent to contact via paediatric and community teams.

Online forums:

In total there will be two online forums, one forum with TYA and one forum with family members. . The charity Wellchild will run separate TYA and family member forums, with Mencap and ICU Steps assisting with advertising and directing potential participants to the forums.

The charities will advertise the online forums on their websites, directing potential participants to the charity's Facebook page for more information about the study, including governance. Having provided basic demographic details, they will be directed to closed Facebook groups hosted by the

charities to respond to questions posted there. Potential participants will be requested to provide some basic demographic information (to determine eligibility) before being invited to join the forum. There will not be further follow up for online forum participants.

Surveys:

Separate surveys will be developed for:
1. Staff in AICUs nationally and staff in paediatric centres involved in preparing teenagers for transition in clinical specialities where patients are likely to require AICU admission (e.g. transition nurses, hospital transition leads, specialist nurses for patient groups for whom transition to AICU is more likely). MH professionals who support ICU staff when TYA are admitted with a MH crisis.
2. TYA aged 16-21 years who have had at least one PICU admission >14 years and at least one admission to AICU.
3. Family members of TYA who meet the criteria listed above.

Staff will be recruited via professional groups and societies, relevant social media channels and charities who support the transition of teenagers to adult services. Study information and a QR code linking to the survey will be distributed by the groups, societies and charities. At PICs recruited for the interviews, information and the QR code will be provided to staff by PICs. We will also use a snowballing approach to increase survey participant numbers, inviting staff to forward information to colleagues for whom it would be relevant.
Health professionals: Study information and a QR code linking to the survey will be distributed via professional groups and societies (e.g. Paediatric Critical Care Society, Intensive Care Society, Royal College of Paediatrics and Child Health, Royal College of Physicians Acute Care, UK Intensive Care Society, British Association of Critical Care Nurses), relevant social media channels and charities who support the transition of teenagers to adult services (who suggested this so that their transition nurses in particular complete the survey). At interview sites, information and the QR code will be provided to staff by the PICs. The team will also use a snowballing approach to increase survey participant numbers, inviting staff to forward information to colleagues for whom it would be relevant.

TYA and family members: TYA and family members: Information about the study and QR codes linking to the separate TYA and family surveys (including a QR code for an easy read version) will be provided specialist clinics providing care to TYA who meet the inclusion criteria, such as TYA with neurodevelopmental conditions, congenital heart disease, those requiring long term ventilation) and displayed on the partner charity websites and other patient charity websites.

Participants will be asked to complete the survey once and will not be followed-up further.

Work Package 3

Not applicable

8 CONSENT

Work Package 1

The team are applying for section 251 approval with HRA CAG to transfer identifiers from PICANet and ICNARC to NHSE England, to transfer pseudonymised record level data from NHSE, PICANet, and

ICNARC and to link and process the pseudonymised HES CC, HES, Civil registrations mortality data (ONS), PICANet and ICNARC data.

National data Opt-out will be requested and the audits have approval from the Health Research Authority Confidentiality Advisory Group to process confidential patient information without consent for both non-research and research purposes under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support' of the NHS Act 2006) for data collected in England and Wales.

Pseudonymised record level health and demographic data will be held at UCL for the dataset analysis. The data relates to the clinical characteristics and healthcare resource utilisation from teenage years to early adulthood of people who used intensive care as a young person, and how these relate to intensive care use after age 16.

Work Package 2

Semi-structured 1-1 Interviews:

Participant information sheets, consent forms, and consent to contact forms for each participant group will be developed in conjunction with the patient co-applicant and will include appropriately tailored information for TYA with learning disabilities/autism and bereaved families as well as specific information sheets for those who have chosen not to transfer.

