

# A longitudinal, mixed-methods investigation of the physical, cognitive, emotional, social health outcomes and the support needs of children and their family members in the first year after a PICU discharge

<b>Submission date</b> 11/11/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/03/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Current plain English summary as of 18/01/2022:

### Background and study aims

Each year 20,000 children become very ill or injured and need specialist care within a Paediatric Intensive Care Unit (PICU). Most children survive. However, these children and their families may experience problems after they have left the PICU. These can include physical (breathing, eating and drinking), functional (moving and concentration), and/or emotional problems (stress and fears) to themselves and their families (parents and siblings). These have the potential to affect health, place burdens on parents/carers, impact on education and social development. However, we currently do not know which children and families experience problems, when the problems occur, and what causes them. We want to understand the physical, functional, emotional and social consequences of being on PICU to children (aged 1 month-17 years), their parents and siblings, in the first-year after a PICU admission. We will conduct a study that will collect information from these children, their parents and siblings, who have been admitted to PICU over a year to see if there are any changes over time. In addition, some families will take part in interviews in order to explore their care and support needs.

### Who can participate?

1. Child aged 1 month to 17 years at the point of PICU admission, who will be discharged alive from the PICU in next 48 hours
2. Their parents or legal guardians
3. Their siblings aged 8 or older

### What does the study involve?

To do this, we want to follow up 334 children, their parents, and their siblings from 10 PICUs. Information will be collected over the first-year after they have left the PICU. Information will be

collected (over the telephone or via the internet) at 1 month, 3 months, 6 months, and 12 months after leaving PICU. At 3 and 9 months, we will invite up to 40 families to take part in a face-to-face or telephone interview to talk about their health care needs.

What are the possible benefits and risks of participating?

There may not be any specific benefits to participating in this study. However, participating in this research will help us to understand what children/young people and their families' outcomes are like in the first year after PICU and whether there are ways we can improve the support for these children and their families. All participants over the age of 5 years will receive a £15 voucher at the end of the study as a token of appreciation. Furthermore for those that participate in the interview will receive an additional £10 voucher. There are no particular risks to participating in this study. Participants will receive the same medical treatment whether they take part or not. By completing the questionnaires participants will be asked to think about a potentially difficult time and for some, this may be upsetting. If this is the case then the participant can withdraw from the study at any time without giving a reason. Furthermore, if participants would like to speak to someone about how they are feeling then the study team can help signpost the participants to support.

Where is the study run from?

Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?

April 2019 to March 2023

Who is funding the study?

NIHR Academy (UK)

Who is the main contact?

Dr Joseph Manning

Joseph.Manning@nottingham.ac.uk

---

Previous plain English summary:

Background and study aims

Each year 20,000 children become very ill or injured and need specialist care within a Paediatric Intensive Care Unit (PICU). Most children survive. However, these children and their families may experience problems after they have left the PICU. These can include physical (breathing, eating and drinking), functional (moving and concentration), and/or emotional problems (stress and fears) to themselves and their families (parents and siblings). These have the potential to affect health, place burdens on parents/carers, impact on education and social development. However, we currently do not know which children and families experience problems, when the problems occur, and what causes them. We want to understand the physical, functional, emotional and social consequences of being on PICU to children (aged 1 month-17 years), their parents and siblings, in the first-year after a PICU admission. We will conduct a study that will collect information from these children, their parents and siblings, who have been admitted to PICU over a year to see if there are any changes over time. In addition, some families will take part in interviews in order to explore their care and support needs.

Who can participate?

1. Child aged 1 month to 17 years at the point of PICU admission, who will be discharged alive

- from the PICU in next 48 hours
2. Their parents or legal guardians
  3. Their siblings aged 8 or older

#### What does the study involve?

To do this, we want to follow up 300 children, their parents, and their siblings from 5 PICUs. Information will be collected over the first-year after they have left the PICU. Information will be collected (over the telephone or via the internet) at 1 month, 3 months, 6 months, and 12 months after leaving PICU. At 3 and 9 months, we will invite up to 24 families to take part in a face-to-face or telephone interview to talk about their health care needs.

#### What are the possible benefits and risks of participating?

There may not be any specific benefits to participating in this study. However, participating in this research will help us to understand what children/young people and their families' outcomes are like in the first year after PICU and whether there are ways we can improve the support for these children and their families. All participants over the age of 5 years will receive a £15 voucher at the end of the study as a token of appreciation. Furthermore for those that participate in interview will receive an additional £10 voucher. There are no particular risks to participating in this study. Participants will receive the same medical treatment whether they take part or not. By completing the questionnaires participants will be asked to think about a potentially difficult time and for some this may be upsetting. If this is the case then the participant can withdraw from the study at any time without giving a reason. Furthermore, if participants would like to speak to someone about how they are feeling then the study team can help signpost the participants to support.

#### Where is the study run from?

Nottingham University Hospitals NHS Trust (UK)

#### When is the study starting and how long is it expected to run for?

April 2019 to March 2023

#### Who is funding the study?

NIHR Academy (UK)

#### Who is the main contact?

Dr Joseph Manning  
Joseph.Manning@nottingham.ac.uk

#### Study website

<https://sites.google.com/nihr.ac.uk/oceanic/home>

## Contact information

#### Type(s)

Scientific

#### Contact name

Dr Joseph Manning

#### Contact details

C3084, C-floor, South Block  
Nottingham Children's Hospital  
Queen's Medical Centre Campus  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH  
+44 (0)7812 275027  
Joseph.Manning@nottingham.ac.uk

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

269642

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

CPMS 43559, IRAS 269642

## Study information

### Scientific Title

A multi-centre longitudinal mixed-methods study to explore the Outcomes of ChildrEn and fAmilies in the first year after paediatric Intensive Care: the OCEANIC study

### Acronym

OCEANIC

### Study objectives

Current study hypothesis as of 18/01/2022:

Each year 20,000 children become very ill or injured and need specialist care within a Paediatric Intensive Care Unit (PICU). Most children survive. However, these children and their families may experience problems after they have left the PICU. These can include physical (breathing, eating and drinking), functional (moving and concentration), and/or emotional problems (stress and fears) to themselves and their families (parents and siblings). These have the potential to affect health, place burdens on parents/carers, impact on education and social development. However, we currently do not know which children and families experience problems, when the problems occur, and what causes them.

