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Abstract

Family-Reported Experiences Evaluation (FREE) study: a mixed-methods study to evaluate families' satisfaction with adult critical care services in the NHS

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Background: To improve care it is necessary to feed back experiences of those receiving care. Of patients admitted to intensive care units (ICUs), approximately one-quarter die, and few survivors recollect their experiences, so family members have a vital role. The most widely validated tool to seek their views is the Family Satisfaction in the Intensive Care Unit questionnaire (FS-ICU).

Objectives: To test face and content validity and comprehensibility of the FS-ICU (phase 1). To establish internal consistency, construct validity and reliability of the FS-ICU; to describe family satisfaction and explore how it varies by family member, patient, unit/hospital and other contextual factors and by country; and to model approaches to sampling for future use in quality improvement (phase 2).

Design: Mixed methods: qualitative study (phase 1) and cohort study (phase 2).

Setting: NHS ICUs ($n = 2$, phase 1; $n = 20$, phase 2).

Participants: Health-care professionals, ex-patients, family members of ICU patients ($n = 41$, phase 1). Family members of ICU patients ($n = 12{,}303$, phase 2).

Interventions: None.

Main outcome measures: Key themes regarding each item of the 24-item FS-ICU (FS-ICU-24) (phase 1). Overall family satisfaction and domain scores of the FS-ICU-24 (phase 2).

Results: In phase 1, face validity, content validity and comprehensibility were good. Adaptation to the UK required only minor edits. In phase 2, one to four family members were recruited for 60.6% of 10,530 patients (staying in ICU for 24 hours or more). Of 12,303 family members, 7173 (58.3%) completed the questionnaire. Psychometric assessment of the questionnaire established high internal consistency and criterion validity. Exploratory factor analysis indicated new domains: *satisfaction with care*, *satisfaction with information* and *satisfaction with the decision-making process*. All scores were high with skewed distributions towards more positive scores. For family members of ICU survivors, factors associated with increased/decreased satisfaction were age, ethnicity, relationship to patient, and visit frequency, and patient factors were acute severity of illness and invasive ventilation. For family members of ICU non-survivors, average satisfaction was higher but no family member factors were associated with increased/decreased satisfaction; patient factors were age, acute severity of illness and duration of stay. Neither ICU/hospital factors nor seasonality were associated. Funnel plots confirmed significant variation in family satisfaction across ICUs. Adjusting for family member and patient characteristics reduced variation, resulting in fewer ICUs identified as potential outliers. Simulations suggested that family satisfaction surveys using short recruitment windows can produce relatively unbiased estimates of average family satisfaction.

Conclusions: The Family-Reported Experiences Evaluation study has provided a UK-adapted, psychometrically valid questionnaire for overall family satisfaction and three domains. The large sample size allowed for robust multilevel multivariable modelling of factors associated with family satisfaction to inform important adjustment of any future evaluation.

Limitations: Responses to three free-text questions indicate the questionnaire may not be sensitive to all aspects of family satisfaction.

Future work: Reservations remain about the current questionnaire. While formal analysis of the free-text questions did not form part of this proposal, brief analysis suggested considerable scope for improvement of the FS-ICU-24.

Study registration: Current Controlled Trials ISRCTN47363549.

Funding details: The National Institute for Health Research Health Services and Delivery Research programme.

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List of abbreviations

APACHE	Acute Physiology and Chronic Health Evaluation
CD	coefficient of determination
CFI	comparative fit index
CI	confidence interval
CLRN	comprehensive local research network
CMP	Case Mix Programme
CRN	Clinical Research Network
CTU	Clinical Trials Unit
FREE	Family-Reported Experiences Evaluation
FS-ICU	Family Satisfaction in the Intensive Care Unit questionnaire
ICNARC	Intensive Care National Audit & Research Centre
ICU	intensive care unit
ICUsteps	Intensive Care Unit Support Teams for Ex-Patients
IQR	interquartile range
NIHR	National Institute for Health Research
NVQ	National Vocational Qualification
PI	principal investigator
QODD	Quality of Dying and Death
R&D	research and development
RMSEA	root-mean-squared error of approximation
SAPS	Simplified Acute Physiology Score
SD	standard deviation
SMG	Study Management Group
SSC	Study Steering Committee
TLI	Tucker–Lewis index

Plain English summary

What was the problem/question?

To improve care in the NHS, the experiences of patients need to be fed back to the managers organising the care and the doctors and nurses providing the care. This is difficult for intensive care units (ICUs). Roughly one-quarter of the patients die. Few survivors remember their experiences. It is therefore important for family members to provide feedback on their satisfaction with the ICU.

What did we do?

First, we adapted the Canadian Family Satisfaction in the Intensive Care Unit questionnaire for the UK. We checked if the questions were relevant, easy to understand and important to family members in the UK. We then invited over 12,000 family members (of adult patients staying 24 hours or more in 20 ICUs across the country) to complete the UK version of the questionnaire after their relative left the ICU.

What did we find?

More than 7100 family members (close to 60%) filled in the questionnaire. The results showed that the questionnaire was useful in measuring family satisfaction. We also found that family members whose relative passed away were more satisfied with the ICU than family members whose relative survived.

What does this mean?

Our version of the questionnaire could be used to measure family satisfaction in the future. However, more work needs to be done to make sure it picks up all the important details of family satisfaction. As so many people took part, we can now bring all of their information together (such as their age and how ill the patient was) to help improve family satisfaction in the ICU.

Scientific summary

Background

Historically, the patient had no real voice and professionals judged the quality of health-care services; now, the patient is central in the hope that this will contribute to quality improvement. Each year, over 100,000 adults are admitted to adult general intensive care units (ICUs) in the NHS; approximately one-quarter do not survive to leave hospital and patients who do survive often have little recollection of their experience. Families, therefore, play a vital role.

A number of tools have been developed to seek the views of family members but the most widely validated is the Family Satisfaction in the Intensive Care Unit questionnaire (FS-ICU), which assesses overall family satisfaction and purports to measure two main conceptual domains: *satisfaction with care* and *satisfaction with decision-making*.

Objectives

The aim of the Family-Reported Experiences Evaluation (FREE) study was to inform future use of the FS-ICU questionnaire in quality improvement programmes in adult general ICUs in the UK NHS.

The objectives are:

- to test face and content validity and 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 varies by family member, patient, unit/hospital and other contextual factors and by country
- to model approaches to sampling to achieve representative sampling for future use of the FS-ICU in quality improvement in the NHS.

Methods

A mixed-methods study: a qualitative study to address the first objective above (phase 1) and a cohort study to address the remaining objectives (phase 2).

Phase 1

The qualitative study comprised:

- four focus groups with health-care professionals and with representatives from the charity Intensive Care Unit Support Teams for Ex-Patients
- cognitive interviews (up to three rounds) with family members of ICU patients.

Data from the focus groups were analysed by item of the 24-item FS-ICU (FS-ICU-24). The key themes and comments from each were summarised to inform potential changes to the questionnaire. Cognitive interviews involved four to eight participants. At the end of each round, any wording of items was modified, if necessary, and it was then tested in subsequent rounds. Interviews continued until no fresh insights emerged. Family members for the cognitive interviews were purposively selected to ensure a spread across sociodemographic factors likely to influence understanding of the FS-ICU-24.

Phase 2

The cohort study was a multicentre study nested in the Case Mix Programme (CMP), the national clinical audit of adult general ICUs in England, Wales and Northern Ireland. All ICUs actively participating in the CMP were invited to express interest in taking part. A stratified random sample was chosen to select 20 representative adult general ICUs and to minimise selection bias.

A family member was defined as a person who had a close familial, social or emotional relationship to the patient and was not restricted solely to next of kin. Family members of patients who spent 24 hours or more in a participating ICU were eligible if they were aged ≥ 18 years, had physically visited the patient's bedside at least once after 24 hours and had a UK postal address. Up to four eligible family members per patient could be invited to take part. The recruitment period was 12 months, chosen to avoid potential bias from seasonal variation. To minimise selection bias, the first four family members to visit the patient after 24 hours were identified and were asked for consent to participate. Patients for whom at least one family member had been recruited were followed up to discharge from ICU. A secure web portal, hosted by the Intensive Care National Audit & Research Centre (ICNARC), was set up to enable staff at participating ICUs to enter patient and family member data. Approximately 3 weeks after the patient had been discharged from, or died in, the ICU, a questionnaire pack was sent (during the first month of recruitment, family members of non-surviving patients were additionally sent the Quality of Dying and Death questionnaire). Translation was conducted, on request. If no response was received within 4 weeks, then a reminder was sent with another questionnaire pack. No further follow-up of family members was made. Data from completed questionnaires were entered centrally into a secure database at the ICNARC Clinical Trials Unit. Questionnaire data were linked to CMP data prior to analysis.

Results

Phase 1

Face and content validity and comprehensibility of the FS-ICU were good and adaptation to the UK setting required only relatively minor edits: changes to section heading titles, clarification of wording of questions, clarification of North American to UK English, addition to existing guidance, general formatting and enhanced design of the layout.

Phase 2

Overall, at least one family member was recruited for 60.6% ($n = 6380$) of the 10,530 patients who stayed in the ICU for 24 hours or more and who were visited in the ICU by one or more eligible family members. Recruitment varied across ICUs, ranging from 41.2% to 79.4%.

Overall, an average of two family members per patient were recruited and the first family member was recruited within a median of 2 days (interquartile range 1–3 days) of patient admission to ICU. Of 12,303 family members who were sent a questionnaire pack, a total of 7173 (58.3%) completed and returned the questionnaire, varying across ICUs from 48.9% to 73.8%.

Family member response varied by age group (37.7% for < 30 years of age compared with 74.6% for the 60–69 years age group); by gender (61.6% for females compared with 53.8% for males); by ethnicity (59.9% for white compared with 40.8% for Asian and 35.0% for black ethnicity); by level of deprivation, based on postcode (52.7% for the most deprived compared with 63.9% for the least deprived); by education (a trend for higher response with increasing level of education); and by relationship to the patient – highest for patient's partner (70.0%) or parent (64.1%). Family members documented in ICU records as next of kin or who lived with the patient were more likely to complete the questionnaire (66.1% and 65.0%, respectively) than those who were/did not (53.4% and 55.6%, respectively). Family members for whom English was their first language were more likely to complete the questionnaire (59.1%) than those for whom it was not (42.7%).

Psychometric assessment established that the questionnaire has a high degree of internal consistency, demonstrated by Cronbach's alpha > 0.9 for the overall family satisfaction score and for both domain scores, and has criterion validity among family members of non-survivors (no suitable instrument was available for family members of survivors). Although response rates were lower for some items, there was no evidence that this represented a lack of comprehensibility or acceptability. There was some evidence of redundancy among items within each domain; however, the detail of knowing which particular items scored higher or lower was considered to be important for its applicability to drive quality improvement. Substituting an alternative item on satisfaction with the amount of control (from phase 1) led to only a minor increase in Cronbach's alpha for the overall family satisfaction score and the *satisfaction with decision-making* domain score. The two-factor solution for the original FS-ICU-24, with domains of *satisfaction with care* and *satisfaction with decision-making*, was not a good fit with the FREE study data, and exploratory factor analysis suggested the domain of *satisfaction with decision-making* encompassed two separate constructs, which we have termed *satisfaction with information* and *satisfaction with the decision-making process*.

The original FS-ICU scores – overall family satisfaction score and two domain scores *satisfaction with care* and *satisfaction with decision-making* – were generated and reported. The two further domain scores, informed by the results of the full psychometric assessment, were also generated and reported across five different populations. The populations were:

- all returned questionnaires (any items answered for a given score)
- complete returned questionnaires (all items answered for a given score)
- incomplete returned questionnaires (any items unanswered for a given score)
- returned questionnaires with ≥ 70% items answered for a given score
- returned questionnaires with ≥ 60% items answered for a given score.

A response of ≥ 70% to items for a given score reflected the traditional approach to scoring the FS-ICU questionnaire and a response of ≥ 60% to items for a given score reflected updated results from the psychometric assessment. Scores from complete questionnaires provided the highest mean and median values for overall and domain family satisfaction scores. Overall and domain scores were high (mean values ranging from 76 to 88 across overall and domain scores) and all showed a left-skewed distribution. Values from the traditional approach to scoring, defined by a response of ≥ 70% to items, did not differ when defined by a modified response rate of ≥ 60%.

Levels of non-response to items varied considerably, particularly with regard to responses of 'not applicable'. A complete-case analysis, using only family members who completed all 24 items, would therefore be based on only 59% of respondents, giving considerable potential for bias, particularly as the complete responders tended to have higher levels of satisfaction. Using an item-level approach to multiple imputation of missing values resulted in scores with a similar distribution to alternative approaches but it enabled inclusion of all responders, regaining potentially important information from the family members who completed fewer than 60% of items.

Family satisfaction was substantially higher for family members of ICU non-survivors than for family members of ICU survivors and this, in combination with the potential for factors to have different relationships with satisfaction for ICU survivors and non-survivors, led us to select a stratified approach to the subsequent analysis to identify determinants of family satisfaction, developing separate models for ICU survivors and non-survivors.

Determinants of family satisfaction varied by whether or not the patient survived the ICU. Factors associated with overall family satisfaction for family members of ICU survivors were family members' age, ethnicity, relationship to patient (next of kin and/or living with patient) and visit frequency, and patients' acute severity of illness and receipt of invasive mechanical ventilation. There were no family member factors associated with overall family satisfaction for family members of ICU non-survivors; the patient factors were age, acute severity of illness and duration of stay. Despite the large size of the FREE study, there was some indication that the smaller sample size of family members of ICU non-survivors may have hindered identification of other factors seen for family members of ICU survivors, for example ethnicity. Neither the ICU/hospital factors nor seasonality were associated with overall family satisfaction.

Funnel plots of overall family satisfaction scores and domain scores confirmed that there was significant variation in family satisfaction across the ICUs. Multiple imputation provided greater power to identify potentially outlying ICUs. Adjusting for family member and for patient characteristics using the multilevel multivariable models reduced variation across ICUs and resulted in fewer ICUs being identified as potential outliers. Adjustment is, therefore, important to avoid falsely identifying ICUs as outliers because of the characteristics of either their patients or their family members.

Limited to the confines of the FREE study (patients staying in the ICU for 24 hours or more and timing/administration of questionnaires), simulations suggested that family satisfaction surveys using short recruitment windows can produce relatively unbiased estimates of the ‘true’ average family satisfaction. Recruitment windows may need to be 6 weeks or longer to obtain sufficient sample size from smaller ICUs, though an alternative approach – whereby each ICU recruits until a fixed sample size is reached – gave more stability in the precision of the estimated family satisfaction scores across ICUs. Recruiting each patient’s nominated next of kin resulted in higher response rates and is likely to be the preferred approach. Recruiting family members of only patients who stayed in the ICU for at least 48 hours also resulted in higher recruitment rates. Given no association with seasonality, timing of satisfaction surveys appeared to be unimportant.

Comparison with other studies using the FS-ICU-24, internationally, indicated the strengths of the FREE study. Other than the requirement for a patient to be in the ICU for 24 hours, no further selection of patients or of family members occurred: first, to avoid biases that selection might introduce and, second, to provide an empirical basis to inform selection of patients and family members in future studies evaluating family satisfaction in ICUs using the FS-ICU-24 or equivalent, to maximise recruitment and response. A further strength of the FREE study was the use of evidence-based practice for maximising response to postal surveys, which yielded a very similar response rate to other studies but in a much larger sample size of family members. Employing the same mode and timing of delivery of the FS-ICU-24, for family members of both ICU survivors and ICU non-survivors, is a further strength, allowing meaningful comparison between the groups. The large sample size has allowed important multilevel multivariable modelling of the determinants of family satisfaction and indicates that all previous studies have been too small and, therefore, underpowered when attempting to evaluate these. One weakness of the FREE study was the burden on ICUs to recruit up to four family members for each patient staying 24 hours or more over a 12-month period and the resultant recruitment rate.

Conclusions

The FREE study has provided a UK-adapted, psychometrically valid questionnaire providing an overall family satisfaction score and three domain scores: *satisfaction with care*, *satisfaction with information* and *satisfaction with the decision-making process*. The large sample size of family members has allowed robust multilevel multivariable modelling of factors associated with overall family satisfaction to inform important adjustment of any future evaluation using this questionnaire. Finally, a potential sampling frame has been proposed for routine use.

Reservations remain, however, about the current UK FS-ICU-24 questionnaire. In addition to the high mean overall family satisfaction and domain scores it generated, leaving little room for even higher scores to indicate the impact of any improvement measures, other, more qualitative data collected as part of the FREE study indicate that the questionnaire may not be sensitive to all aspects of family satisfaction. While formal analysis of these more qualitative data did not form part of this proposal, brief analysis has indicated that there may be scope for considerable improvement and that (1) a detailed analysis of the rich data generated as part of the FREE study, combining both quantitative and qualitative elements, is warranted and (2) primary research to test the utility of the new questionnaire focusing on its ability to detect change, that is its sensitivity, would be useful.

The FREE study and the FREE study database are an important foundation and resource for future studies evaluating family satisfaction in UK critical care.

Study registration

This study is registered as ISRCTN47363549.

Funding

Funding for this study was provided by the Health Services and Delivery Research programme of the National Institute for Health Research.

Chapter 1 Introduction

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' (p. 8) and would 'include much wider use of effective tools like . . . patient experience data and real-time feedback' (p. 14).[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' (p. 24).[2] In drawing up this framework, the Department of Health noted that 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 health-care 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 the effectiveness of health care. National surveys of patients' experiences of health care have become a feature of NHS regulation. 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 intensive care, however, poses an additional challenge. Each year, over 100,000 adults are admitted to adult general intensive care units (ICUs) in the NHS and approximately one-quarter do not survive to leave hospital (yet the quality of the dying process is an important aspect of the humanity of intensive care). In addition, predominantly because of the acute severity of their illness, but also because of the treatments used to support them, patients who survive often are unable to participate in discussions regarding their care, as they have little recollection of the experience in the ICU.[5] Families, therefore, play a vital role.[6] Rather than restricting insights to a select subgroup of surviving patients who remember their intensive 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 members directly, thus ensuring coverage for both surviving and non-surviving patients.

With greater recognition and acceptance of the contribution of patients, since the middle of the 1990s, there has been a large increase in the development of instruments (questionnaires) and a burgeoning research literature on their uses and benefits. Some have described family satisfaction with intensive care as an abstract concept, 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 health-care professionals, and that it may be influenced by many factors including families' expectations, information and communication, family-related factors (such as attitudes towards life and death, social, cultural and religious background, etc.), hospital infrastructure and process of care.[7] A number of tools have been developed but the most widely validated is the Family Satisfaction in the Intensive Care Unit questionnaire (FS-ICU)[8] (see *Appendix 1*), which assesses family satisfaction and purports to measure two main conceptual domains: *satisfaction with care* and *satisfaction with decision-making*.

The original FS-ICU, developed in Canada, consisted of 34 items, which were generated from conceptual frameworks of patient satisfaction, quality end-of-life care, existing research on needs of critically ill families, existing literature on family satisfaction or dissatisfaction with medical decision-making, existing validated satisfaction surveys and a pilot study.[8] The questionnaire was designed with two conceptual sections. The first section broadly assessed overall quality of care (18 items) and the second section assessed satisfaction with decision-making (16 items). Following initial validation in a single hospital setting in Ontario, Canada, it was subsequently validated in a multicentre study in six sites across Canada.[9,10]

Further studies have addressed the face/content, construct, sensitivity and responsiveness of the FS-ICU.[11] 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) or redundancy (high Cronbach's alpha) and those measuring another construct (identified by principal component analysis). The 24-item version (FS-ICU-24) increases its feasibility for future administration and performed well in head-to-head comparisons with other measures of ICU quality.[11]

It is widely acknowledged that cultural and linguistic differences between, and even within, countries means 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,[12] 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 Short Form questionnaire-36 items (SF-36).[13] 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.[13] The SF-36 has been established as a valid measure for use in the UK following cross-cultural validation and extensive psychometric testing[14,15] and population norms have been derived from large cohorts.[16]

Cross-cultural validation of the FS-ICU has been conducted in North America[11] and Switzerland[17] but has not been undertaken in the UK. The measurement properties of the instrument need to be fully understood, including interpretation of the scores and what constitute clinically or socially meaningful differences in scores, as an important and necessary prerequisite 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%), with 71 (75%) rating the acceptability of the questionnaire as 'very good' to 'excellent'.[18] 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.

The Department of Health has indicated that patients' views are essential to achieving high-quality care.[1–3] The Family-Reported Experiences Evaluation (FREE) study directly addresses the challenges of incorporating patients' views in intensive care by incorporating family members' views (in recognition of the fact that a representative sample of patients' views is unachievable) into improving the quality of adult intensive care services. There is no doubt that the benefits of gaining information and insights from family members could revolutionise quality improvement in adult intensive care and 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 any direct incorporation of routine surveying of family members' views into a quality improvement programme for adult intensive care services in the UK.

The overall aim of the FREE study was to inform valid, representative and cost-effective future use of the FS-ICU questionnaire into quality improvement programmes for adult intensive care services in the NHS in the UK. The objectives 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
    - family member characteristics
    - patient characteristics
    - unit/hospital characteristics
    - other contextual factors
    - country
- 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.

The FREE study was a mixed-methods study divided into two phases directly related to the objectives as follows:

- phase 1 – a preliminary, qualitative study to address the first objective above
- phase 2 – a cohort study to address the remaining objectives.

Chapter 2 Phase 1 of the Family-Reported Experiences Evaluation study

Introduction

Phase 1 of the FREE study was a preliminary, qualitative study with the following objectives:

1. to test the face and content validity and the comprehensibility of the original FS-ICU-24 questionnaire[11] (see *Appendix 1*)
2. to modify the FS-ICU-24, if required, for the UK setting/use in phase 2.

This chapter reports the methods and results of phase 1 of the FREE study.

Methods

The FS-ICU-24 is divided into sections as follows:

- demographics – six questions asking for information about the respondent and their relationship to the patient
- part 1: satisfaction with care – 14 items that contribute to the overall family satisfaction score and the *satisfaction with care* domain score
- part 2: family satisfaction with decision-making around the care of critically ill patients – 10 items that contribute to the overall family satisfaction score and the *satisfaction with decision-making* domain score.

In addition to the above, the following questions are included at the end of part 2: family satisfaction with decision-making around the care of critically ill patients:

- three questions for family members of patients who died in the ICU, asking for their views on the end-of-life care of the patient
- three questions providing the respondent with an opportunity to provide comments to the ICU on how to make care provided in the ICU better and things that were done well; and suggestions that the respondent feels might be helpful to the ICU staff.

To test the face and content validity and the comprehensibility of the FS-ICU-24, this qualitative study comprised:

- focus group discussions with health-care professionals and with representatives from the charity Intensive Care Unit Support Teams for Ex-Patients (ICUsteps)
- cognitive interviews with family members of critically ill patients.

Research governance

The FREE study was sponsored by the Intensive Care National Audit & Research Centre (ICNARC) and phase 1 was co-ordinated by the Newcastle Clinical Trials Unit (CTU). An ethics application was made to the National Research Ethics Service Yorkshire and the Humber Research Ethics Committee on 14 August 2012 and received a favourable opinion on 17 October 2012.

The National Institute for Health Research (NIHR) Clinical Research Network (CRN) Portfolio details high-quality clinical research studies that are eligible for support from the NIHR CRN in England. The FREE study was adopted onto the NIHR CRN Portfolio on 14 September 2012.

Global NHS permissions were obtained from the lead comprehensive local research network (CLRN) – Northumberland, Tyne and Wear – and local NHS permissions were obtained for the two NHS hospital trusts that participated in phase 1. A study site agreement, based on the model agreement for non-commercial research in the health service, was signed by each participating NHS hospital trust and the sponsor (ICNARC).

Study management

Phase 1 of the study was led by EM (coinvestigator) and SW (lead clinical investigator) with support from the Study Management Group (SMG), which comprised the chief investigator (KR) and other coinvestigators (DAH, SH, DKH, LH, AR, MR). An experienced research associate was employed to conduct, transcribe and analyse the focus group discussions and cognitive interviews.

Recruitment of NHS hospital trusts

Two NHS hospital trusts were recruited to take part in the study: one in Newcastle upon Tyne and one in London.

Focus groups

Four focus group discussions were conducted with:

1. health-care professionals involved in the delivery of intensive care (to inform whether or not the FS-ICU-24 covered all dimensions relevant to the quality of intensive care in the NHS and on which a family member might be expected to have a view and the relevance and redundancy of items)
2. representatives from ICUsteps (for a further perspective on the face and content validity of the FS-ICU).

Recruitment of health-care professionals

An invitation was sent by e-mail to health-care professionals working in ICUs within the North of England Critical Care Network and within the participating NHS hospital trust in London for expressions of interest to take part in a focus group discussion. Two focus group discussions were held; one was held in Newcastle upon Tyne and the other was held in London. The aim was to recruit between 8 and 12 participants for each focus group discussion, ensuring a representative sample of the multidisciplinary intensive care team including doctors, nurses, physiotherapists and other allied health-care professionals of varying grades of seniority.

Recruitment of representatives from Intensive Care Unit Support Teams for Ex-Patients

The charity ICUsteps circulated an invitation among its membership (which includes ex-patients, their family members and health-care professionals working in intensive care) for expressions of interest to take part in a focus group discussion. Two focus group discussions were held; one was held in Milton Keynes and the other was held in South Tyneside. The aim was to recruit between 8 and 12 participants representing patients, family members and health-care professionals working in intensive care.

Informed consent

Before focus group discussions commenced, participants were provided with written information about the study and informed that the focus group discussion would be recorded using a digital voice recorder and transcribed. Participants were informed that any information that could identify themselves, patients, hospitals or health-care professionals would be removed during the transcription process and that, following transcription of the discussion, the digital recording would be destroyed. Participants were invited to sign a consent form, which was countersigned in their presence by the research associate. One copy was given to the participant and one copy was filed in the investigator site file.

Conduct of the focus groups

The focus group discussions were facilitated by the research associate. At the beginning of each discussion, ground rules (e.g. that all views were welcome, that one participant should speak at a time and that confidentiality should be observed by all participants) were established and agreed by the group.

Health-care professionals

The focus group discussions started with a free-ranging discussion on the quality of intensive care. The participants were then presented with the FS-ICU-24 and asked to comment on the relevance and redundancy of each of the items. Participants were also asked to consider whether or not the FS-ICU-24 covered all dimensions they considered relevant to the quality of intensive care and on which a family member might be expected to have a view.

Representatives from Intensive Care Unit Support Teams for Ex-Patients

The focus group discussions started with a general discussion on participants' experiences of intensive care. The participants were then presented with the FS-ICU-24 and asked to comment on whether or not the questions were relevant and important to their experience and whether or not all the main themes related to their views of family satisfaction with intensive care were covered, and, if not, what was omitted.

Transcription

The digital recordings of the focus group discussions were transcribed by the research associate. All identifiable information, such as names (e.g. of patients, family members or intensive care staff members), was removed. Once transcriptions were complete, the digital recordings were destroyed (confidentially).

Data analysis

Data from the focus group discussions were analysed by FS-ICU-24 item. The key themes and comments from each of the discussions were summarised for each of the FS-ICU-24 items by the research associate and reviewed by EM and SW in consultation with DKH. Any potential changes to the questionnaire that were indicated following the focus group discussions were discussed with the wider SMG before any changes were made.

Cognitive interviews

Up to three rounds of cognitive interviews were planned, each involving four to eight participants.[19] At the end of each round of interviews, the findings were reviewed by the research associate with EM and SW. The wording of items was modified, if necessary, and then tested in subsequent rounds of interviews. Interviews continued until no fresh insights emerged.

Participants: family members

Family members for the cognitive interviews were purposively selected to ensure a spread across sociodemographic factors likely to influence understanding of the FS-ICU-24, including age, sex, relationship to the patient, level of education, socioeconomic status and whether or not English was the first language (while translation was used in phase 2 of the FREE study, phase 1 was restricted to English speakers only).

Family members of patients admitted to three ICUs within the NHS hospital trust in Newcastle upon Tyne were invited to take part. As planned for phase 2 of the FREE study, a family member was defined as a person who had a close familial, social or emotional relationship to the patient and was not restricted solely to next of kin. Family members of patients who had spent 24 hours or more in a participating ICU were eligible to take part in the study if they were aged 16 years or more, unless they:

- were unable to speak and read English
- were considered by the research nurse to lack capacity to provide informed consent or the cognitive ability to complete and discuss the FS-ICU-24
- were considered by the research nurse to be too distressed to be approached about a research study
- had previously taken part in the study.

Screening and recruitment

Trained intensive care research staff identified and approached potentially eligible family members about participating. Verbal information about the study was provided to the family member, which included the purpose of the study, the consequences of participating, data security and funding. This information was also provided in a participant information sheet, along with the name and contact details of the lead investigators for phase 1 of the FREE study (EM and SW).

Family members were given at least 24 hours to consider whether or not they wished to participate. Once the research nurse was satisfied that the family member had read and understood the participant information sheet and that all of their questions about the study had been answered, the family member was invited to complete and sign the expression of interest form, which was passed on to the research associate. The expression of interest form requested the following demographic information to inform the purposive sampling: full name and contact details; age; sex; relationship to the patient; level of education; occupation; whether or not English was their first language; and ethnicity. The original completed expression of interest form was filed in the investigator site file, a copy was given to the participant and a copy was given to the research associate.

The research nurse notified the research associate of the patient's discharge from, or death in, the ICU. If the family member met the purposive sampling criteria, the research associate telephoned them 3 weeks later to invite them to participate in a cognitive interview. If the family member agreed, then a meeting was arranged at a mutually convenient time and location: either the family member's home or a quiet interview room at one of the hospitals within the NHS hospital trust or at Newcastle University.

Of the family members who expressed an interest in taking part in the study, there were some who were not needed for interview, either because the patient was still in the ICU when the study ended or because interviews had already been conducted with family members from their demographic group. In these cases, the research associate contacted the family member to explain and thank them for their interest in the study.

Conduct of the cognitive interviews

Before the interview started, the participant was asked by the research associate for permission to record the interview using a digital voice recorder and for the interview to be transcribed. Participants were informed that any information that could identify themselves, the patient, the hospital or health-care staff would be removed during the transcription process and that, following transcription of the interview, the digital recording would be destroyed. Participants were invited to sign a consent form, which was countersigned in their presence by the research associate. One copy was given to the participant and one copy was filed in the investigator site file.