At the start of the interviews all participants will be asked to provide verbal (for virtual interviews) or written (for face to face interviews) consent for their participation and for the interviews to be audio recorded. They will have the opportunity to ask any questions. The researcher will reassure all participants about confidentiality and the fact that they will not be identifiable from any dissemination. The researcher will also ensure that all participants are aware that they can stop the interview at any time and a stop sign will be negotiated prior to the interviews commencing, particularly for the TYA. If appropriate, TYA and family members will be provided with information about support services at the end of the interview.

Online forums:

Participants volunteering to take part in the online forums do so by following the links provided on the partner charity websites. They will be directed to further information on the process including the governance regarding their information and their discussion posts. They will be informed that they can discontinue at any time and will be informed that their data will be anonymised.

Surveys:

All surveys will be anonymous with basic demographic details collected to check eligibility. Consent will be inferred from completion.

Work Package 3

Not applicable.

9 DATA ANALYSIS

Work Package 1

Data preparation:

The analysts will clean each dataset by identifying inconsistencies across patient records and anomalous/implausible parameter values (e.g., distinct admissions with incompatible diagnoses recorded for the same patient). The standalone PICANet and ICNARC datasets will be organised into patient level datasets showing a patient's use over time of paediatric and adult ICU respectively. For the linked dataset, they will combine overlapping events (inpatient stays, ICU stays, outpatient appointments and A&E attendances) across datasets into 'spells of care'. [46] Each spell of care will be characterised by the event or events it contains. A patient's timeseries of spells defines their trajectory through the hospital system.

Data analysis (linked dataset):

The analysts will identify the main cohort of patients who had at least one further ICU spell after the age of 16 (in an adult or paediatric ICU). In addition, they will identify a comparator cohort of patients who had at least one ICU stay aged 14-15 but did not have records of ICU use after the age of 16 and did not die before the age of 16. They will describe the ICU use of these cohorts in terms of: the distribution of the number of ICU stays between 14 and 16 and between 16 and 21 (main cohort only); lengths of each ICU stay; survival outcomes.

Additional data analysis will be conducted on a subset of the main OPTICAL cohort, namely those TYA who had at least one further ICU spell after the age of 16 with a MH crisis (in an adult or paediatric ICU) following a prior admission to PICU aged 14 or over with a MH crisis. The comparator cohort will be patients who had at least one ICU stay aged 14 or over with a MH crisis but did not have records of ICU use related to MH crises after the age of 16 (up to 21) and did not die before the age of 16. In addition, we will pick up MH related admissions to AICU in the entire linked cohort.

Using the entire linked dataset and the main and comparator cohorts, we will further explore the number and characteristics of TYA admitted to PICU aged 14 and over for a MH crisis who are subsequently admitted to an AICU, including information on the reason for ICU admission, underlying health conditions, weight, severity of illness markers, region, ethnicity and deprivation.

Developing code mappings and assigning patients to groups

Each spell of care will have several codes recorded that provide information about the patient's reason for admissions and other health problems (comorbidities) across the different linked datasets. There will be ICD-10 information from HES, ICNARC Coding Method (ICM) information from ICNARC CMP data, acute speciality information from HES (particularly Outpatients) and Read codes from PICANet. Together with the clinical and data co-applicants, the analyst team will develop mappings that can use the available diagnosis, comorbidity and demographic (including age, sex, ethnicity, weight, and Index of Multiple Deprivation) information to assign patients into clinically meaningful, distinct patient groups that have different patterns of ICU use (number of admissions and lengths of stay), within the main and comparator cohorts of patients (Figure 1). Initial mappings will be developed using the linked dataset to ensure that we capture the transitioning population, and then checked and refined on the larger standalone datasets, particularly PICANet.

