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# Family Reported Experiences Evaluation (FREE) Study

**Submission date**
19/03/2013

**Recruitment status**
No longer recruiting

**Registration date**
28/05/2013

**Overall study status**
Completed

**Last Edited**
21/12/2015

**Condition category**
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
The NHS is striving to be genuinely centred on patients and their carers. One important aspect in improving care in the NHS is to ensure that experiences of those receiving care are fed back directly to those organising and delivering care to ensure that patients and their family/loved ones have a positive experience of care. Nowhere is this more important than in critical care (also known as intensive care).
Each year, over 100,000 patients are admitted to adult, general critical care units in the UK and just over a third do not survive to leave hospital. Because of their very severe illness, but also the nature of the treatments used by health professionals in an attempt to save life, most patients who survive have little recollection of their experience in the critical care unit and many have ongoing health-related issues that prevent obtaining valid recollection.
However, another group of individuals, namely family/loved ones, play a vital role in support of patients both during the critical care unit/hospital stay and afterwards at home. Family/loved ones experiences of critical care, pertaining to their satisfaction with the quality of care provided both for those who survive and for those who do not, are not currently requested with a view to improving critical care services in the NHS.
A number of tools have been developed to measure family satisfaction and the most widely validated is the Family Satisfaction in the Intensive Care Unit (FS-ICU) questionnaire, which assesses family satisfaction measuring two main conceptual domains: satisfaction with care; and satisfaction with decision-making. The FS-ICU was initially developed and validated in a single hospital setting in Ontario, Canada, and subsequently validated in a multicentre study in six sites across Canada.
It is widely acknowledged that cultural and linguistic differences between, and even within, countries mean that an instrument developed and validated in one place cannot simply be used in another without careful cross-cultural adaptation and validation. Therefore, before the FS-ICU can be introduced into quality improvement programmes in the NHS, the questionnaire must be tested. The FREE Study will take a UK adaptation of the FS-ICU questionnaire and test it in a systematic and rigorous manner. Furthermore the study will evaluate families satisfaction with adult critical care services to inform feasible and cost-effective future use of the FS-ICU in the NHS.

Who can participate?
The participants in this study are family members (aged 18 years +) of patients in critical care. Family members are defined as a person/group of persons with close familial, social or emotional relationship to the patient. Twenty adult, general critical care units will identify up to four family members for all consecutive patients admitted to their unit and staying 24 hours or more.

What does the study involve?
Up to four family members of consecutive patients who stay in the critical care unit for longer than 24 hours will be approached by an authorised staff member and invited to participate. Informed consent will be obtained for a questionnaire to be posted to the family member. Three weeks after the patient is discharged from the critical care unit a questionnaire with a stamped addressed envelope will be sent to the family member(s) who agreed to participate. If no response is received, a second questionnaire will be sent four weeks after the initial mailing. Following this no further contact will be made.

What are the possible benefits and risks of participating?
Participants will be contributing to an important study aiming to identify the best way to improve care and provide feedback to intensive care units in the NHS.
Risks to participants are minimal. Participants (family members of patients in critical care) will be contacted three weeks after the patient has left the critical care unit. This could potentially be a distressing time. Participants will be informed about the timing of the questionnaire and that they do not have to fill it in if they do not wish to. Questionnaires will only be sent to participants who have provided informed consent.

Where is the study run from?
Participants (family members of patients in critical care) will be recruited in 20 NHS adult general critical care units across the UK.

When is the study starting and how long is it expected to run for?
It is anticipated that participant recruitment will start in May 2013 and continue until 2014. The duration of recruitment will be one year, chosen to avoid bias from seasonal variation in case mix and workload.

Who is funding the study?
This research study is being funded by the NIHR Health Services and Delivery Research (HS&DR) Programme.

Who is the main contact?
Emma Walmsley, FREE Study Coordinator, ICNARC
free@icnarc.org

### Study website
http://www.icnarc.org/

# Contact information

### Type(s)
Scientific

### Contact name

Prof Kathryn Rowan

### Contact details
ICNARC
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
ICNARC/02/06/12

# Study information

### Scientific Title
Family Reported Experiences Evaluation (FREE) Study: an evaluation of families satisfaction with adult critical care services in the NHS

### Acronym
FREE

### Study objectives
The overall aim of the FREE Study is to inform valid, representative and cost-effective future use of the Family Satisfaction in the Intensive Care Unit (FS-ICU) questionnaire into quality improvement programmes for adult critical care services in the NHS in the UK.

On 16/04/2014 the following changes were made to the trial record:
1. The anticipated start date was changed from 07/05/2013 to 28/05/2013
2. The anticipated end date was changed from 07/05/2014 to 06/07/2014
3. The target number of participants was changed from 19,250 to 14,200

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES Committee South Central - Berkshire B, 20/02/2013, REC reference: 13/SC/0037

### Study design
Multi-centre prospective cohort study

### Primary study design

Observational

### Secondary study design
Cohort study

### Study setting(s)
Hospital

### Study type(s)
Screening

### Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

### Health condition(s) or problem(s) studied
Family satisfaction with critical care services in the NHS

### Interventions
Up to four family members of consecutive patients who stay in the critical care unit for longer than 24 hours, who agree to participate, will be sent a questionnaire three weeks after the patient is discharged from critical care.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Family satisfaction with adult critical care services as measured by the Family Satisfaction in the Intensive Care Unit (FS-ICU).

### Secondary outcome measures
To explore how family satisfaction, measured with the FS-ICU, varies by:
1. Family member
2. Patient characteristics
3. Unit/hospital characteristics
4. Other contextual factors

### Overall study start date
28/05/2013

### Completion date
06/07/2014

## Eligibility

### Key inclusion criteria

Any family member* (aged 18 years +) of a patient staying in the adult, general critical care unit for more than 24 hours after admission who:
1. Visits the patient at least once
2. Has a UK postal address, and
3. Has not already been recruited into the FREE Study

[* A family member is defined as a person who has a close familial, social or emotional relationship to the patient and is not restricted solely to next-of-kin]

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
14,200

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
28/05/2013

### Date of final enrolment
06/07/2014

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**ICNARC**
London
United Kingdom
WC1V 6AZ

## Sponsor information

### Organisation
Intensive Care National Audit & Research Centre (ICNARC) (UK)

### Sponsor details
Napier House
24 High Holborn
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WC1V 6AZ
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icnarc@icnarc.org

### Sponsor type
Research organisation

### Website
http://www.icnarc.org/

### ROR
https://ror.org/057b2ek35

## Funder(s)

### Funder type
Government

### Funder Name
NIHR Health Services and Delivery Research (HS&DR) Programme (UK) REF: 11/2003/56

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/12/2015 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |