icnarc intensive care national audit & research centre

free
Family Reported Experiences Evaluation

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

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| Study Sponsor: | **Intensive Care National Audit & Research Centre (ICNARC)** |
| Study funder: | **NIHR Health Services and Delivery Research (HS&DR) Programme** |
| Funder reference: | **11/2003/56** |
| Protocol version: | **Version 1.3** |
| Protocol version date: | **12/02/2014** |

| Role, Name and Position | |
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NHS
National Institute for Health Research

# Administration

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# Protocol Version History

| **Protocol:** | | **Amendments:** | | |
|---|---|---|---|---|
| **Version no.** | **Date** | **Amendment no.** | **Protocol Section (no./title)** | **Summary of main changes from previous version.** |
| V1.1 | 11/04/2013 | 1 | Appendix 1 & 2 | Minor semantic and formatting changes to the FS-ICU and QODD questionnaires |
| V1.2 | 18/10/2013 | 2 | Appendix 1 | Minor semantic changes to the FS-ICU |
| V1.3 | 12/02/2014 | 3 | 1.Protocol summary<br>7.1.Statistics<br>10.3.Study Steering Committee | Update to estimated sample size<br><br>Amendment to Study Steering Committee Chair |

# Contents

# Abbreviations

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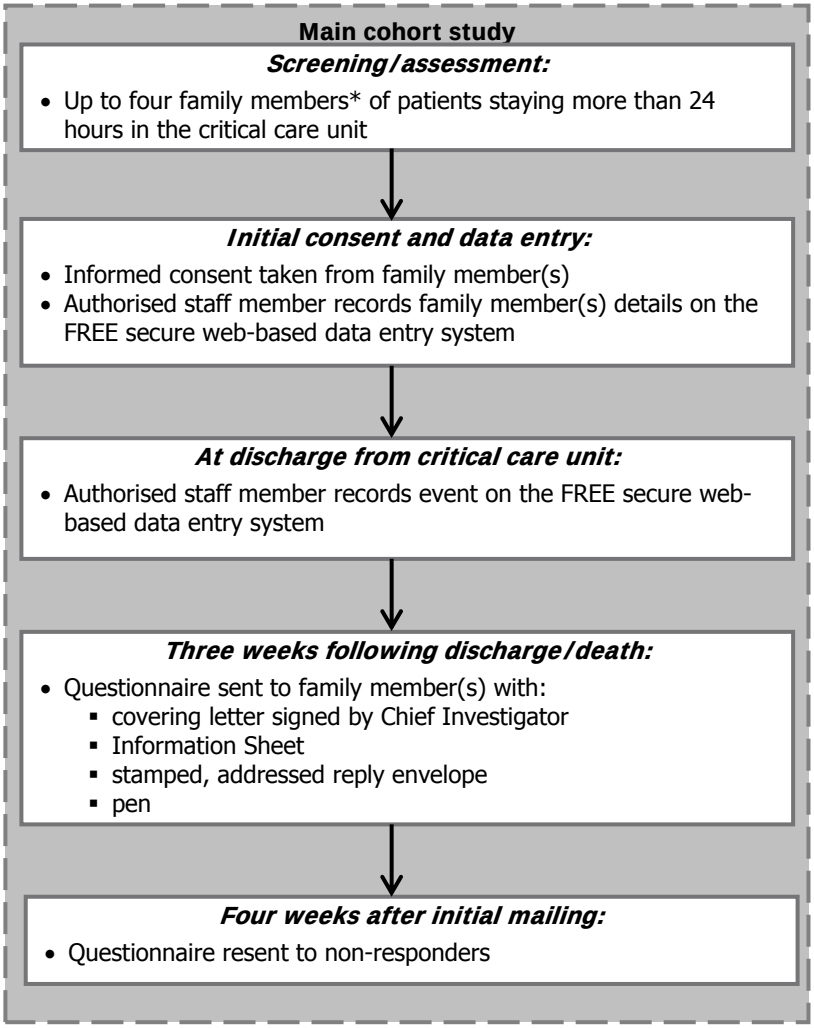
|---|---|
| CMP | Case Mix Programme |
| CTU | Clinical Trials Unit |
| FREE | Family Report Experiences Evaluation |
| FS-ICU | Family Satisfaction in the Intensive Care Unit |
| GCP | Good Clinical Practice |
| HS&DR | Health Services and Delivery Research |
| ICH | International Conference on Harmonisation |
| ICNARC | Intensive Care National Audit & Research Centre |
| MRC | Medical Research Council |
| NHS | National Health Service |
| NIHR | National Institute for Health Research |
| PI | Principal Investigator |
| QODD | Quality Of Dying and Death |
| R&D | Research & Development |
| REC | Research Ethics Committee |
| SMG | Study Management Group |
| SOP | Standard Operating Procedure |

# 1. Protocol summary

## Summary of study design

| | |
|---|---|
| **Title:** | Family Reported Experiences Evaluation (FREE) Study: an evaluation of families' satisfaction with adult critical care services in the NHS |
| **Short Title/acronym:** | Family Reported Experiences Evaluation (FREE) Study |
| **Sponsor name** | ICNARC |
| **Funder name & reference:** | NIHR Health Services & Delivery Research Programme, 11/2003/56 |
| **Design:** | Prospective cohort study |
| **Overall aim:** | 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 |
| **Objectives:** | • The test the face and content validity and the comprehensibility of the FS-ICU<br>• To establish the internal consistency, construct validity and reliability of the FS-ICU<br>• To describe family satisfaction using the FS-ICU and explore how family satisfaction, measured with the FS-ICU, varies by:<br>o family member<br>o patient characteristics<br>o unit/hospital characteristics<br>o other contextual factors; and<br>o country (through comparison with FS-ICU data from Canada)<br>• 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 |
| **Target accrual:** | Approximately 14,200 family members of approximately 7,100 critical care patients |
| **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:<br>• visits the patient at least once after 24 hours<br>• has a UK postal address, and<br>• has not already been recruited into the FREE Study<br>[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] |
| **Exclusion criteria:** | Family member(s) of patients readmitted to the critical care unit |
| **Planned number of units:** | 20 units |
| **Anticipated duration of recruitment:** | 12 months |
| **Duration of follow up:** | Three weeks following discharge from critical care |
| **Definition of end of Study:** | End of study is defined as last questionnaire returned |

**Figure 1 Study flow diagram**




*Family member is defined as a person with close familial, social or emotional relationship to the patient, not restricted solely to next-of-kin.

# 2. Background

In July 2010, the White Paper "Equity and excellence: Liberating the NHS" set out a vision for the NHS that was "genuinely centred on patients and carers" and would "include much wider use of effective tools like… patient experience data and real-time feedback".[1] In addition, the NHS Outcome Framework 2011/12 recognised "ensuring that people have a positive experience of care" as one of the five key domains of quality reflecting "the importance of providing a positive experience of care for patients, service users and carers".[2] In drawing up this Framework, the National Quality Board identified urgent and emergency care as an important area for the development of Quality Standards related to experiences of care.

Historically, the patient had no real voice and professionals judged the quality of healthcare services; now, the patient is central in the hope that this will contribute to quality improvement. Patients offer a complementary perspective to that of clinicians, providing unique information and insights into both the humanity and effectiveness of healthcare. National surveys of patients' experiences of healthcare have become a feature of NHS regulation over the past few years. Patients' views are no longer deemed optional in achieving high quality care[3] but their use is not without some challenges.[4]

Gaining patients' insights into adult critical care, however, poses an additional challenge. Each year, over 100,000 adults are admitted to adult, general critical care units in the NHS and approximately one third do not survive to leave hospital (yet the quality of the dying process is an important aspect of the humanity of critical care). In addition, predominantly because of the severity of their illness, but also due to the treatments used to support them, most patients are unable to participate in discussions regarding their care and, in those that survive, there is often little recollection of the experience in the critical care unit (http://www.healthtalkonline.org – patients' experiences of critical care). Family, therefore, play a vital role (http://www.healthtalkonline.org – family and close friends' experiences of critical care). Rather than restricting insights to a select subgroup of surviving patients who remember the critical care experience and relying on family to act as proxy respondents for those who do not, an alternative approach has been pursued: to seek the views of family directly, thus ensuring coverage for both surviving and non-surviving patients.

With greater recognition and acceptance of the contribution of patients, over the past two decades, there has been a large increase in the development of rigorous instruments (questionnaires) and a burgeoning research literature on their uses and benefits. Family satisfaction with critical care has been described as an abstract concept, by some; while others have gone on to describe it in some detail. The latter indicate that it reflects the extent to which perceived needs and expectations of the family members of critically ill patients are met by healthcare professionals and it may be influenced by many factors including families' expectations, information and communication, family-related factors (such as attitudes towards life and death, and social, cultural and religious background, etc.), hospital infrastructure and process of care.[5] A number of tools have been developed but the most widely validated is the Family Satisfaction in the Intensive Care Unit questionnaire (FS-ICU),[6] (Appendix 1) 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,[6] and subsequently validated in a multicentre study in six sites across Canada.[7] Further studies have addressed the face/content, construct, sensitivity and responsiveness of the instrument.[8] In 2007, it underwent further refinement, including reduction of the number of items from 34 to 24 by identifying items with poor response, poor discrimination (floor/ceiling effects), redundancy (high Cronbach's α) and those measuring another construct (identified by principal component analysis).

The 24 item version increases its feasibility for future administration and performs well in head-to-head comparisons with other measures of ICU quality.[8]

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 checking of psychometric properties. The most common approach to developing cross-cultural instruments is the sequential approach,[9] in which an instrument is initially developed and the psychometric properties are validated in one culture; it is subsequently translated (if necessary) and the properties re-established in other cultures. This approach is exemplified by the International Quality of Life Assessment project, which produced cross-cultural adaptations of the SF-36.[10] By showing that minimum standards (e.g. application of recognised criterion values, replication of original factor structures and tests of discriminant validity) are met across a range of cross-cultural adaptations, and that performance in a new adaptation is similar to that of the original version, one can have greater confidence that the instrument can be considered to have international applicability.[10] The SF-36 has been established as a valid measure for use in the UK following cross-cultural validation and extensive psychometric testing [11;12] and population norms have been derived from large cohorts.[13]

Cross-cultural validation of the FS-ICU has been conducted in North America[8] and Switzerland[14] but not in the UK. The measurement properties of the instrument needs to be fully understood, including interpretation of the scores, what constitutes clinically or socially meaningful differences in scores, as an important and necessary pre-requisite before its introduction into quality improvement programmes in the NHS. In the UK, the feasibility and acceptability of using the FS-ICU has been assessed in a single centre pilot study and, of 146 questionnaires distributed, 95 were returned (response rate 66%) and with 71 (75%) rating the acceptability of the questionnaire as "very good" to "excellent".[15] In addition, if meaningful comparisons of providers are going to be made then other issues need to be addressed: representativeness of the family members included; the sampling frame and sample size required; and the relationship between family experience and patient outcome.

There is no doubt that the benefits of gaining information and insights from family members could revolutionise quality improvement in adult critical care. However, current enthusiasm for involving patients and family members in measuring the humanity and effectiveness of adult critical care should not obscure the challenges. The Family Reported Experiences Evaluation (FREE) Study hopes to address these challenges for adult critical care services in the NHS by measuring family members' views in a systematic and rigorous manner as a first step to incorporating them into clinical practice.

The Department of Health has indicated that patients' views are essential to achieving high quality care.[1-3] The FREE Study directly addresses the challenges of incorporating patients' views in critical care by incorporating family members' views (in recognition of the fact that a representative sample of patients' views is unachievable), into quality improvement of adult critical care services. There is considerable evidence that the need to continue to involve patients/family members will be sustained within policy for the future. The FREE Study is a necessary precursor to directly incorporating routine surveying of family members' views into a quality improvement programme for adult critical care services in the UK Routine feedback should lead to improved organisation and delivery of critical care services in the NHS.

# 3. Study aim and objectives

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

The objectives of the FREE Study are:

- to test the face and content validity and the comprehensibility of the FS-ICU;
- to establish the internal consistency, construct validity and reliability of the FS-ICU;
- to describe family satisfaction using the FS-ICU and explore how family satisfaction, measured with the FS-ICU, varies by:
    - o family member;
    - o patient characteristics;
    - o unit/hospital characteristics;
    - o other contextual factors; and
    - o country (through comparison with FS-ICU data held in Canada);
- 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.

# 4. Study design

The FREE Study is a mixed methods study comprising a psychometric evaluation (FREE-Qual) leading to a multicentre cohort study.

The objectives of the FREE Study will be addressed in two sub-studies.

**FREE-Qual**
FREE- Qual is a qualitative study (see: Section 5) which will address the first objective by testing the face and content validity and the comprehensibility of the validated Canadian FS-ICU. Modifications to the FS-ICU questionnaire will then be made, if required.

**The FREE Study**
FREE is a multicentre cohort study (see: Section 6) which will address the remaining objectives using the UK adaptation of the FS-ICU questionnaire (FREE-Qual).

Staff at twenty adult, general critical care units will identify up to four family members for consecutive patients admitted to their unit who stay more than 24 hours. Family members who consent to take part will be sent a questionnaire three weeks following patient discharge from the critical care unit.

The recruitment period will be one year, chosen to avoid bias from seasonal variation in case mix and workload. A psychometric assessment of the FS-ICU will be undertaken using data collected during the first month.

# 5. FREE-Qual

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| Research Ethics Committee reference: | 12/YH/0415 |
| Sponsor reference: | ICNARC/02/05/12 |
| NIHR CRN Portfolio ID number: | 112459 |
| Protocol version: | 1.0 |
| Protocol version date: | 31 July 2012 |

## 5.1 Objectives

- To test the face and content validity and the comprehensibility of the FS-ICU
- To modify the FS-ICU questionnaire, if required, using the findings from objective one.

## 5.2 Study design

### 5.2.1 "Translation" of FS-ICU questionnaire

The FS-ICU uses North American English. The research team will review the questionnaire and render into UK English any words or items that require 'translation' (e.g. 'junior doctor' for 'resident'). DKH, the developer of the FS-ICU, will advise on whether semantic equivalence has been maintained.

### 5.2.2 Cognitive interviews

Once an agreed UK English version has been achieved, a series of cognitive interviews16 will be conducted with a purposive sample of family members of critically ill patients to establish face and content validity and comprehensibility. The sample will be selected to ensure a spread across socio-demographic factors likely to influence understanding, e.g. age, gender, relationship to ICU patient, level of education, socio-economic status, and whether English is the first language.
The interviews will be undertaken by an experienced Research Associate from the Institute of Health and Society, Newcastle University. The participants will be asked to complete the FS-ICU in 'think aloud' mode to indicate, as they complete the questionnaire, how they are interpreting each item and formulating their response. If interviewees struggle with concurrent think aloud, a cognitive debriefing approach will be adopted instead. Here, the individuals will self-complete the questionnaire, and will then be probed by the researcher as to their interpretation of each item and how and why they chose the response option that they did. At the end of each interview, the interviewee will be asked (a) whether they consider each questions in the FS-ICU to be relevant and important and (b) whether all the main themes related to family satisfaction with critical care have been covered, and if not, what has been omitted. The 'think aloud' interpretation and responses to the debriefing probes will be transcribed, summarised and fed back to DKH, who will advise on whether the interpretation placed on each item was the intended meaning.
Up to 3 rounds of cognitive interviews will take place, each involving 4-8 interviewees (the precise number will depend on whether any fresh insights are emerging from successive interviews). A digital voice recording will be made by the researcher; this will be transcribed, and any details that may identify participants, patients, staff or hospitals will be removed in the transcription process. At the end of each round, question wording will be modified, if necessary, and the new version used in the next round.