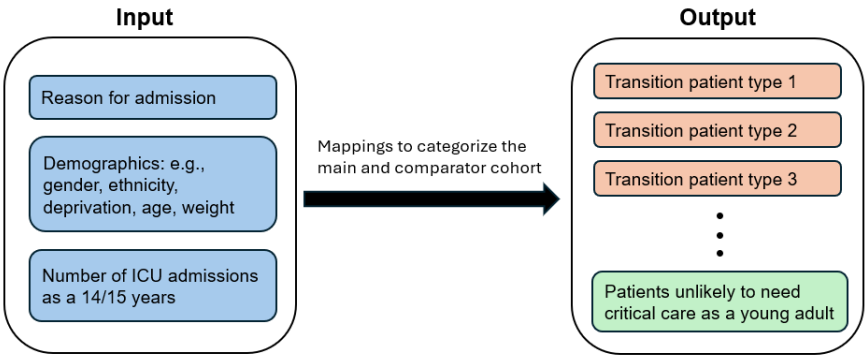


Figure 1 - Schematic of developing mappings to categorise the main cohort (patients who transition to adult ICU) and comparator cohort (patients who are unlikely to need adult ICU as a young person).

Exploring risk factors for transition and patterns of hospital use

Using the entire linked dataset and the main and comparator cohorts, the team will further explore:
• Number and characteristics of 14-15 year olds transitioning between PICU and AICU (main cohort) and potential factors in ICU stays aged 14/15 associated with ICU use after 16 (entire linked dataset), including information on the reason for ICU admission, underlying health conditions, weight, severity of illness markers, region, ethnicity and deprivation;
• patterns of hospital use (inpatient, outpatient, A&E) before and after age 16, indicative costs of providing care (based on publicly available average national costs per critical care service and currency code (HRG)) and any regional or demographic variations in resource use; (main and comparator datasets)
• possible signals for suboptimal transition (e.g., more frequent A&E visits) and associations with any identified risk factors (main cohort).
• the proportion and characteristics of TYA admitted to PICU aged 14 years and over for a MH crisis and subsequently admitted to an ICU with a MH crisis after age 16 (up to 21).
• the characteristics of TYA who experienced both a PICU and AICU admission in the linked dataset, and had a mental health related AICU admission (regardless of reason for PICU admission).

Data analysis (standalone datasets):

Within the standalone datasets, it will not be possible to identify patients who received intensive care as both a 14-15 year old and a young person over 16, outside of the subset of linked patients.

PICANet

Instead, the analysts will adapt the mappings developed on the linked dataset to assign patients to groups who are likely to require intensive care over the age of 16 and those who are less likely to need further intensive care. These will not be perfect mappings, because the standalone dataset does not contain all of the fields of the linked dataset. They will explore and compare patterns of PICU use between the assigned patient groups, potentially enabling in the future early identification of patients likely to need ICU in early adulthood. They will also examine to what extent the cohort of PICU patients likely to transition to adult intensive care has grown over time, enabling assessments of how demand for AICU resource and transition support might grow in the future.

ICNARC CMP

The analysts will adapt the mappings developed on linked dataset (Figure 1) to assign patients to groups who were likely to have required intensive care at age 14 or 15 and those who were more likely to have accessed intensive care first after the age of 16. These will not be perfect mappings because the standalone dataset does not contain all the fields of the linked dataset. The team will explore and compare patterns of AICU use between the assigned groups, including intensive care use after the age of 21 to improve our understanding of future resource use of former PICU patients in adulthood, and will also produce an updated description of AICU use by children aged <16 years. [25]

Overall methodological approach:

The primary aim of WP1 is to provide the first detailed understanding of the number and characteristics of patients who transition from paediatric to adult intensive care. Thus, most of the analysis will be descriptive. Statistical methods will include Classification and Regression Tree (CART) & Lasso Regression analyses for developing the mappings of patients to transition groups by reasons for admission, demographic factors, and patterns of ICU use. Outcomes, and how they vary across groups, will be reported using multiple variables regression and survival analysis. Competing risk analysis methods for outcomes (Kaplan-Meier, cumulative incidences, multivariable Cox and cause-specific hazard models) will be used to account for censoring and the competing risk of death before transition after age 16 where necessary.