We want to understand the physical, functional, emotional and social consequences of being on PICU to children (aged 1 month-17 years), their parents and siblings, in the first-year after a PICU admission. We will conduct a study that will collect information from these children, their parents and siblings, who have been admitted to PICU over a year to see if there are any changes

over time. In addition, some families will take part in interviews in order to explore their care and support needs.

To do this, we want to follow up 334 children, their parents, and their siblings from 10 PICUs. Information will be collected over the first-year after they have left the PICU. Information will be collected (over the telephone or via the internet) at 1 month, 3 months, 6 months, and 12 months after leaving PICU. At 3 and 9 months, we will invite up to 40 families (20 families at each timepoint) to take part in a face-to-face or telephone interview to talk about their health care needs.

To improve care, we will share our results with national organisations, healthcare commissioners, policy makers and the international paediatric intensive care community.

---

### Previous study hypothesis:

Each year 20,000 children become very ill or injured and need specialist care within a Paediatric Intensive Care Unit (PICU). Most children survive. However, these children and their families may experience problems after they have left the PICU. These can include physical (breathing, eating and drinking), functional (moving and concentration), and/or emotional problems (stress and fears) to themselves and their families (parents and siblings). These have the potential to affect health, place burdens on parents/carers, impact on education and social development. However, we currently do not know which children and families experience problems, when the problems occur, and what causes them.

We want to understand the physical, functional, emotional and social consequences of being on PICU to children (aged 1 month-17 years), their parents and siblings, in the first-year after a PICU admission. We will conduct a study that will collect information from these children, their parents and siblings, who have been admitted to PICU over a year to see if there are any changes over time. In addition, some families will take part in interviews in order to explore their care and support needs.

To do this, we want to follow up 300 children, their parents, and their siblings from 5 PICUs. Information will be collected over the first-year after they have left the PICU. Information will be collected (over the telephone or via the internet) at 1 month, 3 months, 6 months, and 12 months after leaving PICU. At 3 and 9 months, we will invite up to 24 families to take part in a face-to-face or telephone interview to talk about their health care needs.

To improve care, we will share our results with national organisations, healthcare commissioners, policy makers and the international paediatric intensive care community.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 25/11/2019, West Midlands – Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; Tel: +44 (0)207 104 8010; Email: [nrescommittee.westmidlands-blackcountry@nhs.net](mailto:nrescommittee.westmidlands-blackcountry@nhs.net)), REC ref: 19/WM/0290

### **Study design**

Observational; Design type: Cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Support needs of children and family members following discharge from the paediatric intensive care unit (PICU)

**Interventions**

Current interventions as of 18/01/2022:

This is a multi-centre longitudinal mixed-methods study of children and their families' outcomes and support needs in the first-year post-PICU. This will involve a mixed-methods design of two linked work-packages (WP): WP1-quantitative study; WP2 – qualitative study.

**Setting and sampling:**

Participants for this study include: (1) child PICU survivors; (2) parents/legal guardians; (3) siblings. Participants will be recruited from five PICUs in Children's Hospitals across England. These sites include: Nottingham University Hospitals NHS Trust; Birmingham Women and Children's Hospital NHS Foundation Trust; University Hospitals of Bristol NHS Trust; Great Ormond Street Hospital NHS Foundation Trust; Alder Hey Children's NHS Foundation Trust. They have been selected as sites for this study as they vary in unit size, case mix, geographical location, and patient demographic.

**Work-package 1:**

A consecutive sampling strategy will be employed. Each site will screen daily over a six-month period and invite all eligible children to participate in the study. Data from screening logs, including refusal to participate and admission numbers at each site, will be collected and used to contextualise the reporting of the analysis.

Data will be collected on the PICU survivor, at least one eligible parent/legal guardian, and a sibling who are able to provide assent and complete surveys independently.

- PICU survivor: If able, all child patients'  $\geq 8$  years of age will be asked to self-report. When indicated (because of their child's age or cognitive capacity), one parent who is the child's primary care provider will be asked to consistently serve as their child's proxy. When more than one parent meets criteria and are willing, parents will self-select who will serve as their child's proxy. Children becoming cognitive capable over the course of the study will be asked to self-report when able.

- Parent: At least one parent/legal guardian living with the patient will be invited to participate

and complete the family surveys. If more than one parent agrees to participate they will be asked to complete their surveys independently of their partner.

- Siblings: A sibling,  $\geq 8$  years of age who can complete surveys independently, lives with the patient, and who have not been PICU hospitalized will be invited to participate and provide assent.