The cognitive interviews were conducted by the research associate. Participants were asked to complete the FS-ICU-24 in 'think aloud' mode, indicating, as they completed it, how they were interpreting each item and formulating their response. If participants struggled with concurrent 'think aloud', then a cognitive debriefing approach was adopted instead. In these instances, the participants self-completed the FS-ICU-24 and were then probed by the research associate about their interpretation of each item and how and why they chose the response option they did. At the end of each interview, the participants were asked:

- if they considered each of the questions in the FS-ICU-24 to be relevant and important to their experience
- if, in their opinion, all the main themes related to family satisfaction with intensive care had been covered and, if not, then what had been omitted.

Transcription

The digital recordings of the cognitive interviews were transcribed by the research associate. All identifiable information, such as names (e.g. of patients, family members or intensive care staff members), were removed. Once the transcriptions were complete, the digital recordings were destroyed (confidentially).

Data analysis

Data from the cognitive interviews were analysed by FS-ICU-24 item. The key themes and comments from each of the cognitive interview participants were summarised for each question and reviewed by EM and SW in consultation with DKH. Any potential changes to the questionnaire that were indicated following each round of cognitive interviews were discussed with the wider SMG before any changes were made.

Results

Participating NHS hospital trusts

Local research and development (R&D) approval was obtained at the NHS hospital trust in London for the London-based focus group discussion (with health-care professionals) and at the NHS hospital trust in Newcastle for the Newcastle-based focus group discussion (with health-care professionals) and for recruitment of family members for the cognitive interviews.

Participants

Focus group discussions: health-care professionals

The first focus group discussion was held in Newcastle on 28 November 2012 with seven participants comprising two consultant doctors, two junior doctors, one sister/charge nurse, one staff nurse and one allied health-care professional.

The second focus group discussion was held in London on 16 January 2013 with seven participants comprising two consultant doctors, one junior doctor, two sister/charge nurses and two staff nurses.

Focus group discussions: representatives from Intensive Care Unit Support Teams for Ex-Patients

The first focus group discussion was held in Milton Keynes on 2 December 2012 with nine participants comprising five former intensive care patients, two family members of former intensive care patients and two health-care professionals involved in delivery of intensive care, of whom one was also a family member of a former intensive care patient.

The second focus group discussion was held in South Tyneside on 28 February 2013 with six participants comprising two former intensive care patients, three family members of former intensive care patients and one health-care professional involved in delivery of intensive care.

Cognitive interviews

Eighty-three family members of patients admitted to the three ICUs within the NHS hospital trust in Newcastle were approached about taking part in a cognitive interview. Of these, 41 (49.4%) expressed an interest in taking part and were given a participant information sheet and, of these, 30 (73.2%) completed and signed the expression of interest form.

Twelve family members of nine patients were successfully contacted and cognitive interviews were conducted with them. The 12 cognitive interviews were conducted in three rounds as follows: four interviews conducted between 11 and 15 January 2013; six interviews conducted between 26 and 30 January 2013; and two interviews conducted on 8 February 2013.

Characteristics of cognitive interview participants

Of the 12 participants, 11 were white British and one was Asian British. They ranged in age from 32 to 66 years, with a mean age of 48 years, and two-thirds ($n = 8$) were female. The average age at which participants left full-time education was 18 years, ranging from 15 to 21 years (*Table 1*).

Thematic analysis

Themes that emerged from the focus group discussions and cognitive interviews have been combined and are presented for each of the FS-ICU-24 items below.

Demographics

The first section of the FS-ICU-24 comprises six questions asking for information about the respondent and their relationship to the patient.

> *Sex (response options: Male/Female)*

There were no issues identified by participants and no changes were made.

> *Age (response required age to be indicated)*

There were no issues identified by participants and no changes were made.

> *I am the patient's (response options include: Wife/Husband/Son/Daughter/etc.)*

Participants suggested adding relationship options, such as 'friend', 'neighbour' and 'son/daughter-in-law'. It was acknowledged that it would be impossible to have a comprehensive list of options and that the response option of 'other' with a free-text space to enter the details would suffice. Additional relationship options were added.

> *Before this most recent event, have you been involved as a family member of a patient in ICU (Intensive Care Unit)? (response options: Yes/No)*

TABLE 1 Characteristics of participants for cognitive interviews

Round	Date of interview (2013)	Sex	Age (years)	Age on leaving full-time education (years)	Relationship to the patient
1	11 January	Male	66	15	Husband
	14 January	Female	63	16	Wife
	15 January	Female	32	18	Daughter
	15 January	Male	32	21	Stepson
2	26 January	Female	36	18	Daughter-in-law
	26 January	Male	43	16	Son
	26 January	Female	52	17	Daughter
	29 January	Female	62	15	Sister
	29 January	Female	52	21	Mother
	30 January	Male	33	16	Husband
3	8 February	Female	38	21	Daughter
	8 February	Female	61	16	Wife

There were no major issues identified and no changes were made. It is of note that a number of participants in the cognitive interviews took some time to recall the information required to respond to this question and one participant (during an interview with the 61-year-old wife and the 38-year-old daughter of an ICU patient) asked if this meant 'any ICU ever?'

> *Do you live with the patient? If no, then on average how often do you see the patient? (response options: More than weekly/Weekly/Monthly/Yearly/Less than once a year)*

Although this question was considered easy to answer, it generated debate during the focus group discussions about its purpose and what it implied about the strength of the relationship to the patient. There were discussions about how often a relative might visit the patient (if they did not share a home). Participants in the cognitive interviews who did not live with their relative (the patient) mentioned telephoning them to keep in touch. There was general agreement that perhaps the response categories were not sufficiently discriminating to capture the range of likely experiences; in particular, the gap between seeing someone 'monthly' and 'yearly'. The SMG agreed to add additional response options: 'every 2 to 3 months' and 'every 4 to 6 months'.

During the first round of cognitive interviews, participants also queried the purpose of this question. DKH confirmed that it was to gauge how well the family member knew the patient and their health and other issues. In response to participants' comments, a new question was proposed to further tap into this construct as follows: 'How would you rate your knowledge of the patient and their health issues? (response options: excellent/very good/good/fair/poor)'.

This question was tested in the second round of cognitive interviews. Further feedback indicated there was some confusion about the time frame of reference for this new item vis-à-vis the patient's admission to ICU. The question was amended to 'how would you rate your knowledge of the patient's health issues prior to them coming to the ICU?' This was then tested in the third round of cognitive interviews. No further issues with comprehensibility of the question were raised and the question was retained.

> *Where do you live? (response options: In the city where the hospital is located/Out of town)*

A number of participants found the response option 'out of town' to be an imprecise term and hard to interpret. The majority of cognitive interview participants considered that they were from 'out of town', a pattern of response which could be related to the recruiting NHS hospital trust being a tertiary referral centre within the north-east of England.

At the focus group held with health-care professionals in London, there was discussion about the possibility that the difficulty in travelling across a large city was comparable with coming from 'out of town'. Participants suggested that this question should ask more directly about the ease of travel to the ICU for family members, which DKH confirmed was the intention of the question. A replacement question was proposed as follows: 'How would you rate the ease of travelling from your home to the hospital? (response options: excellent/very good/good/fair/poor)'. This was tested in subsequent cognitive interviews and discussed at the final focus group (held in South Tyneside with representatives from ICUsteps) and found to work well. The reworded question was retained.

Part 1: satisfaction with care

The second section of the FS-ICU-24 comprises 14 items that contribute to the overall family satisfaction score and to the *satisfaction with care* domain score. The 14 items were divided up under six subheadings: 'how did we treat your family member (the patient)?' (four items); 'how did we treat you?' (four items); 'nurses' (two items); 'physicians (all doctors, including residents)' (one item); 'the ICU' (one item); and 'the waiting room' (two items).

Response options to the first 13 of the 14 items were ‘excellent/very good/good/fair/poor’, with a further option of ‘not applicable’. The response options to the last item were ‘very dissatisfied/slightly dissatisfied/mostly satisfied/very satisfied/completely satisfied’.

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]*

During one of the focus group discussions and during the first round of cognitive interviews the concept of ‘dignity’ was mentioned and participants commented that a lot of NHS literature and posters refer to ‘dignity’. In the later rounds of cognitive interviews, participants were specifically asked about the construct of dignity. Participants thought that courtesy, respect and compassion were all important characteristics. One participant commented that courtesy, respect and compassion are separate characteristics and that it would be possible for a member of ICU staff to exhibit courtesy and respect but without showing compassion. It was suggested that this question could potentially be split into two, with one question asking about courtesy and respect and a separate question asking about compassion.

The SMG considered whether to substitute (with ‘dignity’) or drop the word ‘courtesy’ but it was concluded that this might alter the sense of the item and have an adverse impact on the validity of the FS-ICU-24. These decisions took into account advice from DKH and the intent of the item, which was to obtain the family member’s overall assessment of the constructs of concern and caring, and the words ‘courtesy’, ‘respect’ and ‘compassion’ were simply to orient family members to this construct. No changes were made.

Symptom management (how well the ICU staff assessed and treated your family member’s symptoms)

> *Q2: Pain*

There were no issues identified by participants and no changes were made.

> *Q3: Breathlessness*

There were no issues identified by participants and no changes were made.

It is of note that some participants suggested that a family member’s assessment of breathlessness could be subjective, which was deemed reasonable.

> *Q4: Agitation*

There were no major issues identified by participants and no changes were made.

It is of note that participants commented on the different types of agitation they had witnessed in their family members (the patients). For example, one participant noted that the patient had been agitated because the bed was uncomfortable, while two others (a 52-year-old mother of an ICU patient and a 32-year-old male relative of an ICU patient) noted it was because the patient was unable to speak because of the ‘breathing tube’. Participants also commented that it is common for patients to panic on waking up but acknowledged that the word ‘panic’ would not work as an alternative to the word ‘agitation’.

How did we treat you?

Q5: Consideration of your needs (how well the ICU staff showed an interest in your needs)

There were no major issues identified by participants and no changes were made.

None of the participants in either the focus group discussions or the cognitive interviews suggested there was any need for changes to this item. It is of note that the health-care professionals (who participated in the focus group discussions) interpreted the needs of family members as being around facilities at the hospital/ICU such as car parking or availability of refreshments. In contrast, family members (who were interviewed) considered that their own material needs were secondary and indicated that they were more concerned with communication and being kept informed of the patient's progress. Although these differing perspectives provided interesting insights, it was not felt that any changes to this item were indicated.

Q6: Emotional support (how well the ICU staff provided emotional support)

There were no major issues identified by participants and no changes were made.

It is of note that participants in the focus groups discussed how 'needs' of family members (referred to in Q5 above) and 'emotional support' could be regarded as being similar or the same, as the principal need of some family members is emotional support. Participants in the cognitive interviews who identified themselves as the next of kin felt that this concept of emotional support was important; however, they felt it was likely to be less important or relevant to more distant relatives, such as a son-in-law/daughter-in-law.

Q7: Co-ordination of care (the teamwork of all the ICU staff who took care of your family member)

Some participants in the cognitive interviews talked about poor handovers between staff, and good and poor teamwork, and made comparisons with their previous experiences at other ICUs and hospitals. This was considered likely to amplify responses from family members rather than indicative of a need to change the wording of this item.

Some participants in the focus group discussions asked why this item was included under the heading of 'how did we treat you?' They suggested that this item should be moved or placed under a separate subheading. The item was moved to come under a new subheading, 'teamwork', which was added.

Q8: Concern and caring by ICU staff (the courtesy, respect and compassion ***you*** *were given)*

Participants in one focus group commented that this question seemed to be returning to the issue of emotional support, which had already been addressed in Q6. It also prompted further discussion about how 'courtesy', 'respect' and 'compassion' differ. Participants in the cognitive interview reiterated that a nurse can be polite without being compassionate. As for Q6, participants also mentioned the concept of dignity being an important consideration.

In response to the feedback from participants, a change to the wording of this item was considered. It was decided, however, that the original wording should be retained to facilitate comparison with other studies that have used the FS-ICU-24. Furthermore, there was no other wording of the item that was universally preferred.

Nurses

Q9: Skill and competence of ICU nurses (how well the nurses cared for your family member)

There were no major issues identified by participants and no changes were made.

It is of note that, during the focus group discussions, some of the health-care professionals questioned whether or not family members can judge the skill and competence of the nurses. In addition, one of the participants in the cognitive interviews commented that they did not feel that they could make this judgement.

> *Q10: Frequency of communication with ICU nurses (how often nurses communicated to you about your family member's condition)*

The item was regarded as a potential problem by some of the cognitive interview participants. Participants recruited from the same ICU provided responses to this question that ranged from 'excellent' to 'poor'. Some participants commented that they felt that the nurse should approach them and provide information about the patient. If this had not happened, then they tended to provide a negative response such as 'poor'. Family members who were not the patient's immediate next of kin tended to respond more negatively to this item, possibly reflecting the fact that they were less likely to have received the same amount of information as, for example, the patient's immediate next of kin.

Health-care professionals participating in the focus group discussions commented that doctors tend not to volunteer information immediately upon meeting a family member. One participant (an ICU nurse who worked in a follow-up clinic) noted 'You would introduce yourself and establish who they are and use discretion if they want information.'

The SMG agreed that the comments from participants provided useful insight into why responses might vary within and across ICUs and between different family members for the same patient, but no changes were made to this item. It was noted that one of the objectives of phase 2 of the FREE study was to explore how family satisfaction varied by family member and ICU/hospital characteristics (see *Chapter 7*).

Doctors

> *Q11: Skill and competence of ICU doctors (how well doctors cared for your family member)*

There were no issues identified by participants and no changes were made.

The ICU

> *Q12: The atmosphere of the ICU was?*

During the first round of cognitive interviews, participants commented that they found the word 'atmosphere' to be ambiguous. Their responses to this question indicated that they were variously thinking about concepts ranging from the temperature of the ICU to the friendliness of the ICU. Participants suggested that the word 'mood' or 'environment' might be better alternatives. DKH confirmed that the intent of the question was to capture family members' impression of the general 'feel' of the ICU. For subsequent rounds of cognitive interviews, 'atmosphere' was replaced with 'mood'. However, participants found 'mood' ambiguous and suggested that the (original) word 'atmosphere' would be better. The SMG concluded, therefore, that the word 'atmosphere' should be retained but with the word 'mood' in parentheses to convey the sense of what was meant by 'atmosphere' as follows: 'The atmosphere (mood) of the ICU was?'

The waiting room

> *Q13: The atmosphere in the Waiting Room was?*

During the cognitive interviews, there were similar comments as for Q12 relating to the word 'atmosphere'. DKH confirmed that the intent of the question was to capture family members' impression of the general 'feel' of the waiting room. This question was therefore worded along similar lines to Q12, as follows: 'The atmosphere (mood) in the ICU waiting room was?'

> *Q14: 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?)*

Participants felt that this was an important item; however, many of the participants in the cognitive interviews commented on the phrasing of the question and found it difficult to interpret the meaning of the question. Participants said that they felt that family members would want as much as possible done for their relative in the ICU. One participant asked if the question was about end-of-life care. Some of the health-care professionals, who took part in the focus group discussions, considered the first sentence of this question to be patronising. Other focus group participants disagreed with the reversal of the response options for this item, ranging from 'very dissatisfied' to 'completely satisfied' as opposed to the response options ranging from 'excellent' to 'poor' for the previous items.

Based on comments from participants during the first two focus group discussions and the initial round of cognitive interviews, the wording of the question was modified for the subsequent round of cognitive interviews to 'how satisfied were you with the LEVEL or amount of health care your family member received in the ICU bearing in mind their likely wishes?' The intention was to focus the question on the patient and what they might want rather than what the family member might want for the patient.

Participants who took part in subsequent rounds of cognitive interviews did not find the revised wording of the question to be any clearer than the original. This view was echoed during the final focus group discussion. In particular the rider 'bearing in mind their likely wishes' was not considered to be helpful.

The SMG was concerned that removing the introductory sentence might change the meaning of this item. Furthermore, DKH noted that studies in Canada[11] had found this item correlated well with overall family satisfaction. Given this, combined with the feedback from participants, the SMG agreed the question should not be modified. The order of the response options (i.e. reversed) was also retained because of concerns that any change would affect the factorial validity of the FS-ICU-24; however, a rider was added to alert the respondent to the order of the responses.

Part 2: family satisfaction with decision-making around the care of critically ill patients

The third section of the FS-ICU-24 comprises 10 items that contribute to the overall family satisfaction score and to the *satisfaction with decision-making* domain score. The 10 items were divided up under two subheadings: 'information needs' (six items) and 'process of making decisions' (four items).

Response options to the first six items were 'excellent/very good/good/fair/poor' with a further option of 'not applicable'. The response options to the remaining items are provided below with the item.

Comments from participants in the cognitive interviews indicated that the instructions for this part of the FS-ICU-24 were clear; however, several participants stated that they had had no involvement in decision-making relating to the patient's (their family member's) health care. Clinical members of the SMG (DKH, AR, SW) noted that, although in both Canada and the UK the aim is to involve family members as much as possible in the decision-making process in an intensive care setting, there are contextual differences with respect to legal frameworks. In Canada, if an adult loses the mental capacity to make decisions about their health care, a substitute decision-maker is appointed, who is usually the next of kin. This is in contrast to the situation in England, where doctors, working under the Mental Capacity Act 2005,[20] make decisions in the patient's best interests, taking into account the views of family members.

Information needs

> *Q1: Frequency of communication with ICU doctors (how often doctors communicated to you about your family member's condition)*

There were no major issues identified by participants and no changes were made.

Notably, many of the participants in the cognitive interview commented that they had little contact with the doctors. It was noted that more distant relatives (i.e. not the immediate next of kin) would be likely to have less contact with doctors and might, therefore, give a more negative response to this question. Participants suggested that this item should be moved to follow the item asking about communication with the nurses (Q10 in part 1: satisfaction with care). This was considered by the SMG and rejected because of the impact that reordering items might have on the construct validity of the FS-ICU-24; DKH indicated that the item asking about communication with the nurses was designed to address the construct 'process of care' whereas this item asking about communication with doctors was designed to address the construct 'process of decision-making'.

> *Q2: Ease of getting information (willingness of ICU staff to answer your questions)*

There were no issues identified by participants and no changes were made.

It is of note that some of the participants in the cognitive interviews commented that the ease of getting information depended on whether communication was face to face or by telephone. That is to be expected; it is generally easier to get information face to face than by telephone.

> *Q3: Understanding of information (how well ICU staff provided you with explanations that you understood)*

There were no issues identified by participants and no changes were made.

> *Q4: Honesty of information (the honesty of information provided to you about your family member's condition)*

There were no issues identified by participants and no changes were made.

It is of note that the health-care professionals who took part in the focus group discussions did not like the word 'honesty' used in this context because the antonym is 'dishonesty' and they felt that the wording of the question 'implies we would lie' (ICU nurse). Participants suggested the words 'openness' or 'transparency' as alternatives to 'honesty'. However, participants in the cognitive interviews and in the focus groups with representatives from ICUsteps had no concerns with the word 'honesty'. In the light of this, the SMG agreed no changes should be made.

> *Q5: Completeness of information (how well the ICU staff informed you what was happening to your family member and why things were being done)*

There were no issues identified by participants and no changes were made.

> *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.)*

There were no issues identified by participants and no changes were made.

It is of note that the health-care professionals disliked the rider 'did you get a similar story from the doctor, nurse, etc.' They specifically disliked the word 'story', which implies that information given to family members is not honest. Participants in the cognitive interviews raised no issues with this item. The SMG agreed that this item should remain unchanged.

Process of making decisions

> *Q7: Did you feel included in the decision-making process? (response options: I felt very excluded/I felt somewhat excluded/I felt neither included nor excluded/I felt somewhat included/I felt very included)*

Some participants in the cognitive interviews felt that this question was not applicable to them because, for example, the patient's admission to the ICU had been planned following elective surgery. In these instances, participants had commented that the patient had usually been conscious and had retained the mental capacity to make their own decisions throughout their stay in the ICU.

Other cognitive interview participants commented that, although they were kept informed about the decisions being taken by the intensive care staff, they were not actively involved in the decision-making process. More distant family members (i.e. not the immediate next of kin) reported having had less communication with the intensive care staff and not being involved in the decision-making process. In the light of these comments, the SMG agreed a 'not applicable' response option should be added.

> *Q8: Did you feel supported during the decision-making process? (response options: I felt totally overwhelmed/I felt slightly overwhelmed/I felt neither overwhelmed nor supported/I felt supported/I felt very supported)*

In considering the response options to this item (listed above), participants who took part in the early round of cognitive interviews commented that one could be 'totally overwhelmed' but still be 'well supported'. Participants suggested that the word 'overwhelmed' should be replaced by the word 'unsupported' in the response options to this item. The revised response options were tested and performed well in the subsequent round of cognitive interviews and at the final focus group discussion. This change to the response options was therefore retained. The SMG agreed that a 'not applicable' response option should be added.

> *Q9: Did you feel you had control over the care of your family member? (response options: 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)*

Most of the participants in the cognitive interviews felt that this item did not apply to them, while others expressed uncertainty whether or not they would have expected to have good control over the care their family member received. Similar views were expressed by participants who took part in the focus group discussions.

The SMG discussed the background to this question and the differences in the legal frameworks between Canada and the UK as regards adults who lose the mental capacity to make decisions about their health care (see above). The SMG acknowledged that contextual and cultural differences might result in lower scores for this item in a UK setting but there were no compelling reasons to drop it. A 'not applicable' response option was added.

It was agreed, however, that a new question should be added to assess satisfaction with the amount of control the respondent (family member) felt they had over the care of their family member (patient) as follows: 'How satisfied were you with the amount of control you had over the care of your family member? (response options: excellent/very good/good/fair/poor)'.

> *Q10: When making decisions, did you have adequate time to have your concerns addressed and questions answered? (response options: I could have used more time/I had adequate time)*

Many of the cognitive interview participants commented that in an intensive care setting decisions often need to be made very quickly and therefore felt that a 'not applicable' option was needed for this question. The SMG agreed this option should be added.

For family members of patients who died in the intensive care unit

Three questions are included in the third section of the FS-ICU-24 for family members of patients who died in the ICU. These questions do not contribute to the overall family satisfaction score or to the *satisfaction with care* and *satisfaction with decision-making* domain scores.

> *If your family member died during the ICU stay, please answer the following questions (11–13). If your family member did not die, please skip to question 14.*

The health-care professionals expressed concern about the appropriateness of these questions and potential distress to bereaved family members, particularly as, during phase 2 of the FREE study, family members would receive the questionnaire 3 weeks after the patient had died in the ICU. However, participants in the cognitive interviews, who were all family members, were less concerned about the 3-week time frame. The questions were considered to be important and some participants suggested that they might be better in a separate questionnaire. Given concerns about potential distress to bereaved family members, participants commented that consideration needed to be given to how these questions were introduced to make them more acceptable. To this end, the SMG agreed that a rider should be added to orient respondents to the theme of the three questions and to explain the reason for asking the questions as follows:

> *If your family member died in the ICU, we would like to ask 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 dying patients.*

> *Q11: Which of the following best describes your views? (response options: I felt my family member's life was prolonged unnecessarily/was slightly prolonged unnecessarily/was neither prolonged nor shortened unnecessarily/was slightly shortened unnecessarily/was shortened unnecessarily)*

Many of the health-care professionals felt uncomfortable with this question and the response options. They talked about the Liverpool Care Pathway and the negative publicity around its application in the NHS. Many were concerned that some of the response options might precipitate the start of a complaints procedure. Similarly, some cognitive interview participants commented that if a family member selected the response option 'I felt my family member's life was slightly shortened unnecessarily' or 'I felt my family member's life was shortened unnecessarily' it might trigger the start of legal action against the NHS hospital trust. DKH noted that the experience in Canada has been that most respondents have tended to choose the response option 'I felt my family member's life was neither prolonged nor shortened unnecessarily'.

> *Q12: During the final hours of your family member's life, which of the following best describes your views? (response options: I felt that he/she was very uncomfortable/was slightly uncomfortable/was mostly comfortable/was very comfortable/was totally comfortable)*

There were no major issues identified by participants and no changes were made.

It is of note that the health-care professionals were generally comfortable with this question and the response options. Participants in the cognitive interviews commented that this would be an important question for some family members.

> *Q13: During the last few hours before your family member's death, which of the following best describes your views? (response options: 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)*

There were no major issues identified by participants and no changes were made.

It is of note that the word 'abandoned' was considered to be emotive by many participants (both family members and health-care professionals) but there were no suggestions for an alternative word apart from 'unsupported'. However, participants acknowledged the concept of abandonment and felt that it was important.

Summary of changes to the 24-item Family Satisfaction in the Intensive Care Unit questionnaire

The changes, agreed by the SMG, to the original FS-ICU-24 are summarised below. KR and EW led on implementing the agreed changes and on the reformatting/redesign of the questionnaire to enhance response.

About you

The section heading 'demographics' in the original FS-ICU-24 was changed to 'about you' to simplify the language. Changes made to this section were as follows:

- Additional response options were provided for the question asking about the respondent's relationship to the patient.
- A question asking 'are you the patient's next of kin?' was added to ascertain if the respondent considered themselves the patient's next of kin.
- Additional response options were provided for the question asking about how frequently the respondent saw the patient if they did not live with them.
- A question 'how would you rate your knowledge of the patient's health issues prior to them coming to the ICU?' was added, with five response options ranging from 'excellent' to 'poor'.
- The question 'where do you live?' on the original questionnaire was replaced with the question 'how would you rate the ease of travelling from your home to the hospital?' with five response options ranging from 'excellent' to 'poor'.

Satisfaction with care

The section heading in the original FS-ICU-24 was kept. Changes made to this section were as follows:

- The item asking about co-ordination of care (originally one of four items under the subheading 'how did we treat you?') was moved to come under a new subheading, 'teamwork', and follows 'how did we treat you?'
- The subheading 'physicians' was replaced with 'doctors', as this term was more familiar to a UK population.
- The item 'the atmosphere of the ICU was?' was modified to read 'the atmosphere (mood) of the ICU was?'
- The item 'the atmosphere in the ICU waiting room was?' was modified to read 'the atmosphere (mood) in the ICU waiting room was?'
- A rider 'please pay attention to the order of responses' was added to the item asking about satisfaction with the level or amount of health care the patient received, to alert respondents to the order of the response options (in reverse order), and a new subheading, 'level/amount of health care', was added.

Satisfaction with decision-making

The section heading in the original FS-ICU-24 was kept. Changes made to this section were as follows:

- For items 7–10 under the subheading 'the process of decision-making', the following sentence was added to the guidance notes: 'If your family member was able to make decisions for themselves while in the ICU, then some questions may not be applicable to you; in that case, please tick not applicable'.
- A response option of 'not applicable' was added to the items related to the process of making decisions.
- The response options for the item about how supported the respondent felt during the decision-making process were modified slightly – the word 'overwhelmed' was replaced with 'unsupported'.

Additional questions

In addition to the 24 items that contribute to the *satisfaction with care* and *satisfaction with decision-making* domain scores, there are three questions for family members of patients who died in the ICU, which ask for their views on the end-of-life care of their family member (the patient).

The following change was made to the guidance notes: 'If your family member died during the ICU stay, please answer the following questions (11–13)' was replaced with '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.'

Following the three questions above, a question was added for all family members, as follows: 'How satisfied were you with the amount of control you had over the care of your family member?', with five response options ranging from 'very dissatisfied' to 'completely satisfied'.

Finally, for consistency, the word 'hospital' was replaced by the word 'ICU' for the last question, asking for comments and suggestions that the family member felt might be helpful to staff.

In addition, a cover page was created with three additional questions (not included in the original FS-ICU-24) as follows:

- 'today's date', to establish when the questionnaire was completed in relation to the patient's discharge from, or death in, the ICU
- 'did you complete the questionnaire alone/with help?', to establish whether the questionnaire had potentially been completed by one or more family members
- 'approximately how many times did you visit your family member in the ICU?', to establish the frequency with which the family member visited the patient in the ICU.

In addition, a reminder of the definition of a family member was provided.

General formatting

The UK FS-ICU-24 was designed in the form of a booklet and titled 'The FREE Study Questionnaire' to ensure that family member participants in the cohort study (described in *Chapter 3*) identified the questionnaire as related to the FREE study. The FREE study logo was incorporated and the colours of headings, page borders and questionnaire item numbers were selected to reflect the logo colour scheme and to enhance the aesthetics of the questionnaire. Headings and subheadings were enlarged to varying degrees to help respondents navigate the questionnaire. The guidance notes were presented in the form of bullet points (rather than paragraphs of text) to make the information easier to read and understand. Phrases such as 'check the box' were translated to the UK English equivalent, for instance 'tick the box'. For each item, a tick box was provided for each of the response options to clearly signpost how the response should be provided, as well as being aesthetically pleasing.

The UK 24-item Family Satisfaction in the Intensive Care Unit questionnaire

The final version of the UK FS-ICU-24 questionnaire (see *Appendix 2*), adapted from the original Canadian FS-ICU-24 questionnaire, is outlined below. The questionnaire comprised three parts: demographic information about the family member completing the questionnaire (under the heading *About you*), satisfaction with care and satisfaction with decision-making.

The first part of the questionnaire asked for information about the family member completing the questionnaire as follows:

Part 1: about you

Q1: I am . . . (Response options: male/female.)

Q2: I am . . . (Response: age in years.)

Q3: I am the patient's . . . (Response options include wife/husband/mother/father/etc.)

Q4: Are you the patient's next of kin? (Response options: 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)? (Response options: yes/no.)

Q6: Do you live with the patient? (If the patient has died, did you live with the patient?) (Response options: 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?) (Response options: ranging from more than once a week to 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? (Response options: excellent/very good/good/fair/poor.)

Q8: How would you rate the ease of travelling from your home to the hospital? (Response options: excellent/very good/good/fair/poor.)

Part 2: satisfaction with care

Fourteen items covered satisfaction with care; note that item 2 (Q2) was split into three parts, all asking about symptom management. For 13 of the 14 items, the response options were 'excellent/very good/good/fair/poor' with an additional option of 'N/A' (not applicable). For item 12, about satisfaction with the level or amount of health care, the response options were 'very dissatisfied/slightly dissatisfied/mostly satisfied/very satisfied/completely satisfied'.

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].

Q2: Symptom management (how well the ICU staff assessed and treated your family member's symptoms):

(a) pain
(b) breathlessness
(c) agitation.

How did we treat you?

Q3: consideration of your needs (how well the ICU staff showed an interest in your needs).

Q4: emotional support (how well the ICU staff provided emotional support).

Q5: concern and caring by ICU staff (the courtesy, respect and compassion you were given).