Work Package 2

Semi-structured 1-1 Interviews: Transcripts will be analysed using Framework analysis.[48] The first 5 interviews for each participant group will be analysed and the topic guides revised if indicated before subsequent interviews are undertaken. This is a recognised method to enable evolving themes to be identified and included in subsequent interviews. Data pertaining to mental health experiences and impacts will be analysed separately from other interview topics.

Online forums: Analysis of the transcripts will be undertaken by the research team (including the parent coapplicant), with members of the PPI group. The transcripts will be thematically analysed.[52]

Surveys: The research team will use descriptive analyses to characterise the samples, e.g. frequencies, medians and interquartile ranges, and non-parametric tests to compare across groups, e.g. participant groups, TYA age groups, paediatric/adult professionals. Free text will be analysed thematically.

Work Package 3

WP3 will involve systematic evidence synthesis and formal problem structuring methods using the data from WP2.

Systematic evidence synthesis:

A hyper-framework will be created using the separate data frameworks and analytical themes established from the interviews (health professionals; young adults; families), online forums (young adults; families), and surveys (health professionals; young adults and families) conducted in WP2. Analytical themes judged to be very similar across analyses but addressed from a different perspective (e.g. a family or health professional perspective) will be merged into a 'hyper-theme' and hyper-themes organised along a patient journey to create a single hyper-framework. Data within hyper-themes will be categorised as reflecting an underlying service problem, a candidate service improvement (e.g. a cited example of good practice) or neither, with data considered 'neither' discarded from the synthesis. Within each hyper-theme, data representing the same underlying

service problem will be grouped to form a set of 'archetypal service problems', each associated with characterisations of the problem from different perspectives. Candidate service improvements from the transition literature and expert group that directly address one of the archetypal problems will be added to the hyper-framework. Similar candidate improvements will be combined creating a set of potential service improvements linked to the archetypal problems.

Formal problem structuring methods:

Operational Research problem structuring methods (e.g. soft systems methodology [55]) will be used to acknowledge and engage multiple perspectives in systematically considering potential changes to transition services, incorporating relevant evidence generated in the study.

10 PATIENT AND PUBLIC INVOLVEMENT (PPI)

This proposal is rooted in powerful testimony from TYA and their families on the challenges of transitioning to AICU and the lack of preparation or pathway for TYA who will require AICU (also highlighted by our partner charities). It was directly influenced by our PPI coapplicant with first-hand experience of transition to AICU.

The PPI co-applicant will chair a diverse and inclusive PPI group with 3-4 TYA, 3-4 family members and 3-4 charity representatives. They will meet twice in year 1, 3 times in year 2 and twice in year 3 (in-person once per year). Each PPI member will contribute 3.5 days over the course of the project. We will hold a one-day face to face event, co-facilitated by our parent co-app, at which they will co-design, with the WP2 researchers and in consultation with the wider research team, patient information, surveys and questions for the discussion forums, and ensure that the project remains patient and family focused and accessible to all. They will also lead the dissemination of findings to patients and families and be offered the opportunity to contribute to journal publications and conference presentations. Appropriate training will be offered by experienced trainers. The team aim to recruit at least one TYA with a learning disability who will be individually supported by a consultant nurse in learning disabilities. Terms of reference will be established for the group.

11 FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by UCL, and deemed sufficient to cover the requirements of the study.

The research costs for the study have been supported by the NIHR (award number: **NIHR156314**) for the amount of £943,605.48, with the research contract signed on the 22nd September 2023. A supplement of £69,509.29 was awarded in response to the NIHR Mental Health Research Initiative to include new mental health research within OPTICAL.

A sub-contractual collaboration agreement is in place between UCL and partner organisations (host institutions for each co-applicant). An amendment to the collaboration agreement is being put in place for the supplement for mental health research.