#### Data collection and measures

WP1. Data will be collected from each child (or proxy), their parent, and sibling (if appropriate) prospectively over the first-year post-PICU discharge. Currently there is no standardised or agreed set of outcome measures for research with the PICU patient population. Therefore, the outcome measures used in this study were selected for their validity, reliability, ease of use, availability in electronic versions and previous use with population under investigation. Furthermore, the focus and selection of these measures was informed by the PICS-p framework, contemporary literature, and consultation with patients, public, and PICU clinicians. In line with feedback from this PPI, outcomes will be collected at six time-points: Baseline status (pre-PICU discharge); at PICU discharge; 1, 3, 6 and 12 months post-PICU discharge.

(a) Baseline status and demographic data will be collected through extraction from the medical records and parent report prior to PICU discharge. This will include: Participant characteristics; past medical history; current medical history; PICU discharge diagnosis; PICU length of stay; PICU activity including number of days of mechanical ventilation; other therapies.

Completion of the Paediatric Quality of Life Inventory Version 4.0 (PedsQL™), Paediatric Overall Performance Category (POPC) and Paediatric Cerebral Performance Category (PCPC) based on the child's status two-weeks prior to PICU admission.

(b) PICU admission and activity data (PICANet Data download): The site investigator (or their designated nominee) will collect the NHS number, date of birth, and date of PICU admission for each child PICU survivor recruited into the study. This data will be stored separately from the OCEANIC outcomes data on a local password protect and encrypted database. Using this information, the site investigator (or their designated nominee) will identify the child PICU survivor who has been recruited into the study on the PICANet data collection web-based system and insert their OCEANIC unique study ID onto the system. Each site will then be able to conduct a data download of a pseudo-anonymised dataset containing the PICANet minimum dataset (admission details and activity data) of OCEANIC participants from that site. This will include: demographic and socioeconomic data (participant's date of birth, sex, ethnicity, first 4 digits of their post code); pre-PICU health status (past medical history including underlying conditions and co-morbidities); and acute illness data (PIM2/PIM3; PICU admission and discharge diagnoses; co-morbidities; operations and invasive procedures performed; type of admission; PICU and hospital LOS, duration of mechanical ventilation, high frequency oscillatory ventilation, extracorporeal membrane oxygenation, renal replacement therapy, and vasopressor/inotropic support; sedative medications and days of exposure). This dataset will be sent back to the study Chief Investigator using an encrypted and password protected file via NHS email.

(c) PICU-discharge (within 72 hours), 1, 3, 6 and 12 months: Data will be collected either face-to-face (if inpatient), via telephone interview, online survey completion, or paper mail dependent on the preference of the child, parent, and sibling. All participants will be followed for one year. Where possible each participant will self-report. However, for children that are unable to self-report (due to age or cognition), a parent will proxy-report.

#### Data collection tools:

##### Child related

1. PedsQL™ 4.0 (Pediatric Quality of Life Inventory) Generic Core Scales and Infant Scales – Acute Version measures health-related quality of life (HRQOL) in infants, children and adolescents aged 1 month to 17 years old. The PedsQL™ Generic Core Scales are used for children  $\geq 2$  years of age. They are 23-item child self-report and parent proxy-report scales with four domains:

physical functioning, emotional functioning, social functioning, and school functioning. The PedsQL Infant Scales are used for children <2 years of age and consist of 36-45 items, depending on age, with 5 domains: physical functioning, physical symptoms, emotional functioning, social functioning, and cognitive functioning. Like the Generic Core Scales, the Infant Scales generate a total score. Both sets of instruments have good validity and reliability, have been widely used.

2. PedsQL™ Multi-dimensional Fatigue Scale is an 18-item scale that encompasses three domains: (1) General Fatigue; (2) Sleep/Rest Fatigue and (3) Cognitive Fatigue. The instructions ask how much of a problem each item has been during the past one month. The PedsQL™ Multidimensional Fatigue Scale comprises parallel children self-report and parent proxy-report formats. Higher scores indicate better HRQOL (lower fatigue symptoms).

3. PedsQL™ Pediatric Pain Questionnaire is a generic symptom-specific instrument to measure pain in patients with acute and chronic health conditions. We will use question #2, which asks participants capable of self-reporting to identify a point on a 100 mm line that best shows the worst pain the subject experienced in the past week. Anchors include “no hurting, no discomfort, or no pain” and “hurting a whole lot, very uncomfortable, severe pain”.

4. Functional Status Scale (FSS), an assessment method developed and validated to quantify functional status. The FSS includes 6 domains: mental status, sensory, communication, motor function, feeding, and respiratory. The FSS is amenable to studies of this nature due to ease of administration, its granularity, and objectivity of assessment compared to other available methods and has been used in other outcome studies.

5. Paediatric Cerebral Performance Category (PCPC) and the Paediatric Overall Performance Category (POPC) quantify short-term cognitive impairments and functional morbidity.<sup>27</sup> The POPC scale is dependent on the PCPC scale, as the PCPC status is included in POPC. Studies of patients with scores of 1–4 at PICU discharge, hospital discharge, and one- and six-month follow-up show association with the Stanford Binet Intelligence Quotient, Bayley scales, and Vineland Adaptive Behaviour Scale.

6. Strengths and Difficulties Questionnaire (SDQ) is a behavioural screening questionnaire used to evaluate emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour. The SDQ quantifies low, medium, and high risk of emotional, behavioural, hyperactivity concentration disorders, or any disorder.

7. Child Revised Impact of Events Scale (CRIES-8) is an eight-item screen for post-traumatic stress symptoms in children aged between 7 and 18 years, with established reliability and validity. It has been used with children who have experienced many types of trauma, including the PICU population. A cut-off score of 17 or greater has been found to classify correctly over 80% of children with a diagnosis of post-traumatic stress disorder.