Teamwork

Q6: co-ordination of care (the teamwork of all the ICU staff who took care of your family member).

Nurses

Q7: skill and competence of ICU nurses (how well the nurses cared for your family member).

Q8: frequency of communication with ICU nurses (how often nurses communicated to you about your family member's condition).

Q9: skill and competence of ICU doctors (how well doctors cared for your family member).

The intensive care unit

Q10: the atmosphere (mood) of the ICU was . . .?

The waiting room

Q11: the atmosphere (mood) in the ICU waiting room was . . .?

Level/amount of health care

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?

Part 3: satisfaction with decision-making

This part of the questionnaire included 17 questions. All family members were asked to complete the first 10 items, which cover satisfaction with decision-making around the care of the critically ill patient. For 6 of the 10 items the response options were 'excellent/very good/good/fair/poor' with an additional option of 'N/A'. For the remaining four items, the response options are provided with the item.

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

Information needs

Q1: frequency of communication with ICU doctors (how often doctors communicated to you about your family member's condition).

Q2: ease of getting information (willingness of ICU staff to answer your questions).

Q3: understanding of information (how well ICU staff provided you with explanations that you understood).

Q4: honesty of information (the honesty of information provided to you about your family member's condition).

Q5: completeness of information (how well ICU staff informed you what was happening to your family member and why things were being done).

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.)].

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.

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.

Family members of patients who died were asked to complete the questions listed below. Family members of survivors were asked to 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 view?

- 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.

All family members are asked to complete question 14 as follows:

Q14: how satisfied were you with the amount of control you had over the care of your family member (response options: very dissatisfied/slightly dissatisfied/mostly satisfied/very satisfied/completely satisfied)?

The last three questions have free-text responses, providing an opportunity for family members to make comments and suggestions on the care provided in the ICU.

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

Q16: do you have 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.

Scores

The domain scores and the overall family satisfaction score are derived from the 14 items that comprise the domain *satisfaction with care* and the 10 items that comprise the domain *satisfaction with decision-making*. Each item response is scored on a scale from 0 (least satisfied) to 100 (most satisfied) as follows: poor/very dissatisfied, 0; fair/slightly dissatisfied, 25; good/mostly satisfied, 50; very good/very satisfied, 75; and excellent/completely satisfied, 100. Responses to items 7, 8, 9 and 10 in the domain *satisfaction with decision-making* are scored as follows:

Q7: did you feel included in the decision-making process?

- I felt very excluded, 0.
- I felt somewhat excluded, 25.
- I felt neither included nor excluded, 50.
- I felt somewhat included, 75.
- I felt very included, 100.

Q8: did you feel supported during the decision-making process?

- I felt totally unsupported, 0.
- I felt slightly unsupported, 25.
- I felt neither supported nor unsupported, 50.
- I felt supported, 75.
- I felt very supported, 100.

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, 0.
- I felt somewhat out of control and that the health care system took over and dictated the care my family member received, 25.
- I felt neither in control nor out of control, 50.
- I felt I had some control over the care my family member received, 75.
- I felt that I had good control over the care my family member received, 100.

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

- I could have used more time, 0.
- I had adequate time, 100.

Summary overall family satisfaction scores and domain scores (*satisfaction with care* and *satisfaction with decision-making*) are calculated by averaging the item responses for the items included overall and within each domain, provided at least 70% of items are complete (i.e. 17 out of 24 for the overall family satisfaction score, 10 out of 14 for *satisfaction with care*, 7 out of 10 for *satisfaction with decision-making*).[21]

Discussion

In summary, the face and content validity and comprehensibility of the FS-ICU-24 was good and adaptation to the UK setting required relatively minor edits. These included changes to section heading titles, clarification of wording of questions, addition to existing guidance, clarification of North American English to UK English, general formatting and enhanced design of the layout.

Chapter 3 Set-up and delivery of the cohort study

Introduction

Phase 2 of the FREE study comprised a cohort study, which collected data on family satisfaction with intensive care using the UK FS-ICU-24. This chapter reports the methods and results of the set-up of the study, recruitment of adult general ICUs, recruitment of family members and administration of, and response to, the FS-ICU-24.

Methods

The cohort study was a multicentre study nested in the Case Mix Programme (CMP), the national clinical audit of adult general ICUs in England, Wales and Northern Ireland, established in 1995 and co-ordinated by ICNARC (Scotland has its own separate national clinical audit). Since 2010/11, the National Advisory Group on Clinical Audit and Enquiries has listed the CMP in the Department of Health's 'Quality Accounts' as a recognised national audit.[22]

Nesting the FREE study in the CMP ensured an efficient design (with respect to participating units and data collection) and facilitated efficient management of the study, including monitoring recruitment and adherence to the protocol at participating units.

An initial psychometric assessment of the UK FS-ICU-24 was incorporated into the design of the cohort study based on returned questionnaires received from family members recruited during the first month of the 12-month recruitment period. This was to assess quickly whether or not substantive changes to the UK FS-ICU-24 were required, so that, if necessary, these could be incorporated and recruitment of family members could recommence using the revised UK FS-ICU-24. As part of the initial psychometric assessment, the criterion validity of the UK FS-ICU-24 among family members of critical care non-survivors was assessed by comparison with the Quality of Dying and Death (QODD) questionnaire[23] (see *Appendix 3*). Family members of non-survivors recruited during the first month of recruitment were also sent the QODD questionnaire. No well-validated measure existed that would enable a validity analysis of the UK FS-ICU-24 among family members of ICU survivors. The methods and results of both the initial and full (based on 12 months' data) psychometric assessments of the UK FS-ICU-24 are described in *Chapter 4*.

Research governance

The FREE study was sponsored by ICNARC and phase 2 was co-ordinated by the ICNARC CTU. An ethics application was made to the National Research Ethics Service Committee South Central – Berkshire B on 21 December 2012 and a favourable opinion was received on 20 February 2013.

The CMP has approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002[24] to process patient identifiable information without consent [approval: PIAG 2–10(f)/2005]. Patient identifiable information processed includes NHS number, date of birth, postcode and sex. A satisfactory Information Governance Toolkit score is required for this approval. A legal agreement is made between ICNARC and the participating units ensuring that the identity of the source of all data (of the hospital, of the unit, of the staff and of the patient) shall remain confidential.

The NIHR CRN Portfolio details high-quality clinical research studies that are eligible for support from the NIHR CRN in England. The study was adopted onto the NIHR CRN Portfolio on 28 January 2013.

Following central R&D approval, site-specific information forms were submitted for each NHS hospital trust. A study site agreement, based on the model agreement for non-commercial research in the health service, was signed by each participating NHS hospital trust and the sponsor (ICNARC).

To ensure transparency, the study was registered for an ISRCTN number. Registration was confirmed on 28 May 2013 (ISRCTN47363549).

Following guidelines from the NIHR, a Study Steering Committee (SSC), with a majority of independent members, was convened to oversee the study on behalf of the funder (the NIHR Health Services and Delivery Research programme) and the sponsor (ICNARC). The SSC met annually during the study. It was chaired by an independent member and comprised lay members (representing patient and family member perspectives), clinicians (critical care nurses and doctors) and methodologists [the chief investigator (KR) and lead clinical investigator (SW) representing the SMG].

Management of phase 2

EW was responsible for the day-to-day management of phase 2 of the FREE study with support from the study administrators, the study statistician and the SMG.

Study management group

The SMG was responsible for overseeing day-to-day management of the study and comprised the chief investigator (KR), lead clinical investigator (SW) and coinvestigators (DAH, SH, DKH, LH, EM, AR, MR). The SMG met regularly throughout the study to ensure adherence to the study protocol and to monitor the conduct and progress of the study.

NHS support costs

Resources equivalent to 0.39 whole-time equivalent of a Band 6 research nurse for each participating unit were agreed with the lead CLRN on 26 February 2013. This was based on an average of 385 patient admissions per year, staying in critical care for 24 hours or more, with an estimated average of 2.5 family members per patient. Participating units, assisted by the ICNARC CTU, negotiated resources required locally for the study with their respective R&D departments and CLRNs.

Changes to the protocol

Following favourable opinion of the study protocol from the research ethics committee on 20 February 2013, four non-substantial amendments were submitted and given favourable opinions. In summary these were:

- amendment 1 (April 2013) – minor semantic changes and formatting to the consent form, UK FS-ICU-24 (see *Appendix 2*) and QODD (see *Appendix 3*) questionnaire
- amendment 2 (July 2013) – further minor semantic changes to the consent form
- amendment 3 (October 2013) – further minor semantic changes made to the UK FS-ICU-24
- amendment 4 (February 2014) – revision to the estimated sample size (see *Sample size*) and a change to the chair of the SSC.

Patient and public involvement

Engagement with patients and their family members was vital to ensuring the success of the cohort study. A former critical care patient (LH) and a family member of a former critical care patient (MR) were coinvestigators on the FREE study proposal and as such contributed to the design, conduct, analysis and interpretation of the study. Both were members of the SMG and were closely involved in the conduct and monitoring of the study and are coauthors of this report. The charity ICUsteps provided assistance in identifying family members to be independent members of the SSC.

Intensive care unit recruitment

The study aimed to recruit a representative sample of 20 adult general ICUs from England, Wales and Northern Ireland. Adult general ICUs were defined as ICUs or combined intensive care/high-dependency units. Stand-alone high-dependency units and specialist ICUs (e.g. neurosciences, cardiothoracic) were not eligible for participation in the study. The criteria for inclusion were:

- active participation in the CMP, defined as submission of data no later than 6 weeks after the end of each quarter and returning corrected data validation reports no later than 6 weeks after receipt
- agreement from the local principal investigator (PI) to recruit up to four eligible family members of consecutive patients staying in the unit for 24 hours or more
- provision of timely data on recruited family members entered onto a secure, dedicated, web-based data entry system (web portal)
- commitment to recruit participants for a minimum of 12 months.

All units actively participating in the CMP were invited to express interest in taking part in the study. A stratified random sampling process was chosen to select 20 representative adult general ICUs and to minimise selection bias.

Intensive care units that expressed an interest in taking part in the study were divided by geographical location: England, Wales and Northern Ireland. England, as the largest country, was subdivided into four regions: north-east, north-west, south-east and south-west. Within each country/region, ICUs were divided into those located in university and non-university hospitals and then into large and small ICUs (based on the median number of beds of all ICUs in the CMP). One ICU and one reserve ICU were randomly selected from each group (*Table 2*). Then the 20 randomly selected ICUs were formally invited to take part in the study and asked to sign a confirmation of participation agreement before submission of the site-specific information form to the local R&D. If an ICU declined the invitation to take part in the study, then the reserve ICU was invited.

TABLE 2 Sampling frame for random selection of adult general ICUs

Country	Region	Hospital type	Unit size	Units (*n*)
England	North-east	University	Large	1
			Small	1
		Non-university	Large	1
			Small	1
	North-west	University	Large	1
			Small	1
		Non-university	Large	1
			Small	1
	South-east	University	Large	1
			Small	1
		Non-university	Large	1
			Small	1
	South-west	University	Large	1
			Small	1
		Non-university	Large	1
			Small	1
Wales	–	University	Small	1
		Non-university	Large	1
Northern Ireland	–	University	Large	1
		Non-university	Small	1

Given that intensive care nurses interact daily with patients and their family members, participating ICUs were encouraged, where possible, to appoint a senior critical care nurse as the local PI to lead and oversee the conduct of the study.

Intensive care unit initiation meeting

Before the study was opened to recruitment, a unit initiation meeting was held on 1 May 2013 in London. Local PIs and research staff from the 20 participating ICUs were invited to attend the meeting. The purpose of the meeting was to present the background and rationale for the FREE study and to discuss delivery of the protocol, which included screening and recruiting eligible family members and data collection and validation. The operational challenges of recruiting (including obtaining informed consent) visiting family members of patients in the ICU were discussed in detail at the meeting.

The PI from each participating ICU was required to attend the meeting; however, if a PI was unable to attend, a teleconference meeting was arranged.

Investigator site file

An investigator site file was provided to each participating unit. This contained all essential documents for the conduct of the study, which included the approved study protocol; the delegation of responsibilities log; copies of the approved participant information sheet and consent form; and all standard operating procedures, for example for screening participants, for obtaining informed consent and for collecting and entering data onto the secure web portal. The local PI was responsible for maintaining the investigator site file.

Intensive care unit management

Communication

The study co-ordinator maintained close contact with the local PI and study team at participating ICUs by telephone and e-mail throughout the study.

Teleconferences were held, initially every month, and then every 2 months, with study teams at participating units. The purpose of these was to provide updates on study progress and to provide a forum for ICU study teams to ask questions, discuss local barriers and challenges to the conduct of the study, and share successes and best practice. Notes, including 'hints and tips', from the teleconferences were distributed to all participating ICUs.

Teleconferences were also held with individual unit teams, as required, to address unit-specific issues in the conduct of the study and/or to support training new staff.

Maintenance and motivation

During the study, quarterly newsletters were sent to all participating ICUs. These provided an opportunity to clarify any issues related to the conduct of the study and to share ideas for maximising recruitment, as well as to maintain motivation and involvement through regular updates on progress.

To maintain the profile of the study and motivation at participating ICUs, posters were displayed in staff areas, pocket cards, summarising the eligibility criteria, were distributed, and certificates were given to clinical staff in recognition of their contribution to the study.

Family member recruitment

The study procedures for recruitment and follow-up of family members are summarised in *Figure 1*.

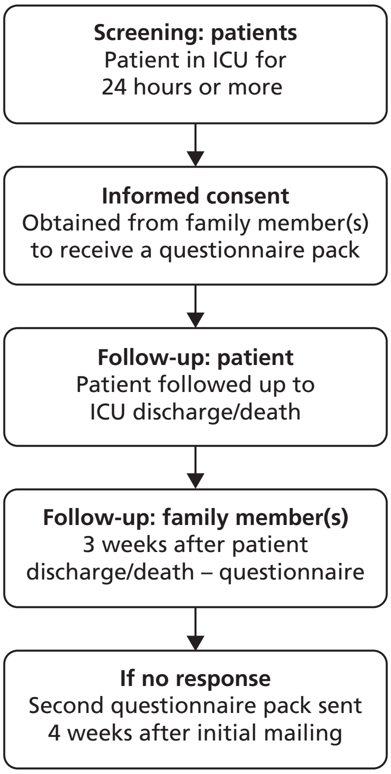


FIGURE 1 Summary of study procedures for recruitment and follow-up of family members.

Eligibility criteria

A family member was defined as a person who had a close familial, social or emotional relationship to the patient and was not restricted solely to next of kin. Family members of patients who had spent ≥ 24 hours in a participating ICU were eligible to take part in the study if they:

- were aged ≥ 18 years
- had physically visited the patient at the bedside at least once after 24 hours
- had a UK postal address
- had not already been recruited into the FREE study.

Family members of patients who were readmitted to the unit (within the same hospital stay) were not eligible during any of the patient's subsequent admissions to the unit. Up to four eligible family members per patient could be invited to take part in the study.

Screening and recruitment

Following the initiation meeting, or teleconference, screening and recruitment was commenced at participating ICUs once the site research agreement had been signed and all necessary approvals were in place. The recruitment period was 12 months, chosen to avoid potential bias from seasonal variation. Family members of patient admissions after the ICU opened to recruitment were eligible to take part in the study; that is, family members of patients already in the ICU on the day the study opened were not eligible to take part.

To promote awareness of the study and facilitate recruitment, posters and information leaflets providing information about the FREE study were displayed in the unit and in family/visitor waiting rooms (see *Appendix 4*).

To minimise selection bias, the first four family members to visit the patient after 24 hours, during their first admission to a participating ICU, were identified and approached by an authorised member of staff about taking part in the study. Information about the study was provided to the family member, which included the purpose of the study, the consequences of taking part or not, data security and funding of the study. This information was also provided in a participant information sheet (see *Appendix 5*), along with the name and contact details of the local PI. This was given to the family member to read before making their decision to take part, or not, in the study. Family members were provided an opportunity to ask questions before being invited to sign the consent form.

Informed consent

Staff members who had received training on the background, rationale and purpose of the FREE study and on the principles of the International Conference on Harmonisation Good Clinical Practice guidelines, specifically in relation to informed consent, were authorised to take informed consent from eligible family members. To support local PIs with staff training, a slide set, approved by the lead CLRN, was provided to all participating ICUs.

Informed consent was a two-stage process: the first was at the time the eligible family member was invited to take part in the study and the second was on receipt of the questionnaire pack.

Stage 1

Once the staff member taking informed consent was satisfied that the family member had read and understood the participant information sheet (see *Appendix 5*) and all their questions about the study had been answered, the family member was asked to give consent for their name and postal address to be entered onto the secure web portal, to enable a questionnaire pack (see *Appendix 6*) to be sent to them asking about their satisfaction with care and decision-making in the ICU 3 weeks after the patient (their relative/friend/etc.) had been discharged from the ICU. The family member was informed that, on receipt of the questionnaire pack, they could opt to withdraw from the study. The family member was invited to sign the consent form, which was countersigned, in their presence, by the authorised staff member. One copy of the signed consent form was provided to the family member and one placed in the investigator site file.

For family members who did not speak English, ICU staff were advised to seek assistance from translation services within the hospital trust. Non-English-speaking family members had the option, at the time of giving informed consent, to ask for the UK FS-ICU-24 and all accompanying documents to be translated (see *Translation of the UK FS-ICU-24*).

Stage 2

On receipt of the questionnaire pack, the family member was invited to complete the questionnaire but also given the option to withdraw from the study by completing and returning the ‘do not wish to participate’ form (see *Appendix 6*). A blank UK FS-ICU-24 returned to the ICNARC CTU was considered to be a refusal. Contact details for the study team at ICNARC were provided in the questionnaire pack (see *Appendix 6*) for family members who had further questions or wished to discuss their participation in the study.

Follow-up

Patients for whom at least one family member had been recruited were followed up until discharge from the ICU. Approximately 3 weeks after the patient had been discharged from, or had died in, the ICU, a questionnaire pack (see *Appendix 6*) was sent from the ICNARC CTU, by post, to the family member(s). Following evidence-based practice[25] for maximising responses to postal surveys, the questionnaire pack included a cover letter, the participant information sheet (see *Appendix 5*), the UK FS-ICU-24 (see *Appendix 2*), a ‘do not wish to participate’ form, a stamped addressed return envelope and a pen. During the first month of recruitment, family members of non-surviving patients were additionally sent the QODD questionnaire[23] (see *Appendix 3*).

If no response was received within 4 weeks after the first questionnaire was posted, a reminder letter was sent with another questionnaire pack. In consultation with the research ethics committee, there was no further follow-up of family members thereafter. For questionnaire packs returned indicating that the recipient was not known at the address, the postal address was checked with the study team at the recruiting ICU.

Follow-up of family members ended on receipt of a completed (or blank) questionnaire, a completed 'do not wish to participate' form or notification to the ICNARC CTU by telephone or e-mail that the family member wished to withdraw from the study, or once the second questionnaire pack had been sent.

Translation of the UK 24-item Family Satisfaction in the Intensive Care Unit questionnaire

Translation of the UK FS-ICU-24 was conducted, on request, using a global language solution provider. The full text of the UK FS-ICU-24 and accompanying documents were translated into the required language and typeset. It was then checked for errors and proofread by a second translator. If translation to another language required a change to how a question was phrased (e.g. it was not possible to translate the question directly from English), then this was discussed with the study team and checked with a second translator to ensure that the meaning of the question had not changed.

Data collection

A secure web portal, hosted by ICNARC, was set up to enable staff at participating ICUs to enter patient and family member data. Data for the FREE study were collected to:

- enable identification of patients staying in the ICU for 24 hours or more during the study period
- record the name and postal address of family members who had consented to take part in the study
- enable a questionnaire pack to be sent to family members 3 weeks following the patient's discharge from, or death in, the ICU
- describe the sociodemographic profile of family members who consented to take part in the study
- enable linkage to the CMP database to monitor recruitment to the study and adherence to the protocol at participating ICUs.

Patient data

In order to link data from family members to patients in participating ICUs, minimal patient data, routinely collected for the CMP, were entered onto the secure web portal as follows:

- NHS number, CMP admission number and date of birth – to enable linkage of the FREE study database to the CMP database
- date of admission to the ICU – to confirm that the patient had been in the ICU for 24 hours or more
- date of discharge from the ICU and status at discharge from the ICU – to enable the questionnaire pack to be sent to the family member(s) 3 weeks after the patient had been discharged from, or had died in, the ICU.

In addition, participation (yes/no) of the patient in a clinical research study during their ICU stay was recorded. The rationale for this was that it could potentially affect whether or not family members agreed to take part in the study (if they had already been approached about the patient taking part in a clinical research study) or their satisfaction with the ICU (e.g. if the clinical research study necessitated additional investigations and/or monitoring of the patient).

Case Mix Programme data

Data for the CMP are collected by trained data collectors to precise rules and definitions. The data then undergo extensive local and central validation for completeness, illogicalities and inconsistencies prior to pooling.

Data collected for the CMP take the form of patient identifiers, demographics, acute severity of illness, outcome and activity for admissions to each ICU. All admissions are followed up for the entire length of their acute hospital stay, both within the hospital housing the CMP ICU and to their ultimate discharge from acute hospital. Raw data are collected for all variables, rather than categorised, derived or aggregated data or scores.

The following data were extracted from the CMP database:

- demographics:
  - date of birth
  - gender
  - postcode – to enable linkage to census data to score deprivation
- case mix:
  - Acute Physiology and Chronic Health Evaluation (APACHE) II score and predicted risk of hospital death[26]
  - ICNARC physiology score and predicted risk of hospital death[27]
    (note: raw physiology data are submitted to ICNARC and the scores and predicted risk of hospital death are calculated centrally using standard algorithms to avoid any bias)
  - source of admission to the ICU
  - location immediately prior to the source of admission
    [note: if either of these is theatre and recovery in the hospital housing the ICU, data are collected on the type of surgery (elective or emergency) using the classification of the National Confidential Enquiry into Perioperative Deaths]
- outcomes:
  - status (alive/dead) at discharge from the ICU
  - status (alive/dead) at discharge from acute hospital
- activity:
  - length of stay in the ICU – calculated (in fractions of days) from the dates and times of admission to and discharge from the ICU
  - length of stay in hospital – calculated (in whole days) from the dates of admission and of discharge
  - readmissions to the ICU within the same hospital stay – identified from the postcode, date of birth and gender, and confirmed by the participating ICUs.

Family member data

At the time of providing consent, family members were asked to complete a short data collection form (see *Appendix 7*), which asked for contact and sociodemographic information as follows:

- contact information:
  - name – title, initial(s) and surname
  - full postal address, including postcode
  - relationship to the patient – e.g. husband, wife, brother, sister, son, daughter
  - whether or not they lived with the patient
  - first language
  - whether or not translation of the UK FS-ICU-24 and accompanying documents was required and, if so, the language

- sociodemographic information:
  - age group (18–29 years/30–39 years/40–49 years/50–59 years/60–69 years/70–79 years/≥ 80 years)
  - gender (male/female)
  - ethnicity (white/mixed/Asian or Asian British/black or black British/other)
  - highest level of education [NVQ (National Vocational Qualification)] levels 1 or 2, equivalent to GCSE or O-level/NVQ level 3, equivalent to A-level, AS-level or Higher School Certificate/NVQ Level 4 or 5, equivalent to degree, Higher degree, HNC (Higher National Certificate), HND (Higher National Diploma)/other].

These data were entered onto the secure web portal, along with whether or not the family member was documented by the ICU staff as the nominated next of kin.

The questionnaire pack sent to family members included the UK FS-ICU-24 (see *Appendix 2* and description in *Chapter 2*) and, for family members of non-survivors recruited during the first month of recruitment, the QODD questionnaire[23] (see *Appendix 3*). The QODD questionnaire (version 3.2A) is a 25-item questionnaire about the patient's experiences at the end of life that was developed and validated in North America. Only very minor changes were made to the questionnaire, for example translating words from US English to UK English. One question, asking about health-care costs, was removed, as this is not applicable in the UK. The questionnaire was formatted in the same style as the UK FS-ICU-24.

Screening log

To enable full and transparent reporting for the study, the CMP admission number and the date of ICU admission for patients who stayed in the ICU for 24 hours or more and for whom no family members were recruited were recorded in the screening log. The reason for no family member(s) being recruited was also recorded, which included no eligible family members visited; no eligible family member(s) approached to take part in the study (i.e. missed); family member(s) refused to take part in the study; and eligible family member(s) were recruited but subsequently withdrew from the study. No patient or family identifiers were recorded in the screening log.

Monitoring recruitment of family members

Recruitment of family members was closely monitored. Data entered onto both the secure web portal and the ICU screening logs were checked weekly against the estimated number of patient admissions to the ICU based on CMP data. The number of family members recruited in the previous 7 days was compared with the weekly average recruited. Any discrepancies or other concerns relating to recruitment were discussed with the local PI and ICU study team.

Every month, an ICU recruitment report, based on data entered onto the secure web portal and the ICU screening log, was produced and reviewed with the local PI. The report included the total number of patient admissions (who stayed for 24 hours or longer) and the total number of eligible family members who were and were not recruited during the previous month and how these compared with the monthly averages. The percentage of patients for whom no family member was recruited, particularly where family members had been missed (i.e. not approached about the study), was highlighted and discussed with the local PI.

Data management

Data management was an ongoing process. Data collected for the study were monitored and checked throughout the recruitment period to ensure that data were as complete and accurate as possible. The secure web portal was monitored daily by the study team at the ICNARC CTU to ensure that data entry at participating ICUs was timely, both to enable questionnaire packs to be sent out on time to family members and to allow time for translation of the UK FS-ICU-24 and accompanying documents, where required. Details of family members (name and postal address) recruited were checked for completeness to avoid unnecessary delays in sending out questionnaires.

Every quarter, data entered on the secure web portal and the ICU screening logs were linked to data in the CMP database. Any queries relating to discrepancies in the number of patient admissions (who stayed for 24 hours or more) during the previous quarter or any issues with data linkage were investigated and resolved in consultation with the ICU study team.

Data from completed questionnaires were entered centrally into a secure database at the ICNARC CTU following a standard operating procedure. All identifiable information, such as names (e.g. of patients, family members or critical care staff members), were removed. If a family member provided a comment rather than ticking one of the response options, the comment was recorded and reviewed by two members of the SMG. All queries relating to data entry were reviewed by two members of the SMG (SH/EW) and any disagreement was reviewed and discussed with a third (KR).

Quality checks of data entered were conducted every 2 months. A 20% random sample of questionnaires entered was checked for accuracy of data entry and any issues with data quality were addressed with the ICNARC CTU team. All fields in the database with missing data were checked against the paper UK FS-ICU-24.

Network support

To maintain the profile of the study, regular updates on study progress were provided at quarterly meetings of the NIHR CRN Critical Care Specialty Group and at local CLRN meetings. In addition, updates were provided at national meetings, such as the Annual Meeting of the CMP and the UK Critical Care Research Forum.

Sample size

The duration of recruitment was 1 year, chosen to avoid bias from seasonal variation. Data from the CMP database indicated that an average of 520 patients are admitted per ICU per year. Of these, 74% (385 patients per ICU per year) stayed at least 24 hours, corresponding to approximately 7700 patients across 20 ICUs. No data existed on the average number of family members per patient who visit the ICU. It was assumed that, with an average of 2.5 family members per patient, approximately 19,250 family members would be recruited over a 12-month recruitment period. Assuming a 66% response rate to the postal questionnaire,[18] it was estimated that a total sample of approximately 12,700 responses associated with 6700 patients would be received. Using available FS-ICU-24 data, published and unpublished, mean baseline satisfaction domain scores of 80 with standard deviation (SD) 20 were expected. This sample size would therefore 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 estimated sample size was revised following completion of the first full quarter of recruitment. Revised targets were calculated for each site based on recruitment of an average of two family members for 80% of patients staying at least 36 hours in the ICU, allowing that on average 10% of patients may have no family members visit. For the purpose of the revised estimate, 36 hours was chosen, instead of 24 hours, to allow for family members of short-term patients who might not have an opportunity to visit during the period of 24–36 hours. Based on the revised ICU targets, it was expected that 14,200 family members (of 7100 patients) would be recruited. Assuming a 60% response rate, it was estimated that a total sample of approximately 8500 responses associated with 5500 patients would be achieved. This sample size would retain $> 90\%$ 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.

Statistical analysis

A descriptive analysis was conducted to describe the:

- representativeness of ICUs that participated in the study (ICU characteristics)
- duration of participation of ICUs in the study
- recruitment and follow-up of family members, overall and by participating ICU

- patient characteristics and outcomes associated with recruitment and non-recruitment of family members, overall and by participating ICU
- patient characteristics and outcomes associated with the number of family members per patients recruited, overall and by participating ICU
- characteristics of family members recruited
- time taken from first mailing of the questionnaire pack to receipt of a completed questionnaire
- response rate from family members to the questionnaire, overall and by ICU
- patient characteristics and outcomes associated with the response, or non-response, of family members to the questionnaire
- family member characteristics associated with response, or non-response, to the questionnaire.

Discrete variables were summarised as numbers and percentages, which were calculated according to the number of ICUs for which, or individuals for whom, data were available; where values were missing, the denominator is stated in the table. Continuous variables were summarised by standard measures of central tendency and dispersion: mean and SD and/or median and interquartile range (IQR).

Results

Adult general intensive care units

Of the 210 adult general ICUs participating in the CMP in November 2012, 142 (67.6%) expressed an interest in taking part in the study. Twenty ICUs, plus 20 reserve ICUs, were randomly selected to ensure a representative sample of ICUs with respect to geographical location, hospital type (university/non-university) and size of ICU. The 20 ICUs were formally invited to take part in the study and 19 of them accepted. One ICU declined to take part and the corresponding reserve ICU was contacted and accepted the invitation.

Of the 20 ICUs, 19 obtained local R&D approval and the study opened to recruitment on 28 May 2013. One ICU withdrew from the study on 5 July 2013, as it was unable to secure adequate resources (NHS support costs) from its CLRN for the study. The corresponding reserve ICU accepted the invitation to take part and opened to recruitment on 4 September 2013. The remaining 19 ICUs opened to recruitment between 28 May and 8 July 2013 (*Figure 2*). Delays to opening included issues relating to confirmation of NHS support costs from the CLRN, delays in obtaining R&D approval and delays in local set-up, such as staff training.

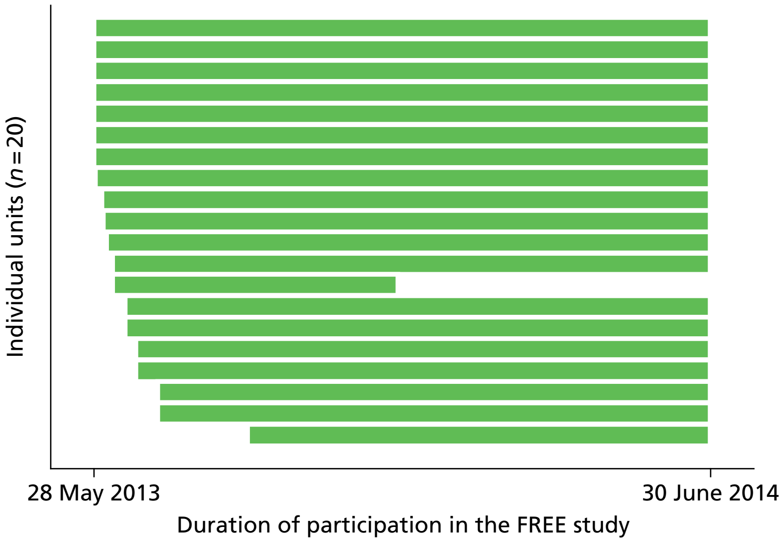


FIGURE 2 Duration of participation of critical care ICUs.

One ICU closed to recruitment on 10 December 2013 because local resource issues meant that the ICU had to withdraw temporarily from participation in the CMP. As a result, no CMP data from this ICU were available for the study analysis. The remaining 19 ICUs continued recruiting family members of patients admitted to the ICU up to 30 June 2014 (*Figure 2*). The last family member was recruited on 29 July 2014. Complete CMP data for the period 28 May 2013 to 30 June 2014 were received from the 19 ICUs.

Representativeness of intensive care units

The characteristics of the 20 ICUs that participated in the FREE study compared with all ($n = 210$) adult general ICUs in the CMP are presented in *Table 3*. Compared with all ICUs in the CMP, there was a higher proportion of large ICUs (more than 14 beds) and a higher proportion of ICUs located in Wales and Northern Ireland in the FREE study. The proportions of ICUs located in university and non-university hospitals were similar (see *Table 3*).

The characteristics and outcomes of all admissions to 19 of the 20 ICUs that participated in the FREE study, during the period 28 May 2013 to 30 June 2014, were similar to admissions to all CMP ICUs during the same period (*Table 4*). The mean age of patients was 61.5 years and more than half were male (56.5% in FREE study ICUs; 55.0% in CMP ICUs). The proportion of patients admitted following either elective (26.1% in FREE study ICUs; 22.9% in CMP ICUs) or emergency surgery (19.0% in FREE study ICUs; 18.4% in CMP ICUs) was similar in the two groups of ICUs. Admissions were similar with respect to severity of illness, based on the ICNARC model predicted risk of death [median (IQR) 0.09 (0.03–0.30) for FREE study ICUs; 0.11 (0.03–0.33) for CMP ICUs). Approximately 14% (14.0% in FREE study ICUs; 14.4% in CMP ICUs) of patients died in the ICU and around 21% (20.6% and 21.3%, respectively) died before leaving hospital. The ICU median length of stay was the same for ICU survivors in all CMP ICUs and FREE study ICUs [2.2 (IQR 1.0–4.9) days] and similar for non-survivors [1.9 (IQR 0.7–5.1) days in FREE study ICUs; 2.1 (IQR 0.7–5.7) days in CMP ICUs].

The characteristics and outcomes of patients who stayed in the ICU for more than 24 hours were also similar in the two groups of ICUs (*Table 5*).

TABLE 3 Representativeness of ICUs (ICU characteristics)

Characteristic	CMP ICUs, *n* (%)	FREE ICUs, *n* (%)
Total, *N*	210	20
Region		
South-east	60 (28.6)	4 (20.0)
South-west	33 (15.7)	4 (20.0)
North-east	48 (22.9)	4 (20.0)
North-west	47 (22.4)	4 (20.0)
Wales	13 (6.2)	2 (10.0)
Northern Ireland	9 (4.3)	2 (10.0)
Type of hospital		
Non-university	112 (53.3)	10 (50.0)
University	98 (46.7)	10 (50.0)
Size of ICU		
Small (< 14 beds)	142 (67.6)	10 (50.0)
Large (≥ 14 beds)	68 (32.4)	10 (50.0)

TABLE 4 Characteristics and outcomes for all admissions to ICUs participating in the FREE study and in the CMP

Parameter	CMP	FREE study
Total number of ICUs	209[a]	19[a]
Total number of admissions	149,779	18,270
Mean age (years) (SD)	61.5 (18.0)	61.5 (18.0)
Sex male (%)	82,444 (55.0)	10,316 (56.5)
Ethnicity, *n* (%)		
White	135,767 (90.6)	16,439 (90.0)
Asian	4815 (3.2)	439 (2.4)
Black	3250 (2.2)	327 (1.8)
Other	2434 (1.6)	445 (2.4)
Not stated	3513 (2.3)	620 (3.4)
Mean distance (km) from patient home to hospital (SD), median (IQR) [*N*]	25.0 (54.2), 8.7 (3.9–19.3) [128,169]	31.7 (64.5), 9.2 (4.2–20.8) [18,090]
APACHE II severe comorbidities, *n* (%)		
0	123,437 (82.4)	14,742 (80.7)
1	20,906 (14.0)	2648 (14.5)
2	5053 (3.4)	793 (4.3)
≥ 3	383 (0.3)	87 (0.5)
Admission type, *n* (%)	149,765	18,270
Medical	87,940 (58.7)	10,039 (54.9)
Elective surgery	34,284 (22.9)	4761 (26.1)
Emergency surgery	27,541 (18.4)	3470 (19.0)
Surgical status of surgical admissions, *n* (%)	61,825	8231
Planned surgery	28,267 (45.7)	3985 (48.4)
Unplanned surgery	33,558 (54.3)	4246 (51.6)
Mean ICNARC physiology score (SD)	16.9 (9.3)	16.5 (9.2)
Median ICNARC predicted risk of death (IQR) [*N*]	0.10 (0.03–0.33) [142,654]	0.09 (0.03–0.30) [17,261]
Mean APACHE II acute physiology score (SD)	11.4 (6.1)	11.3 (5.9)
Mean APACHE II score (SD)	15.7 (7.0)	15.6 (6.9)
Median APACHE II predicted risk of death (IQR) [*N*]	0.12 (0.04–0.29) [132,197]	0.11 (0.04–0.28) [16,193]
Mechanical ventilation during first 24 hours, *n* (%) [*N*]	58,687 (39.4) [148,975]	7008 (38.5) [18,187]
ICU mortality, *n* (%) [*N*]	21,505 (14.4) [149,779]	2560 (14.0) [18,270]
Acute hospital mortality, *n* (%) [*N*]	29,945 (21.0) [142,670]	3550 (20.6) [17,266]
ICU length of stay (days), mean (SD), median (IQR) [*N*]		
Overall	4.7 (8.0), 2.2 (1.0–5.0) [149,741]	4.6 (7.8), 2.1 (1.0–4.9) [18,270]
Survivors	4.7 (7.9), 2.2 (1.0–4.9) [128,236]	4.6 (7.9), 2.2 (1.0–4.9) [15,710]
Non-survivors	5.0 (9.0), 2.1 (0.7–5.7) [21,505]	4.4 (7.6), 1.9 (0.7–5.1) [2560]

continued

TABLE 4 Characteristics and outcomes for all admissions to ICUs participating in the FREE study and in the CMP (*continued*)

Parameter	CMP	FREE study
Acute hospital length of stay (days), mean (SD), median (IQR) [*N*]		
Overall	21.1 (29.8), 12.0 (6.0–25.0) [142,176]	22.1 (30.5), 12.0 (6.0–26.0) [17,207]
Survivors	22.5 (30.6), 13.0 (7.0–26.0) [112,292]	23.5 (30.7), 14.0 (7.0–27.0) [13,662]
Non-survivors	16.0 (26.1), 7.0 (2.0–19.0) [29,884]	16.6 (29.3), 7.0 (2.0–19.0) [3545]

[*N*], number of patients for whom the information was available.
a Excludes one ICU, for which no CMP data were available.

TABLE 5 Characteristics of and outcomes for patients admitted to ICUs participating in the FREE study and in the CMP who stayed for ≥ 24 hours

Parameter	CMP	FREE study
Total number of ICUs	209[a]	19[a]
Total number of patients	106,284	12,328
Mean age (years) (SD)	62.0 (17.4)	62.1 (17.4)
Sex male (%)	59,029 (55.5)	6999 (56.8)
Ethnicity, *n* (%)		
White	96,349 (90.7)	11,094 (90.0)
Asian	3482 (3.3)	302 (2.4)
Black	2258 (2.1)	223 (1.8)
Other	1744 (1.6)	293 (2.4)
Not stated	2451 (2.3)	416 (3.4)
Mean distance (km) from patient home to hospital (SD), median (IQR) [*N*]	25.5 (55.3), 8.5 (3.8–19.2) [91,485]	31.3 (64.9), 9.0 (4.1–19.6) [12,199]
APACHE II severe comorbidities, *n* (%)		
0	87,232 (82.1)	10,013 (81.2)
1	15,098 (14.2)	1765 (14.3)
2	3677 (3.5)	495 (4.0)
≥ 3	277 (0.3)	55 (0.4)
Admission type, *n* (%)	106,275	12,328
Medical	65,900 (62.0)	7078 (57.4)
Elective surgery	20,505 (19.3)	2838 (23.0)
Emergency surgery	19,870 (18.7)	2412 (19.6)

TABLE 5 Characteristics of and outcomes for patients admitted to ICUs participating in the FREE study and in the CMP who stayed for ≥ 24 hours (*continued*)

Parameter	CMP	FREE study
Surgical status of surgical admissions, *n* (%)	40,375	5250
Planned surgery	16,833 (41.7)	2368 (45.1)
Unplanned surgery	23,542 (58.3)	2882 (54.9)
Mean ICNARC physiology score (SD)	17.5 (8.5)	17.1 (8.5)
Median ICNARC predicted risk of death (IQR) [*N*]	0.13 (0.04–0.35) [105,629]	0.12 (0.03–0.33) [12,221]
Mean APACHE II acute physiology score (SD)	11.9 (5.7)	11.7 (5.6)
Mean APACHE II score (SD)	16.2 (6.6)	16.1 (6.5)
Median APACHE II predicted risk of death (IQR) [*N*]	0.15 (0.05–0.32) [101,232]	0.14 (0.05–0.31) [11,846]
Mechanical ventilation during first 24 hours, *n* (%) [*N*]	46,199 (43.5) [106,095]	5240 (42.6) [12,312]
ICU mortality, *n* (%) [*N*]	13,825 (13.0) [106,284]	1570 (12.7) [12,328]
Acute hospital mortality, *n* (%) [*N*]	21,861 (20.7) [105,632]	2502 (20.5) [12,221]
ICU length of stay (days), mean (SD), median (IQR) [*N*]		
Overall	5.9 (8.4), 3.2 (1.9–6.4) [106,251]	5.7 (7.9), 3.1 (1.9–6.2) [12,328]
Survivors	5.8 (8.1), 3.1 (1.9–6.1) [92,426]	5.7 (7.9), 3.1 (1.9–6.1) [10,758]
Non-survivors	7.1 (10.1), 3.9 (2.0–8.1) [13,825]	6.1 (7.7), 3.7 (1.9–6.9) [1570]
Acute hospital length of stay (days), mean (SD), median (IQR) [*N*]		
Overall	24.1 (31.4), 14.0 (7.0–29.0) [105,546]	24.7 (30.6), 15.0 (7.0–29.0) [12,206]
Survivors	25.4 (32.3), 15.0 (8.0–30.0) [83,704]	26.1 (31.3), 16.0 (8.0–31.0) [9706]
Non-survivors	19.3 (27.5), 10.0 (4.0–23.0) [21,842]	19.0 (26.9), 10.0 (4.0–22.0) [2500]

[*N*], number of patients for whom the information was available.

a Excludes one ICU for which no CMP data were available.

Patients

Between 28 May 2013 and 30 June 2014 there were 18,757 admissions to the 20 participating ICUs, of which 1677 were readmissions to the ICU during the same hospital stay. Of the 17,080 patients admitted to critical care during the study period, 4341 (25.4%) stayed for less than 24 hours. Of the remaining 12,739 patients (74.6%), who stayed in the ICU for 24 hours or more, nine were excluded from the study because they were discharged from the ICU after 1 August 2014. This was because there was insufficient time before the database was closed (on 12 September 2014) for a questionnaire to be posted to and completed by their family members. In total, data from 12,730 patients were included in the analysis.

Of these 12,730 patients, there were 5788 (45.5%) for whom no family member was recruited because there were no eligible family members or no eligible family members visited the patient during their stay in the ICU ($n = 2200$ patients); or the family members were not approached about the study or were approached but not recruited because, for example, they did not visit the patient again in the ICU ($n = 3588$). Family members of 6942 (54.5%) patients were invited to take part in the study. Of these, the family members of 547 patients refused the invitation. For 15 patients, family members were recruited but subsequently withdrew because they no longer wished to take part or were withdrawn because they were found to be ineligible for the study (*Figure 3*).

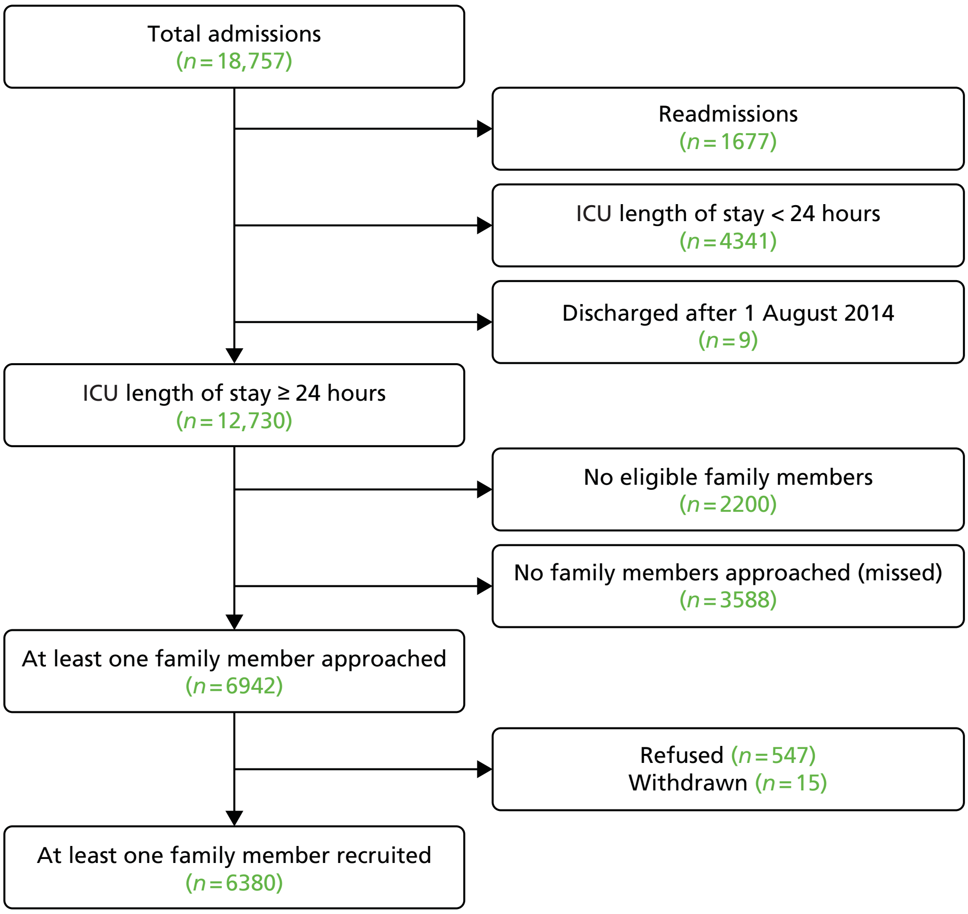


FIGURE 3 Flow of patient admissions.

Overall, at least one family member was recruited for 60.6% ($n = 6380$) of the 10,530 patients who stayed in the ICU for 24 hours or more and who were visited in the ICU by one or more eligible family members. Recruitment varied across ICUs, ranging from 41.2% to 79.4% of patients with one or more eligible family members recruited (*Table 6*).

No family member(s) were recruited for 39.4% of patients because eligible family members were not approached ($n = 3588$, 34.1%), the family member(s) refused the invitation to take part ($n = 547$, 5.2%) or the family member(s) withdrew or were withdrawn from the study ($n = 15$, 0.1%). There was considerable variation across ICUs in the reasons reported for non-recruitment of family members (*Table 7*). For example, the proportion of patients whose family members were not approached ranged from 15.7% to 56.9% of patients.

TABLE 6 Number of patients with and without family members recruited, overall and by ICU

ICU	Total	Patients with at least one family member recruited (%)	Patients with no family members recruited (%)
A	613	393 (64.1)	220 (35.9)
B	288	212 (73.6)	76 (26.4)
C	484	232 (47.9)	252 (52.1)
D	354	281 (79.4)	73 (20.6)
E	370	254 (68.6)	116 (31.4)
F	822	475 (57.8)	347 (42.2)
G	967	611 (63.2)	356 (36.8)
H	353	278 (78.8)	75 (21.2)
I	261	141 (54.0)	120 (46.0)
J	315	229 (72.7)	86 (27.3)
K	498	239 (48.0)	259 (52.0)
L	469	209 (44.6)	260 (55.4)
M	639	384 (60.1)	255 (39.9)
N	767	498 (64.9)	269 (35.1)
O	242	179 (74.0)	63 (26.0)
P	901	519 (57.6)	382 (42.4)
Q	350	256 (73.1)	94 (26.9)
R	686	460 (67.1)	226 (32.9)
S	357	147 (41.2)	210 (58.8)
T	794	383 (48.2)	411 (51.8)
Total	10,530	6380 (60.6)	4150 (39.4)

TABLE 7 Number of patients with and without family members recruited (including reasons for non-recruitment), overall and by ICU

ICU	One or more family members recruited (%)	Reasons for non-recruitment		
		Not approached (%)	Refused (%)	Withdrawn (%)
A	393 (64.1)	160 (26.1)	60 (9.8)	–
B	212 (73.6)	71 (24.7)	5 (1.7)	–
C	232 (47.9)	234 (48.3)	17 (3.5)	1 (0.2)
D	281 (79.4)	62 (17.5)	11 (3.1)	–
E	254 (68.6)	109 (29.5)	6 (1.6)	1 (0.3)
F	475 (57.8)	296 (36.0)	50 (6.1)	1 (0.1)
G	611 (63.2)	325 (33.6)	29 (3.0)	2 (0.2)
H	278 (78.8)	57 (16.1)	18 (5.1)	–
I	141 (54.0)	108 (41.4)	11 (4.2)	1 (0.4)
J	229 (72.7)	77 (24.4)	9 (2.9)	–
K	239 (48.0)	207 (41.6)	52 (10.4)	–
L	209 (44.6)	234 (49.9)	26 (5.5)	–
M	384 (60.1)	218 (34.1)	36 (5.6)	1 (0.2)
N	498 (64.9)	224 (29.2)	43 (5.6)	2 (0.3)
O	179 (74.0)	38 (15.7)	22 (9.1)	3 (1.2)
P	519 (57.6)	313 (34.7)	66 (7.3)	3 (0.3)
Q	256 (73.1)	94 (26.9)	–	–
R	460 (67.1)	176 (25.7)	50 (7.3)	–
S	147 (41.2)	203 (56.9)	7 (2.0)	–
T	383 (48.2)	382 (48.1)	29 (3.7)	–
Overall	6380 (60.6)	3588 (34.1)	547 (5.2)	15 (0.1)

The characteristics and outcomes of patients for whom at least one family was recruited, compared with those of patients for whom no family member was recruited, are presented in *Table 8*. Patients with no family members recruited were more likely to have been admitted to ICU following elective surgery (27.7%) than patients for whom at least one family member was recruited (18.5%) and were less likely to have been mechanically ventilated during their first 24 hours in the ICU (36.9% vs. 48.1%, respectively). In addition, their median (IQR) ICNARC predicted risk of death was 0.08 (0.03–0.28) compared with 0.16 (0.05–0.37) for patients for whom at least one family member was recruited. Even so, the ICU mortality rate for patients for whom no family members were recruited was higher than patients for whom at least one family member was recruited (14.7% vs. 10.9%). This is probably because the group of patients for whom no family members were recruited included a mix of low-risk patients (e.g. admitted following elective surgery), who tend to have a short stay (24 hours or less) in the ICU, and very sick (high-risk) patients, whose family members were not approached about the study because of the severity of their illness. During the study, ICU staff reported that family members of very sick patients, particularly those who were clearly distressed, were often not approached about taking part.

Overall, an average of two family members per patient were recruited. The first family member was recruited within a median (IQR) of 2 (1–3) days of the patient's admission to the ICU. However, there was considerable variation across ICUs in the number of family members per patient recruited (*Table 9*).

TABLE 8 Case mix and outcome of patients with and without family member(s) recruited

Parameter	One or more family members recruited	No family members recruited
Total, *N*	6233[a]	6095[b]
Mean age (years) (SD)	62.2 (17.2)	62.0 (17.5)
Sex male (%)	3492 (56.0)	3507 (57.5)
Ethnicity, *n* (%)		
White	5688 (91.3)	5406 (88.7)
Asian	145 (2.3)	157 (2.6)
Black	84 (1.3)	139 (2.3)
Other	134 (2.1)	159 (2.6)
Not stated	182 (2.9)	234 (3.8)
Median distance (km) from patient home to hospital (IQR) [*N*]	9.0 (4.2–19.5) [6182]	8.9 (4.1–19.7) [6017]
APACHE II severe comorbidities, *n* (%)		
0	5058 (81.1)	4955 (81.3)
1	897 (14.4)	868 (14.2)
2	253 (4.1)	242 (4.0)
≥ 3	25 (0.4)	30 (0.5)
Admission type, *n* (%)	6233	6095
Medical	3851 (61.8)	3227 (52.9)
Elective/scheduled surgery	1150 (18.5)	1688 (27.7)
Emergency/urgent surgery	1232 (19.8)	1180 (19.4)
Surgical status of surgical admissions *n* (%)	2382	2868
Planned surgery	951 (39.9)	1417 (49.4)
Unplanned surgery	1431 (60.1)	1451 (50.6)
Mean ICNARC physiology score (SD)	18.1 (8.3)	16.0 (8.6)
Median ICNARC predicted risk of death (IQR) [*N*]	0.16 (0.05–0.37) [6160]	0.08 (0.03–0.28) [6061]
Mean APACHE II acute physiology score (SD)	12.1 (5.5)	11.2 (5.7)
Mean APACHE II score (SD)	16.6 (6.4)	15.6 (6.6)
Median APACHE II predicted risk of death (IQR) [*N*]	0.17 (0.06–0.34) [5952]	0.11 (0.04–0.27) [5894]
Mechanical ventilation during first 24 hours, *n* (%) [*N*]	2995 (48.1) [6225]	2245 (36.9) [6087]
ICU mortality, *n* (%) [*N*]	677 (10.9) [6233]	893 (14.7) [6095]
Acute hospital mortality, *n* (%) [*N*]	1180 (19.2) [6160]	1322 (21.8) [6061]

continued

TABLE 8 Case mix and outcome of patients with and without family member(s) recruited (*continued*)

Parameter	One or more family members recruited	No family members recruited
ICU length of stay (days), mean (SD), median (IQR) [*N*]		
Overall	7.9 (9.7), 4.8 (2.8–8.9) [6233]	3.5 (4.7), 2.1 (1.5–3.8) [6095]
Survivors	7.7 (9.7), 4.7 (2.7–8.8) [5556]	3.5 (4.6), 2.1 (1.5–3.7) [5202]
Non-survivors	9.1 (9.4), 6.0 (3.7–10.7) [677]	3.8 (4.9), 2.3 (1.5–4.2) [893]
Acute hospital length of stay (days), *mean* (SD), *median* (IQR) [*N*]		
Overall	28.4 (32.2), 18.0 (10.0–35.0) [6150]	20.8 (28.3), 12.0 (6.0–23.0) [6056]
Survivors	29.8 (33.3), 19.0 (10.0–36.0) [4972]	22.2 (28.6), 13.0 (7.0–25.0) [4734]
Non-survivors	22.7 (26.6), 13.0 (7.0–27.0) [1178]	15.7 (26.7), 7.0 (3.0–16.0) [1322]

[*N*], number of patients for whom the information was available.
a Excludes 147 patients for whom no CMP data available.
b Excludes 255 patients for whom no CMP data available.

TABLE 9 Number of patients with one or more family members recruited, overall and by ICU

ICU	Mean number of family members recruited per patient	Number of family members recruited per patient (%)				Median days from patient admission to recruitment of first family member (IQR)
		1	2	3	4	
A	1.8	196 (49.9)	125 (31.8)	46 (11.7)	26 (6.6)	2 (1–3)
B	2.6	35 (16.5)	66 (31.1)	54 (25.5)	57 (26.9)	1 (1–3)
C	1.9	94 (40.5)	80 (34.5)	37 (15.9)	21 (9.1)	2 (1–3)
D	2.3	79 (28.1)	91 (32.4)	59 (21.0)	52 (18.5)	2 (1–3)
E	1.9	106 (41.7)	89 (35.0)	39 (15.4)	20 (7.9)	2 (1–2)
F	1.8	195 (41.1)	187 (39.4)	68 (14.3)	25 (5.3)	2 (1–3)
G	1.7	283 (46.3)	235 (38.5)	73 (11.9)	20 (3.3)	2 (1–4)
H	2.6	54 (19.4)	87 (31.3)	65 (23.4)	72 (25.9)	2 (1–3)
I	2.2	41 (29.1)	51 (36.2)	29 (20.6)	20 (14.2)	2 (1–3)
J	2.1	86 (37.6)	71 (31.0)	42 (18.3)	30 (13.1)	3 (2–4)
K	1.7	129 (54.0)	71 (29.7)	29 (12.1)	10 (4.2)	2 (1–3)
L	1.8	103 (49.3)	65 (31.1)	27 (12.9)	14 (6.7)	2 (1–4)
M	2.1	146 (38.0)	120 (31.3)	69 (18.0)	49 (12.8)	2 (1–2)
N	2.0	190 (38.2)	159 (31.9)	96 (19.3)	53 (10.6)	2 (1–3)
O	1.8	80 (44.7)	68 (38.0)	15 (8.4)	16 (8.9)	1 (1–2)
P	2.0	205 (39.5)	175 (33.7)	75 (14.5)	64 (12.3)	2 (1–2)
Q	1.6	142 (55.5)	83 (32.4)	24 (9.4)	7 (2.7)	2 (1–3)
R	1.6	246 (53.5)	150 (32.6)	50 (10.9)	14 (3.0)	2 (1–2)
S	1.7	68 (46.3)	56 (38.1)	17 (11.6)	6 (4.1)	2 (1–3)
T	2.0	160 (41.8)	114 (29.8)	60 (15.7)	49 (12.8)	2 (1–4)
Total	2.0	2638 (41.3)	2143 (33.6)	974 (15.3)	625 (9.8)	2 (1–3)

Family members

Characteristics of family members

A total of 12,346 family members were recruited into the study between 29 May 2013 and 29 July 2014. The largest group (44.8%) of family members who took part in the study were aged between 40 and 60 years of age and approximately two-thirds (63.3%) were female. Approximately one-third (33.9%) of family members reported being the patient's child and a quarter (25.2%) reported being the patient's partner. Just over one-third (39.4%) were reported by the ICU to be the nominated next of kin. A similar proportion (33.1%) of family members reported that they lived with the patient (*Table 10*).

TABLE 10 Characteristics of family members recruited

Characteristic	Family members recruited
Total number of family members recruited	12,346
Age group (years), *n* (%)	12,068
< 30	1429 (11.8)
30–39	1590 (13.2)
40–49	2760 (22.9)
50–59	2646 (21.9)
60–69	2131 (17.7)
70–79	1211 (10.0)
≥ 80	301 (2.5)
Sex, *n* (%)	12,145
Female	7687 (63.3)
Male	4458 (36.7)
Ethnicity, *n* (%)	12,346
White	11,379 (92.2)
Asian	355 (2.9)
Black	161 (1.3)
Other	195 (1.6)
Not stated	256 (2.1)
Deprivation, *n* (%)	11,740
1 (least deprived)	2113 (18.0)
2	2406 (20.5)
3	2415 (20.6)
4	2545 (21.7)
5 (most deprived)	2261 (19.3)
Median distance (km) from family member home to hospital (IQR) [*N*]	11.6 (5.1–30.7) [11,803]
Relationship, *n* (%): 'I am the patient's . . .'	12,343
Partner	3105 (25.2)
Child	4186 (33.9)
Parent	1054 (8.5)
Sibling	1271 (10.3)
Other relative	1973 (16.0)
Other non-relative	754 (6.1)

continued

TABLE 10 Characteristics of family members recruited (*continued*)

Characteristic	Family members recruited
Next of kin, *n* (%)	11,702
No	7086 (60.6)
Yes	4616 (39.4)
Lives with patient, *n* (%)	12,343
No	8255 (66.9)
Yes	4088 (33.1)
Education level, *n* (%)	
NVQ 1 or 2	3147 (25.5)
NVQ 3	2086 (16.9)
NVQ 4 or 5	2936 (23.8)
Other	2124 (17.2)
Not stated	2053 (16.6)
First language, *n* (%)	
Not English	335 (2.7)
English	12,011 (97.3)

[*N*], number of family members for whom the information was available.