The partner organisations are given below:

1. Imperial College London

2. Great Ormond Street Hospital NHS Trust
3. Rotherham NHS Foundation Trust
4. Sheffield Children's NHS Foundation Trust
5. University of Leicester
6. Intensive Care National Audit & Research Centre
7. Kings College London
8. Independent – PPI co applicant

The partner charities are given below:

1. WellChild, a charity that supports children and young people with complex and life limiting conditions and their families.
2. Mencap, charity for people with a learning disability.
3. ICUSteps, an intensive care patient support charity.

Research costs for the charities cover facilitating contact with potential interview participants, promoting the survey, running the online forums, supporting recruitment of PPI members to the steering committee, PPI group and expert group, and dissemination.

In this study there are no excess treatment costs and no use, or supply from third parties, of specific equipment.

12 DATA HANDLING AND MANAGEMENT

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller for all work packages and GOSH is also a data controller for work package 2. The UCL Data Protection Officer is at data-protection@ucl.ac.uk. The GOSH data protection officer is Anna Ferrant at your.data@gosh.nhs.uk. The data processors are UCL and GOSH. The study will be collecting the following personal data:

Work Package 1

The research team will seek approval from Health Research Authority (HRA), NHS Research Ethics Committee (REC) and Confidential Advisory Group (CAG) for permission to use unconsented, routinely collected national data. They will submit applications to NHSE, ICNARC and PICANet / HQIP to access and link data (see flow diagram for linkage process). All study datasets will be securely held within the University College London (UCL) Data Safe Haven.

Standalone datasets: ICNARC and PICANet will transfer to the UCL Data Safe Haven standalone datasets of all records (any year or age) for patients who had at least one ICU admission recorded aged 14 to 21 years. ICNARC and PICANet will include pseudonymised record study ID and patient study ID.

Linked dataset: NHS England will identify the cohort in HES CC and identify all records in HES APC, OP and A&E relating to that cohort from 2017-2023 (at least one year follow up). NHS England will send a pseudonymised clinical dataset and latest life status data from HES/ONS to UCL Data Safe Haven. PICANet and ICNARC will send all identifiers of patients who had at least one PICU / AICU admission aged 14 and 15 from Jan 2017 to one year prior to the date of data extraction to NHSD for linkage to HES CC. They will include the same pseudonymised record study IDs already sent to UCL for the

standalone datasets. NHS England will then send the pseudonymised ICNARC CMP record IDs and pseudonymised PICANet record IDs for successfully linked records to UCL. UCL analysts will then incorporate the linked ICNARC CMP and PICANet records, using the record study IDs from the standalone datasets already held, to the linked HES/ONS dataset provided by NHS England.

Work Package 2

Semi-structured 1-1 Interviews:

Interview responses will constitute personal data and include participants' experience of transition, barriers, expectations, concerns, information requirements, perceptions of change in how care is delivered (e.g. family centred care to person centred care) and any associated challenges, examples of good practice, requirements for support and experiences of receiving it, advance care planning and associated pathways, goals of care and suggestions for improvements (including an idea of priority for these). Participants will also be asked to provide some basic demographic details.

Contact details collected to arrange interviews will be stored separately to interview responses. All interview transcripts will be anonymised, with any identifying details removed.

Online forums:

Participants volunteering to take part in the online forums do so by following the links provided on the charity website. They will be directed to further information on the process including the governance regarding their information and their discussion posts. They will be informed they can discontinue at any time, and will be informed that their data will be anonymous.

Online forum responses will include experiences and perceptions from patients and their families. At the end of the 3-month forum, the charities will remove any identifying information from the discussion transcript and send the anonymised transcript to the research team. Participants will also be asked to provide some basic demographic details but the research team will only be sent aggregated details by each charity, rather than individual participant details. Demographic data are being collected to enable eligibility to be checked and for characterisation of the sample. No forum responses will be linked to individual participant demographic details.

Surveys:

Survey responses will be anonymous and will expand on the topics covered in the interviews and online forums. Participants will also be asked to provide some basic demographic details for characterisation of the sample but no identification of participants will be possible from this information

Work Package 3

Not applicable.

13 MATERIAL/SAMPLE STORAGE

All quantitative data will be stored in the ISO27001 certified UCL Data Safe Haven, which conforms to the NHS Information Governance Toolkit. Interviews will be transcribed by a trusted third party (TakeNote/Verbit Go) and password protected anonymised transcripts will be stored on a secure server at Great Ormond Street Hospital (GOSH) and on UCL's Data Safe Haven. Charities will

anonymise the online forum transcripts before sending them to the research team for storage on the GOSH and UCL servers. No identifiable information will be collected in the surveys, data from which will be stored on the GOSH and UCL servers. We will comply with UK GDPR and UCL's data confidentiality procedures.

14 PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCL.

- The Sponsor considers the procedure for obtaining funding from NIHR to be of sufficient rigour and independence to be considered an adequate peer review.

The study was deemed to require regulatory approval from the following bodies: HRA and NHS REC Favourable Opinion and Confidentiality Advisory Group Approval. **Before any site can recruit participants into the study,** the Chief Investigator/Principal Investigator or designee will ensure that the appropriate regulatory approvals have been issued, and NHS Confirmations of Capacity and Capability and Sponsor green lights are in place.

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor, REC and HRA will be retained. The Chief Investigator will notify the Sponsor and REC of the end of the study.

It is the Chief Investigator's responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Sponsor and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the Sponsor and REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the Sponsor and to the REC and HRA.

15 ASSESSMENT AND MANAGEMENT OF RISK

Work Package 1

As this part of the study is using retrospective, routinely collected patient data only, the risk it presents is the possibility of breaching confidentiality.

Therefore, the following steps have been taken to minimise this risk:

- Personal identifiers will be transferred from the audits PICANet and ICNARC to NHS England and not to UCL
- Personal identifiers from audit and national data will not be held at UCL
- Each data provider will provide the pseudonymisation study ID with the record level data

- UCL will link data using the pseudonymisation study ID
- Only authorised, trained members of the study team will have access to the data

Work Package 2

The following steps will be taken to minimise risk:

Semi-structured 1:1 interviews:

- Contact details will be collected from 1:1 interview participants and will be stored on secure GOSH servers and the UCL data safe haven only
- Responses and demographic details from interviews will be pseudonymised and stored separately from contact details
- Only authorised, trained members of the study team will have access to the data
- All interview participants will be made aware that they can stop the interview at any time and a stop sign will be negotiated before the interviews start, particularly for the TYA
- Participants will be able to take a break or reschedule continuation of the interview if they become distressed
- Participants will be informed that, should they disclose any information which suggests that either they or someone else is at risk of harm, the researcher will need to discuss this outside of the interview and escalate to the appropriate people (local PI and/or hospital safeguarding lead) as appropriate
- TYA and family members will be provided with information about support services at the end of the interview, should this be needed

Online forums:

- The online forums are being managed by three charities WellChild, Mencap, and ICUSteps.
- Forum transcripts will be stripped of all identifiers, and transferred securely to GOSH and UCL in anonymised format
- Transcripts will be stored securely on GOSH and UCL servers.

Surveys:

- Survey data from patients, carers and staff will be anonymised
- Survey responses will be securely transferred to GOSH and UCL servers.

The research team note that although UCL will only have pseudonymised data and no patient identifiers, the constellation of diagnoses, treatments and age details could lead to some unusual patients being identified from a combination of this data even without patient identifiers. We are mitigating this risk by treating the audit and interview data as if it were identifiable throughout by using the UCL Data Safe Haven which a technical solution for storing, handling and analysing identifiable data. It has been certified to the ISO27001 information security standard and conforms to NHS Digital's Information Governance Toolkit. We will also ensure that all analysts with access to the Data Safe Haven have governance training.

