



The OPTICAL Study Privacy Notice

What is the OPTICAL Study?

OPTICAL (Optimising Paediatric Transition to Intensive Care for Adults) is a research study funded by the UK National Institute for Health and Care Research (NIHR) through their Health and Social Care Delivery Research Programme (NIHR HSDR Ref: NIHR156314). The Chief Investigator is Professor Sonya Crowe (University College London), the Principal Investigator is Dr Padmanabhan Ramnarayan (Imperial College London), and the study sponsor is University College London (UCL).

The OPTICAL Study respects your privacy and is committed to protecting your personal data. Please read this privacy notice carefully – it describes the data that each data source will provide to us and information about your rights.

What information is being used?

Data will be sourced by four methods to better understand the experiences of teenage and young adult (TYA) patients, carers and health professionals during the transition from NHS paediatric intensive care units (ICUs) to adult ICUs to help improve the care received and the patient/family experience during this transition.

We will be analysing pre-existing data on approximately 200,000 patients from

- the Paediatric Intensive Care Audit Network (PICANet) (data controller Healthcare Quality Improvement Partnership (HQIP));
- the Intensive Care National Audit & Research Centre Case Mix Programme (ICNARC CMP) (data controller ICNARC);
- Hospital Episode Statistics (HES) Critical Care dataset (data controller NHS England (NHSE));
- HES (inpatient, outpatient, and A&E encounter data) (data controller NHSE)
- Civil Registrations mortality data (data controller NHSE).

For the analysis of pre-existing data, UCL researchers will receive clinical data for included patients from each data source with personal information stripped out and replaced with a Study ID number. This is known as pseudonymised data. That means that UCL researchers will not have access to names, addresses, dates of birth, or any hospital or NHS numbers. This clinical data will be held at University College London's secure data safe haven, Gower Street, London WC1E 6BT. University College London is the data controller for this research dataset.

We will be collecting data on patient experiences (by 1:1 interviews and surveys) from approximately 420 participants (patients, families, health professionals) identified through multiple Patient Identification Centers (PICs) across England. Interview data will be pseudonymised and stored securely on Great Ormond Street Hospital (GOSH) servers and the UCL data safe haven. Survey responses will be anonymised, meaning that the data will not include any personal identifiers or a study ID that will link to personal identifiers held elsewhere. GOSH and UCL are joint data controllers for this data.

We will also be working with three national charities (Mencap, Wellchild and ICUSteps) to develop online forums to elicit patient and family perspectives. The charities themselves will set up and oversee these forums and will transfer anonymised transcripts to the OPTICAL Study team. We expect to receive forum responses from approximately 200 participants.

Why are we using this data?

Advances in medical care have contributed to the increased life expectancy of children with certain conditions such as cystic fibrosis and congenital heart disease, leading to a growing population who require regular follow-up and treatment in adult healthcare services as they leave childhood. While the importance of high-quality transition practices to adult ICU services has been recognised for specific conditions, there are few established transition pathways for TYA with complex conditions, intellectual disability, and neurodevelopmental disorders, despite over 60% of TYA being admitted to PICU with chronic complex conditions. With transition being particularly discomfiting for TYA with complex conditions and their families due to its association with a dislocation of care and deterioration of wellbeing, the need to optimise this transition to adult ICU services for patients and their families is critical.

The NHS has commissioned the OPTICAL study to generate the evidence base for improving the care received and patient/family experience for teenagers transitioning from paediatric to adult ICU services. This includes collecting data on the experiences of patients, carers, and health professionals of ICU transition and establishing targeted improvements in the processes and support for the transition to adult ICU.

How will this data be stored, for how long and who has access to it?

The pseudonymised audit and interview data, and contact details obtained from Patient Identification Centre's once consent to contact has been obtained, will be stored on secure servers at GOSH and in UCL's bespoke data safe haven which has been certified to meet all NHS information security and governance standards. Contact details will be held in a separate folder on the data safe haven, with access permissions restricted only to members of the team who may need to initiate contact. These systems will help to prevent your data from being accidentally lost, used, or accessed in an unauthorised way, altered, or disclosed. We have established procedures to deal with any suspected data breach and you and any applicable regulator will be notified of a breach where we are legally required to do so.

Anonymised data collected from surveys and online forums will be held only by members of the study team involved with its analysis or storage.

Only researchers with a legitimate need to see the data for the purpose of carrying out their job, will have access to the data. All results from the research data will be published only in aggregated and anonymised form.

The OPTICAL study runs until July 2026 and the datasets containing audit and national data will be stored at UCL for a further 3 years to give the researchers time to make the overall results public, before being securely deleted. Interview and survey data will be retained for a further 15 years after study completion.

We will not transfer any personal data outside of the European Economic Area (EEA).

What is our legal basis for using your data?

Data Protection Legislation requires that we meet certain conditions before we are allowed to use your data in the way described in this notice. Our agreed basis is known as 'Public Task', where the use of your data is necessary for the performance of a task carried out in the public interest.