Patient characteristics and outcomes associated with recruitment of family members

Tables 11 and *12* show the patient characteristics and outcomes associated with recruitment and non-recruitment of family members, respectively. The proportion of patients for whom no eligible family members were recruited was higher for patients admitted to the ICU on a Thursday (53.8%) or Friday (54.7%) than on other days of the week (e.g. Monday, 42.5%) (see *Table 12*). This probably reflects the lack of research staff available at weekends, when these patients would have been in the period from 24 to 48 hours in the ICU, thereby triggering their family members to be screened for eligibility. As expected, the longer the patient spent in the ICU, the more likely it was that at least one family member was recruited into the study; 55% of patients who stayed between 48 hours and 7 days and 79% of patients who stayed for ≥ 7 days had one or more family members recruited, compared with 14.3% of patients who stayed between 24 and 36 hours. Although numbers were small, recruitment of family members was lowest for patients who were of black ethnicity compared with other ethnic groups; 37.7% of patients who were of black ethnicity had one or more family members recruited, compared with 51.3% who were of white ethnicity and 48.0% who were of Asian ethnicity. Patients in the least deprived group (based on postcode) were more likely to have at least one family member recruited (53.4%) than the most deprived group (47.4%) (see *Table 11*). A higher proportion of patients admitted following elective surgery had no family members recruited (59.5%) than either patients admitted following emergency surgery (48.9%) or patients who were medical (non-surgical) admissions (45.6%) (see *Table 12*). These patients were less sick and would have had a shorter length of stay in the ICU and therefore less opportunity for family members to be recruited. The number of family members recruited per patient was generally higher with increasing severity of illness, based on the ICNARC physiology score and predicted risk of death,[27] as these patients tend to stay longer in the ICU, thereby providing greater opportunity for family members to be recruited. However, patients who did not survive the ICU were less likely to have had a family member recruited (43.1%) than patients who survived the ICU (51.6%) (see *Table 12*), suggesting that family members of the sickest patients were less likely to have been approached.

TABLE 11 Patient characteristics and outcomes associated with recruitment of one or more family members

	Number of family members recruited				
Parameter	1	2	3	4	Total
Total, *N* (%)[a]	2570 (20.8)	2087 (16.9)	957 (7.8)	619 (5.0)	6233 (50.6)
Day of admission, *n* (%)					
Sunday	293 (22.5)	241 (18.5)	125 (9.6)	88 (6.8)	747 (57.5)
Monday	431 (22.3)	325 (16.8)	147 (7.6)	96 (5.0)	999 (51.7)
Tuesday	449 (23.1)	341 (17.6)	142 (7.3)	84 (4.3)	1016 (52.3)
Wednesday	386 (20.0)	339 (17.6)	142 (7.4)	94 (4.9)	961 (49.8)
Thursday	338 (17.7)	312 (16.3)	133 (7.0)	99 (5.2)	882 (46.2)
Friday	363 (18.7)	279 (14.4)	151 (7.8)	84 (4.3)	877 (45.3)
Saturday	310 (22.5)	250 (18.1)	117 (8.5)	74 (5.4)	751 (54.5)
ICU length of stay, *n* (%)					
24–30 hours	104 (8.4)	50 (4.1)	17 (1.4)	6 (0.5)	177 (14.3)
30–36 hours	61 (10.8)	42 (7.4)	10 (1.8)	6 (1.1)	119 (21.0)
36–48 hours	319 (16.6)	151 (7.9)	61 (3.2)	25 (1.3)	556 (28.9)
48 hours to 7 days	1430 (24.2)	1166 (19.7)	420 (7.1)	234 (4.0)	3250 (55.0)
≥ 7 days	656 (24.3)	678 (25.1)	449 (16.6)	348 (12.9)	2131 (79.0)
Age group (years), *n* (%)					
< 30	149 (20.3)	116 (15.8)	56 (7.6)	44 (6.0)	365 (49.7)
30–39	169 (22.0)	112 (14.6)	61 (8.0)	35 (4.6)	377 (49.2)
40–49	278 (21.7)	180 (14.0)	100 (7.8)	68 (5.3)	626 (48.8)
50–59	395 (21.1)	309 (16.5)	127 (6.8)	111 (5.9)	942 (50.3)
60–69	604 (21.3)	528 (18.6)	215 (7.6)	132 (4.6)	1479 (52.1)
70–79	611 (20.5)	510 (17.1)	266 (8.9)	146 (4.9)	1533 (51.5)
≥ 80	364 (19.6)	332 (17.9)	132 (7.1)	83 (4.5)	911 (49.1)
Sex, *n* (%)					
Female	1163 (21.8)	891 (16.7)	408 (7.6)	284 (5.3)	2746 (51.5)
Male	1407 (20.1)	1196 (17.1)	549 (7.8)	335 (4.8)	3487 (49.9)
Ethnicity, *n* (%)					
White	2340 (21.1)	1897 (17.1)	878 (7.9)	573 (5.2)	5688 (51.3)
Asian	61 (20.2)	52 (17.2)	20 (6.6)	12 (4.0)	145 (48.0)
Black	36 (16.1)	31 (13.9)	12 (5.4)	5 (2.2)	84 (37.7)
Other	66 (22.5)	41 (14.0)	16 (5.5)	11 (3.8)	134 (45.7)
Not stated	67 (16.1)	66 (15.9)	31 (7.5)	18 (4.3)	182 (43.8)
Median distance (km) from patient home to hospital (IQR) [*N*]	9.1 (4.2–20.3) [2542]	9.6 (4.4–21.2) [2073]	8.6 (4.0–17.2) [954]	7.8 (3.8–16.0) [613]	9.0 (4.2–19.5) [6182]

continued

TABLE 11 Patient characteristics and outcomes associated with recruitment of one or more family members (*continued*)

	Number of family members recruited				
Parameter	**1**	**2**	**3**	**4**	**Total**
Deprivation, *n* (%)	2538	2069	954	612	6173
1 (least deprived)	411 (22.2)	347 (18.8)	147 (8.0)	83 (4.5)	988 (53.4)
2	503 (22.6)	378 (17.0)	193 (8.7)	109 (4.9)	1183 (53.2)
3	502 (20.3)	430 (17.4)	204 (8.3)	124 (5.0)	1260 (51.0)
4	588 (21.0)	444 (15.9)	213 (7.6)	147 (5.3)	1392 (49.8)
5 (most deprived)	534 (18.8)	470 (16.5)	197 (6.9)	149 (5.2)	1350 (47.4)
Admission type, *n* (%)					
Medical	1470 (20.8)	1279 (18.1)	654 (9.2)	448 (6.3)	3851 (54.4)
Elective surgery	573 (20.2)	393 (13.8)	134 (4.7)	50 (1.8)	1150 (40.5)
Emergency surgery	527 (21.8)	415 (17.2)	169 (7.0)	121 (5.0)	1232 (51.1)
Surgical status, *n* (%)					
Planned surgery	475 (20.1)	335 (14.1)	108 (4.6)	33 (1.4)	951 (40.2)
Unplanned surgery	625 (21.7)	473 (16.4)	195 (6.8)	138 (4.8)	1431 (49.7)
ICNARC physiology score quartile, *n* (%)					
1 (low)	747 (20.6)	482 (13.3)	160 (4.4)	79 (2.2)	1468 (40.6)
2	617 (20.9)	481 (16.3)	201 (6.8)	114 (3.9)	1413 (48.0)
3	646 (23.1)	553 (19.8)	258 (9.2)	167 (6.0)	1624 (58.0)
4 (high)	560 (18.9)	571 (19.3)	338 (11.4)	259 (8.7)	1728 (58.3)
ICNARC predicted risk of death quartile, *n* (%)					
1 (low)	637 (20.7)	371 (12.0)	145 (4.7)	49 (1.6)	1202 (39.0)
2	659 (21.4)	505 (16.4)	167 (5.4)	136 (4.4)	1467 (47.6)
3	694 (22.5)	613 (19.9)	288 (9.3)	182 (5.9)	1777 (57.7)
4 (high)	580 (18.8)	598 (19.4)	357 (11.6)	252 (8.2)	1787 (58.0)
ICU outcome, *n* (%)					
Survived	2351 (21.9)	1857 (17.3)	821 (7.6)	527 (4.9)	5556 (51.6)
Died	219 (13.9)	230 (14.6)	136 (8.7)	92 (5.9)	677 (43.1)

[*N*], number of patients for whom the information was available.
a Excludes 147 patients for whom no CMP data available.

TABLE 12 Patient characteristics and outcomes associated with non-recruitment of family members

Parameter	No family members recruited (total)[a]	No eligible family members	Eligible family members not approached
Total, *N* (%)	6095 (49.4)[b]	2155 (17.5)[c]	3380 (27.4)[d]
Day of admission, *n* (%)			
Sunday	553 (42.5)	195 (15.0)	290 (22.3)
Monday	934 (48.3)	307 (15.9)	527 (27.3)
Tuesday	925 (47.7)	343 (17.7)	483 (24.9)
Wednesday	967 (50.2)	363 (18.8)	518 (26.9)
Thursday	1029 (53.8)	395 (20.7)	566 (29.6)
Friday	1060 (54.7)	324 (16.7)	657 (33.9)
Saturday	627 (45.5)	228 (16.5)	339 (24.6)
ICU length of stay, *n* (%)			
24–30 hours	1057 (85.7)	586 (47.5)	452 (36.6)
30–36 hours	448 (79.0)	207 (36.5)	226 (39.9)
36–48 hours	1367 (71.1)	526 (27.4)	775 (40.3)
48 hours to 7 days	2656 (45.0)	710 (12.0)	1654 (28.0)
≥ 7 days	567 (21.0)	126 (4.7)	273 (10.1)
Age group (years), *n* (%)			
< 30	370 (50.3)	124 (16.9)	220 (29.9)
30–39	390 (50.8)	150 (19.6)	188 (24.5)
40–49	657 (51.2)	249 (19.4)	344 (26.8)
50–59	932 (49.7)	333 (17.8)	520 (27.7)
60–69	1360 (47.9)	466 (16.4)	751 (26.5)
70–79	1443 (48.5)	515 (17.3)	791 (26.6)
≥ 80	943 (50.9)	318 (17.2)	566 (30.5)
Sex, *n* (%)			
Female	2588 (48.5)	903 (16.9)	1436 (26.9)
Male	3507 (50.1)	1252 (17.9)	1944 (27.8)
Ethnicity, *n* (%)			
White	5406 (48.7)	1856 (16.7)	3065 (27.6)
Asian	157 (52.0)	45 (14.9)	86 (28.5)
Black	139 (62.3)	63 (28.3)	59 (26.5)
Other	159 (54.3)	76 (25.9)	70 (23.9)
Not stated	234 (56.3)	115 (27.6)	100 (24.0)
Median distance (km) from patient home to hospital (IQR) [*N*]	8.9 (4.1–19.7) [6017]	8.6 (3.9–19.8) [2118]	9.4 (4.3–20.1) [3344]

continued

TABLE 12 Patient characteristics and outcomes associated with non-recruitment of family members (*continued*)

Parameter	No family members recruited (total)[a]	No eligible family members	Eligible family members not approached
Deprivation, *n* (%)	6013	2117	3341
1 (least deprived)	861 (46.6)	303 (16.4)	491 (26.6)
2	1042 (46.8)	354 (15.9)	598 (26.9)
3	1210 (49.0)	426 (17.2)	684 (27.7)
4	1402 (50.2)	474 (17.0)	778 (27.8)
5 (most deprived)	1498 (52.6)	560 (19.7)	790 (27.7)
Admission type, *n* (%)			
Medical	3227 (45.6)	1060 (15.0)	1796 (25.4)
Elective surgery	1688 (59.5)	708 (24.9)	909 (32.0)
Emergency surgery	1180 (48.9)	387 (16.0)	675 (28.0)
Surgical status, *n* (%)			
Planned surgery	1417 (59.8)	595 (25.1)	763 (32.2)
Unplanned surgery	1451 (50.3)	500 (17.3)	821 (28.5)
ICNARC physiology score quartile, *n* (%)			
1 (low)	2152 (59.4)	884 (24.4)	1157 (32.0)
2	1533 (52.0)	558 (18.9)	842 (28.6)
3	1175 (42.0)	394 (14.1)	643 (23.0)
4 (high)	1235 (41.7)	319 (10.8)	738 (24.9)
ICNARC predicted risk of death quartile, *n* (%)			
1 (low)	1880 (61.0)	798 (25.9)	988 (32.1)
2	1615 (52.4)	599 (19.4)	891 (28.9)
3	1305 (42.3)	424 (13.8)	723 (23.5)
4 (high)	1295 (42.0)	334 (10.8)	778 (25.2)
ICU outcome, *n* (%)			
Survived	5202 (48.4)	1946 (18.1)	2834 (26.3)
Died	893 (56.9)	209 (13.3)	546 (34.8)

[*N*], number of patients for whom the information was available.

a Number includes family members who refused or withdrew from the study.

b Excludes 255 family members of patients for whom no CMP data available.

c Excludes 45 family members of patients for whom no CMP data available.

d Excludes 203 family members of patients for whom no CMP data available.

Response rate

Of the 12,346 family members recruited, 12,303 (99.7%) were sent a questionnaire pack between 21 and 50 days following the patient's discharge or death (allowing for delays in this information being entered onto the secure web portal).

The remaining 43 (0.3%) family members were not sent a questionnaire pack because either information (e.g. postal address) provided was incomplete or the date the patient was discharged from the ICU was not provided by the ICU staff or was provided more than 50 days after the patient had been discharged from, or had died in, the ICU.

Of the 12,303 family members who were sent a questionnaire pack, no response was received from 4634 (37.7%) family members, the pack was returned as 'not known at this address' (and no further contact information was available from the ICU) for 55 (0.4%) family members and 441 (3.6%) family members refused the invitation to complete the questionnaire. A total of 7173 (58.3%) family members completed and returned the questionnaire (*Figure 4*).

A total of 55 family members requested that the questionnaire and accompanying documents be translated (*Table 13*). Of these 55 family members, 14 (25.5%) completed the questionnaire, 1 (1.8%) refused, 40 (72.7%) did not respond and for 3 (5.5%) the questionnaire was returned as 'not known at this address'.

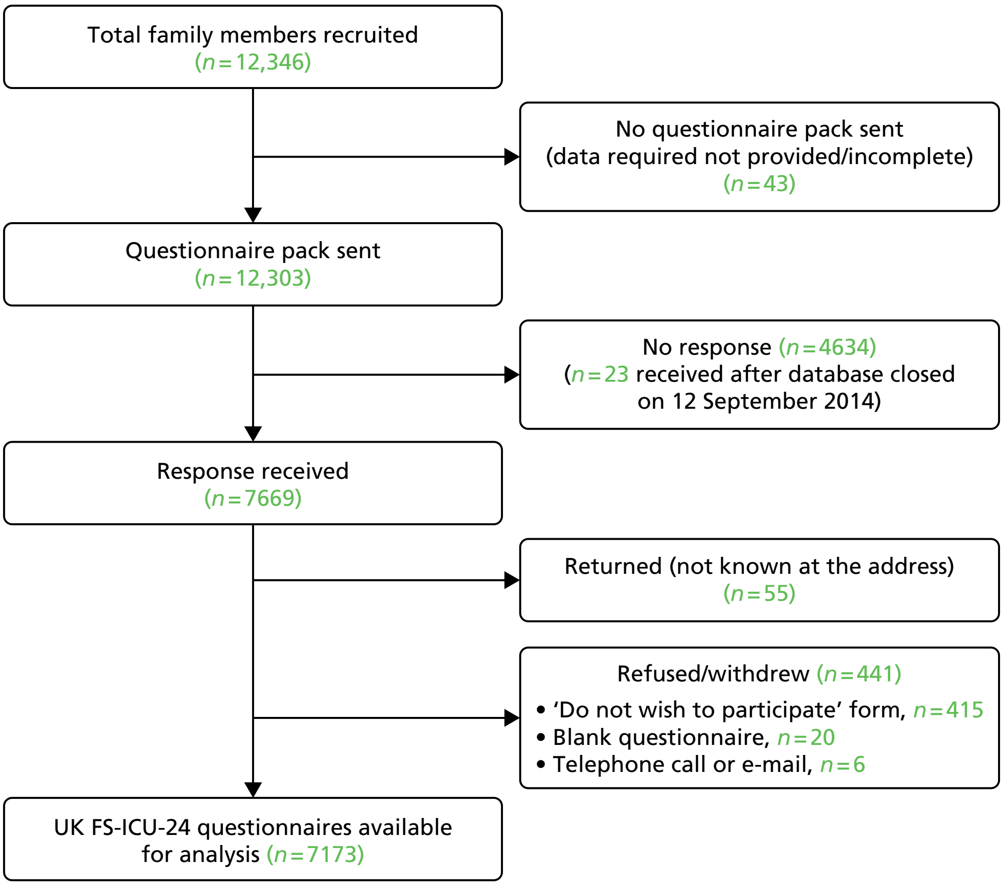


FIGURE 4 Family members' response to postal questionnaire.

TABLE 13 Languages requested

Language	Number of requests
Urdu	14
Welsh	8
Punjabi	5
Polish	4
Tamil	4
Gujarati	3
Romanian	3
Bengali	2
Chinese (Cantonese)	2
Lithuanian	2
Portuguese	2
Arabic	1
Greek	1
Slovakian	1
Spanish	1
Thai	1
Turkish	1

The time, in days, from the questionnaire pack being sent to receipt of a completed questionnaire is presented in *Figure 5*. Overall, questionnaires were returned within a median of 10 (IQR 6–31) days. Most were returned after the first questionnaire pack was sent, although there was a modest increase in the response rate after the second questionnaire pack was posted; a second questionnaire pack was sent to just over half (54.9%) of family members 4 weeks after the first questionnaire pack.

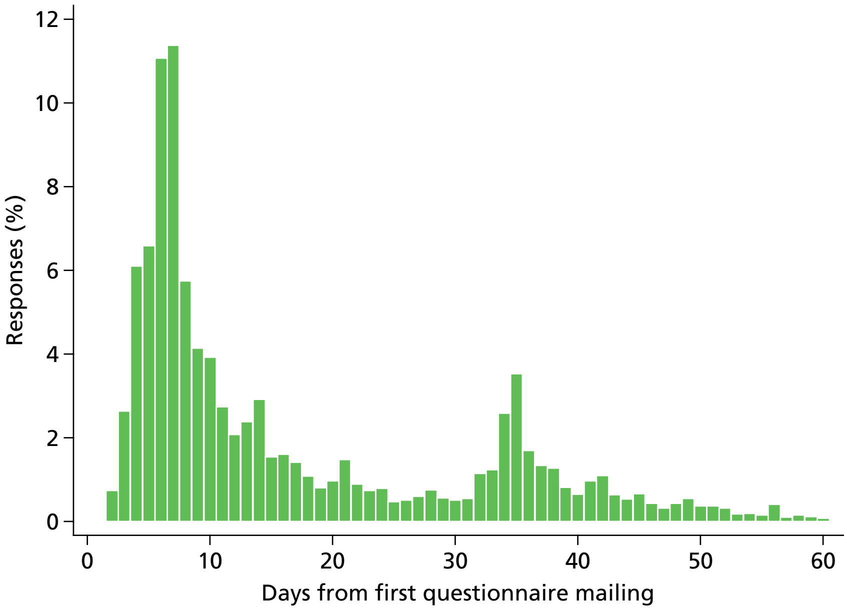


FIGURE 5 Time taken (in days) from first mailing to receipt of a completed questionnaire.

There was variation across ICUs in the proportion of family members who completed the questionnaire, ranging from 48.9% to 73.8% of the family members recruited. Although the overall rate of refusal was low (3.6%), there was some variation across ICUs, ranging from 1.2% to 5.2% of family members refusing to complete the questionnaire (*Table 14*).

Patient characteristics associated with family member response

Family members of older patients were more likely to complete the questionnaire (e.g. for patients < 30 years old, a completed questionnaire was received from 52.9% of family members compared with 64.6% of family members of patients > 80 years), as were family members of male patients (60.4% vs. 56.4% for female patients). The response rate from family members of patients of white ethnicity (59.8%) was higher than other ethnic groups such as Asian (44.2%) and black (38.2%) ethnicity. There was an association between the level of deprivation (based on the patient's postcode) and completion of a questionnaire: family members of patients in the least deprived group were more likely to complete the questionnaire than were family members of patients in the most deprived group (63.9% vs. 52.7%). The response from family members of the sickest patients (based on the ICNARC predicted risk of death) was slightly higher than from family members of the least sick patients (62.2% vs. 55.5%), although the response was similar for family members of critical care survivors and non-survivors (58.4% and 60.2%, respectively) (*Table 15*).

Family member characteristics associated with response

The characteristics of family members (collected in the ICU following informed consent) who did and did not complete a questionnaire are presented in *Table 16*. Generally, the response rate was higher among family members in the older age groups than in the younger age groups. For example, the response rate in family members under 30 years of age was 37.7% compared with 74.6% for the 60- to 69-year-old age group. A higher proportion of females (61.6%) than males (53.8%) completed the questionnaire. Family members of white ethnicity were more likely to complete the questionnaire than family members of Asian or black ethnicity (59.9%, 40.8% and 35.0%, respectively). There was a trend of lower response rates with increasing level of deprivation (based on postcode): 52.7% of family members in the most deprived group completed the questionnaire compared with 63.9% in the least deprived group. There was also a trend for higher response rates with increasing level of education. With respect to the family member's relationship to the patient, the highest response rates were observed among family members who described themselves as the patient's partner (70.0%) or parent (64.1%). In addition, family members who were documented in the hospital records as the next of kin or who lived with the patient were more likely to complete the questionnaire (66.1% and 65.0%, respectively) than those who were not the documented next of kin or did not live with the patient (53.4% and 55.6%, respectively). Family members for whom English was their first language were more likely to complete the questionnaire (59.1%) than those for whom it was not (42.7%).

TABLE 14 Response rate of family members, by ICU

ICU	Questionnaire pack 1 sent (%)	Questionnaire pack 2 sent (%)	Completed UK FS-ICU-24 received (%)	Reason for no UK FS-ICU-24 received			Time taken (days) for receipt of UK FS-ICU-24, mean (SD), median (IQR) [*N*]
				No response (%)	Return to sender (not delivered) (%)	Refusal (%)	
A	682 (99.1)	375 (54.5)	386 (56.6)	265 (38.9)	4 (0.6)	27 (4.0)	18.1 (18.0), 10.0 (6.0–29.0) [386]
B	531 (95.3)	281 (50.4)	327 (61.6)	184 (34.7)	2 (0.4)	18 (3.4)	18.2 (19.9), 10.0 (6.0–30.0) [327]
C	449 (100.0)	239 (53.2)	258 (57.5)	172 (38.3)	3 (0.7)	16 (3.6)	18.2 (17.5), 11.0 (7.0–25.0) [258]
D	646 (100.0)	376 (58.2)	354 (54.8)	261 (40.4)	4 (0.6)	27 (4.2)	19.2 (20.0), 10.5 (7.0–30.0) [354]
E	481 (100.0)	224 (46.6)	321 (66.7)	138 (28.7)	2 (0.4)	20 (4.2)	17.3 (16.7), 10.0 (6.0–24.0) [321]
F	873 (100.0)	469 (53.7)	510 (58.4)	315 (36.1)	3 (0.3)	45 (5.2)	17.4 (17.2), 9.0 (6.0–29.0) [508]
G	1051 (99.9)	639 (60.7)	554 (52.7)	464 (44.1)	5 (0.5)	28 (2.7)	18.9 (18.6), 10.0 (6.0–33.0) [554]
H	711 (100.0)	437 (61.5)	369 (51.9)	314 (44.2)	4 (0.6)	24 (3.4)	19.8 (20.2), 12.0 (7.0–33.0) [369]
I	310 (100.0)	135 (43.5)	200 (64.5)	94 (30.3)	–	16 (5.2)	15.5 (15.2), 9.0 (6.0–18.0) [200]
J	474 (100.0)	229 (48.3)	303 (63.9)	153 (32.3)	3 (0.6)	15 (3.2)	17.7 (17.5), 10.0 (6.0–26.0) [302]
K	392 (98.5)	189 (47.5)	265 (67.6)	116 (29.6)	1 (0.3)	10 (2.6)	20.1 (24.6), 10.0 (6.0–28.0) [265]
L	370 (100.0)	169 (45.7)	273 (73.8)	88 (23.8)	–	9 (2.4)	19.2 (17.5), 11.0 (7.0–34.0) [272]
M	789 (100.0)	434 (55.0)	474 (60.1)	281 (35.6)	3 (0.4)	31 (3.9)	19.6 (19.3), 11.0 (7.0–33.0) [473]
N	1008 (100.0)	585 (58.0)	540 (53.6)	436 (43.3)	9 (0.9)	23 (2.3)	18.3 (18.9), 10.0 (6.0–30.0) [539]
O	325 (100.0)	180 (55.4)	202 (62.2)	112 (34.5)	–	11 (3.4)	19.9 (18.5), 11.5 (6.0–33.0) [202]
P	1034 (99.8)	641 (61.9)	506 (48.9)	471 (45.6)	5 (0.5)	52 (5.0)	20.6 (19.4), 13.0 (6.0–34.0) [504]
Q	408 (100.0)	223 (54.7)	251 (61.5)	148 (36.3)	3 (0.7)	6 (1.5)	19.6 (19.9), 10.0 (7.0–33.0) [250]
R	750 (99.7)	410 (54.5)	442 (58.9)	268 (35.7)	–	40 (5.3)	19.2 (22.1), 9.0 (7.0–31.0) [442]
S	255 (100.0)	150 (58.8)	154 (60.4)	96 (37.6)	2 (0.8)	3 (1.2)	21.9 (21.9), 13.0 (6.0–34.0) [154]
T	764 (100.0)	397 (52.0)	484 (63.4)	258 (33.8)	2 (0.3)	20 (2.6)	19.4 (22.8), 10.0 (6.0–30.0) [483]
Total	12,303 (99.7)	6782 (54.9)	7173 (58.3)	4634 (37.7)	55 (0.4)	441 (3.6)	18.9 (19.5), 10.0 (6.0–31.0) [7163]

[*N*], number of patients for whom the information was available.

TABLE 15 Patient characteristics and outcomes associated with family member response

Parameter	No response (%)	Refusal (%)	Full response (%)
Total	4515[a]	438[b]	7019[c]
Patient age group (years)			
< 30	326 (45.4)	12 (1.7)	380 (52.9)
30–39	337 (47.8)	14 (2.0)	354 (50.2)
40–49	534 (44.9)	31 (2.6)	623 (52.4)
50–59	774 (42.6)	46 (2.5)	997 (54.9)
60–69	1017 (36.3)	93 (3.3)	1691 (60.4)
70–79	1005 (33.5)	145 (4.8)	1846 (61.6)
≥ 80	522 (29.9)	97 (5.6)	1128 (64.6)
Critical care length of stay			
24–30 hours	107 (39.2)	13 (4.8)	153 (56.0)
30–36 hours	74 (37.2)	8 (4.0)	117 (58.8)
36–48 hours	318 (35.6)	35 (3.9)	540 (60.5)
48 hours to 7 days	2230 (37.8)	215 (3.6)	3452 (58.5)
≥ 7 days	1786 (37.9)	167 (3.5)	2757 (58.5)
Sex			
Female	2096 (39.8)	200 (3.8)	2968 (56.4)
Male	2419 (36.1)	238 (3.5)	4051 (60.4)
Ethnicity			
White	3994 (36.5)	412 (3.8)	6546 (59.8)
Asian	146 (54.3)	4 (1.5)	119 (44.2)
Black	93 (61.2)	1 (0.7)	58 (38.2)
Other	130 (54.6)	7 (2.9)	101 (42.4)
Not stated	152 (42.1)	14 (3.9)	195 (54.0)
Deprivation	4476	430	6962
1 (least deprived)	606 (32.6)	65 (3.5)	1190 (63.9)
2	764 (33.9)	85 (3.8)	1405 (62.3)
3	855 (35.0)	102 (4.2)	1488 (60.9)
4	1078 (40.4)	104 (3.9)	1488 (55.7)
5 (most deprived)	1173 (44.5)	74 (2.8)	1391 (52.7)
Admission type			
Medical	2943 (38.2)	260 (3.4)	4509 (58.5)
Elective/scheduled surgery	679 (34.9)	93 (4.8)	1174 (60.3)
Emergency/urgent surgery	893 (38.6)	85 (3.7)	1336 (57.7)
Surgical status of surgical admissions			
Planned surgery	530 (33.3)	76 (4.8)	984 (61.9)
Unplanned surgery	1042 (39.0)	102 (3.8)	1526 (57.2)

continued

TABLE 15 Patient characteristics and outcomes associated with family member response (*continued*)

Parameter	No response (%)	Refusal (%)	Full response (%)
ICNARC physiology score quartiles			
1 (low)	1336 (39.4)	116 (3.4)	1941 (57.2)
2	1109 (38.9)	113 (4.0)	1628 (57.1)
3	1008 (36.5)	85 (3.1)	1667 (60.4)
4 (high)	1062 (35.8)	124 (4.2)	1783 (60.1)
ICNARC predicted risk of death quartiles			
1 (low)	1227 (41.0)	106 (3.5)	1661 (55.5)
2	1156 (38.6)	101 (3.4)	1735 (58.0)
3	1122 (37.5)	111 (3.7)	1760 (58.8)
4 (high)	1010 (33.7)	120 (4.0)	1863 (62.2)
Critical care ICU outcome			
Survived	4019 (38.2)	360 (3.4)	6149 (58.4)
Died	496 (34.3)	78 (5.4)	870 (60.2)
Participating in a research study			
No	4026 (38.0)	385 (3.6)	6197 (58.4)
Yes	263 (35.2)	23 (3.1)	461 (61.7)
Not stated	226 (36.6)	30 (4.9)	361 (58.5)

a Excludes 96 family members of patients for whom no CMP data available.
b Excludes three family members of patients for whom no CMP data available.
c Excludes 154 family members of patients for whom no CMP data available.