8. Children's Hope Scale (CHS) is a very brief, six-item self-report measure of children's perceptions that their goals can be met. It has been validated for use in children and young people aged 8-17 years consisting of both healthy populations and children with a range of physical illnesses. Scores were invariant across age groups, gender, and race/ethnicity. Scores correlated significantly and in the theorized direction with external measures of similar constructs, including observer ratings of hope, and self-ratings of self-worth and depression.

#### Parent related

1. PedsQL™ Family Impact Module, applies to measuring the impact of paediatric chronic health conditions on their family functioning. Dimensions include: physical functioning; emotional functioning; social functioning; cognitive functioning; communication; worry; daily activities; family relationships; and financial issues).

2. State-Trait Anxiety Inventory 6 (STAI-6) is a self-reported questionnaire that assesses symptoms of anxiety. It is a short version of the Spielberger State Anxiety Scale (SSA), with a cut-off point at 1 SD above the mean to indicate clinically relevant symptoms.

3. Patient Health Questionnaire-4 (PHQ-4) is a 4 item inventory rated on a 4 point Likert-type scale. Its items are drawn from the first two items of the 'Generalized Anxiety Disorder–7 scale'



(GAD-7) and the 'Patient Health Questionnaire-8' (PHQ-8). Its purpose is to allow for very brief and accurate measurement of depression and anxiety. PHQ-4 scores are strongly associated with decrements in multiple domains of functional impairment; the anxiety and depression subscales make unique overall contributions to the PHQ-4, both in terms of factorial and criterion validity; and perhaps most importantly: the results indicate that anxiety has a substantial independent effect on functioning, and even more so when co-morbid with depression.

4. The Post Traumatic Stress Disorder (PTSD) Checklist for DSM-5 (PCL-5) is a 20-item self-report measure that assesses the presence and severity of PTSD symptoms. Items on the PCL-5 correspond with DSM-5 criteria for PTSD. The PCL-5 can be used to quantify and monitor symptoms over time, to screen individuals for PTSD, and to assist in making a provisional or temporary diagnosis of PTSD.

#### Sibling related

1. PedsQL™ 4.0 (outlined above).

2. SDQ (outlined above). NB. Siblings will be expected to self-report on all measures. However, for siblings under the age of 10 the SDQ measure will be done by parent proxy report. This is because the SDQ measure is only validated via parent proxy reporting.

3. Multidimensional Assessment of Caring Activities (MACA-YC18) a self-report measure that can be used to provide an index of the total amount of caring activity undertaken by the young person, as well as six subscale scores for domestic tasks, household management, personal care, emotional care, sibling care, and financial/practical care. The MACA-YC18 was designed as a short, easy-to-use measure able to provide an index of the extent of caring activities a young person is engaged in. Higher scores indicate greater levels of caring activity.

4. Positive and Negative Outcomes of Caring (PANOC-YC20) a self-report measure that can be used to provide an index of positive and negative outcomes of caring. The PANOC-YC20 consists of two 10-item subscales: (1) positive responses, and (2) negative responses, which collectively assess the subjective cognitive and emotional impact of caring in young people with higher scores indicating greater positive and negative responses, respectively.

5. Children's Hope Scale (outlined above).

#### Work-package 2:

Semi-structured qualitative interviews will be conducted to explore care needs at 3 months and 9 months post-PICU discharge. As advocated in the child health literature, a pragmatic and participant-centred approach (based on choice, participation, and flexibility) to collecting qualitative data will be employed. Interviews will be conducted with children, parents/legal guardians, and siblings either collectively or separately. Interviews will take place at the participants' preferred time and method (e.g. face-to-face, telephone). Interviews based on a topic guide that will be developed using the current literature and are proposed to cover the following subjects: experienced problems and needs for support, care-giving roles and responsibilities. All interviews will be audio-recorded and transcribed verbatim.

#### Steering group:

A steering group will be formed of national clinical experts in the field that include: Dr Lyvonne Tume - Associate Professor in Child Health and Senior PICU Nurse, University of Salford (Chair); Dr Gillian Colville - Consultant Clinical Psychologist, St Georges NHS Trust; Dr Sarah Redsell, Associate Professor of Child Health Research, University of Nottingham; Dr Barney Scholefield, Clinician Scientist and Paediatric Intensivist, University of Birmingham; Professor Jo Wray, Health Psychologist and Professor, Great Ormond Street Hospital. They will complement the core research team providing expert clinical guidance to ensuring that the OCEANIC study will be delivered to time, target and to a high standard.

### Ethics and governance:

This study will be conducted according to the NHS Research Ethics Guidelines and core principles which aim to maximise the benefit to society and minimise harm. The OCEANIC study will include participation of NHS patients, requiring approval from the HRA and NHS RES.

Once eligibility criteria are confirmed, the site investigator will approach and provide written study information to the parent/legal guardian and child for consideration of study participation. PPI undertaken as part of the development of this study identified that this can be a particularly challenging time for families and involve heightened emotional responses. Therefore, the initial approach will be undertaken by the usual care team in a sensitive manner. Children and families will be given time to consider whether they wish to participate and will have the opportunity to contact the PI to ask questions before making a decision. The site investigator will then obtain informed consent from the parent/legal guardian of all children who meet the study eligibility criteria. Children who are able to provide assent will be asked for this when they are cognitively capable. Those aged over 16 years and who have the capacity to consent will complete the informed consent autonomously. For parents and siblings informed consent/assent procedures will be undertaken.

---

### Previous interventions:

This is a multi-centre longitudinal mixed-methods study of children and their families' outcomes and support needs in the first-year post-PICU. This will involve a mixed-methods design of two linked work-packages (WP): WP1-quantitative study; WP2 – qualitative study.

### Setting and sampling:

Participants for this study include: (1) child PICU survivors; (2) parents/legal guardians; (3) siblings. Participants will be recruited from five PICUs in Children's Hospitals across England. These sites include: Nottingham University Hospitals NHS Trust; Birmingham Women and Children's Hospital NHS Foundation Trust; University Hospitals of Bristol NHS Trust; Great Ormond Street Hospital NHS Foundation Trust; Alder Hey Children's NHS Foundation Trust. They have been selected as sites for this study as they vary in unit size, case mix, geographical location, and patient demographic.

### Work-package 1:

A consecutive sampling strategy will be employed. Each site will screen daily over a six-month period and invite all eligible children to participate in the study. Data from screening logs, including refusal to participate and admission numbers at each site, will be collected and used to contextualise the reporting of the analysis.

Data will be collected on the PICU survivor, at least one eligible parent/legal guardian, and a sibling who are able to provide assent and complete surveys independently.

- PICU survivor: If able, all child patients'  $\geq 8$  years of age will be asked to self-report. When indicated (because of their child's age or cognitive capacity), one parent who is the child's primary care provider will be asked to consistently serve as their child's proxy. When more than one parent meets criteria and are willing, parents will self-select who will serve as their child's proxy. Children becoming cognitive capable over the course of the study will be asked to self-report when able.
- Parent: At least one parent/legal guardian living with the patient will be invited to participate and complete the family surveys. If more than one parent agrees to participate they will be asked to complete their surveys independently of their partner.
- Siblings: A sibling,  $\geq 8$  years of age who can complete surveys independently, lives with the

patient, and who have not been PICU hospitalized will be invited to participate and provide assent.

#### Data collection and measures

WP1. Data will be collected from each child (or proxy), their parent, and sibling (if appropriate) prospectively over the first-year post-PICU discharge. Currently there is no standardised or agreed set of outcome measures for research with the PICU patient population. Therefore, the outcome measures used in this study were selected for their validity, reliability, ease of use, availability in electronic versions and previous use with population under investigation. Furthermore, the focus and selection of these measures was informed by the PICS-p framework, contemporary literature, and consultation with patients, public, and PICU clinicians. In line with feedback from this PPI, outcomes will be collected at six time-points: Baseline status (pre-PICU discharge); at PICU discharge; 1, 3, 6 and 12 months post-PICU discharge.

(a) Baseline status and demographic data will be collected through extraction from the medical records and parent report prior to PICU discharge. This will include: Participant characteristics; past medical history; current medical history; PICU discharge diagnosis; PICU length of stay; PICU activity including number of days of mechanical ventilation; other therapies.

Completion of the Paediatric Quality of Life Inventory Version 4.0 (PedsQL™), Paediatric Overall Performance Category (POPC) and Paediatric Cerebral Performance Category (PCPC) based on the child's status two-weeks prior to PICU admission.

(b) PICU admission and activity data (PICANet Data download): The site investigator (or their designated nominee) will collect the NHS number, date of birth, and date of PICU admission for each child PICU survivor recruited into the study. This data will be stored separately from the OCEANIC outcomes data on a local password protect and encrypted database. Using this information, the site investigator (or their designated nominee) will identify the child PICU survivor who has been recruited into the study on the PICANet data collection web-based system and insert their OCEANIC unique study ID onto the system. Each site will then be able to conduct a data download of a pseudo-anonymised dataset containing the PICANet minimum dataset (admission details and activity data) of OCEANIC participants from that site. This will include: demographic and socioeconomic data (participant's date of birth, sex, ethnicity, first 4 digits of their post code); pre-PICU health status (past medical history including underlying conditions and co-morbidities); and acute illness data (PIM2/PIM3; PICU admission and discharge diagnoses; co-morbidities; operations and invasive procedures performed; type of admission; PICU and hospital LOS, duration of mechanical ventilation, high frequency oscillatory ventilation, extracorporeal membrane oxygenation, renal replacement therapy, and vasopressor/inotropic support; sedative medications and days of exposure). This dataset will be sent back to the study Chief Investigator using an encrypted and password protected file via NHS email.

(c) PICU-discharge (within 72 hours), 1, 3, 6 and 12 months: Data will be collected either face-to-face (if inpatient), via telephone interview, online survey completion, or paper mail dependent on the preference of the child, parent, and sibling. All participants will be followed for one year. Where possible each participant will self-report. However, for children that are unable to self-report (due to age or cognition), a parent will proxy-report.

#### Data collection tools:

##### Child related

1. PedsQL™ 4.0 (Pediatric Quality of Life Inventory) Generic Core Scales and Infant Scales – Acute Version measures health-related quality of life (HRQOL) in infants, children and adolescents aged 1 month to 17 years old. The PedsQL™ Generic Core Scales are used for children ≥2 years of age. They are 23-item child self-report and parent proxy-report scales with four domains: physical functioning, emotional functioning, social functioning, and school functioning. The PedsQL Infant Scales are used for children <2 years of age and consist of 36-45 items, depending on age, with 5 domains: physical functioning, physical symptoms, emotional functioning, social

functioning, and cognitive functioning. Like the Generic Core Scales, the Infant Scales generate a total score. Both sets of instruments have good validity and reliability, have been widely used.

2. PedsQL™ Multi-dimensional Fatigue Scale is an 18-item scale that encompasses three domains: (1) General Fatigue; (2) Sleep/Rest Fatigue and (3) Cognitive Fatigue. The instructions ask how much of a problem each item has been during the past one month. The PedsQL™ Multidimensional Fatigue Scale comprises parallel children self-report and parent proxy-report formats. Higher scores indicate better HRQOL (lower fatigue symptoms).