### 5.2.3. Focus Groups

A series of 3 focus groups will be undertaken facilitated by the Research Associate.

Two focus groups will be undertaken with multidisciplinary teams of healthcare professionals involved in the delivery of critical care to further inform whether the FS-ICU covers all dimensions they consider relevant, from a family member's perspective, to the quality of critical care (and on which a family member could be expected to have a view). The groups will be representative of the multidisciplinary critical care team – including doctors, nurses, and physiotherapists – and will be selected and conducted in two different geographical regions, the North East of England and London. At the end of a free-ranging discussion, the healthcare professionals will be presented with the FS-ICU and will be asked to comment on the relevance and redundancy of items. Focus group discussions will be recorded, transcribed and thematically analysed. This will provide a further perspective on face and content validity of the FS-ICU.

A third focus group will be undertaken with representatives from the charity ICUsteps (The Intensive Care Unit Support Teams for Ex-Patients, Registered Charity No. 1117033.) This support group, which was founded in 2005 by ex-patients, their relatives and ICU staff, will provide the final perspective on the face and content validity of the FS-ICU. The methods will mirror those for the healthcare professional focus groups.

If findings from the cognitive interviews or focus groups suggest that one or more items from the FS-ICU should be dropped, this will be discussed with DKH and the rationale for deletion or retention recorded. Similarly, if additional content is suggested by family members, healthcare professionals, or representatives from ICUsteps, appropriate items (with the same response format as existing FS-ICU items) will be drafted and tested through further cognitive interviews with family members.

## 5.3 Study procedures

### 5.3.1 Identification of participants

Cognitive Interviews: Critical Care research nurses will identify suitable family members during their daily (Monday to Friday) screening rounds of the 4 adult ICUs in Newcastle Upon Tyne Hospitals NHS Trust.

The inclusion criteria for inviting family members to participate in the cognitive interviews are:

- Have a family member who has spent > 24 hrs on ICU;
- Family member is an adult ( ≥16 years).

The exclusion criteria are:

- Inability of family member to speak and read English (though those for whom English is not their first language will be purposefully included);
- Family member is considered by the research nurse to lack capacity to consent, or the cognitive ability to complete and discuss a questionnaire;
- Family member is considered by the research nurse to be too upset to take part in research;

- Family member has previously taken part in the FREE-Qual study (though the inclusion of multiple family members for a single ICU patient will be allowed).

The aim at this time is to validate a postal questionnaire in UK English so we will not be providing interpreters or translated versions for patients unable to read or speak English. We are keen to include family members whose first language is not English and will purposefully include them in our study. In time, and when established in UK practice, we recognise the need to produce validated translations of the FS-ICU into languages commonly required in the NHS. We will therefore record the number of family members who have to be excluded because of lack of English, and will identify the languages into which the FS-ICU may need to be translated in the future.

Between 5 to 10% of patients are re-admitted to ICU during the same hospital admissions and we do not wish to interview the same family member on more than one occasion.
The research nurses, who are experienced in talking to relatives of critically ill patients, will approach family members and ask them if they are interested in taking part in the study. They will offer a participant information sheet (PIS) and answer any immediate questions. The family members will be given at least 24 hours to consider whether they wish to participate before being asked if they have any further questions and whether they would like complete and sign the 'expression of interest form' to be passed to the Research Associate. This form will request some demographic details – name, age, gender, ethnicity, level of education, socio-economic status, whether English is their first language and their relationship to the patient. The original form will be kept in the Investigator Site File (ISF) and a copy given to the participant.

The research nurses will then pass on a paper copy of the 'expression of interest form' to the Research Associate (RA) at Newcastle University and will notify the RA when the related patient has been discharged from ICU. Three weeks after discharge from ICU the RA will make telephone contact with the family members, if they meet the purposive sampling criteria, and will arrange a meeting at a mutually convenient time and location.

This meeting could either be in the family member's own home or in a quiet interview room at the Freeman Hospital, RVI or Newcastle University as appropriate. The cognitive interviews could take up to one hour to complete and the RA will be guided by the family member as to their comfort and ease with the process. Prior to commencing the interview, the RA will answer any further questions the family member may have and will then ask the family member to sign an informed consent form. The original form will be kept in the Investigator Site File (ISF) and a copy will be given to the participant.

Some family members will inevitably not be needed for interview, either because their relative is still in ICU when the study finished or the RA already had sufficient information from that particular demographic group. In these cases the RA will make contact, explain the reasons and thank the family member for their interest.

The research nurses already have full access to the clinical records of patients on critical care in Newcastle Upon Tyne Hospitals NHS Trust; as such they are best placed to undertake screening. The RA will then only be dealing with family members who have already signed the 'expression of interest' form and consented to having their details released to the RA.

The research nurses will maintain a screening log to avoid asking the same family members more than once. The screening log will include date, bed number, initials of patient and family member, and if they are ineligible or decline, the reasons why (including not being able to speak and read

English). These reasons may provide useful information for the design of the questionnaire/PIS for the full FREE Study and for any subsequent translations required.

**Focus Groups:** invitations will be circulated by email to invite participants (staff members) from within the existing Clinical Critical Care Networks in Newcastle upon Tyne and London. The charity ICUsteps will also be asked to circulate an invitation among its membership. We will then convene 3 separate focus group meetings, of 8 to 12 people, to achieve as representative a sample as possible. For the staff focus groups this will include nurses, doctors and physiotherapists of varying grades of seniority.

## 5.4 Consent

**Cognitive Interviews:** Written informed consent will be taken by the Research Associate at the time of the interview.

**Focus Groups:** Written informed consent will be taken by the Research Associate at the time of the focus group.

### 5.4.1 Withdrawal of Consent

Participants have the right to withdraw from the study at any time, for any reason and without giving a reason. If the family member decides to stop part way through the interview, they will be asked if the data already collected may remain in the study for analysis.

## 5.5 Adverse Events

In the highly unlikely event of a participant becoming unwell or injuring themselves during their participation in this study the research the Research Associate will notify the local PI, who will then notify the Sponsor and the REC as required. Participants in the interviews and focus groups will be reassured that they need not discuss anything they find distressing and that the interview will be temporarily or permanently halted if they become very upset. If the family member indicates the need for on-going help/support the Research Associate will direct them towards their own General Practitioner in the first instance and will also notify the CI.

## 5.6 Data Management

At the time of consent, the participants in the cognitive interviews or focus groups will be allocated a unique study number. This will be used, along with their initials, on the consent form and any other study documentation. All study documentation – screening logs, consent forms, and contact details of family members - will be stored in a locked filing cabinet in a secure office used by the Critical Care Research Teams at the Freeman Hospital and Royal Victoria Infirmary. In transcripts of interviews and focus groups, identifiable data (e.g. names) will be removed or replaced by a pseudonym.

The study documentation from the cognitive interviews and focus groups will be stored securely (locked filing cabinets in rooms with restricted access; password protected computer files) in the Institute of Health and Society, Newcastle University, supervised by Professor Elaine McColl. Following transcription and checking of the audio files and completion of the FREE-Qual Study, the audio files from the cognitive interviews and focus groups will be deleted. No data with the

potential to identify participant, patients, staff or hospitals will be transcribed from the audio files. To this end, in transcripts of interviews and focus groups, identifiable data (e.g. names) will be removed or replaced by a pseudonym.

A study Master File will be set-up, containing all the required documentation – protocol, PIS, consent form, Trust R&D approval, REC approval etc. Once the study is completed all study documentation will be archived by the local PI in the Critical Care Research office for a period of 10 years.

All data generated from this study will be stored in accordance with the Data Protection Act 1998.

# 6. FREE Study

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| Research Ethics Committee reference: | 13/SC/0037 |
| Sponsor reference: | ICNARC/02/06/12 |
| NIHR CRN Portfolio ID number: | 13880 |
| Protocol version: | 1.2 |
| Protocol version date: | 18 October 2013 |

## 6.1 Critical care unit inclusion criteria

To take part in the FREE Study, critical care units must fulfil the following inclusion criteria:

- agreement from the Principal Investigator (PI) to recruit up to four family members for consecutive patients staying more than 24 hours;
- provision of timely data on family members on the FREE secure web-based data entry system;
- commitment to recruit participants for a minimum of 12 months (up to a maximum of 17 months);
- active participation in the Case Mix Programme (CMP).

At each participating unit, a PI will be identified and who will be responsible for the conduct of the study locally.

## 6.2 Selection of units

To ensure a representative sample (e.g. geographical coverage, teaching/non-teaching) of UK critical care units, stratified random sampling will be used to select adult general critical care units.

## 6.3 Family member eligibility criteria

A family member (aged 18 or over) of a patient staying in the critical care unit for more than 24 hours after admission who:

- visits the patient at least once after 24 hours
- has a UK postal address; and
- has not already been recruited into the FREE Study.

Family members of patients readmitted to the critical care unit are excluded.

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

## 6.4 Informed Consent

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 who will provide information about the FREE Study. The first four family members who visit the patient will be approached. Each family member approached will be provided with an Information Sheet which will be supplemented with oral information from authorised staff members about the FREE Study. The Information Sheet will

include information about the purpose of the study, the consequences of taking part or not, data security and funding of the study. Contact details for the local PI will also be included. Family members will be given the opportunity to ask questions.

After the authorised staff member is satisfied that the Information Sheet and Consent Form have been read and understood, they will invite the family member to sign the Consent Form and will then add their own name and countersign in the presence of the family member. A copy of the signed Consent Form will be given to the family member and a copy placed in the Investigator Site File.

## 6.5 Study procedures

The FS-ICU questionnaire (Appendix 1) will be posted to family members, who consent to take part in the study, three weeks after the patient leaves the critical care unit. During the first month of recruitment only, family members of non-surviving patients will also be asked to complete the FS-ICU and QODD questionnaire (Appendix 2). One follow-up mailing will be conducted, four weeks after the original.

## 6.6 Assessments

### 6.6.1 Data collection

The following data will be collected from family members who consent to take part in the study to enable the FS-ICU questionnaire to be posted to them:

- title, initials and surname;
- postal address;
- their relationship to the patient.

In addition, brief demographic data (e.g. age group, ethnic group) will be collected to enable description of the study population.

The following data will be collected to enable the FS-ICU questionnaire to be sent to family member(s), who consent to take part in the study, three weeks after the patient is discharged from the critical care unit:

- date and time of patient admission to the critical care unit;
- date of patient discharge from the critical care unit or date of death in the critical care unit.

## 6.7 Data management

All data collected at participating units will be entered onto the FREE secure web-based data entry system and will be subject to validation checks built into the system. The PI will be responsible for timely and quality data. Collection and entry of data may be delegated to an appropriately trained member of the research team.

All electronic identifiable data will be encrypted and all study documents stored securely either at the participating unit (e.g. signed Consent Forms) or at the ICNARC Clinical Trials Unit (CTU) (e.g. completed FS-ICU questionnaires), as appropriate.

Family members will be asked to return completed questionnaires to the ICNARC CTU. Data from the questionnaires will be entered onto a secure database at ICNARC by trained members of staff. No identifiable information will be recorded on the FS-ICU or QODD questionnaires.

ICNARC is registered under the Data Protection Act 1998 and all ICNARC CTU staff undergo training in data protection and security and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP).

## 6.8 Participant withdrawal

If a family member informs the PI or other staff members that they wish to withdraw from the study, then the PI or authorised staff member will be responsible for ensuring that all data are removed from the FREE secure web-based data entry system.

If a family member returns a questionnaire to the ICNARC CTU indicating that they no longer wish to take part in the study, then all identifiable information (i.e. name and address) will be removed from the FREE secure web-based data entry system and no further questionnaires will be sent.

# 7. Statistics

## 7.1 Sample size and recruitment rate calculation

The duration of recruitment will be one year, chosen to avoid bias from seasonal variation in case mix and workload. Data from the CMP database indicates that an average of 520 patients are admitted per unit, per year, and of these, 74% stay at least 24 hours, corresponding to 7,700 patients (approximately 19,250 family members). Assuming an average of 2.5 family members per patient and a 66% response rate,[15] a total sample of approximately 12,700 responses, associated with 6,700 patients will be achieved. Using available FS-ICU data, published and unpublished, we anticipate mean baseline satisfaction domain scores of 80 with standard deviation 20. This sample size will give >90% power to detect ($p<0.01$) a binary patient factor present in 10% of the patient population associated with an increase or decrease in domain score of 4 points.

The sample size estimate was updated following completion of the first full quarter of recruitment, based on the CMP data submitted for that quarter from the actual participating sites and FREE Study data collected. Revised targets were calculated for each site based on successful recruitment of an average of 2 family members for 80% of patients staying at least 36 hours[1] in the critical care unit, allowing that on average 10% of patients may have no family members visit. Based on these revised targets, we anticipate recruitment of 14,200 family members (of 7,100 patients). Assuming a 60% response rate, a total sample of approximately 8,500 responses associated with 5,500 patients will be achieved. This sample size retains >90% power to detect ($p<0.01$) a binary patient factor present in 10% of the patient population associated with an increase or decrease in domain score of 4 points.

## 7.2 Statistical analysis

**Psychometric assessment**
Once completed questionnaires have been returned from family members recruited during the first month of recruitment (approximately 1000) and the data entered onto a secure database at the ICNARC CTU, a psychometric assessment of the FS-ICU will be rapidly undertaken. If results from the psychometric assessment demand substantive changes to the FS-ICU questionnaire, then these will be incorporated into a new version of the FS-ICU questionnaire and recruitment and data collection will re-commence and continue for 12 months.

The methods used in the psychometric assessment will mirror those employed in the North American validation study[8] and utilise their FS-ICU scoring algorithm. The analysis will comprise the following steps: descriptive analysis; item reduction; factor analysis; reliability analysis; and validity analysis. Brief methods for each step are outlined below.

*Descriptive analysis*
Item descriptive statistics (percentage missing, percentage floor/ceiling scores, frequencies, median and interquartile range) will be computed for each site and all sites combined.

[1] FREE is recruiting family members for all patients staying 24 hours or more, however for the purpose of estimating targets we have excluded patients staying less than 36 hours - given family members of short term patients may not visit before discharge from critical care

*Item reduction*
In adapting an existing validated measure for use in another culture, there is a tension between the desirability of keeping the instrument in its previously validated form and the need to ensure scale integrity, which might require dropping poorly performing items. The following criteria will be used to tag items for possible removal:

- items with high item non-response rates (>10%), suggesting irrelevance or lack of comprehensibility or acceptability;
- items with poorer discrimination (>70% selecting the lowest or highest category);
- redundant items (item to own-scale Cronbach's alpha of 0.8, corrected for overlap); and
- items measuring a construct other than that intended (component loadings <0.4 in principal components analysis).

Items meeting the above criteria will be discussed with Dr Daren Hayland before a final decision on removal.

*Factor analysis*
Confirmatory factor analytic techniques will be used to test the goodness of fit of the two-factor solution for the FS-ICU developed in the North American validation study.[8]

*Reliability analysis*
Internal consistency will be evaluated through calculation of item-total correlations and Cronbach's alpha.[16] Item-total correlations <0.4 or Cronbach's alpha <0.8 will be taken as indicative of potential lack of internal consistency.