TABLE 16 Family member characteristics associated with response to UK FS-ICU-24

Parameter	No response	Refusal	Full response
Total, *N*	4611	441	7173
Age group (years), *n* (%)			
< 30	861 (61.2)	16 (1.1)	530 (37.7)
30–39	827 (52.6)	23 (1.5)	721 (45.9)
40–49	1208 (44.2)	63 (2.3)	1465 (53.5)
50–59	886 (33.8)	80 (3.1)	1654 (63.1)
60–69	440 (20.8)	97 (4.6)	1580 (74.6)
70–79	220 (18.3)	117 (9.8)	862 (71.9)
≥ 80	58 (19.5)	32 (10.8)	207 (69.7)
Not stated	111 (39.9)	13 (4.7)	154 (55.4)
Sex, *n* (%)			
Female	2663 (35.0)	261 (3.4)	4689 (61.6)
Male	1866 (42.3)	172 (3.9)	2373 (53.8)
Not stated	82 (40.8)	8 (4.0)	111 (55.2)
Ethnicity, *n* (%)			
White	4111 (36.5)	415 (3.7)	6747 (59.9)
Asian	196 (56.3)	10 (2.9)	142 (40.8)
Black	101 (64.3)	1 (0.6)	55 (35.0)
Other	97 (50.8)	5 (2.6)	89 (46.6)
Not stated	106 (41.4)	10 (3.9)	140 (54.7)
Deprivation, *n* (%)	4370	420	6832
1 (least deprived)	634 (30.3)	84 (4.0)	1376 (65.7)
2	803 (33.6)	84 (3.5)	1502 (62.9)
3	851 (35.6)	98 (4.1)	1443 (60.3)
4	1045 (41.6)	86 (3.4)	1380 (55.0)
5 (most deprived)	1037 (46.4)	68 (3.0)	1131 (50.6)
Median distance (km) from family member home to hospital (IQR) [*N*]	10.7 (4.6–29.4) [4394]	10.7 (5.4–25.3) [424]	12.3 (5.3–33.2) [6867]
Relationship, *n* (%): 'I am the patient's . . .'			
Partner	786 (25.6)	137 (4.5)	2151 (70.0)
Child	1780 (42.9)	78 (1.9)	2292 (55.2)
Parent	338 (32.6)	34 (3.3)	665 (64.1)
Sibling	480 (38.3)	56 (4.5)	717 (57.2)
Other relative	898 (45.7)	80 (4.1)	987 (50.2)
Other non-relative	329 (44.1)	56 (7.5)	361 (48.4)
Next of kin, *n* (%)			
No	3009 (42.9)	258 (3.7)	3747 (53.4)
Yes	1380 (30.2)	167 (3.7)	3023 (66.1)
Not stated	222 (34.6)	16 (2.5)	403 (62.9)

continued

TABLE 16 Family member characteristics associated with response to UK FS-ICU-24 (*continued*)

Parameter	No response	Refusal	Full response
Living with patient, *n* (%)			
No	3357 (41.1)	275 (3.4)	4543 (55.6)
Yes	1252 (30.9)	166 (4.1)	2629 (65.0)
Not stated	2 (66.7)	0 (0.0)	1 (33.3)
Education level, *n* (%)			
NVQ 1 or 2	1284 (41.2)	104 (3.3)	1731 (55.5)
NVQ 3	870 (42.1)	49 (2.4)	1149 (55.6)
NVQ 4 or 5	1032 (35.6)	49 (1.7)	1819 (62.7)
Other	702 (33.4)	128 (6.1)	1272 (60.5)
Not stated	723 (35.5)	111 (5.5)	1202 (59.0)
First language *n* (%)			
Not English	182 (55.5)	6 (1.8)	140 (42.7)
English	4429 (37.2)	435 (3.7)	7033 (59.1)

[*N*], number of family members for whom the information was available.

Discussion

In summary, a representative sample of 20 adult general ICUs participated in phase 2 of the FREE study. Overall, at least one family member was recruited for 60.6% ($n = 6380$) of the 10,530 patients who stayed in the ICU for 24 hours or more and who were visited in the ICU by one or more eligible family members. Recruitment varied across the ICUs, ranging from 41.2% to 79.4%. Overall, an average of two family members per patient were recruited and the first family member was recruited within a median of 2 (IQR 1–3) days of the patient's admission to ICU. Of the family members who were sent a questionnaire pack, a total of 7173 (58.3%) family members completed and returned the questionnaire.

Family member responses varied by:

- Age – 37.7% of family members under 30 years of age responded, compared with 74.6% for the 60- to 69-year old age group.
- Gender – 61.6% of females responded, compared with 53.8% of males.
- Ethnicity – 59.9% of white family members responded, compared with 40.8% of Asian ethnicity and 35.0% of black ethnicity.
- Level of deprivation (based on postcode) – 52.7% in the most deprived responded, compared with 63.9% in the least deprived.
- Education – there was a trend for higher response rates with increasing level of education.
- Relationship to the patient – the highest response rates were observed for family members who described themselves as the patient's partner (70.0%) or parent (64.1%). Family members documented as the next of kin or who lived with the patient were more likely to respond (66.1% and 65.0%, respectively) than those who were not the documented next of kin or did not live with the patient (53.4% and 55.6%, respectively).
- Language – family members for whom English was the first language were more likely to respond (59.1%) than those for whom it was not (42.7%).

Chapter 4 Psychometric assessment of the UK 24-item Family Satisfaction in the Intensive Care Unit questionnaire

Introduction

This chapter reports the psychometric assessment of the UK FS-ICU-24 in the FREE study. The psychometric assessment comprised an initial psychometric assessment, using data from an internal pilot study, to establish if any changes to the questionnaire were required, and a full psychometric assessment, conducted using the final FREE study data set.

Methods

Initial psychometric assessment

The initial psychometric assessment was conducted using responses from family members of patients who were discharged from, or died in, the ICU between the start of the study and 12 July 2013 (i.e. to whom initial questionnaires were sent out up to 2 August 2013) and with a returned questionnaire received by the ICNARC CTU by 9 September 2013.

Only one family member response per patient was used in the initial psychometric assessment. Where multiple family member responses associated with the same patient had been received, the first family member (according to the order entered on the FREE study secure, web-based data entry system, corresponding to the order in which they visited the patient after 24 hours) was used in the analysis.

Item responses were rescaled and, where relevant, reversed, according to the developer's rules, so that each response was on a scale from 0 (least satisfied) to 100 (most satisfied). The overall family satisfaction score and domain scores (*satisfaction with care* and *satisfaction with decision-making*) were calculated by averaging the item responses for the items included overall/within each domain, provided at least 70% of items had been completed (i.e. 17 out of 24 for the overall family satisfaction score, 10 out of 14 for *satisfaction with care* and 7 out of 10 for *satisfaction with decision-making*). Code for processing of FS-ICU-24 responses was translated from SPSS (Statistical Package for the Social Sciences, version not known, IBM Corporation, Armonk, NY, USA) syntax files available from www.thecarenet.ca.

Patients with a family member included in the initial psychometric assessment were described by their age in years (mean with SD, and number and percentage by decade of age), sex, surgical status (elective/scheduled surgery, emergency/urgent surgery or non-surgical), ICNARC physiology score (mean and SD),[27] APACHE II score (mean and SD),[26] ICU outcome (alive or dead) and ICU length of stay (median and quartiles for survivors and non-survivors). Family members included in the initial psychometric assessment were described by their age in years (mean with SD, and number and percentage by decade of age), sex and relationship to the patient (partner, parent, child, sibling, other relative or other non-relative).

The following descriptive statistics were reported for each individual item on the UK FS-ICU-24:

- number and percentage of missing responses
- number and percentage of responses in each category
- median and quartiles of item response.

The following descriptive statistics were reported for the overall family satisfaction score and for each domain score (*satisfaction with care* and *satisfaction with decision-making*):

- number and percentage of missing scores (response to fewer than 70% of items)
- number and percentage with floor (0) and ceiling (100) scores
- median, quartiles, minimum and maximum of score.

The following criteria were used to flag items for possible removal:

- items with high rates of non-response or 'not applicable' responses (> 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 correlation > 0.8, corrected for overlap)
- items measuring a construct other than that intended (component loading < 0.4 in confirmatory principal components analysis).

Principal components analysis was performed using expectation-maximisation estimation of the covariance matrix to account for missing data[28] with columnwise average nominal sample size.[29]

Items meeting the above criteria were discussed among the SMG (including DKH, as representative of the original FS-ICU authors) before a final decision on removal.

Internal consistency (reliability) was evaluated through calculation of the item to own scale correlations and Cronbach's alpha for each domain.[30] Item to own scale correlations < 0.4 or Cronbach's alpha < 0.8 were taken as indicative of lack of internal consistency.

Confirmatory factor analysis techniques were used to test the goodness of fit of the two-factor solution for the FS-ICU-24 – that is, the division into the domains of *satisfaction with care* and *satisfaction with decision-making* – developed in the North American validation study.[11] Structural equation models were used to estimate the factor loadings for the two-factor solution, using full information maximum likelihood assuming data were missing at random.[31] Goodness of fit was assessed by the likelihood ratio chi-squared statistic versus the saturated model, root mean-squared-error of approximation (RMSEA), comparative fit index (CFI), Tucker–Lewis index (TLI) and coefficient of determination (CD). Values of RMSEA < 0.08, CFI > 0.9 and TLI > 0.9 were taken to indicate a good fit.[32]

The criterion validity of the UK FS-ICU-24 among family members of non-survivors was assessed by comparison with the QODD questionnaire. The hypotheses tested were that higher values for the overall family satisfaction score and the two domain scores of the UK FS-ICU-24 would be highly correlated (Pearson correlation coefficients > 0.6) with 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) would be moderately correlated (Spearman's rank correlation coefficients 0.4–0.6) with the *satisfaction with care* domain score. Finally, responses to specific items on the QODD were compared with specific items on the UK FS-ICU-24 (assessed by Spearman's rank correlation coefficients), as detailed in *Table 17*.

Full psychometric assessment

The full psychometric assessment was conducted on the final FREE study data set. As with the initial psychometric assessment, only one family member response per patient was used in the full psychometric assessment; however, the approach to selecting the family member was revised to prioritise those most likely to give complete and informative responses. Where multiple family member responses associated with the same patient had been received, priority was given to the family member(s) identified by the site as the patient's next of kin, followed by the patient's spouse or partner, then parents or children and finally other family members. Where more than one family member was given equal highest priority, the first family member to visit (according to the order entered on the FREE study secure, web-based data

TABLE 17 Comparison of specific items on the UK FS-ICU-24 with specific items on the QODD

UK FS-ICU-24 item	QODD item	Hypothesis
Concern and caring by ICU staff? The courtesy, respect and compassion your family member (the patient) was given	How often did your loved one appear to keep his/her dignity and self-respect?	Similar question, expect weak to moderate correlation (0.2–0.6)
How well the ICU staff assessed and treated your family member's symptoms: pain	How often did your loved one appear to have his/her pain under control?	Very similar question, expect high correlation (> 0.6)
How well the ICU staff assessed and treated your family member's symptoms: breathlessness	How often did your loved one appear to breathe comfortably?	Very similar question, expect high correlation (> 0.6)
Skill and competence of ICU nurses? How well the nurses cared for your family member	Rate the care your loved one received from all doctors and other health care providers (including nurses, caseworkers, and other health care professionals) during the last several days of his or her life while in the ICU	Similar question but not identical staff groups, expect moderate correlation (0.4–0.6)
Skill and competence of ICU doctors? How well the doctors cared for your family member	Rate the care your loved one received from his or her doctor during the last several days of his or her life while in the ICU	Very similar question, expect high correlation (> 0.6)
During the final hours of your family member's life, which of the following best describes your views: I felt he/she was very uncomfortable, slightly uncomfortable, etc.	How often did your loved one appear to have his/her pain under control?	Similar question, expect weak to moderate correlation (0.2–0.6)
	How often did your loved one appear at peace with dying?	Similar question, expect weak to moderate correlation (0.2–0.6)
	How often did your loved one appear unafraid of dying?	Similar question, expect weak to moderate correlation (0.2–0.6)

entry system, corresponding to the order in which they visited the patient after 24 hours) was used in the analysis.

Completed questionnaires were coded and scored as for the initial psychometric assessment. However, following the results of the initial psychometric assessment, an alternative, lower, threshold of 60% of items having been completed (i.e. 15 out of 24 for the overall family satisfaction score, 9 out of 14 for *satisfaction with care* and 6 out of 10 for *satisfaction with decision-making*) was considered for calculation of the scores. This lower threshold was considered to permit family members who did not answer the four questions relating to involvement in decision-making to be included in the analysis.

The patients, family members, item responses and scores were described as for the initial psychometric assessment. Items with high item non-response rates (> 10%) were taken as indicative of possible irrelevance or lack of comprehensibility or acceptability. Items with poorer discrimination (> 70% selecting the lowest or highest category) were taken as indicative of possible floor/ceiling effects. Item to own scale correlation > 0.8, corrected for overlap, was taken as indicative of possible redundancy. Component loadings < 0.4 in a confirmatory principal components analysis, conducted using the same methods as for the initial psychometric assessment, were taken as indicative of an item measuring a construct other than intended.

Internal consistency was evaluated through calculation of the item to own scale correlations and Cronbach's alpha for each domain.[30] Item to own scale correlations < 0.4 or Cronbach's alpha < 0.8 were taken as indicative of lack of internal consistency.

Confirmatory factor analysis techniques were used to test the goodness of fit of the two-factor solution for the FS-ICU-24 developed in the North American validation study[11] using the same methods as for the initial psychometric assessment.

Exploratory factor analysis was undertaken using polychoric correlations, which assume that ordinal data are representative of an underlying continuous distribution,[33] considering models with two or three principal factors. Initially orthogonal (varimax) rotations[34] were applied and subsequently oblique (promax, power 3) rotations were considered to allow for correlation between dimensions.[35] Multiple imputation using fully conditional specification[36] was used to account for item-level non-response.

Performance-importance plots were used to identify items that may form likely candidates for quality improvement.[37] Each point in the performance-importance plot corresponds to one item on the UK FS-ICU-24. The Spearman's rank correlation between each item and the overall family satisfaction score or domain score is plotted on the *y*-axis against the percentage of respondents rating the item as 'excellent' on the *x*-axis. The plot is divided into quadrants at the mean values on the *x*- and *y*-axes. Points in the upper left quadrant correspond to items that are highly correlated with overall satisfaction but have a lower than average proportion of 'excellent' ratings and therefore show potential for improvement.

Results

Initial psychometric assessment

At the point of data lock for the initial psychometric assessment, 992 family members had been consented for 481 patients who were discharged from, or died in, 19 participating ICUs between 28 May 2013 and 12 July 2013. Of these, 565 (57%) family members had returned questionnaires, representing 357 (74%) patients from 18 units (the one unit to have no questionnaires returned started the study only on 8 July 2013 and had only two consented family members). The first family member for each patient (based on the order in which sites identified them) was included in the analysis ($n = 357$).

Characteristics of the patients and family members included in the initial psychometric assessment are reported in *Table 18*.

Responses to individual items on the UK FS-ICU-24 are reported in *Table 19* (*satisfaction with care*), *Table 20* (*satisfaction with decision-making*) and *Table 21* (*satisfaction with decision-making, if your family member died in the ICU*). Characteristics of the UK FS-ICU-24 overall family satisfaction score and domain scores are summarised in *Table 22*, and the distributions of the scores are shown in *Figure 6*. Among the 284 (80%) family members for whom both domain scores could be calculated, correlation between the two domains was 0.790 (*Figure 7*).

TABLE 18 Characteristics of patients and family members included in the initial psychometric assessment

Characteristic	Patients ($n = 357$)	Family members ($n = 357$)
Mean age[a] (years) (SD)	64.3 (15.7)	55.7 (15.5)
Age[b] (years), *n* (%)		
< 30	12 (3.4)	23 (6.5)
30–39	14 (3.9)	33 (9.4)
40–49	35 (9.8)	62 (17.6)
50–59	50 (14.0)	88 (25.0)
60–69	91 (25.5)	75 (21.3)
70–79	98 (27.5)	52 (14.8)
≥ 80	57 (16.0)	19 (5.4)
Sex,[c] *n* (%)		
Female	137 (42.8)	243 (68.1)
Male	183 (57.2)	114 (31.9)
Relationship to patient, *n* (%)		
Partner	N/A	147 (41.2)
Parent		28 (7.8)
Child		97 (27.2)
Sibling		29 (8.1)
Other relative		35 (9.8)
Other non-relative		21 (5.9)
Surgical status,[c] *n* (%)		
Elective/scheduled surgery	68 (21.3)	N/A
Emergency/urgent surgery	55 (17.2)	
Non-surgical	197 (61.6)	
Mean ICNARC physiology score[c] (SD)	18.1 (8.2)	N/A
Mean APACHE II score[c] (SD)	17.0 (6.2)	N/A
ICU outcome, *n* (%)		
Alive	313 (87.7)	N/A
Dead	44 (12.3)	
Median ICU length of stay[c] (days) (IQR)		
All patients	3.8 (2.2–6.1)	N/A
ICU survivors	3.7 (2.1–6.2)	
ICU non-survivors	4.1 (2.4–5.6)	

N/A, not applicable.

[a] Age in years not reported for 12 family members (3.4%).

[b] Age group not reported for five family members (1.4%).

[c] Patient data require linkage to CMP – not available for 37 patients (10.4%).

TABLE 19 UK FS-ICU-24 responses to items about *satisfaction with care* in the initial psychometric assessment ($n = 357$)

Item	No response (%)	N/A (%)	Response (%)					Median (IQR)	Mean (SD)	Item to own scale correlation	Cronbach's alpha if item removed
			Excellent	Very good	Good	Fair	Poor				
How did we treat your family member (the patient)?											
Concern and caring by ICU staff?	2 (0.6)	0 (0)	247 (69.2)	82 (23.0)	20 (5.6)	4 (1.1)	2 (0.6)	100 (75–100)	90 (17)	**0.805**	0.941
Symptom management?											
Pain	3 (0.8)	10 (2.8)	200 (58.1)	102 (29.7)	32 (9.3)	5 (1.5)	5 (1.5)	100 (75–100)	85 (21)	0.741	0.942
Breathlessness	7 (2.0)	**46 (12.9)**	171 (56.3)	89 (29.3)	34 (11.2)	6 (2.0)	4 (1.3)	100 (75–100)	84 (21)	0.716	0.942
Agitation	7 (2.0)	**43 (12.0)**	148 (48.2)	97 (31.6)	45 (14.7)	13 (4.2)	4 (1.3)	75 (75–100)	80 (23)	0.764	0.941
How did we treat you?											
Consideration of your needs?	2 (0.6)	5 (1.4)	181 (51.7)	102 (29.1)	50 (14.3)	10 (2.9)	7 (2.0)	100 (75–100)	81 (24)	**0.844**	0.939
Emotional support?	4 (1.1)	31 (8.7)	143 (44.4)	100 (31.1)	47 (14.6)	22 (6.8)	10 (3.1)	75 (75–100)	77 (27)	**0.826**	0.940
Concern and caring by ICU staff?	2 (0.6)	6 (1.7)	184 (52.7)	104 (29.8)	44 (12.6)	10 (2.9)	7 (2.0)	100 (75–100)	82 (23)	**0.837**	0.939
Teamwork											
Co-ordination of care?	3 (0.8)	4 (1.1)	189 (54.0)	112 (32.0)	42 (12.0)	4 (1.1)	3 (0.9)	100 (75–100)	84 (20)	**0.820**	0.940
Nurses											
Skill and competence of ICU nurses?	1 (0.3)	1 (0.3)	239 (67.3)	89 (25.1)	20 (5.6)	7 (2.0)	0 (0)	100 (75–100)	89 (17)	**0.814**	0.941
Frequency of communication with ICU nurses?	3 (0.8)	12 (3.4)	170 (49.7)	102 (29.8)	40 (11.7)	23 (6.7)	7 (2.0)	75 (75–100)	80 (25)	0.796	0.940

Doctors											
Skill and competence of ICU doctors?	2 (0.6)	13 (3.6)	200 (58.5)	101 (29.5)	32 (9.4)	5 (1.5)	4 (1.2)	100 (75–100)	86 (20)	0.762	0.942
The ICU											
The atmosphere (mood) of the ICU was?	2 (0.6)	1 (0.3)	156 (44.1)	129 (36.4)	53 (15.0)	12 (3.4)	4 (1.1)	75 (75–100)	80 (22)	0.731	0.942
The waiting room											
The atmosphere (mood) in the ICU waiting room was?	5 (1.4)	**35 (9.8)**	67 (21.1)	101 (31.9)	82 (25.9)	49 (15.5)	18 (5.7)	75 (50–75)	62 (29)	0.446	**0.951**
Level/amount of health care			***Completely satisfied***	***Very satisfied***	***Mostly satisfied***	***Slightly dissatisfied***	***Very dissatisfied***				
How satisfied were you with the LEVEL or amount of health care your family member received in the ICU?	1 (0.3)	–	174 (48.9)	114 (32.0)	44 (12.4)	8 (2.2)	16 (4.5)	75 (75, 100)	80 (26)	0.431	**0.951**

N/A, not applicable.

Values are number (%) unless specified. Percentages are reported out of all respondents for the options 'No response' and 'N/A' and out of valid responses (i.e. excluding 'No response' and 'N/A') for all other options. Bold text indicates items flagged for discussion on potential item reduction/redundancy.

TABLE 20 UK FS-ICU-24 responses to items about *satisfaction with decision-making* in the initial psychometric assessment ($n = 357$)

Question			Response (%)								
Information needs	**No response (%)**	**N/A (%)**	**Excellent**	**Very good**	**Good**	**Fair**	**Poor**	**Median (IQR)**	**Mean (SD)**	**Item to own scale correlation**	**Cronbach's alpha if item removed**
Frequency of communication with ICU doctors?	3 (0.8)	30 (8.4)	93 (28.7)	94 (29.0)	70 (21.6)	38 (11.7)	29 (9.0)	75 (50–100)	64 (32)	0.741	0.931
Ease of getting information?	2 (0.6)	12 (3.4)	153 (44.6)	108 (31.5)	45 (13.1)	26 (7.6)	11 (3.2)	75 (75–100)	77 (27)	**0.821**	0.927
Understanding of information?	2 (0.6)	14 (3.9)	145 (42.5)	114 (33.4)	58 (17.0)	18 (5.3)	6 (1.8)	75 (75–100)	77 (24)	**0.811**	0.928
Honesty of information?	3 (0.8)	12 (3.4)	160 (46.8)	109 (31.9)	52 (15.2)	14 (4.1)	7 (2.0)	75 (75–100)	79 (24)	**0.804**	0.928
Completeness of information?	2 (0.6)	10 (2.8)	145 (42.0)	115 (33.3)	48 (13.9)	24 (7.0)	13 (3.8)	75 (75–100)	76 (27)	**0.857**	0.925
Consistency of information?	3 (0.8)	19 (5.3)	119 (35.5)	122 (36.4)	56 (16.7)	24 (7.2)	14 (4.2)	75 (50–100)	73 (27)	**0.836**	0.926
The process of making decisions			**I felt very included**	**I felt somewhat included**	**I felt neither included nor excluded**	**I felt somewhat excluded**	**I felt very excluded**				
Did you feel included in the decision-making process?	6 (1.7)	**91 (25.5)**	112 (43.1)	47 (18.1)	64 (24.6)	19 (7.3)	18 (6.9)	75 (50–100)	71 (31)	0.641	0.935
			I felt very supported	**I felt supported**	**I felt neither supported nor unsupported**	**I felt slightly unsupported**	**I felt totally unsupported**				
Did you feel supported during the decision-making process?	5 (1.4)	**100 (28.0)**	94 (37.3)	71 (28.2)	57 (22.6)	8 (3.2)	22 (8.7)	75 (50–100)	71 (30)	0.686	0.933

			I felt that I had good control	**I felt I had some control**	**I felt neither in control nor out of control**	**I felt somewhat out of control**	**I felt really out of control**				
Did you feel you had control over the care of your family member?	4 (1.1)	**77 (21.6)**	77 (27.9)	55 (19.9)	91 (33.0)	20 (7.2)	33 (12.0)	50 (50–100)	61 (32)	0.643	0.935
			I had adequate time				**I could have used more time**				
When making decisions, did you have adequate time to have your concerns addressed and questions answered? (note: two options)	6 (1.7)	**150 (42.0)**	177 (88.1)	–	–	–	24 (11.9)	100 (100–100)	88 (33)	0.566	**0.938**

N/A, not applicable.
Values are number (%) unless specified. Percentages are reported out of all respondents for the options ‘No response’ and ‘N/A’ and out of valid responses (i.e. excluding ‘No response’ and ‘N/A’) for all other options. Bold text indicates items flagged for discussion on potential item reduction/redundancy.

TABLE 21 UK FS-ICU-24 responses to questions about *satisfaction with decision-making (if your family member died in the ICU)* in the initial psychometric assessment ($n = 44$)

Question	No response (%)	N/A (%)	Response (%)					Median (IQR)	Mean (SD)
			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		
Which of the following best describes your views?[a]	2 (4.5)	0 (0)	2 (4.8)	1 (2.4)	36 (85.7)	1 (2.4)	2 (4.8)	100 (100–100)	88 (31)
			I felt that he/she was totally comfortable	**I felt that he/she was very comfortable**	**I felt that he/she was mostly comfortable**	**I felt that he/she was slightly uncomfortable**	**I felt that he/she was totally uncomfortable**		
During the final hours of your family member's life, which of the following best describes your views	2 (4.5)	0 (0)	11 (26.2)	17 (40.5)	8 (19.0)	1 (2.4)	5 (11.9)	75 (50–100)	67 (31)
			I felt very supported by the health-care team	**I felt supported by the health-care team**	**I felt neither abandoned nor supported by the health-care team**	**I felt abandoned by the health-care team**	**I felt very abandoned by the health-care team**		
During the last few hours before your family member's death, which of the following best describes your views	2 (4.5)	0 (0)	26 (61.9)	10 (23.8)	2 (4.8)	0 (0)	4 (9.5)	100 (75–100)	82 (30)

N/A, not applicable.

[a] Middle response scored 100, responses at either extreme scored 0, and intermediate responses scored 50.

Values are number (%) unless specified. Percentages are reported out of all respondents for the options 'no response' and 'N/A' and out of valid responses (i.e. excluding 'no response' and 'N/A') for all other options. Note that these questions are not included in calculating the overall family satisfaction score or domain score. Bold text indicates items flagged for discussion on potential item reduction.

TABLE 22 UK FS-ICU-24 overall family satisfaction score and domain scores in the initial psychometric assessment ($n = 357$)

Score	Not scored (< 70% response)	Scored (≥ 70% response)	Floor (0%)	Ceiling (100%)	Range	Median (IQR)	Mean (SD)	Skewness	Cronbach's alpha
Overall family satisfaction	18 (5.0)	339 (95.0)	0 (0)	16 (4.7)	10–100	83 (70–93)	79 (19)	–1.2	0.964
Satisfaction with care domain	9 (2.5)	348 (97.5)	0 (0)	43 (12.4)	14–100	86 (73–95)	82 (17)	–1.4	0.946
Satisfaction with decision-making domains	71 (19.9)	286 (80.1)	1 (0.3)	30 (10.5)	0–100	78 (60–93)	73 (23)	–0.9	0.937

Values are number (%) unless specified. Percentages are reported out of all respondents for 'not scored' and 'scored' and out of scored responses (i.e. those with responses to at least 70% of items within the domain) for floor and ceiling scores.

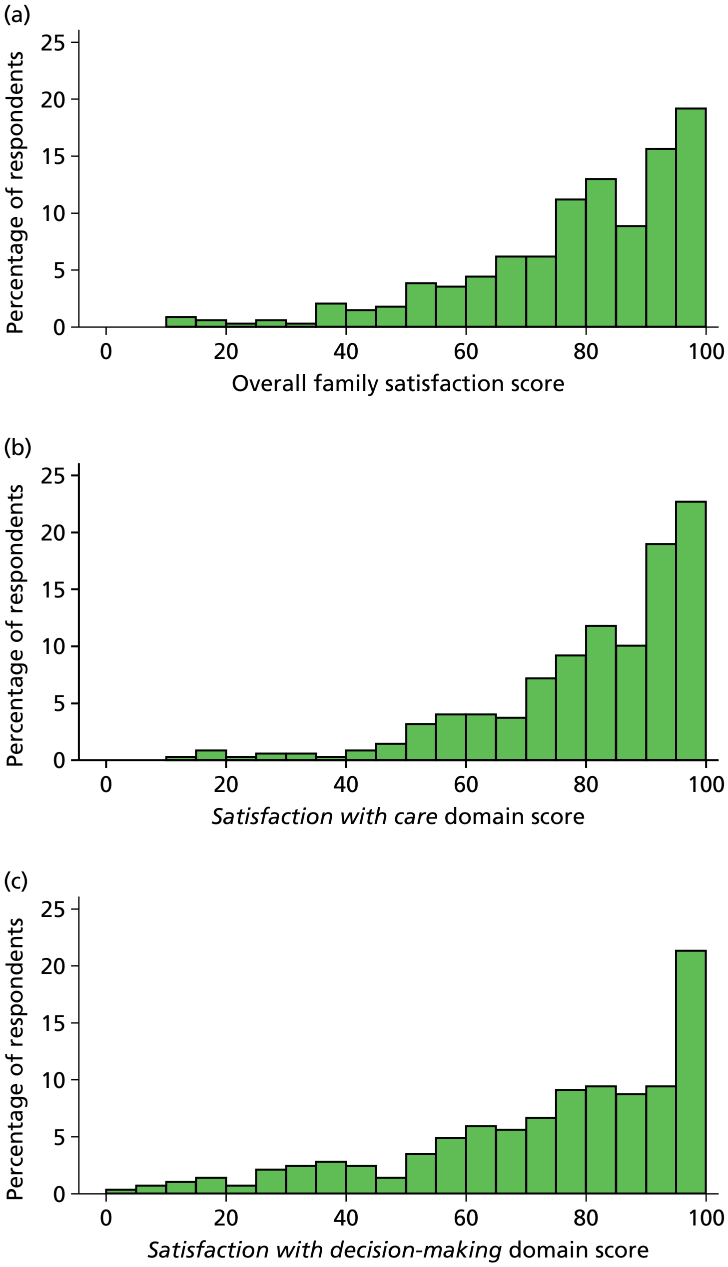


FIGURE 6 Distribution of UK FS-ICU-24 overall family satisfaction score and domain scores in the initial psychometric assessment.

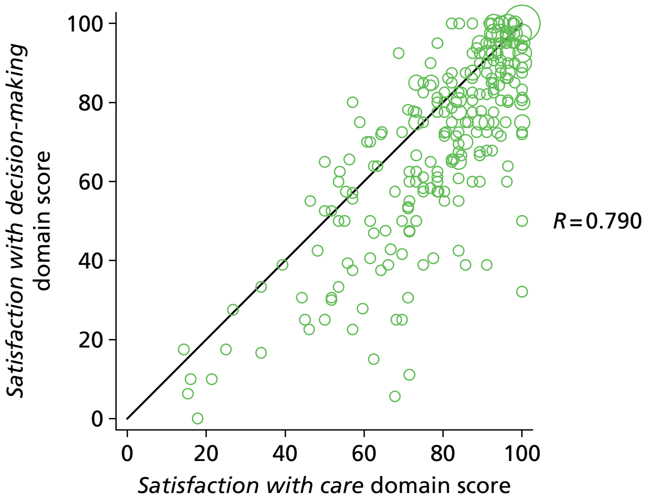


FIGURE 7 Correlation between UK FS-ICU-24 domain scores in the initial psychometric assessment ($n = 284$). The size of circle is proportional to the number of respondents.

