

## Background

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The Department of Health has indicated that patients' views are essential to achieving high quality care. Gaining patients' insights into adult critical care, however, poses additional challenges. Given the severity of illness of patients in critical care, there is a high mortality rate and patients who do survive often have little recollection of their experience.

Rather than restricting insights to a select subgroup of surviving patients who remember critical care and relying on family to act as proxy respondents for non-survivors, an alternative approach could be pursued: to seek the views of family directly (who play a vital role in support of patients), thus ensuring coverage for both surviving and non-surviving patients.

A number of tools have been developed to assess family satisfaction, the most widely validated is the Family Satisfaction in the Intensive Care Unit (FS-ICU) questionnaire which was initially developed and tested in Canada.

## Aim and objectives

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### Aim:

The FREE Study aims to inform the valid, representative and cost-effective future use of the FS-ICU questionnaire in quality improvement programmes for adult critical care services in the NHS.

### Objectives:

1. To test the face and content validity and the comprehensibility of the FS-ICU;
2. To establish the internal consistency, construct validity and reliability of the FS-ICU;
3. To describe family satisfaction using the FS-ICU and explore variation by family member, patient characteristics, unit/hospital characteristics and other contextual factors;
4. To model approaches to sampling to achieve representative sampling for feasible, cost-effective future use of the FS-ICU in quality improvement in the NHS.

## What is FREE?

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A mixed methods study – psychometric evaluation leading to multicentre cohort study nested in the Case Mix Programme (CMP)

## Two-phase study

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### FREE-Qual

A four-month preliminary study to address objective one including: cognitive interviews with family members\* of patients admitted to critical care units and focus groups with members of critical care teams. Two units participating.

### FREE Study

The main study will address objectives two to four. Up to four family members\* of consecutive patients staying 24 hours or more in the critical care unit will be identified and asked for informed consent for a questionnaire to be posted three weeks following the patient's discharge from the unit. The duration of data collection will be one year, chosen to avoid bias from seasonal variation in case mix and workload.

To achieve a representative (e.g. wide geographical spread) sample of units, adult general critical care units actively participating in the CMP will be randomly selected and invited to participate.

\* *Family members are defined as a person/group of persons with close familial, social or emotional relationship to the patient.*

## FREE Study sites/participants

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- **20 units actively participating in the CMP** (adult general critical care units)
- **Family members** of patients staying 24 hours or more in the critical care unit

## Research governance

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### FREE-Qual

- Research Ethics Committee approval:  
The Proportionate Review Sub-committee of  
the NRES Committee Yorkshire & The Humber  
- Humber Bridge (12/YH/0415)

### FREE

- Research Ethics Committee approval:  
NRES Committee South Central - Berkshire B  
(13/SC/0037)

## Funding

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NIHR Health Services and Delivery Research  
(HS&DR) programme (11/2003/56)

### FREE-Qual

NIHR CRN Portfolio Study

- Portfolio number: 13101
- CSP number: 112459

### FREE

NIHR CRN Portfolio Study

- Portfolio number: 13880
- CSP number: 111441
- NHS Support Costs negotiated equivalent to:  
0.39 WTE Research Nurse (Band 6)

## Sponsor

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ICNARC

## Study Management

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ICNARC Clinical Trials Unit

## Team

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### Chief Investigator

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## For further information

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