*Validity analysis*
The criterion validity of the FS-ICU among family members of non-survivors will be assessed by comparison with the QODD questionnaire.[17] All family members of non-survivors during the first month will be sent a QODD questionnaire along with the FS-ICU. The hypotheses that will be tested are that higher values for the two summary domain scores of the FS-ICU (satisfaction with care and satisfaction with decision-making) are associated with higher values for the overall QODD score, and that scores on four specific items in the QODD (pain control, breathing comfort, care by doctors, care by all providers[8]) will be moderately correlated with FS-ICU scores. No sufficiently well-validated measure exists to conduct a validity analysis of the FS-ICU among family members of critical care survivors.

**Main analysis**
Family satisfaction will be described by summarising the responses to the 24 individual questionnaire items of the FS-ICU and the two summary domain scores for satisfaction with care and satisfaction with decision-making. Variation in satisfaction across the critical care units will be summarised by presenting the domain scores for each unit, anonymised, in the form of funnel plots,[18] both before and after adjustment for family member, patient and unit/hospital characteristics.

Variation in family satisfaction by: family member characteristics (e.g. relationship to the patient); patient/admission characteristics; unit/hospital characteristics; and other contextual factors will be explored using multilevel linear regression modelling. The outcomes for the regression models will be the two domain scores for satisfaction with care and satisfaction with decision-making. Models will be stratified by the survival status of the patient at discharge from the critical care unit. The levels of the model will be: level 1, family member; level 2, patient/critical care unit admission; level 3, unit/hospital. Family member characteristics entered into the models will include: age; sex; and relationship to the patient. Patient/admission characteristics will include: age; sex; severe chronic conditions in the past medical history; surgical status (elective surgery, emergency surgery, non-surgical); acute severity of illness (ICNARC Physiology Score[19]); and length of stay in the critical

care unit. Unit/hospital characteristics will include: teaching status; and number of beds in the critical care unit. Contextual factors will include: month of the year (seasonality). Non-linearity in the relationship between continuous predictors and satisfaction will be modelled using restricted cubic splines.

Variation in family satisfaction by country will be explored by comparing data collected for the FREE study with FS-ICU data from Canada (and available to DKH) in the context of a multilevel linear regression model with a similar structure to that above. Country comparisons will be adjusted for the age, sex and relationship to the patient of the family member and for patient characteristics consistently recorded in the different datasets.

As routinely surveying family members of all patients admitted to a critical care unit would neither be feasible nor cost-effective, understanding the association between patient factors and family satisfaction will enable an appropriately stratified sampling frame to be explored and developed.

A number of potential alternative sampling frames will be constructed based on results of the regression models, and varying the numbers of patients sampled and the timing(s) of the samples within the year. Potential sampling frames include: 100% sampling over a short timeframe; simple random sampling; and random sampling stratified by patient/admission characteristics (e.g. age, sex, survival status, length of stay). The representativeness of the proposed sampling frames will be assessed by assessing the correlation between the FS-ICU domain scores calculated in the sample and in the total population for each critical care unit. Uncertainty in the correlation will be assessed using bootstrapping techniques.

# 8. Ethical compliance

## 8.1 Central ethical compliance

The FREE Study will be conducted in accordance with the approved Study Protocol, ICH GCP guidelines, the Data Protection Act 1998, the Medical Research Council's (MRC) Guidelines for Good Clinical Practice in Clinical Trials and Good Research Practice: Principles and guidelines (which are based on the principles of ICH GCP), as well as the ICNARC CTU's research policies and procedures.

### 8.1.1 FREE-Qual

The study will be conducted in accordance with the ethical principles founded in the Declaration of Helsinki. As family members are being recruited through the NHS, because of their relationship to NHS patients, favourable ethical opinion from an NHS REC as well as full R&D approval will be required before starting this study.

It is anticipated that the key ethical considerations with this study will be around ensuring that the cognitive interviews with the family members are conducted sensitively and respectfully. The family members may well be stressed and worried at the time they are approached by the research nurses. At the time of interview, three weeks after their family member was discharged from ICU, they will have recently gone through a stressful and emotional event and may still have significant caring responsibilities. The critical care research nurses are experienced in approaching families for consent for studies, and have undergone further training in the consent process organised by Northumberland Tyne and Wear CLRN. The Research Associate will also be experienced and skilled in communication with members of the public. In addition, before the family members are contacted by the Research Associate, the research nurses will check the electronic patient record

system of Newcastle upon Tyne Hospitals NHS Foundation Trust to see that their loved one has not died/been readmitted elsewhere after discharge from the ICU. This is to limit the chance of an approach to interview in those cases, if at all possible.

A second consideration is the risk that family members may feel like they themselves, rather than the questionnaire, are been tested, and may feel embarrassed or under pressure if they don't understand the wording of a question. Family members will be reassured that they are not being assessed personally, but rather the aim is to find out whether the questionnaire is understandable and acceptable to people like them.

Otherwise, it is anticipated that the ethical issues are likely to be minimal.

It is important to note that the patients in ICU are not the subjects of the research, they play no role in the FREE-Qual study, except that the fact that they are in ICU for more than 24 hours is a requirement for enrolling their family members into the study.

### 8.1.2 FREE Study

A favourable opinion will be obtained from the appropriate Research Ethics Committee (REC) and Local Research & Development (R&D) approval will be obtained prior to commencement of the study at all sites.

The ICNARC CTU will submit annual progress reports to the REC. Amendments to the Study Protocol will be submitted in writing to the REC for approval.

The FREE Study is nested in the CMP, the national comparative audit of patient outcome from critical care, which will enable investigation into whether or not family satisfaction varies by patient characteristics, such as severity of illness. Support for the collection and use of patient identifiable data has been approved for the CMP by the National Information Governance Board for Health and Social Care (NIGB) under Section 251 of the NHS Act 2006 (originally enacted under Section 60 of the Health and Social Care Act 2001) – Approval Number: PIAG 2-10(f)/2005.

## 8.2 Local ethical compliance

It is the responsibility of the PI to obtain the necessary local approvals for the FREE Study, including approval from the NHS Hospital Trust Research & Development (R&D) department. Evidence of local NHS Hospital Trust R&D approval must be provided to the ICNARC CTU prior to the unit commencing recruitment.

The FREE Study will only be conducted at units where all necessary local approvals for the study have been obtained and a Research Agreement between the NHS Hospital Trust (unit) and the ICNARC CTU has been signed.

## 8.3 Confidentiality and data protection

Family members who agree to participate in the study will be asked to provide their full name and postal address to enable the ICNARC CTU to post the FS-ICU questionnaire to them. This information will be entered and stored securely on a secure web-based data entry system. The ICNARC CTU will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified.

ICNARC is registered under the Data Protection Act 1998 and all ICNARC CTU staff undergo data protection and ICH GCP training.

# 9. Study closure

## 9.1 End of study

The "end of the study" will be when the last family member has completed the FS-ICU questionnaire, at which point the 'declaration of end of study' form will be submitted to the REC by the ICNARC CTU.

## 9.2 Archiving study data

At the end of the study, the ICNARC CTU will archive securely all centrally-held study-related documents and electronic data for a minimum of ten years in accordance with the ICNARC CTU Standard Operating Procedure (SOP) on archiving trial/study data based on ICH GCP guidelines. After 10 years, arrangements for confidential destruction of all documents and data will then be made.

It is the responsibility of local PIs to archive all locally-held study-related and essential documents at the hospital for a minimum of ten years after the end of the study. Essential documents are those which enable both the conduct of the study and the quality of the data produced to be evaluated and to show whether the unit complied with the principles of ICH GCP and other applicable regulatory requirements.