A total of seven items were flagged for discussion because of high levels of 'not applicable' responses or non-response:

- three items from *satisfaction with care*:
    - symptom management – breathlessness (12.9% not applicable, 2.0% no response)
    - symptom management – agitation (12.0% not applicable, 2.0% no response)
    - the atmosphere (mood) in the ICU waiting room (9.8% not applicable, 1.4% no response)
- and four items from *satisfaction with decision-making*:
    - Did you feel included in the decision-making process? (25.5% not applicable, 1.7% no response)
    - Did you feel supported during the decision-making process? (28.0% not applicable, 1.4% no response)
    - Did you feel you had control over the care of your family member? (21.6% not applicable, 1.1% no response)
    - When making decisions, did you have adequate time to have your concerns addressed and questions answered? (42.0% not applicable, 1.7% no response).

Following discussion among the SMG, it was agreed that there were good reasons to expect 'not applicable' responses for these items – some patients would not have experienced particular symptoms, some family members would not have used the waiting room and some family members would not have been involved in the decision-making process – and consequently that these did not represent a lack of comprehensibility or acceptability and that the items were relevant to a substantial proportion of family members. All these items were therefore retained in the questionnaire.

Only one item, 'when making decisions, did you have adequate time to have your concerns addresses and questions answered?', had > 70% of respondents selecting either the highest or lowest option. However, this was the only binary item on the questionnaire and therefore it was not considered to represent a lack of discrimination.

Eleven items were flagged for discussion for potential redundancy:

- six items from *satisfaction with care*:
  - concern and caring by ICU staff [towards the patient] (item to own scale correlation 0.805)
  - consideration of the family member's needs (0.844)
  - emotional support [for the family member] (0.826)
  - concern and caring by ICU staff [towards the family member] (0.837)
  - co-ordination of care (0.820)
  - skill and competence of ICU nurses (0.814)
- and five items from *satisfaction with decision-making*:
  - ease of getting information (0.821)
  - understanding of information (0.811)
  - honesty of information (0.804)
  - completeness of information (0.857)
  - consistency of information (0.836).

All of these items were only just over the threshold for discussion (0.8) and it was felt that all items were capturing sufficiently different aspects of satisfaction for all to be retained.

Only one item, 'the atmosphere (mood) in the ICU waiting room' had a component loading of < 0.4 in the confirmatory principal components analysis (*Table 23*). This was only just below the threshold and was considered an important area of potential lower satisfaction.

No concerns were identified over the reliability (internal consistency) of the UK FS-ICU-24. All item to own scale correlations were greater than 0.4 (see *Tables 19* and *20*) and Cronbach's alpha exceeded 0.8 for the overall family satisfaction score (0.96) and for both domain scores (0.95 and 0.94 for *satisfaction with care* and *satisfaction with decision-making*, respectively; see *Table 22*).

The confirmatory factor analysis (*Table 24* and *Figure 8*) indicated that the North American two-factor solution for the FS-ICU-24 (corresponding to the two underlying constructs of *satisfaction with care* and *satisfaction with decision-making*) was not a good fit to the FREE study data (RMSEA > 0.08 and CFI and TLI < 0.9).

Of 44 included family members of a patient who died in the ICU, 36 (82%) returned a completed or partially completed QODD questionnaire and were included in the validity analysis. No concerns were identified over the validity of the UK FS-ICU-24 among family members of patients who died in the ICU. The majority of hypothesised relationships between the scores and individual items of the two instruments were supported by the data (*Table 25*). In particular, the overall family satisfaction score and both domain scores of the UK FS-ICU-24 correlated with the QODD total score (correlation coefficients 0.614, 0.622 and 0.641 for the overall family satisfaction score, *satisfaction with care* domain score and *satisfaction with decision-making* domain score, respectively; *Figure 9*).

Full psychometric assessment

From the final FREE study data set, selecting one family member per patient following the priority order as set out above resulted in a cohort of 4615 family members for the full psychometric assessment. Characteristics of the included patients and family members were similar to those from the initial psychometric assessment, although the revised approach to selecting the family member (to allow for patients with more than one responding family member) resulted in a higher proportion of partners and parents and lower proportions of other relatives and non-relatives (*Table 26*).

TABLE 23 Component loadings from confirmatory principal components analysis for the initial psychometric assessment (nominal sample size = 324)

UK FS-ICU-24 item	Component loadings	
	Component 1	Component 2
Satisfaction with care		
Concern and caring by ICU staff (towards the patient)	0.825	0.214
Symptom management: pain	0.801	0.151
Symptom management: breathlessness	0.793	0.171
Symptom management: agitation	0.810	0.190
Consideration of family member's needs	0.742	0.447
Emotional support	0.685	0.510
Concern and caring by ICU staff (towards the family member)	0.707	0.501
Co-ordination of care	0.789	0.335
Skill and competence of ICU nurses	0.845	0.193
Frequency of communication with ICU nurses	0.696	0.494
Skill and competence of ICU doctors	0.771	0.261
Atmosphere (mood) of the ICU	0.666	0.355
Atmosphere (mood) in the ICU Waiting Room	**0.336**	**0.374**
The LEVEL or amount of health care	0.479	0.133
Satisfaction with decision-making		
Frequency of communication with ICU doctors	0.406	0.675
Ease of getting information	0.563	0.653
Understanding of information	0.590	0.611
Honesty of information	0.612	0.602
Completeness of information	0.595	0.666
Consistency of information	0.553	0.678
Included in decision-making process	0.106	0.773
Supported during decision-making process	0.139	0.792
Control over the care of family member	0.194	0.691
Adequate time to have concerns addressed and questions answered	0.199	0.628
Explained variation		
Proportion of variation explained by component	0.387	0.259
Cumulative proportion of variation explained	0.387	0.646

Bold text indicates items flagged for discussion on potential item reduction (component loadings < 0.4).

TABLE 24 Confirmatory factor analysis: goodness of fit statistics from the initial psychometric assessment

Goodness of fit statistic	Value	*p*-value
Chi-squared statistic (degrees of freedom) vs. saturated model	1073 (251)	< 0.001
RMSEA	0.096	–
CFI	0.884	–
TLI	0.872	–
CD	0.995	–

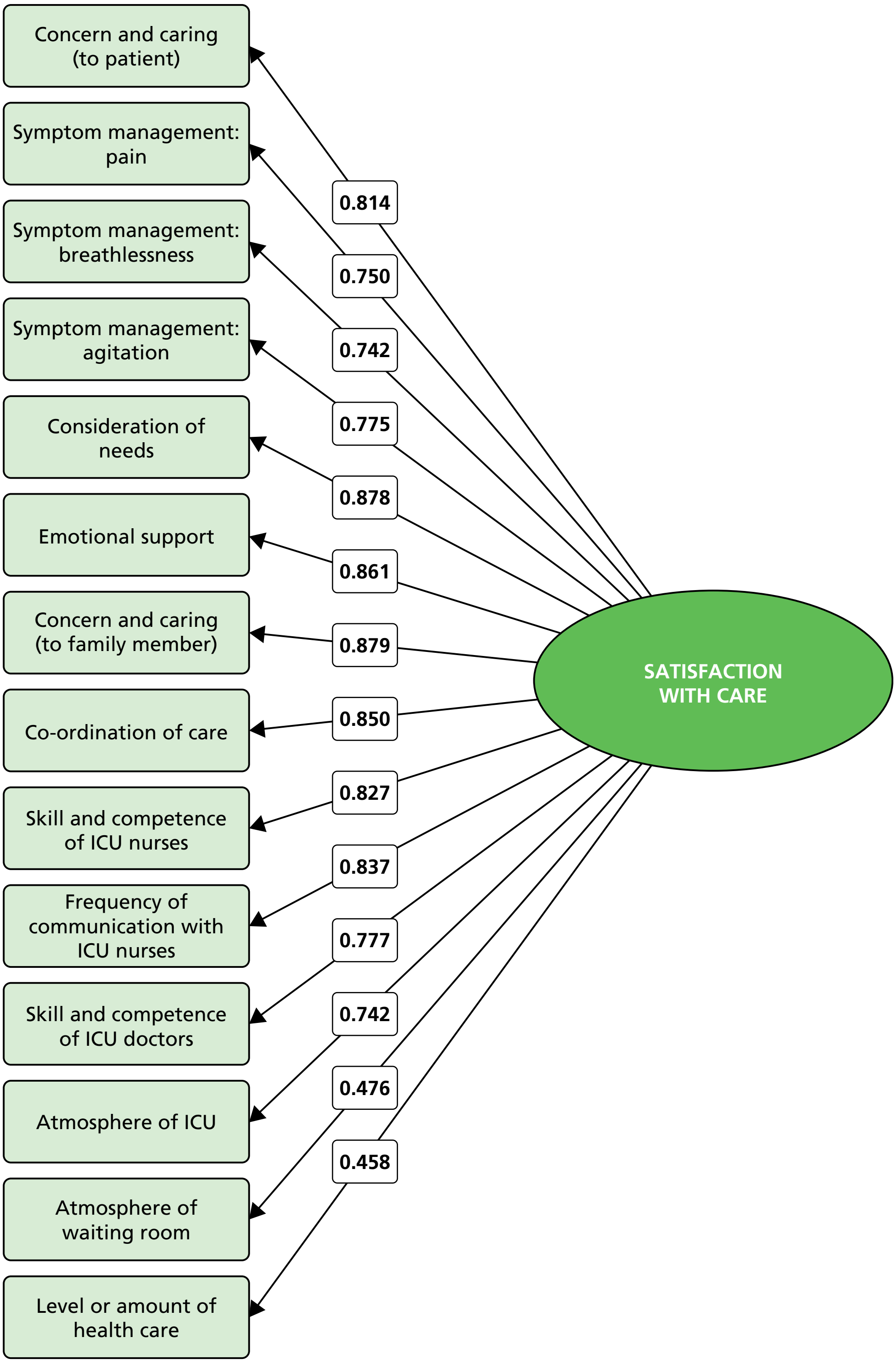


FIGURE 8 Confirmatory factor analysis: structural model and factor loadings from the initial psychometric assessment. (*continued*)

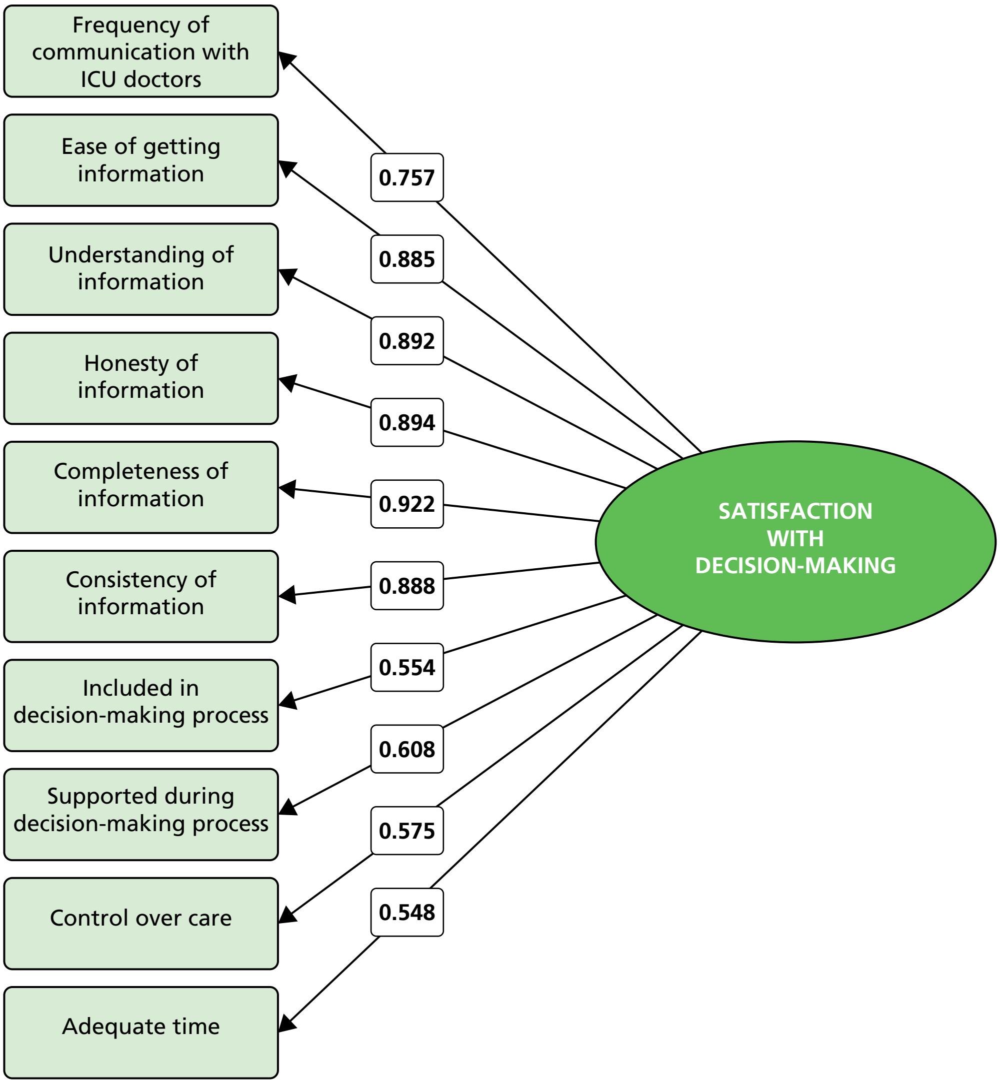


FIGURE 8 Confirmatory factor analysis: structural model and factor loadings from the initial psychometric assessment.

TABLE 25 Validity analysis of family members of non-survivors

UK FS-ICU-24 item or score	QODD item or score	*n*	Correlation coefficient	*p*-value	Hypothesised value of correlation coefficient
Overall family satisfaction score	Total score	23	0.614[a]	0.002	> 0.6
Satisfaction with care domain score	Total score	23	0.622[a]	0.002	> 0.6
Satisfaction with decision-making domain score	Total score	22	0.641[a]	0.001	> 0.6
Satisfaction with care domain score	How often did your loved one appear to have his/her pain under control? How would you rate this aspect of your loved one's dying experience?	33	**0.354**	0.043	0.4–0.6
Satisfaction with care domain score	How often did your loved one appear to breathe comfortably? How would you rate this aspect of your loved one's dying experience?	31	**0.332**	0.068	0.4–0.6
Satisfaction with care domain score	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	35	0.685	< 0.001	0.4–0.6
Satisfaction with care domain score	Rate the care your loved one received from his/her doctor during the last several days of his/her life while in the ICU	33	0.700	< 0.001	0.4–0.6
Concern and caring by ICU staff? The courtesy, respect and compassion your family member (the patient) was given	How often did your loved one appear to keep his/her dignity and self-respect?	30	0.332	0.073	0.2–0.6
How well the ICU staff assessed and treated your family member's symptoms: pain	How often did your loved one appear to have his/her pain under control?	28	**0.464**	0.013	> 0.6
How well the ICU staff assessed and treated your family member's symptoms: breathlessness	How often did your loved one appear to breathe comfortably?	28	**0.084**	0.67	> 0.6
Skill and competence of ICU nurses? How well the nurses cared for your family member	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	35	0.807	< 0.001	0.4–0.6
Skill and competence of ICU doctors? How well the doctors cared for your family member	Rate the care your loved one received from his/her doctor during the last several days of his/her life while in the ICU	33	0.635	< 0.001	> 0.6

TABLE 25 Validity analysis of family members of non-survivors (*continued*)

UK FS-ICU-24 item or score	QODD item or score	*n*	Correlation coefficient	*p*-value	Hypothesised value of correlation coefficient
During the final hours of your family member's life, which of the following best describes your views: I felt he/she was very uncomfortable, slightly uncomfortable, mostly comfortable, very comfortable, totally comfortable	How often did your loved one appear to have his/her pain under control?	29	0.578	0.001	0.2–0.6
During the final hours of your family member's life, which of the following best describes your views: I felt he/she was very uncomfortable, slightly uncomfortable, mostly comfortable, very comfortable, totally comfortable	How often did your loved one appear at peace with dying?	21	0.592	0.005	0.2–0.6
During the final hours of your family member's life, which of the following best describes your views: I felt he/she was very uncomfortable, slightly uncomfortable, mostly comfortable, very comfortable, totally comfortable	How often did your loved one appear unafraid of dying?	17	**0.103**	0.69	0.2–0.6

a Pearson correlation coefficient (all other values are Spearman's rank correlation coefficients).
Bold text indicates correlations that did not support the hypothesised relationships.

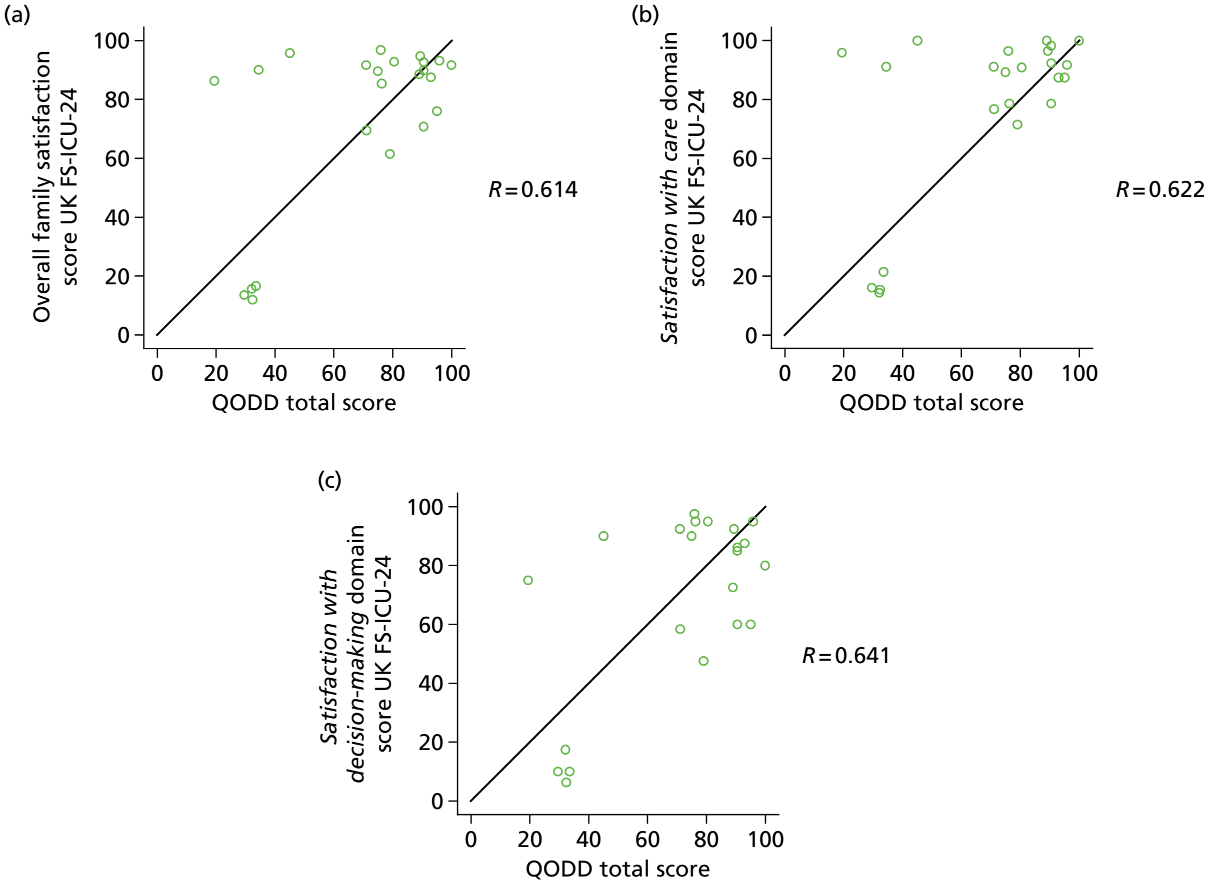


FIGURE 9 Correlation between UK FS-ICU-24 scores and QODD total score.

TABLE 26 Characteristics of patients and family members included in the full psychometric assessment

Characteristic	Patients (*n* = 4615)	Family members (*n* = 4615)
Mean age[a] (years), (SD)	63.2 (16.9)	56.5 (14.3)
Age[b] (years), *n* (%)		
< 30	259 (5.6)	201 (4.4)
30–39	233 (5.0)	356 (7.7)
40–49	423 (9.2)	837 (18.2)
50–59	650 (14.1)	1129 (24.5)
60–69	1134 (24.6)	1200 (26.0)
70–79	1195 (25.9)	695 (15.1)
≥ 80	721 (15.6)	190 (4.1)
Sex,[c,d] *n* (%)		
Female	1945 (43.2)	3097 (67.1)
Male	2561 (56.8)	1516 (32.9)

TABLE 26 Characteristics of patients and family members included in the full psychometric assessment (*continued*)

Characteristic	Patients ($n = 4615$)	Family members ($n = 4615$)
Relationship to patient, *n* (%)		
Partner	N/A	2101 (45.5)
Parent		461 (10.0)
Child		1199 (26.0)
Sibling		389 (8.4)
Other relative		294 (6.4)
Other non-relative		171 (3.7)
Surgical status,[c] *n* (%)		
Elective/scheduled surgery	829 (18.4)	N/A
Emergency/urgent surgery	869 (19.3)	
Non-surgical	2808 (62.3)	
Mean ICNARC physiology score[c] (SD)	18.4 (8.3)	N/A
Mean APACHE II score[c] (SD)	16.8 (6.3)	N/A
ICU outcome, *n* (%)		
Alive	4105 (88.9)	N/A
Dead	510 (11.1)	
Median ICU length of stay[c] (days) (IQR)		
All patients	4.9 (2.9, 9.1)	N/A
ICU survivors	4.8 (2.8, 9.0)	
ICU non-survivors	6.0 (3.6, 10.6)	

N/A, not applicable.
a Age in years not reported for 174 family members (3.8%).
b Age group not reported for seven family members (0.2%).
c Patient data require linkage to CMP – not available for 109 patients from one unit (2.4%).
d Sex not reported for two family members (< 0.1%).

Responses to individual items on the UK FS-ICU-24 are reported in *Table 27* (*satisfaction with care*), *Table 28* (*satisfaction with decision-making*) and *Table 29* (*satisfaction with decision-making, if your family member died in the ICU*). *Table 30* reports the results of a question added to the original FS-ICU questionnaire, 'how satisfied were you with the amount of control you had over the care of your family member?'. There was moderate correlation with the original FS-ICU question, 'did you feel you had control over the care of your family member?' (Spearman's rank correlation 0.529, $p < 0.001$). However, there was some notable discordance. For example, almost one-third of family members who indicated that they 'felt really out of control' indicated that they were either 'completely satisfied' or 'very satisfied' with the amount of control they had.

Using a 60% response threshold for inclusion in the overall family satisfaction score and domain scores made minimal difference to the characteristics of the scores but permitted an additional 508 respondents (11%) to be included in the domain score for *satisfaction with decision-making* and small increases in the numbers of respondents included in the other scores. Results are therefore presented using the 60% threshold. Characteristics of the UK FS-ICU-24 overall family satisfaction score and domain scores are summarised in *Table 31*, and the distributions of the scores are shown in *Figure 10*. Among the 4319 (94%) family members for whom both domain scores could be calculated, correlation between the two domains was 0.770 (*Figure 11*).

TABLE 27 UK FS-ICU-24 responses to items about *satisfaction with care* in the full psychometric assessment ($n = 4615$)

Items			Response (%)								
How did we treat your family member (the patient)?	**No response (%)**	**N/A (%)**	**Excellent**	**Very good**	**Good**	**Fair**	**Poor**	**Median (IQR)**	**Mean (SD)**	**Item to own scale correlation**	**Cronbach's alpha if item removed**
Concern and caring by ICU staff?	32 (0.7)	0 (0.0)	3320 (72.4)	1024 (22.3)	188 (4.1)	38 (0.8)	13 (0.3)	100 (75–100)	91 (16)	0.790	0.932
Symptom management?											
Pain	39 (0.8)	109 (2.4)	2829 (63.3)	1253 (28.1)	307 (6.9)	53 (1.2)	25 (0.6)	100 (75–100)	88 (18)	0.773	0.932
Breathlessness	84 (1.8)	538 (11.7)	2482 (62.2)	1046 (26.2)	342 (8.6)	78 (2.0)	45 (1.1)	100 (75–100)	87 (21)	0.720	0.934
Agitation	98 (2.1)	445 (9.6)	2192 (53.8)	1189 (29.2)	499 (12.3)	141 (3.5)	51 (1.3)	100 (75–100)	83 (23)	0.774	0.932
How did we treat you?											
Consideration of your needs?	35 (0.8)	31 (0.7)	2455 (54.2)	1362 (30.1)	503 (11.1)	161 (3.6)	45 (1.0)	100 (75–100)	83 (22)	0.833	0.930
Emotional support?	39 (0.8)	327 (7.1)	1995 (47.0)	1297 (30.5)	634 (14.9)	236 (5.6)	87 (2.0)	75 (75–100)	79 (25)	0.827	0.931
Concern and caring by ICU staff?	31 (0.7)	45 (1.0)	2565 (56.5)	1308 (28.8)	477 (10.5)	148 (3.3)	41 (0.9)	100 (75–100)	84 (22)	0.839	0.930
Teamwork											
Co-ordination of care?	27 (0.6)	30 (0.7)	2624 (57.6)	1409 (30.9)	424 (9.3)	70 (1.5)	31 (0.7)	100 (75–100)	86 (19)	0.815	0.931
Nurses											
Skill and competence of ICU nurses?	17 (0.4)	5 (0.1)	3203 (69.7)	1101 (24.0)	236 (5.1)	40 (0.9)	13 (0.3)	100 (75–100)	91 (16)	0.807	0.932
Frequency of communication with ICU nurses?	26 (0.6)	70 (1.5)	2302 (50.9)	1366 (30.2)	548 (12.1)	212 (4.7)	91 (2.0)	100 (75–100)	81 (24)	0.787	0.932

Doctors										
Skill and competence of ICU doctors?	36 (0.8)	86 (1.9)	2706 (60.2)	1263 (28.1)	404 (9.0)	76 (1.7)	44 (1.0)	100 (75–100)	86 (20)	0.741	0.933
The ICU											
The atmosphere (mood) of the ICU was?	26 (0.6)	11 (0.2)	2182 (47.7)	1617 (35.3)	625 (13.7)	129 (2.8)	25 (0.5)	75 (75–100)	82 (21)	0.775	0.932
The waiting room											
The atmosphere (mood) in the ICU waiting room was?	39 (0.8)	386 (8.4)	953 (22.7)	1347 (32.1)	1139 (27.2)	582 (13.9)	169 (4.0)	75 (50–75)	64 (28)	0.587	0.941
Level/amount of health care			**Completely satisfied**	**Very satisfied**	**Mostly satisfied**	**Slightly dissatisfied**	**Very dissatisfied**				
How satisfied were you with the LEVEL or amount of health care your family member received in the ICU?	33 (0.7)	–	2446 (53.4)	1470 (32.1)	442 (9.6)	47 (1.0)	177 (3.9)	100 (75–100)	83 (23)	0.571	0.940

N/A, not applicable.
Values are number (%) unless specified. Percentages are reported out of all respondents for the options 'no response' and 'N/A' and out of valid responses (i.e. excluding 'no response' and 'N/A') for all other options.

TABLE 28 UK FS-ICU-24 responses to items about *satisfaction with decision-making* in the full psychometric assessment ($n = 4615$)

Item			Response (%)								
Information needs	**No response (%)**	**N/A (%)**	**Excellent**	**Very good**	**Good**	**Fair**	**Poor**	**Median (IQR)**	**Mean (SD)**	**Item to own scale correlation**	**Cronbach's alpha if item removed**
Frequency of communication with ICU doctors?	45 (1.0)	288 (6.2)	1236 (28.9)	1320 (30.8)	944 (22.0)	450 (10.5)	332 (7.8)	75 (50–100)	66 (30)	0.808	0.916
Ease of getting information?	35 (0.8)	95 (2.1)	1959 (43.7)	1531 (34.1)	667 (14.9)	236 (5.3)	92 (2.1)	75 (75–100)	78 (25)	0.846	0.913
Understanding of information?	36 (0.8)	116 (2.5)	1891 (42.4)	1624 (36.4)	697 (15.6)	190 (4.3)	61 (1.4)	75 (75–100)	79 (23)	0.849	0.913
Honesty of information?	41 (0.9)	117 (2.5)	2157 (48.4)	1452 (32.6)	601 (13.5)	182 (4.1)	65 (1.5)	75 (75–100)	81 (23)	0.843	0.913
Completeness of information?	36 (0.8)	103 (2.2)	2054 (45.9)	1472 (32.9)	602 (13.4)	233 (5.2)	115 (2.6)	75 (75–100)	79 (25)	0.873	0.911
Consistency of information?	42 (0.9)	205 (4.4)	1711 (39.2)	1474 (33.7)	745 (17.1)	299 (6.8)	139 (3.2)	75 (50–100)	75 (29)	0.855	0.912
The process of making decisions			**I felt very included**	**I felt somewhat included**	**I felt neither included nor excluded**	**I felt somewhat excluded**	**I felt very excluded**				
Did you feel included in the decision-making process?	76 (1.6)	1004 (21.8)	1682 (47.6)	717 (20.3)	773 (21.9)	190 (5.4)	173 (4.9)	75 (50–100)	75 (29)	0.714	0.922

			I felt very supported	**I felt supported**	**I felt neither supported nor unsupported**	**I felt slightly unsupported**	**I felt totally unsupported**				
Did you feel supported during the decision-making process?	74 (1.6)	1096 (23.7)	1307 (37.9)	1099 (31.9)	765 (22.2)	113 (3.3)	161 (4.7)	75 (50–100)	74 (27)	0.734	0.920
			I felt that I had good control	**I felt I had some control**	**I felt neither in control nor out of control**	**I felt somewhat out of control**	**I felt really out of control**				
Did you feel you had control over the care of your family member?	81 (1.8)	862 (18.7)	1056 (28.8)	838 (22.8)	1119 (30.5)	379 (10.3)	280 (7.6)	75 (50–100)	64 (30)	0.666	0.926
			I had adequate time				**I could have used more time**				
When making decisions, did you have adequate time to have your concerns addressed and questions answered? (note: 2 options)	95 (2.1)	1864 (40.4)	2329 (87.7)	–	–	–	327 (12.3)	100 (100–100)	88 (33)	0.513	0.928

N/A, not applicable.
Values are number (%) unless specified. Percentages are reported out of all respondents for the options ‘No response’ and ‘N/A’ and out of valid responses (i.e. excluding ‘No response’ and ‘N/A’) for all other options.