3. PedsQL™ Pediatric Pain Questionnaire is a generic symptom-specific instrument to measure pain in patients with acute and chronic health conditions. We will use question #2, which asks participants capable of self-reporting to identify a point on a 100 mm line that best shows the worst pain the subject experienced in the past week. Anchors include “no hurting, no discomfort, or no pain” and “hurting a whole lot, very uncomfortable, severe pain”.

4. Functional Status Scale (FSS), an assessment method developed and validated to quantify functional status. The FSS includes 6 domains: mental status, sensory, communication, motor function, feeding, and respiratory. The FSS is amenable to studies of this nature due to ease of administration, its granularity, and objectivity of assessment compared to other available methods and has been used in other outcome studies.

5. Paediatric Cerebral Performance Category (PCPC) and the Paediatric Overall Performance Category (POPC) quantify short-term cognitive impairments and functional morbidity.<sup>27</sup> The POPC scale is dependent on the PCPC scale, as the PCPC status is included in POPC. Studies of patients with scores of 1–4 at PICU discharge, hospital discharge, and one- and six-month follow-up show association with the Stanford Binet Intelligence Quotient, Bayley scales, and Vineland Adaptive Behaviour Scale.

6. Strengths and Difficulties Questionnaire (SDQ) is a behavioural screening questionnaire used to evaluate emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour. The SDQ quantifies low, medium, and high risk of emotional, behavioural, hyperactivity concentration disorders, or any disorder.

7. Child Revised Impact of Events Scale (CRIES-8) is an eight-item screen for post-traumatic stress symptoms in children aged between 7 and 18 years, with established reliability and validity. It has been used with children who have experienced many types of trauma, including the PICU population. A cut-off score of 17 or greater has been found to classify correctly over 80% of children with a diagnosis of post-traumatic stress disorder.

8. Children's Hope Scale (CHS) is a very brief, six-item self-report measure of children's perceptions that their goals can be met. It has been validated for use in children and young people aged 8-17 years consisting of both healthy populations and children with a range of physical illnesses. Scores were invariant across age groups, gender, and race/ethnicity. Scores correlated significantly and in the theorized direction with external measures of similar constructs, including observer ratings of hope, and self-ratings of self-worth and depression.

#### Parent related

1. PedsQL™ Family Impact Module, applies to measuring the impact of paediatric chronic health conditions on their family functioning. Dimensions include: physical functioning; emotional functioning; social functioning; cognitive functioning; communication; worry; daily activities; family relationships; and financial issues).

2. State-Trait Anxiety Inventory 6 (STAI-6) is a self-reported questionnaire that assesses symptoms of anxiety. It is a short version of the Spielberger State Anxiety Scale (SSA), with a cut-off point at 1 SD above the mean to indicate clinically relevant symptoms.

3. Patient Health Questionnaire-4 (PHQ-4) is a 4 item inventory rated on a 4 point Likert-type scale. Its items are drawn from the first two items of the 'Generalized Anxiety Disorder-7 scale' (GAD-7) and the 'Patient Health Questionnaire-8' (PHQ-8). Its purpose is to allow for very brief and accurate measurement of depression and anxiety. PHQ-4 scores are strongly associated with decrements in multiple domains of functional impairment; the anxiety and depression

subscales make unique overall contributions to the PHQ- 4, both in terms of factorial and criterion validity; and perhaps most importantly: the results indicate that anxiety has a substantial independent effect on functioning, and even more so when co-morbid with depression.

4. The Post Traumatic Stress Disorder (PTSD) Checklist for DSM-5 (PCL-5) is a 20-item self-report measure that assesses the presence and severity of PTSD symptoms. Items on the PCL-5 correspond with DSM-5 criteria for PTSD. The PCL-5 can be used to quantify and monitor symptoms over time, to screen individuals for PTSD, and to assist in making a provisional or temporary diagnosis of PTSD.

#### Sibling related

1. PedsQL™ 4.0 (outlined above).

2. SDQ (outlined above). NB. Siblings will be expected to self-report on all measures. However, for siblings under the age of 10 the SDQ measure will be done by parent proxy report. This is because the SDQ measure is only validated via parent proxy reporting.

3. Multidimensional Assessment of Caring Activities (MACA-YC18) a self-report measure that can be used to provide an index of the total amount of caring activity undertaken by the young person, as well as six subscale scores for domestic tasks, household management, personal care, emotional care, sibling care, and financial/practical care. The MACA-YC18 was designed as a short, easy-to-use measure able to provide an index of the extent of caring activities a young person is engaged in. Higher scores indicate greater levels of caring activity.

4. Positive and Negative Outcomes of Caring (PANOC-YC20) a self-report measure that can be used to provide an index of positive and negative outcomes of caring. The PANOC-YC20 consists of two 10- item subscales: (1) positive responses, and (2) negative responses, which collectively assess the subjective cognitive and emotional impact of caring in young people with higher scores indicating greater positive and negative responses, respectively.

5. Children's Hope Scale (outlined above).

#### Work-package 2:

Semi-structured qualitative interviews will be conducted to explore care needs at 3 months and 9 months post-PICU discharge. As advocated in the child health literature, a pragmatic and participant-centred approach (based on choice, participation, and flexibility) to collecting qualitative data will be employed. Interviews will be conducted with children, parents/legal guardians, and siblings either collectively or separately. Interviews will take place at the participants' preferred time and method (e.g. face-to-face, telephone). Interviews based on a topic guide that will be developed using the current literature and are proposed to cover the following subjects: experienced problems and needs for support, care-giving roles and responsibilities. All interviews will be audio-recorded and transcribed verbatim.