The ICNARC CTU will notify PIs when study documents should be archived and will provide guidance on archiving procedures in the study-specific SOP.

All archived documents, held centrally and locally, should be available for inspection by appropriate authorities upon request.

# 10. Study management

## 10.1 Good research practice

The FREE Study will be managed according to the MRC's Guidelines for Good Clinical Practice in Clinical Trials and Good Research Practice: Principles and guidelines, which are based on the principles of ICH GCP. The ICNARC CTU has developed its own policies and procedures, based on these MRC guidelines, for the conduct of all its research activities. In addition, ICNARC has contractual confidentiality agreements with all members of staff. Policies regarding alleged scientific misconduct and breach of confidentiality are reinforced by disciplinary procedures.

## 10.2 Study Management Group

All day-to-day management of the FREE Study will be the responsibility of the Study Management Group (SMG). Members of the SMG include the FREE Study Coordinator, the Chief Investigators (Professor Kathryn Rowan and Dr Stephen Wright) and the co-investigators. The SMG will meet regularly to discuss management and review progress of the study against timelines/milestones.

### 10.3 Study Steering Committee

The FREE Study will be supervised by the Study Steering Committee, which will be chaired by an independent member, Dr Kathleen Daly, Consultant Nurse, Adult Critical Care Unit, St. Thomas' Hospital.

### 10.4 Role of the ICNARC Clinical Trials Unit

The ICNARC CTU will be responsible for the day-to-day management of the study and will provide study-specific SOPs for all aspects of the study. ICNARC will act as custodian of the data.

## 11. Sponsorship and Indemnity

ICNARC is the sponsor for the FREE Study and holds professional indemnity insurance (Markel International Insurance Co Ltd) to meet the potential legal liability of the sponsor and employees for harm to participants arising from the design and management of the research.

Indemnity to meet the potential legal liability of investigators/collaborators for harm to participants arising from the conduct of the research is provided by the NHS indemnity scheme or through professional indemnity.

## 12. Funding

The FREE Study is funded by the NIHR Health Services & Delivery Research (HS&DR) Programme (Project No. 11/2003/56).

## 13. Dissemination policy

### 13.1 Progress of study

To ensure all stakeholders are kept aware and informed, ongoing progress of the FREE Study will be disseminated to: participating units through newsletters, emails and telephone; to the wider critical care community through relevant professional newsletters, professional meetings and national and international conferences; and to consumers via the ICNARC and ICUsteps websites.

### 13.2 Study results

The results of the FREE Study will be widely and actively disseminated.

Staff from participating units will be invited to a Collaborators' Meeting at which the results of the FREE Study will be presented. All participating units will receive individual, comparative reports on family satisfaction. Variation in family satisfaction across critical care units will be summarised by presenting the domain scores for each unit, anonymised, in the form of funnel plots, both before

and after adjustment for family member, patient and unit/hospital characteristics. Feedback will be elicited from critical care unit staff attending the Collaborators' Meeting on the best mode of presentation with a view to maximizing the potential for using the results to improve quality.

ICNARC has access to both patients and their families and close friends from its recent support and collaboration in three modules (http://www.healthtalkonline.org/Intensive_care/) for the award winning website healthtalkonline (http://www.healthtalkonline.org/) and through its work with ICUsteps, the intensive care patient support charity, on the FREE Study. ICNARC has established strong links with the critical care community, which includes: a large network of NHS critical care units (>200) in the UK through its National Audit Programme and CTU; close links with the Intensive Care Society (ICS), the representative body in the UK for critical care professionals (ICNARC has representation on the ICS Council and membership of the ICS Research Committee); close links with the British Association of Critical Care Nurses (BACCN) and the Royal College of Nursing Critical Care and In-flight Nursing Forum (RCN CCINF); representation on the NIHR Comprehensive Clinical Research Network Critical Care Specialty Group.

The final report to the NIHR HS&DR Programme will present a detailed description of the FREE Study and the results along with recommendations for future policy and practice and future research. The results of the FREE Study will be presented at: regional critical care network meetings; national professional conferences (e.g. ICS, BACCN, RCN CCINF); the Annual Meeting of the ICNARC Case Mix Programme; the Annual Meeting of the UK Critical Care Research Forum; and at national and international critical care conferences/meetings.

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# Appendix 1: FS-ICU

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Family Reported
Experiences Evaluation

## Family Reported Experiences Evaluation
## FREE Study Questionnaire

*The FREE Study aims to help improve intensive care in the NHS using the experiences of family members*

### Completing this questionnaire

Today's date ☐☐/☐☐/☐☐☐☐

Did you complete this questionnaire *(please tick)*
Alone ◯
With help ◯

Approximately how many times did you visit your family member* in the ICU ◯◯ times

** For this study a "family member" is anyone with a close familial, social or emotional relationship to the patient and is not just the next-of-kin.*

***Please post your completed questionnaire in the stamped, addressed envelope provided***

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Family Reported Experiences Evaluation

# *Your opinions about your family member's recent admission to the Intensive Care Unit (ICU)*

- Your family member was a patient in the ICU.
- The questions that follow ask **YOU** about your family member's recent ICU admission.
- We understand that there were probably many doctors, nurses and other staff involved in caring for your family member. We know that there may be exceptions but we are interested in **your overall assessment** of the quality of care delivered.
- We understand that this was probably a very difficult time for you and your family members. We would appreciate you taking the time to provide us with your opinion.
- Please take a moment to tell us what was done well and what could be done to make the ICU better. Please be assured that all responses are confidential. The doctors and nurses who looked after your family member will not be able to identify your responses. If needed, you may add comments to the questionnaire to explain your answer.

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# About you

*Please complete the following to help us know a little about you and your relationship to the patient.*

Q1 I am ○ Male ○ Female

Q2 I am ☐☐☐ years old

Q3 I am the patient's

| | | | |
|---|---|---|---|
| ○ Wife | ○ Husband | ○ Partner | ○ Friend |
| ○ Mother | ○ Father | ○ Sister | ○ Brother |
| ○ Daughter | ○ Son | ○ Aunt | ○ Uncle |
| ○ Niece | ○ Nephew | ○ Grandmother | ○ Grandfather |
| ○ Other | If Other (please specify): | | |

Q4 Are you the patient's next of kin? ○ Yes ○ No

Q5 Before this most recent event, have you been involved as a family member of a patient in an ICU (Intensive Care Unit)? ○ Yes ○ No

Q6 Do you live with the patient?
(If the patient has died, did you live with the patient?) ○ Yes ○ No

If **NO**, then on average how often do you see the patient?
(If the patient has died, how often did you see the patient?)

- ○ More than once a week
- ○ Once a week
- ○ Every 2 weeks
- ○ Once a month
- ○ Every 2 to 3 months
- ○ Every 4 to 6 months
- ○ Once a year
- ○ Less than once a year

Q7 How would you rate your knowledge of the patient's health issues prior to them coming to the ICU?

○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

Q8 How would you rate the ease of travelling from your home to the hospital?

○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

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Family Reported Experiences Evaluation

# Satisfaction with care

*Please tick one box that best reflects your views. If the question does not apply to your family member's stay, then please tick the Not applicable (N/A) box...*

## How did we treat your family member (the patient)?

Q1 **Concern and caring by ICU staff?**

- *The courtesy, respect and compassion your family member (the patient) was given*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

Q2 **Symptom management?**

- *How well the ICU staff assessed and treated your family member's symptoms*

a **- Pain**

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

b **- Breathlessness**

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

c **- Agitation**

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

## How did we treat you?

Q3 **Consideration of your needs?**

- *How well the ICU staff showed an interest in your needs*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

Q4 **Emotional support?**

- *How well the ICU staff provided emotional support*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

Q5 **Concern and caring by ICU staff?**

- *The courtesy, respect and compassion you were given*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

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# Satisfaction with care cont.