Work Package 3

- The workshops will only involve members who have volunteered to be part of the expert committee

16 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

All events and incidents (and near misses) that occur to participants and/ or staff that are **unexpected** and directly **related** to the research study will be reported to the Sponsor the UCL REDCAP incident reporting form and host sites via their Trust reporting systems, and documented in the Trial Master File/Investigator Site File via study-specific incident logs (and related correspondence). This will be completed by the CI or PI. The Sponsor will be responsible for investigating, reviewing, or escalating to a serious breach if required.

16.1 Personal Data Breaches

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer data-protection@ucl.ac.uk, (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data), and to the Sponsor via the UCL REDCAP incident reporting form (https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their Trust incident reporting mechanisms and will document this within their TMF/ISFs.

16.2 Adverse Events and Serious Adverse Events Sponsor Reporting Requirements (if applicable)

Not Applicable

16.3 Incidental Findings in Research

Not Applicable

16.4 Protocol deviations and notification of protocol violations

Protocol deviations are usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the Sponsor. The CI will monitor protocol deviations, and if found to frequently recur, will discuss in the first instance with the Sponsor to determine re-classification and reporting requirements.

A protocol violation is a breach which is likely to effect to a significant degree: –
(a) the safety or physical or mental integrity of the participants of the study; or
(b) the scientific value of the study

The CI and Sponsor will be notified immediately of any case where the above definition applies via research-incidents@ucl.ac.uk or UCL REDCAP incident reporting form.

16.5 Reporting incidents involving a medical device(s)

Not Applicable

16.6 NHS Serious Incidents and near misses

A serious incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a. It is an accident or other incident which results in injury or ill health.
b. It is contrary to specified or expected standard of patient care or service.

c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d. It puts the Trust in an adverse position with potential loss of reputation.
e. It puts Trust property or assets in an adverse position or at risk.

Serious Incidents and near misses will be reported to the Sponsor and Trust Quality & Safety department as soon as the study team becomes aware of them.

16.7 Complaints from research participants

In the first instance, research participant complaints (patients or healthy volunteers) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s), and to the Sponsor via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy; for participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures were undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS and the Sponsor where necessary.

17 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the Sponsor should she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

An independent steering committee ('Oversight Committee') will be appointed to advise and monitor project progress, including a statistician, qualitative health services research academic, 2 clinical academics and 2 PPIE representatives.

A data monitoring and ethics committee will be appointed for the oversight of primary data collected from participants and to monitor these data and make recommendations to the Steering Committee on whether there are any ethical or safety reasons why the study should not continue.

The Chief Investigator and other investigator/collaborators do not have any direct involvement (e.g. financial, shareholding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest.

18 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files. Training will include annual Information Governance training for those working with the data.

19 INTELLECTUAL PROPERTY

If formal site agreements will not be used for the study, but after discussion with the study team, the JRO has determined that there is sufficient need for intellectual property provisions to be covered in a sponsor-site document, insert this text:

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol, the study data and in the results arising directly from the study but excluding all improvements thereto or clinical procedures developed or used independently of the study by each participating site, shall belong to UCL. All intellectual property rights deriving or arising from the material or any derivations of the material provided to UCL by the participating site shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, effectively assigns all such intellectual property rights ("IPR") to UCL and discloses all such know-how to UCL.

Nothing in this section shall be construed so as to prevent or hinder the participating sites from using its own know how or clinical data gained during the performance of the study, as its own risk, in the furtherance of its normal activities or providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information of the infringement of an intellectual property rights of UCL, or their funder. This section does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the study.

20 INDEMNITY ARRANGEMENTS

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

Participants may also be able to claim compensation for injury caused by participation in this clinical study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should be advised to do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

Hospitals selected to participate in this clinical study shall provide clinical negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to University College London upon request.

Additionally, UCL does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity.