#### Steering group:

A steering group will be formed of national clinical experts in the field that include: Dr Lyvonne Tume - Associate Professor in Child Health and Senior PICU Nurse, UWE Bristol (Chair); Dr Gillian Colville - Consultant Clinical Psychologist, St Georges NHS Trust; Professor Sarah Redsell, Professor of Public Health, Anglia Ruskin University, Dr Jo Wray, Health Psychologist and Associate Professor, Great Ormond Street Hospital. They will complement the core research team providing expert clinical guidance to ensuring that the OCEANIC study will be delivered to time, target and to a high standard.

#### Ethics and governance:

This study will be conducted according to the NHS Research Ethics Guidelines and core principles which aim to maximise the benefit to society and minimise harm. The OCEANIC study will include participation of NHS patients, requiring approval from the HRA and NHS RES.

Once eligibility criteria are confirmed, the site investigator will approach and provide written study information to the parent/legal guardian and child for consideration of study participation. PPI undertaken as part of the development of this study identified that this can be a particularly challenging time for families and involve heightened emotional responses. Therefore, the initial approach will be undertaken by the usual care team in a sensitive manner. Children and families will be given time to consider whether they wish to participate and will have the opportunity to contact the PI to ask questions before making a decision. The site investigator will then obtain informed consent from the parent/legal guardian of all children who meet the study eligibility criteria. Children who are able to provide assent will be asked for this when they are cognitively capable. Those aged over 16 years and who have the capacity to consent will complete the informed consent autonomously. For parents and siblings informed consent/assent procedures will be undertaken.

## **Intervention Type**

Other

## **Primary outcome measure**

Child PICU participants:

Quality of life measured using the PedsQL™ 4.0 (Pediatric Quality of Life Inventory) Generic Core Scales and Infant Scales – Acute Version at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months

Parent/legal guardian participants:

Quality of life and functioning measured using PedsQL™ Family Impact Module at PICU discharge, 1 month, 3 months, 6 months, and 12 months

Sibling participants:

Quality of life measured using the PedsQL™ 4.0 (Pediatric Quality of Life Inventory) Generic Core Scales– Acute Version at PICU discharge, 1 month, 3 months, 6 months, and 12 months

## **Secondary outcome measures**

Current secondary outcome measures as of 16/12/2020:

Child PICU participants:

1. Fatigue measured using the PedsQL™ Multi-dimensional Fatigue Scale at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. Pain measured using PedsQL™ Pediatric Pain Questionnaire at PICU discharge, 1 month, 3 months, 6 months, and 12 months
3. Functional status that includes mental status, sensory, communication, motor function, feeding and respiratory measured using the Functional Status Scale (FSS) at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
4. Cognitive impairment and functional morbidity measured by using the Paediatric Cerebral Performance Category (PCPC) and the Paediatric Overall Performance Category (POPC) at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
5. Emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour measured using the Strengths and Difficulties Questionnaire (SDQ) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
6. Post-traumatic stress symptoms measured using the Child Revised Impact of Events Scale (CRIES-8), Young Child PTSD Screen (YCPS) and Child and Adolescent PTSD screen at 3 months, 6 months and 12 months
7. Perceptions that the participants' goals can be met, measured using the Children's Hope Scale (CHS) at PICU discharge, 1 month, 3 months, 6 months, and 12 months

Parent/legal guardian participants:

1. Symptoms of anxiety measured using State-Trait Anxiety Inventory 6 (STAI-6) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. Depression and anxiety measured using the Patient Health Questionnaire-4 (PHQ-4) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
3. The presence and severity of post-traumatic stress disorder symptoms measured using the Post Traumatic Stress Disorder (PTSD) Checklist for DSM-5 (PCL-5) at 3 months, 6 months, and 12 months

Sibling participants:

1. Emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour measured using the Strengths and Difficulties Questionnaire (SDQ) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. The total amount of caring activity undertaken measured using the Multidimensional Assessment of Caring Activities (MACA-YC18) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
3. The subjective cognitive and emotional impact of caring measured using Positive and Negative Outcomes of Caring (PANOC-YC20) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
4. Perceptions that the participants' goals can be met measured using the Children's Hope Scale (CHS) at PICU discharge, 1 month, 3 months, 6 months, and 12 months

---

Previous secondary outcome measures:

Child PICU participants:

1. Fatigue measured using the PedsQL™ Multi-dimensional Fatigue Scale at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. Pain measured using PedsQL™ Pediatric Pain Questionnaire at PICU discharge, 1 month, 3 months, 6 months, and 12 months
3. Functional status that includes mental status, sensory, communication, motor function, feeding and respiratory measured using the Functional Status Scale (FSS) at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
4. Cognitive impairment and functional morbidity measured by using the Paediatric Cerebral Performance Category (PCPC) and the Paediatric Overall Performance Category (POPC) at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
5. Emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour measured using the Strengths and Difficulties Questionnaire (SDQ) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
6. Post-traumatic stress symptoms measured using the Child Revised Impact of Events Scale (CRIES-8) at 3 months, 6 months, and 12 months
7. Perceptions that the participants' goals can be met, measured using the Children's Hope Scale (CHS) at PICU discharge, 1 month, 3 months, 6 months, and 12 months

Parent/legal guardian participants:

1. Symptoms of anxiety measured using State-Trait Anxiety Inventory 6 (STAI-6) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. Depression and anxiety measured using the Patient Health Questionnaire-4 (PHQ-4) at PICU discharge, 1 month, 3 months, 6 months, and 12 months