*Please tick one box that best reflects your views. If the question does not apply to your family member's stay, then please tick the Not applicable (N/A) box...*

## Teamwork

Q6 **Co-ordination of care?**

- *The teamwork of all the ICU staff who took care of your family member*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

## Nurses

Q7 **Skill and competence of ICU nurses?**

- *How well the nurses cared for your family member*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

Q8 **Frequency of communication with ICU nurses?**

- *How often nurses communicated to you about your family member's condition*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

## Doctors

Q9 **Skill and competence of ICU doctors?**

- *How well doctors cared for your family member*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

## The ICU

Q10 **The atmosphere (mood) of the ICU was?**

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

## The Waiting Room

Q11 **The atmosphere (mood) in the ICU Waiting Room was?**

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

## Level/amount of health care

*(For Q12, please pay attention to the order of the responses)*

Q12 **Some people want everything done for their health problems while others do not want a lot done. How satisfied were you with the LEVEL or amount of health care your family member received in the ICU?**

Very dissatisfied ◯ Slightly dissatisfied ◯ Mostly satisfied ◯ Very satisfied ◯ Completely satisfied ◯

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Family Reported Experiences Evaluation

# Family satisfaction with decision making around care of critically ill patients

***Instructions for family members of critically ill patients***

*This part of the questionnaire is designed to measure how you feel about your involvement in decisions related to your family member's health care.*

*In the Intensive Care Unit (ICU), your family member may have received care from different people. We would like you to think about all the care your family member received when you are answering the questions.*

*Please tick **one** box that best describes your feelings...*

## Information needs

Q1 **Frequency of communication with ICU doctors?**

- *How often doctors communicated to you about your family member's condition*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

Q2 **Ease of getting information?**

- *Willingness of ICU staff to answer your questions*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

Q3 **Understanding of information?**

- *How well ICU staff provided you with explanations that you understood*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

Q4 **Honesty of information?**

- *The honesty of information provided to you about your family member's condition*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

Q5 **Completeness of information?**

- *How well ICU staff informed you what was happening to your family member and why things were being done*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

Q6 **Consistency of information?**

- *The consistency of information provided to you about your family member's condition (did you get a similar story from the doctor, nurse, etc.)*

Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor ◯ N/A ◯

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Experiences Evaluation

# Family satisfaction with decision making around care of critically ill patients cont.

*During your family member's stay in the ICU, many important decisions were made regarding the health care he or she received.*

*For the following questions, pick **one** answer from each of the following set of ideas that best matches your views.*

*If your family member was able to make decisions for themselves while on ICU, then some questions may not be applicable to you; in that case, please tick Not applicable.*

## The process of making decisions

Q7 **Did you feel included in the decision making process?**

- I felt very excluded ◯
- I felt somewhat excluded ◯
- I felt neither included nor excluded ◯
- I felt somewhat included ◯
- I felt very included ◯
- Not applicable ◯

Q8 **Did you feel supported during the decision making process?**

- I felt totally unsupported ◯
- I felt slightly unsupported ◯
- I felt neither supported nor unsupported ◯
- I felt supported ◯
- I felt very supported ◯
- Not applicable ◯

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Experiences Evaluation

# Family satisfaction with decision making around care of critically ill patients cont.

Q9 **Did you feel you had control over the care of your family member?**

- I felt really out of control and that the health care system took over and dictated the care my family member received ◯
- I felt somewhat out of control and that the health care system took over and dictated the care my family member received ◯
- I felt neither in control nor out of control ◯
- I felt I had some control over the care my family member received ◯
- I felt that I had good control over the care my family member received ◯
- Not applicable ◯

Q10 **When making decisions, did you have adequate time to have your concerns addressed and questions answered?**

- I could have used more time ◯
- I had adequate time ◯
- Not applicable ◯

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Family Reported
Experiences Evaluation

# Family satisfaction with decision making around care of critically ill patients cont.

*If your family member died in the ICU, we would like to ask you your opinion on how things went in those final days.*

*We know it may be difficult to answer these questions but we would greatly value your input so we can improve the care we provide to dying patients.*

*Please answer the following questions (11-13)...*
***If your family member did not die, please go to question 14.***

Q11 **Which of the following best describes your views:**

- I felt my family member's life was prolonged unnecessarily ◯
- I felt my family member's life was slightly prolonged unnecessarily ◯
- I felt my family member's life was neither prolonged nor shortened unnecessarily ◯
- I felt my family member's life was slightly shortened unnecessarily ◯
- I felt my family member's life was shortened unnecessarily ◯

Q12 **During the final hours of your family member's life, which of the following best describes your views:**

- I felt that he/she was very uncomfortable ◯
- I felt that he/she was slightly uncomfortable ◯
- I felt that he/she was mostly comfortable ◯
- I felt that he/she was very comfortable ◯
- I felt that he/she was totally comfortable ◯

Q13 **During the last few hours before your family member's death, which of the following best describes your views:**

- I felt very abandoned by the health care team ◯
- I felt abandoned by the health care team ◯
- I felt neither abandoned nor supported by the health care team ◯
- I felt supported by the health care team ◯
- I felt very supported by the health care team ◯

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Family Reported Experiences Evaluation

# Family satisfaction with decision making around care of critically ill patients cont.

Q14 **How satisfied were you with the amount of control you had over the care of your family member?**

| Very dissatisfied | Slightly dissatisfied | Mostly satisfied | Very satisfied | Completely satisfied |
|---|---|---|---|---|
| ◯ | ◯ | ◯ | ◯ | ◯ |

Q15 **Do you have any suggestions on how to make care provided in the ICU better?**

Q16 **Do you have any comments on things we did well?**

Q17 **Please add any comments or suggestions that you feel may be helpful to the staff of this ICU**

***We would like to thank you very much for your participation and your opinions.***

# Appendix 2: QODD

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## *A questionnaire for families about a loved one's experiences at the end of life*

- This questionnaire is about experiences that you and your loved one (family member) had during his or her stay in the ICU.
- We are interested in your experiences because we want to improve the care received by patients and family members.
- Some of these questions may be difficult to answer because you may not have had all these experiences. Other questions may be hard to answer because they remind you of a difficult emotional time. Please feel free to skip questions that you find too difficult to answer.
- This questionnaire will be kept entirely confidential. None of the doctors or nurses who provided care to your loved one will see any of your answers.

- From <u>your</u> perspective, we would like to know how often your loved one had the experiences described.
- Please pick a number from 0 to 5 with "0" indicating "None of the time" and "5" indicating "All of the time". Then, we would like you to rate this aspect of your loved one's dying experience (by this we mean their final days) on a scale from 0 to 10, where "0" is a "Terrible experience" and "10" is an "Almost perfect experience".
- Please make your best effort to choose a number, even if you are not completely certain of the answer. If you cannot pick a number, then please circle "Don't know" so that we will know that this is a question you cannot answer.
- We want you to choose a number based on <u>your</u> experience, not what you think your loved one might have answered.

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# During the last several days that your loved one was in the ICU

Q1a **How often did your loved one appear to have his/her pain under control?**
*Please circle one number*

| | |
|---|---|
| None of the time | 0 |
| A little bit of the time | 1 |
| Some of the time | 2 |
| A good bit of the time | 3 |
| Most of the time | 4 |
| All of the time | 5 |
| Don't know | 6 → *Go to question 2a* |

Q1b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

Q2a **How often did your loved one appear to have control over what was going on around him/her?**
*Please circle one number*

| | |
|---|---|
| None of the time | 0 |
| A little bit of the time | 1 |
| Some of the time | 2 |
| A good bit of the time | 3 |
| Most of the time | 4 |
| All of the time | 5 |
| Don't know | 6 → *Go to question 3a* |

Q2b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

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Experiences Evaluation

# During the last several days that your loved one was in the ICU cont.

Q3a **How often was your loved one able to feed him/herself?**
*Please circle one number*

| | |
|---|---|
| None of the time | 0 |
| A little bit of the time | 1 |
| Some of the time | 2 |
| A good bit of the time | 3 |
| Most of the time | 4 |
| All of the time | 5 |
| Don't know | 6 → *Go to question 4a* |

Q3b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

Q4a **How often did your loved one appear to breathe comfortably?**
*Please circle one number*

| | |
|---|---|
| None of the time | 0 |
| A little bit of the time | 1 |
| Some of the time | 2 |
| A good bit of the time | 3 |
| Most of the time | 4 |
| All of the time | 5 |
| Don't know | 6 → *Go to question 5a* |

Q4b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

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# During the last several days that your loved one was in the ICU cont.