21 ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at CORU, UCL for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The study master file will be archived at UCL, in accordance with the UCL Retentions Schedule and Policy. It will be archived for a minimum of 5 years from the study end, and no longer than 20 years from study end.

NB: UCL do not archive student projects and therefore the length of storage is not subject to the standard Sponsor requirements.

22 PUBLICATION AND DISSEMINATION

Outputs will include:

- Academic articles, including the study protocol (published in open-access journals to improve transparency of reporting)
- Conference presentations (e.g., UK Paediatric Critical Care Society (PCCS) Annual Conference, Intensive Care Society (ICS) State of the Art meeting)
- Webinars to present study findings (e.g., through the professional societies and Royal Colleges)
- One-page executive summaries
- Social media posts (including medical Twitter), accessible lay summaries, blogs, vlogs, infographics, slide decks, newsletters and podcasts (disseminated through our study website and partner organisations)
- Our code mapping tables in WP1 and interview topic guides and survey from WP2 will be additional study outputs.

Authorship will be determined by an authorship policy agreed by the co-investigators based on guidance from the International Committee of Medical Journal Editors (ICMJE) and the Committee on Publication Ethics (COPE).

Acknowledgements in outputs will include the following statements:

<u>NIHR</u>

"OPTICAL is funded by the NIHR [Health and Social Care Delivery Research Researcher-led call 22/117 (NIHR156314)]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care."

<u>PICANet & HQIP</u>

"Data has been provided by the Healthcare Quality Improvement Partnership from the PICANet Programme."

<u>ICNARC</u>

"This publication is based on data derived from the Intensive Care National Audit & Research Centre (ICNARC) Case Mix Programme Database. The Case Mix Programme is the national, comparative audit of patient outcomes from adult critical care coordinated by ICNARC. We thank all the staff in the critical care units participating in the Case Mix Programme. For more information on the representativeness and quality of these data, please contact ICNARC. Disclaimer: The views and opinions expressed therein are those of the authors and do not necessarily reflect those of ICNARC"

NHS England

"Hospital Episode Statistics (HES) data, and civil registrations mortality data from the Office for National Statistics (ONS) was provided by NHS England."

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24 APPENDICES

None for version 1

Version 2

Changes made following REC review and feedback from NIHR.

Study summary: Funder contact details removed; Study duration altered.

Section 6 ELIGIBILITY CRITERIA: Clarification of WP1 inclusion criteria.

Version 3

Changes made for non substantial amendment 1 which involved:

Section 7 RECRUITMENT:

i) Changing that PICs will be asked to identify teenagers and young adults (TYA) who meet the inclusion criteria, screening AICU admissions over the previous 6 months to 'screening AICU admissions over the previous two years'.
ii) Providing HRA REC with the information that we will recruit health professionals for 1:1 interviews through our charity partners as well as through the NHS.

IRAS form only: Addition of PIC sites; The addition of a cover letter for the PIC sites to use when approaching potential participants.

Version 4

Changes made for substantial amendment 1 which involved:

Background and rationale: Supporting scientific information has been added for the mental health research.

Secondary objectives: addition of objectives 4 and 5.

Study population: distinction made of the sub group of the study population for objective 4. All of the study population will contribute to the analysis of objective 5.

Sample size: Additional numbers for the mental health research.

Data collection: Information on additional information for all topic guides.

Study schedule: An updated study timeline to include new mental health research timeline, and adjustments to the original timeline to account for delays encountered.

Inclusion criteria: A sub group has been added to the inclusion criteria of each participant group for the semi structured 1:1 interviews and the surveys.

Recruitment: The additional recruitment pathways for recruitment for the 1:1 semi structured interviews have been added.

Data analysis: Planned analyses for the data have been added.

Funding and supply of equipment: Details of the awarded supplement have been added.

References: References for the background to the mental health research have been added.

IRAS form only: Updated topic guides, a new version of the cover letters for consent to contact, summary recruitment information to share with charities and clinical networks.