As the OPTICAL study will be analysing health data from routinely collected audits, we applied for 'section 251 approval' which was reviewed by Confidentiality Advisory Group (CAG). CAG is an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that our application should be supported, and the Decision Maker within the Health Research Authority approved this.

If you participated in the 1:1 interview, you will have provided consent to contact prior to allow us to approach you to participate, and verbal (for virtual interviews) or written (for face-to-face interviews) consent for you or your family member's participation and for the interviews to be audio-recorded.

If you participated in the surveys, consent would have been inferred from completion.

What if I don't want information about me or the family member I care for to be used for the OPTICAL study?

If you do not want information relating to you or the family member you care for to be included in the OPTICAL research data, please contact the PICANet and ICNARC audits by telephone or email (details provided below)

and we will ensure that your information is removed from the OPTICAL study data (Each data controller will let UCL know which data they need to delete).

If you took part in our 1:1 interviews and would like your responses removed from the study please contact [Insert GOSH Research fellow/GOSH PI] at Great Ormond Street Hospital (details provided below).

If you took part in our online forums and would like your responses removed from the study, please contact the charity you took part through (please note that we do not hold any of your personal identifiers so will not be able to remove any of the discussion without the charity's input) (details provided below).

You are free to request this at any time and any decision to request removal of your or your family member's data will not alter the care you receive in any hospital. You also have the right to request access to, and to request to rectify information held about you or the family member you care for.

You can find further information about your rights in UCL's privacy notice: https://www.ucl.ac.uk/legal-services/sites/legal-services/files/ucl_general_research_participant_privacy_notice_v1.pdf

Listed below are several contacts who can help you remove your data from the study should you wish to do so. The OPTICAL study is based at University College London. Please note that the data we will hold will not include the patient identifiers name, address, date of birth or postcode (it will be pseudonymised or anonymised).

If you believe that your or your child's data would be held in the children's intensive care audit (PICANet) or the adult intensive care audit (ICNARC) and would like it removed from the OPTICAL study, please contact:

For PICANet data (children's intensive care):



Data Protection Officer (DPO) - PICANet

Alice Temple
The Secretariat, c/o Level 13
Marjorie and Arnold Ziff Building
University of Leeds
Leeds
LS2 9JT

For ICNARC data (adult intensive care):



Data Protection Officer (DPO) / GDPR
Owner - ICNARC

Scott Carnegie
24 High Holborn
London
WC1V 6AZ
DPO@icnarc.org
020 7831 6878

Unsure who to contact to remove your data from the study or if you would like to discuss your data rights, please contact Sonya Crowe, the lead researcher on the study. Please note that as we do not hold your identifying information, we will redirect you to the appropriate data controller.



Chief Investigator (lead researcher) for OPTICAL

Professor Sonya Crowe
Clinical Operational Research Unit
University College London
4 Taviton Street
London
Tel: 0207 679 4953
Sonya.crowe@ucl.ac.uk

For general data protection queries contact:**Data Protection Officer University College London**

Data Protection & Freedom of Information Officer
University College London
Gower Street
London
WC1E 6BT
Data-protection@ucl.ac.uk

If you took part in one of the 1:1 interviews for this project and you have decided you would like to remove your pseudonymised responses and/or contact details from the study, please contact the [INSERT Research fellow name (TBA)/ GOSH PI] by the details below.

Research Fellow Great Ormond Street Hospital

Name (TBA)
Great Ormond Street Hospital
Great Ormond Street
London
Email (TBC)
Phone number (TBC)

Great Ormond Street Hospital Principal Investigator

Professor Jo Wray
Great Ormond Street Hospital
Great Ormond Street
London
jo.wray@gosh.nhs.uk
0207 829 7822

For general data protection queries contact:**Data Protection Officer Great Ormond Street Hospital**

Anna Ferrant
Great Ormond Street Hospital
Great Ormond Street
London
your.data@gosh.nhs.uk

If you took part in one of the online forums for this project and you have decided you would like to remove your anonymised responses from the study, or any data the charity may hold on you, please contact the charity you completed the forum with.

Mencap
Royal Mencap Society, Head Office
6 Cyrus Way
Peterborough
PE7 8HP
01733 873700
DPO@mencap.org.uk

WellChild
Office 23, Sunningend Business Centre
22 Lansdown Industrial Estate
Cheltenham
Gloucestershire
GL51 8PL
01242 530007

OPTICAL Study Privacy Notice: Version 2: IRAS 338748: 20/05/2024
info@wellchild.org.uk

ICUsteps
Kemp House
152-160 City Road
London
EC1V 2NX
0300 30 20 121
contact@icusteps.org

You also have the right to lodge a complaint with the Information Commissioner's Office (**ICO**) (the UK data protection regulator). For further information on your rights and how to complain to the ICO, please refer to the [ICO website](#).