Q5a **How often did your love one appear to feel at peace with dying?**
*Please circle one number*

| | |
|---|---|
| None of the time | 0 |
| A little bit of the time | 1 |
| Some of the time | 2 |
| A good bit of the time | 3 |
| Most of the time | 4 |
| All of the time | 5 |
| Don't know | 6 → *Go to question 6a* |

Q5b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

Q6a **How often did your loved one appear to be <u>unafraid</u> of dying?**
*Please circle one number*

| | |
|---|---|
| None of the time | 0 |
| A little bit of the time | 1 |
| Some of the time | 2 |
| A good bit of the time | 3 |
| Most of the time | 4 |
| All of the time | 5 |
| Don't know | 6 → *Go to question 7a* |

Q6b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

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Family Reported
Experiences Evaluation

# During the last several days that your loved one was in the ICU cont.

Q7a **How often did your loved one laugh and smile?**
*Please circle one number*

| | |
|---|---|
| None of the time | 0 |
| A little bit of the time | 1 |
| Some of the time | 2 |
| A good bit of the time | 3 |
| Most of the time | 4 |
| All of the time | 5 |
| Don't know | 6 → *Go to question 8a* |

Q7b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

Q8a **How often did your loved one appear to keep his/her dignity and self-respect?**
*Please circle one number*

| | |
|---|---|
| None of the time | 0 |
| A little bit of the time | 1 |
| Some of the time | 2 |
| A good bit of the time | 3 |
| Most of the time | 4 |
| All of the time | 5 |
| Don't know | 6 → *Go to question 9a* |

Q8b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

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Family Reported Experiences Evaluation

# During the last several days that your loved one was in the ICU cont.

Q9a **How often did your loved one spend time with his/her family or friends?**
*Please circle one number*

| | |
|---|---|
| None of the time | 0 |
| A little bit of the time | 1 |
| Some of the time | 2 |
| A good bit of the time | 3 |
| Most of the time | 4 |
| All of the time | 5 |
| Don't know | 6 → *Go to question 10a* |

Q9b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

Q10a **How often did your loved one spend time alone?**
*Please circle one number*

| | |
|---|---|
| None of the time | 0 |
| A little bit of the time | 1 |
| Some of the time | 2 |
| A good bit of the time | 3 |
| Most of the time | 4 |
| All of the time | 5 |
| Don't know | 6 → *Go to question 11a* |

Q10b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

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Family Reported
Experiences Evaluation

# During the last several days that your loved one was in the ICU cont.

*The following questions are answered with either a "Yes" or "No" based on whether your loved one did certain activities.*

*Please rate the quality of that aspect of the dying experience. Again, we are asking you to focus on your loved one's last <u>several</u> days.*

Q11a **Was your loved one touched or hugged by his/her loved ones?**
*Please circle one number*

| | | |
|---|---|---|
| Yes | 1 | |
| No | 2 | |
| Don't know | 3 | → *Go to question 12a* |

Q11b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

Q12a **Did your loved one say goodbye to loved ones?**
*Please circle one number*

| | | |
|---|---|---|
| Yes | 1 | |
| No | 2 | |
| Don't know | 3 | → *Go to question 13a* |

Q12b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

Q13a **Did your loved one clear up any bad feelings with others?**
*Please circle one number*

| | | |
|---|---|---|
| Yes | 1 | |
| No | 2 | |
| Don't know | 3 | → *Go to question 14a* |

Q13b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

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Family Reported Experiences Evaluation

# During the last several days that your loved one was in the ICU cont.

Q14a **Did your loved one have one or more visits from the hospital Chaplain or equivalent offering religious or spiritual support?**
*Please circle one number*

Yes 1

No 2

Don't know 3 → *Go to question 15a*

Q14b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

Q15a **Did your loved one have a religious or spiritual service/ceremony before his/her death?**
*Please circle one number*

Yes 1

No 2

Don't know 3 → *Go to question 16a*

Q15b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

Q16a **Did your loved one have a mechanical ventilator (respirator) breathe for him/her?**
*Please circle one number*

Yes 1

No 2

Don't know 3 → *Go to question 17a*

Q16b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

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Family Reported Experiences Evaluation

# During the last several days that your loved one was in the ICU cont.

Q17a **Did your loved one receive dialysis for his/her kidneys?**
*Please circle one number*

| | | |
|---|---|---|
| Yes | 1 | |
| No | 2 | |
| Don't know | 3 | → *Go to question 18a* |

Q17b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |

*Please answer either "Yes" or "No" if your loved one ever experienced the following. Then, rate the quality of this aspect of your loved one's dying experience.*

Q18a **Did your loved one have his/her funeral arrangements in order prior to death?**
*Please circle one number*

| | | |
|---|---|---|
| Yes | 1 | |
| No | 2 | |
| Don't know | 3 | → *Go to question 19a* |

Q18b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |

Q19a **Did your loved one discuss his/her wishes for end of life care with his/her doctor - for example, resuscitation or intensive care?**
*Please circle one number*

| | | |
|---|---|---|
| Yes | 1 | |
| No | 2 | |
| Don't know | 3 | → *Go to question 20a* |

Q19b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |

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Family Reported Experiences Evaluation

# During the last several days that your loved one was in the ICU cont.

Q20a **Was anyone present at the moment of your loved one's death?**
*Please circle one number*

| | | |
|---|---|---|
| Yes | 1 | |
| No | 2 | |
| Don't know | 3 | → *Go to question 21a* |

Q20b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

Q21a **In the moment before your loved one's death, was he/she:**
*Please circle one number*

| | | |
|---|---|---|
| Awake | 1 | |
| Asleep | 2 | |
| In a coma or unconscious | 3 | |
| Don't know | 4 | → *Go to question 22* |

Q21b **How would you rate this aspect of your loved one's dying experience?**
*Please circle one number*

| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |
|---|---|---|---|---|---|---|---|---|---|---|---|---|

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Family Reported
Experiences Evaluation

# During the last several days that your loved one was in the ICU cont.

Q22 **Overall, how would you rate the quality of your loved one's dying?**
*Please circle one number*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Terrible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Almost perfect |

Q23 **Rate the care your loved one received from all doctors and other health care providers (including nurses and other health care professionals) during the last several days of his/her life while in the ICU.**
*Please circle one number*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Worst healthcare possible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Best healthcare possible |

Q24 **Rate the care your loved one received from his/her doctor during the last several days of his/her life while in the ICU.**
*Please circle one number*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Worst healthcare possible | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Best healthcare possible |

***Thank you for taking the time to complete this survey.***

***If you have any comments, please feel free to add them to the margins of the survey or to the space below, or call to talk with study staff.***

***Contat details are provided on the Information Sheet.***

***Thank you again for your help.***

**Comments**

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Family Reported
Experiences Evaluation

## I do not wish to participate

*If you do not wish to complete this questionnaire, please tick the box and return this sheet in the stamped self-addressed envelope provided*

Today's date ☐☐/☐☐/☐☐☐☐

I do not wish to complete this questionnaire ◯
*(please tick)*