3. The presence and severity of post-traumatic stress disorder symptoms measured using the Post Traumatic Stress Disorder (PTSD) Checklist for DSM-5 (PCL-5) at 3 months, 6 months, and 12 months

Sibling participants:

1. Emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour measured using the Strengths and Difficulties Questionnaire (SDQ) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. The total amount of caring activity undertaken measured using the Multidimensional Assessment of Caring Activities (MACA-YC18) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
3. The subjective cognitive and emotional impact of caring measured using Positive and Negative Outcomes of Caring (PANOC-YC20) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
4. Perceptions that the participants' goals can be met measured using the Children's Hope Scale (CHS) at PICU discharge, 1 month, 3 months, 6 months, and 12 months

**Overall study start date**

01/04/2019

**Completion date**

31/03/2023

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 18/01/2022:

Child:

1. Aged 1 month (and  $\geq 44$  weeks corrected gestational age) to 17 years at the point of PICU admission
2. Will be discharged alive from the PICU in next 48 hours
3. PICU total length of stay (LOS)  $\geq 48$  hours at point of discharge in which the patient received PICU therapies for organ dysfunction (including any of the following invasive mechanical ventilation, vasopressors /inotropes, acute renal replacement therapy, or other extracorporeal life support)
4. At least one parent/legal guardian ( $\geq 18$  years of age or considered emancipated) living with the potential subject

Parent:

1. Parent or legal guardian
2. Cohabits with the child

Sibling:

1. Aged  $\geq 8$  years
  2. Is a sibling of the children PICU survivor
  3. Cohabits with the child PICU survivor for at least 50% of the time
  4. Can independently self-report
-



## Previous inclusion criteria:

### Child:

1. Aged 1 month (and  $\geq 44$  weeks corrected gestational age) to 17 years at the point of PICU admission
2. Will be discharged alive from the PICU in next 48 hours
3. PICU total length of stay (LOS)  $\geq 72$  hours at point of discharge in which the patient received PICU therapies for organ dysfunction (including any of the following invasive mechanical ventilation, vasopressors /inotropes, acute renal replacement therapy, or other extracorporeal life support)
4. At least one parent/legal guardian ( $\geq 18$  years of age or considered emancipated) living with the potential subject

### Parent:

1. Parent or legal guardian
2. Cohabits with the child

### Sibling:

1. Aged  $\geq 8$  years
2. Is a sibling of the children PICU survivor
3. Cohabits with the child PICU survivor for at least 50% of the time
4. Can independently self-report

## Participant type(s)

Mixed

## Age group

Mixed

## Lower age limit

1 Months

## Upper age limit

17 Years

## Sex

Both

## Target number of participants

Planned Sample Size: 1002; UK Sample Size: 1002

## Total final enrolment

787

## Key exclusion criteria

### Child:

1. Previously had a Paediatric ICU/Neonatal ICU admission
2. Active do not resuscitate plan/end of life pathway
3. Child in foster care or under the power of Wardship

Any participant unwilling or unable (i.e. lacking capacity) to provide consent assent

**Date of first enrolment**

04/12/2019

**Date of final enrolment**

09/05/2022

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Nottingham University Hospitals NHS Trust**

Trust Headquarters

Queens Medical Centre

Derby Road

Nottingham

United Kingdom

NG7 2UH

**Study participating centre**

**Birmingham Women's and Children's NHS Foundation Trust**

Steelhouse Lane

Birmingham

United Kingdom

B4 6NH

**Study participating centre**

**Alder Hey Children's NHS Foundation Trust**

Alder Hey Hospital

Eaton Road

Liverpool

United Kingdom

L12 2AP

**Study participating centre**

**University Hospitals Bristol NHS Foundation Trust**

Marlborough Street

Bristol  
United Kingdom  
BS1 3NU

**Study participating centre**

**Great Ormond Street Hospital For Children NHS Foundation Trust**

Great Ormond Street  
London  
United Kingdom  
WC1N 3JH

**Study participating centre**

**Manchester Children's Hospital**

Manchester University NHS Foundation Trust  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**

**Sheffield Children's Hospital**

Clarkson Street  
Sheffield  
United Kingdom  
S10 2TH

**Study participating centre**

**St George's University Hospital**

Blackshaw Road  
Tooting  
London  
United Kingdom  
SW17 0QT

**Study participating centre**

**King's College Hospital**

Denmark Hill  
London  
United Kingdom  
SE5 9RS

**Study participating centre**  
**Royal London Hospital**  
Whitechapel Rd  
London  
United Kingdom  
E1 1FR

## **Sponsor information**

### **Organisation**

Nottingham University Hospitals NHS Trust

### **Sponsor details**

Trust Headquarters  
Queens Medical Centre  
Derby Road  
Nottingham University Hospitals NHS Trust  
Nottingham  
England  
United Kingdom  
NG7 2UH  
+44 (0)115 924 9924 ext. 80676  
researchsponsor@nuh.nhs.uk

### **Sponsor type**

Hospital/treatment centre

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NIHR Academy; Grant Codes: ICA-CL-2018-04-ST2-009

## **Results and Publications**

### **Publication and dissemination plan**

1. Study protocol will be available as a published manuscript in Spring 2020
2. Peer reviewed scientific journals

- 3. Internal report
- 4. Conference presentation
- 5. Publication on website
- 6. Other publication
- 7. Submission to regulatory authorities

**Intention to publish date**

31/03/2024

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol article</a>		17/05/2020	18/03/2025	Yes	No