TABLE 29 UK FS-ICU-24 responses to items about *satisfaction with decision-making (if your family member died in the ICU)* in the full psychometric assessment ($n = 510$)

Item			**Response (%)**						
Which of the following best describes your views[a]	**No response (%)**	**N/A (%)**	**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**	**Median (IQR)**	**Mean (SD)**
	14 (2.7)	0 (0)	13 (2.6)	14 (2.8)	448 (90.3)	14 (2.8)	7 (1.4)	100 (100–100)	93 (22)
During the final hours of your family member's life, which of the following best describes your views			**I felt that he/she was totally comfortable**	**I felt that he/she was very comfortable**	**I felt that he/she was mostly comfortable**	**I felt that he/she was slightly uncomfortable**	**I felt that he/she was totally uncomfortable**		
	11 (2.2)	0 (0)	171 (34.3)	157 (31.5)	131 (26.3)	18 (3.6)	22 (4.4)	75 (50–100)	72 (27)
During the last few hours before your family member's death, which of the following best describes your views			**I felt very supported by the health-care team**	**I felt supported by the health-care tem**	**I felt neither abandoned nor supported by the health-care team**	**I felt abandoned by the health-care team**	**I felt very abandoned by the health-care team**		
	13 (2.5)	0 (0)	301 (60.6)	147 (29.6)	32 (6.4)	8 (1.6)	9 (1.8)	100 (75–100)	86 (21)

N/A, not applicable.

[a] Middle response scored 100, responses at either extreme scored 0 and intermediate responses scored 50.

Values are number (%) unless specified. Percentages are reported out of all respondents for the options 'no response' and 'N/A' and out of valid responses (i.e. excluding 'no response' and 'N/A') for all other options. Note that these questions are not included in calculating the overall family satisfaction score or the domain score.

TABLE 30 Additional question on *satisfaction with decision-making* (*n* = 4615)

Question/response	Response (%) No response (%)	N/A	Completely satisfied	Very satisfied	Mostly satisfied	Slightly dissatisfied	Very dissatisfied	Median (IQR)	Mean (SD)
How satisfied were you with the amount of control you had over the care of your family member?	391 (8.5)	–	1349 (31.9)	1430 (33.9)	1172 (27.7)	178 (4.2)	95 (2.2)	75 (50–100)	72 (24)
Responses to additional question by response to 'Did you feel you had control over the care of your family member?'									
I felt that I had good control (*n* = 1056)	41 (3.9)	–	646 (63.6)	313 (30.8)	38 (3.7)	0 (0)	18 (1.8)	–	–
I felt I had some control (*n* = 838)	31 (3.7)	–	148 (18.3)	417 (51.7)	231 (28.6)	8 (1.0)	3 (0.4)	–	–
I felt neither in control nor out of control (*n* = 1119)	79 (7.1)	–	190 (18.3)	334 (32.1)	472 (45.4)	35 (3.4)	9 (0.9)	–	–
I felt somewhat out of control (*n* = 379)	12 (3.2)	–	32 (8.7)	64 (17.4)	202 (55.0)	64 (17.4)	5 (1.4)	–	–
I felt really out of control (*n* = 280)	16 (5.7)	–	43 (16.3)	40 (15.2)	77 (29.2)	59 (22.3)	45 (17.0)	–	–

N/A, not applicable.

Values are number (%) unless specified. Percentages are reported out of all respondents for the options 'No response' and 'N/A' and out of valid responses (i.e. excluding 'No response' and 'N/A') for all other options. Note that this question is not part of the original FS-ICU questionnaire and was not included in calculating the overall family satisfaction score or the domain score.

TABLE 31 UK FS-ICU-24 overall family satisfaction score and domain scores in the full psychometric assessment (*n* = 4615)

Score	Not scored (< 60% response)	Scored (≥ 60% response)	Floor (0%)	Ceiling (100%)	Range	Median (IQR)	Mean (SD)	Skewness	Cronbach's alpha
Overall family satisfaction	150 (3.3)	4465 (96.7)	1 (0.0)	268 (6.0)	0–100	84 (71–94)	80 (17)	–1.1	0.957
Satisfaction with care domain	54 (1.2)	4561 (98.8)	1 (0.0)	595 (13.0)	0–100	88 (75–96)	83 (16)	–1.3	0.938
Satisfaction with decision-making domain	274 (5.9)	4341 (94.1)	11 (0.3)	541 (12.5)	0–100	80 (63–93)	75 (21)	–1.0	0.925

Values are number (%) unless specified. Percentages are reported out of all respondents for 'Not scored' and 'Scored' and out of scored responses (i.e. those with responses to at least 60% of items within the domain) for floor and ceiling scores.

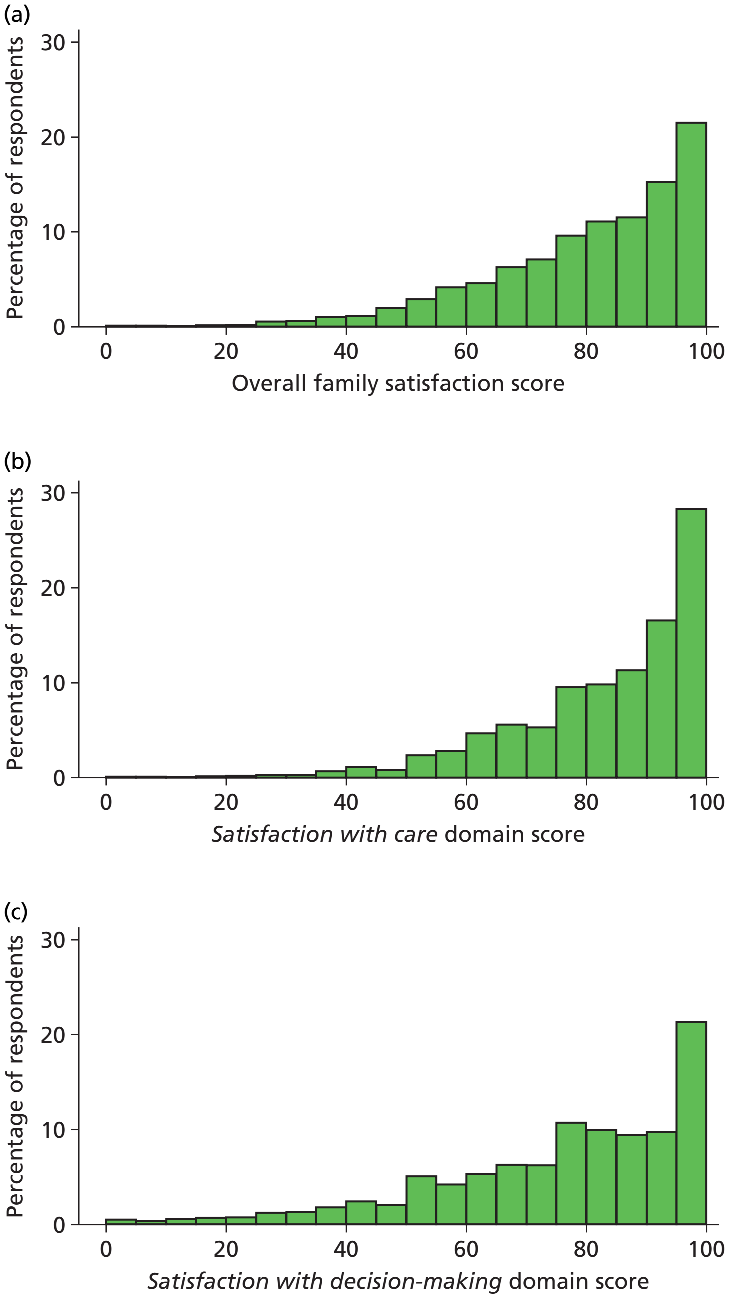


FIGURE 10 Distribution of UK FS-ICU-24 overall family satisfaction score and domain scores in the full psychometric assessment.

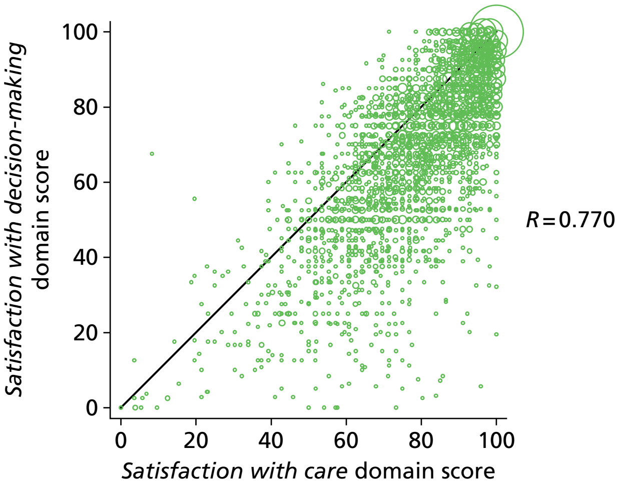


FIGURE 11 Correlation between UK FS-ICU-24 domain scores in the full psychometric assessment ($n = 4319$). Size of circle proportional to number of respondents.

Levels of non-response or 'not applicable' responses were slightly lower in the full psychometric assessment than in the initial psychometric assessment, because the selection process was revised to prioritise family members who were more likely to provide complete responses. However, the same items were identified as having higher levels of non-response, although 'the atmosphere (mood) in the ICU waiting room' no longer reached the 10% threshold. The item 'concern and caring by ICU staff' was identified as having a possible ceiling effect, with 72% of respondents rating this as 'excellent'. The same items as in the initial psychometric assessment were identified as having possible redundancy (item to own scale correlation > 0.8).

All component loadings were ≥ 0.4 in the confirmatory principal components analysis (*Table 32*). However, a number of items were loading on both components, suggesting either correlation between the components and/or the presence of additional important components.

No concerns were identified over the reliability (internal consistency) of the UK FS-ICU-24. All item to own scale correlations were > 0.4 (see *Tables 27* and *28*) and Cronbach's alpha exceeded 0.8 for the overall family satisfaction score (0.957) and for both domain scores (0.938 and 0.925 for *satisfaction with care* and *satisfaction with decision-making*, respectively; see *Table 31*), similarly to the initial psychometric assessment.

Substituting the alternative question on satisfaction with the amount of control increased Cronbach's alpha for the overall family satisfaction score from 0.957 to 0.959 and for the *satisfaction with decision-making* domain score from 0.925 to 0.930.

The confirmatory factor analysis (*Table 33* and *Figure 12*) confirmed the findings from the initial psychometric assessment that the North American two-factor solution for the FS-ICU-24 was not a good fit to the FREE study data (RMSEA > 0.08 and CFI and TLI < 0.9).

TABLE 32 Component loadings from confirmatory principal components analysis for the full psychometric assessment (nominal sample size = 4241)

UK FS-ICU-24 item	Component loadings Component 1	Component 2
Satisfaction with care		
Concern and caring by ICU staff (towards the patient)	**0.792**	0.214
Symptom management: pain	**0.795**	0.170
Symptom management: breathlessness	**0.763**	0.117
Symptom management: agitation	**0.782**	0.184
Consideration of family member's needs	**0.684**	**0.454**
Emotional support	**0.644**	**0.510**
Concern and caring by ICU staff (towards the family member)	**0.687**	**0.475**
Co-ordination of care	**0.768**	0.309
Skill and competence of ICU nurses	**0.806**	0.220
Frequency of communication with ICU nurses	**0.618**	**0.519**
Skill and competence of ICU doctors	**0.654**	0.375
Atmosphere (mood) of the ICU	**0.686**	0.332
Atmosphere (mood) in the ICU Waiting Room	**0.416**	0.348
The LEVEL or amount of health care	**0.502**	0.212
Satisfaction with decision-making		
Frequency of communication with ICU doctors	0.377	**0.702**
Ease of getting information	**0.555**	**0.639**
Understanding of information	**0.556**	**0.641**
Honesty of information	**0.542**	**0.641**
Completeness of information	**0.552**	**0.674**
Consistency of information	**0.516**	**0.671**
Included in decision-making process	0.096	**0.763**
Supported during decision-making process	0.163	**0.755**
Control over the care of family member	0.072	**0.715**
Adequate time to have concerns addressed and questions answered	0.160	**0.609**
Explained variation		
Proportion of variation explained by component	0.352	0.263
Cumulative proportion of variation explained	0.352	0.614

Bold text indicates component loadings of ≥ 0.4.

TABLE 33 Confirmatory factor analysis: goodness of fit statistics from the full psychometric assessment

Goodness of fit statistic	Value	*p*-value
Chi-squared statistic (degrees of freedom) vs. saturated model	10777 (251)	< 0.001
RMSEA	0.095	–
CFI	0.873	–
TLI	0.860	–
CD	0.994	–

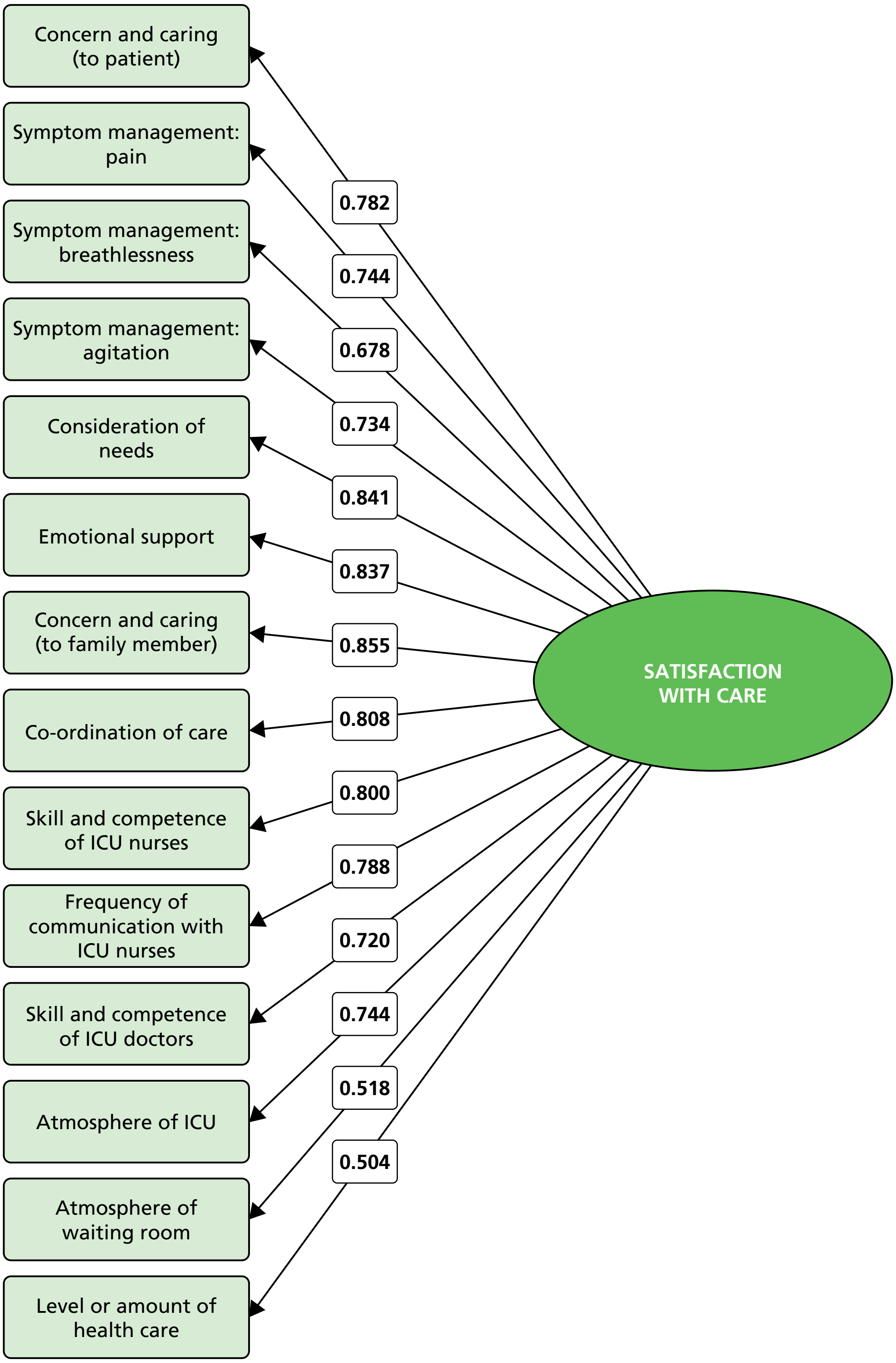


FIGURE 12 Confirmatory factor analysis: structural model and factor loadings from the full psychometric assessment. (*continued*)

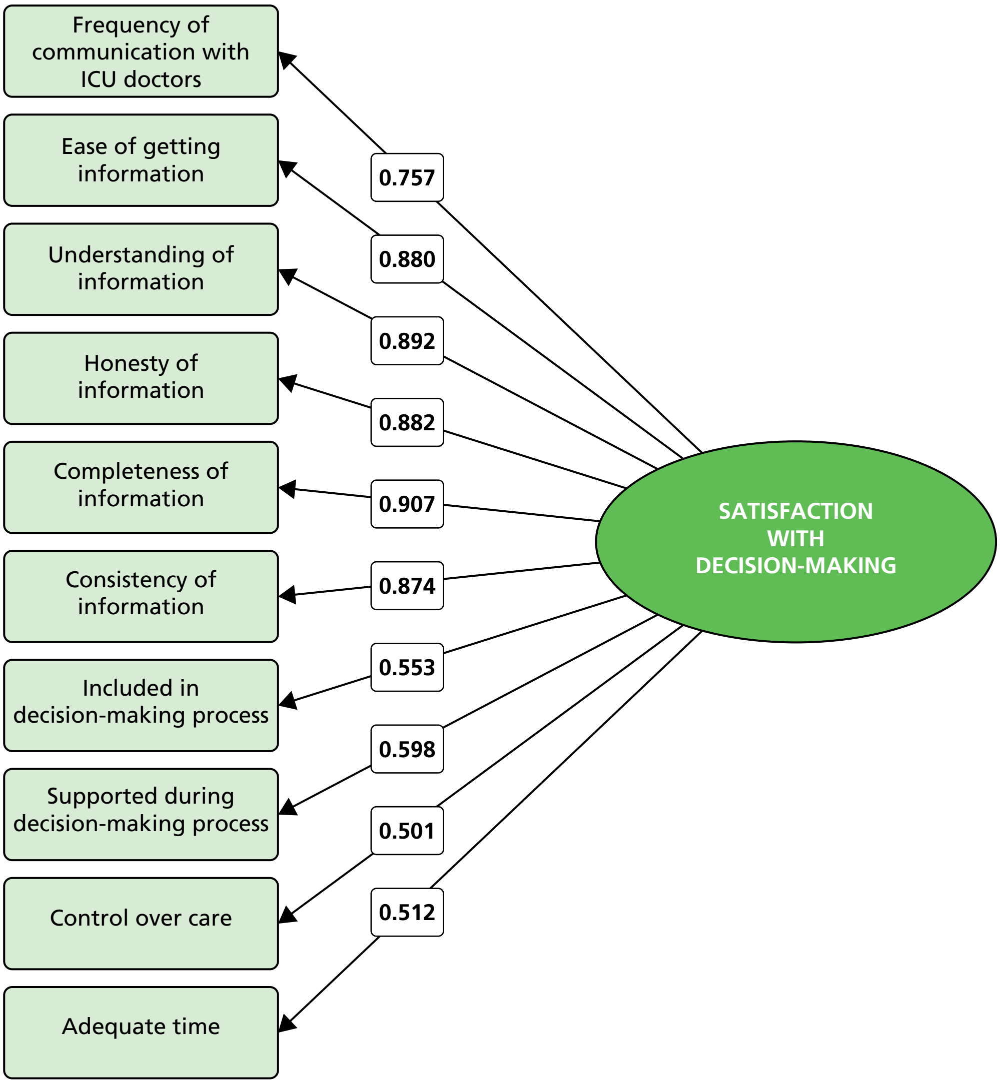


FIGURE 12 Confirmatory factor analysis: structural model and factor loadings from the full psychometric assessment.

The exploratory factor analysis (*Table 34*) identified a three-factor solution, which was a better fit to the FREE study data when validated in a structural equation model (*Table 35* and *Figure 13*) than the North American two-factor solution (RMSEA < 0.08; CFI and TLI > 0.9). This comprised the same domain of *satisfaction with care*, but the domain of *satisfaction with decision-making* was split into two separate factors: *satisfaction with information* (corresponding to the first six items) and *satisfaction with the decision-making process* (final four items). There was considerable correlation between the dimensions; consequently the best-fitting model used an oblique rotation and correlated error terms were permitted in the structural equation model. Correlations between the domain scores for the three domains are shown in *Figure 14*.

Performance-importance plots for the overall family satisfaction score and the two original domain scores are shown in *Figures 15–17*. The performance-importance plot for the overall family satisfaction score suggests that the highest-priority items for quality improvement relate to the provision of information (items 1–6 from the *satisfaction with decision-making* domain) and how well the ICU staff provide emotional support to the family member (item 4 from the *satisfaction with care* domain). The item relating to the atmosphere (mood) in the ICU waiting room (item 11 from the *satisfaction with care* domain) had the lowest proportion of 'excellent' ratings, but was ranked a lower priority for quality improvement because of its lower correlation with the overall family satisfaction score and the *satisfaction with care* domain score.

TABLE 34 Exploratory factor analysis from the full psychometric assessment

	Factor loadings		
UK FS-ICU-24 item	**Factor 1**	**Factor 2**	**Factor 3**
Satisfaction with care			
Concern and caring by ICU staff (towards the patient)	**0.872**		
Symptom management: pain	**0.885**		
Symptom management: breathlessness	**0.876**		
Symptom management: agitation	**0.896**		
Consideration of family member's needs	**0.625**		
Emotional support	0.592		
Concern and caring by ICU staff (towards the family member)	**0.606**		
Co-ordination of care	**0.740**		
Skill and competence of ICU nurses	**0.832**		
Frequency of communication with ICU nurses	0.462		
Skill and competence of ICU doctors	0.492	0.402	
Atmosphere (mood) of the ICU	**0.641**		
Atmosphere (mood) in the ICU Waiting Room	0.365		
The LEVEL or amount of health care	0.521		
Satisfaction with decision-making			
Frequency of communication with ICU doctors		**0.667**	
Ease of getting information		**0.832**	
Understanding of information		**0.863**	
Honesty of information		**0.840**	
Completeness of information		**0.807**	
Consistency of information		**0.795**	
Included in decision-making process			**0.901**
Supported during decision-making process			**0.828**
Control over the care of family member			**0.735**
Adequate time to have concerns addressed and questions answered			0.518
Explained variation			
Proportion of variation explained by factor[a]	0.703	0.690	0.452

[a] Factors are correlated.

Bold text indicates factor loadings of ≥ 0.6. Factor loadings of < 0.4 not shown (except for 'atmosphere (mood) in the ICU waiting room' for which all factor loadings were < 0.4).

TABLE 35 Structural equation model: goodness of fit of the FREE study three-factor solution

Goodness of fit statistic	Value	*p*-value
Chi-squared statistic (degrees of freedom) vs. saturated model	7086 (248)	< 0.001
RMSEA	0.077	–
CFI	0.918	–
TLI	0.908	–
CD	0.998	–

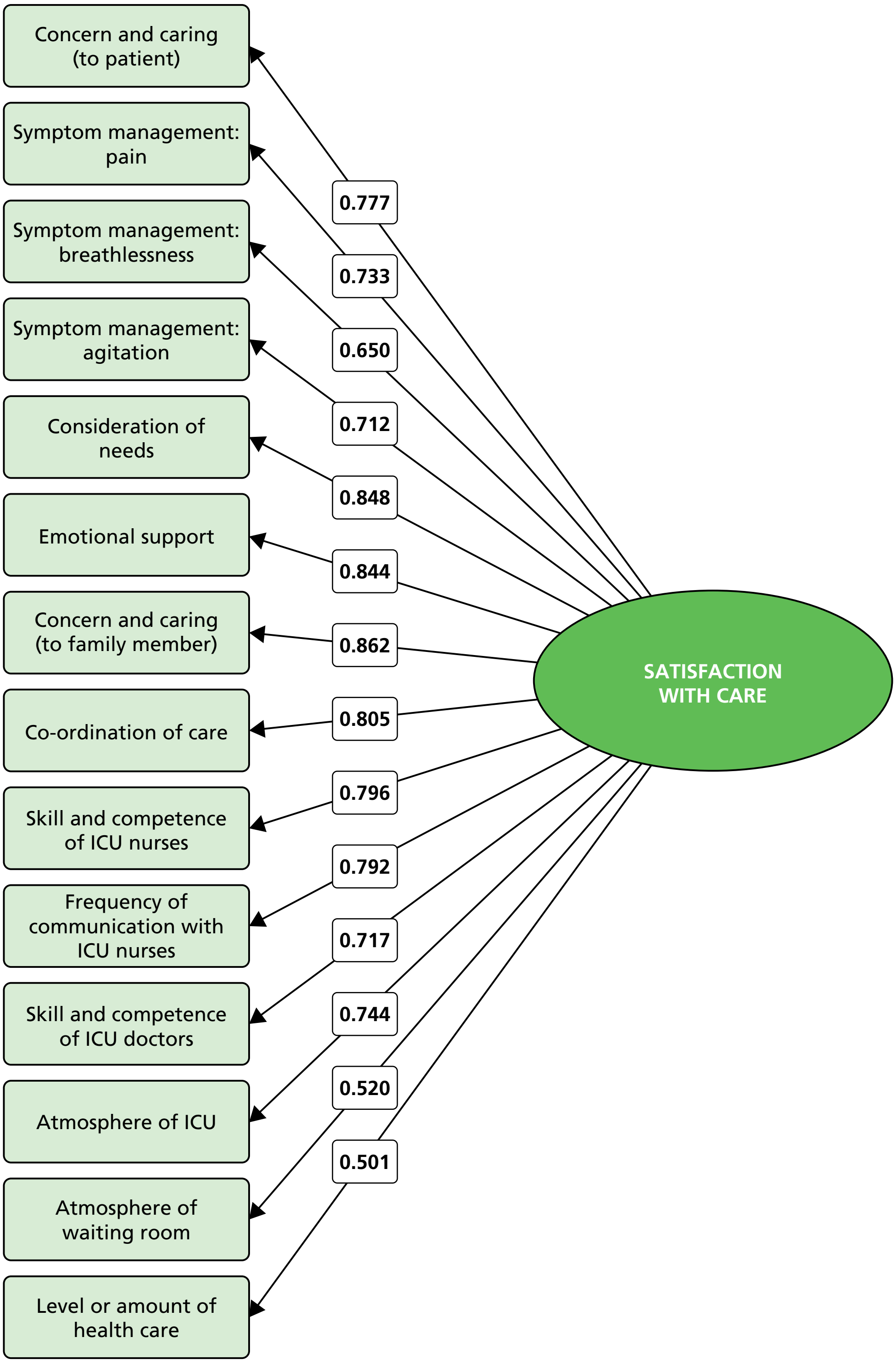


FIGURE 13 Structural equation model: structure and factor loadings for the FREE study three-factor solution. (*continued*)

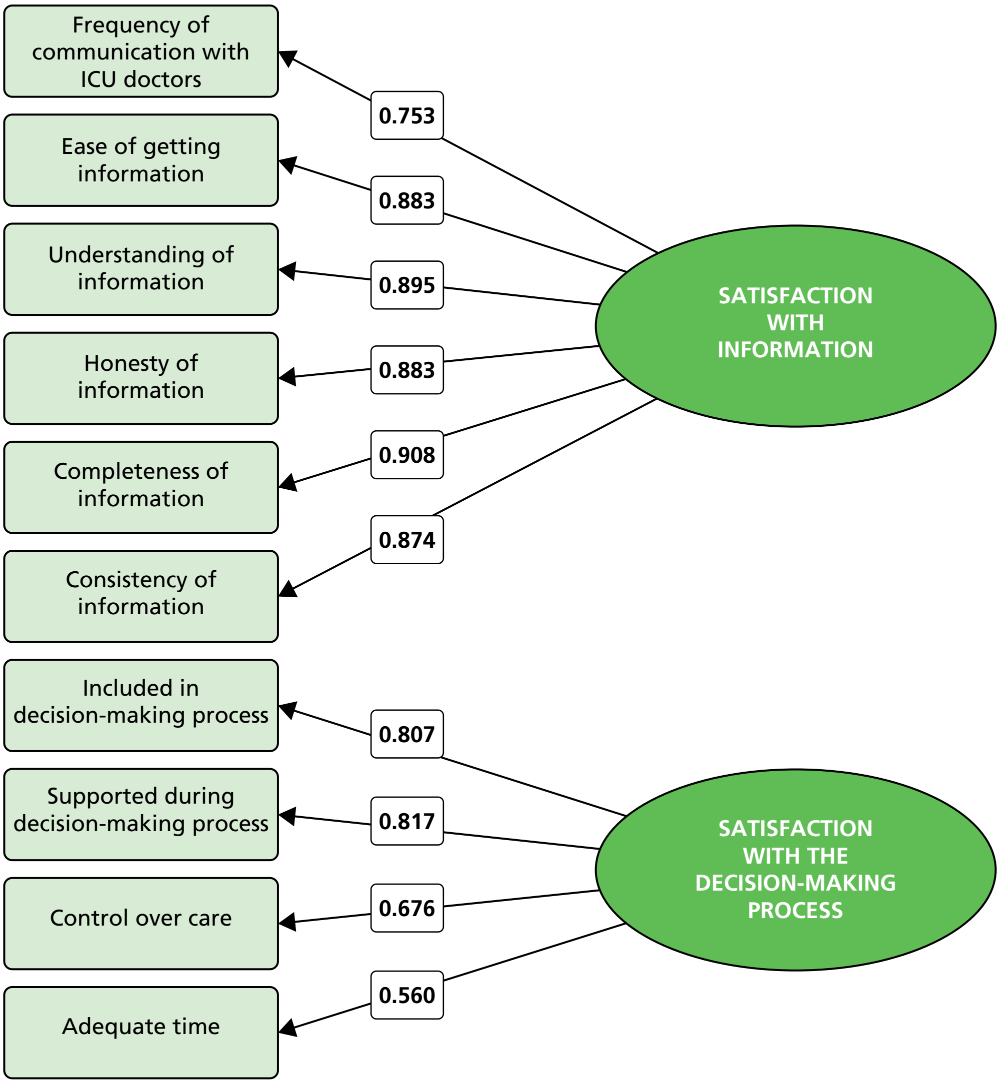


FIGURE 13 Structural equation model: structure and factor loadings for the FREE study three-factor solution.

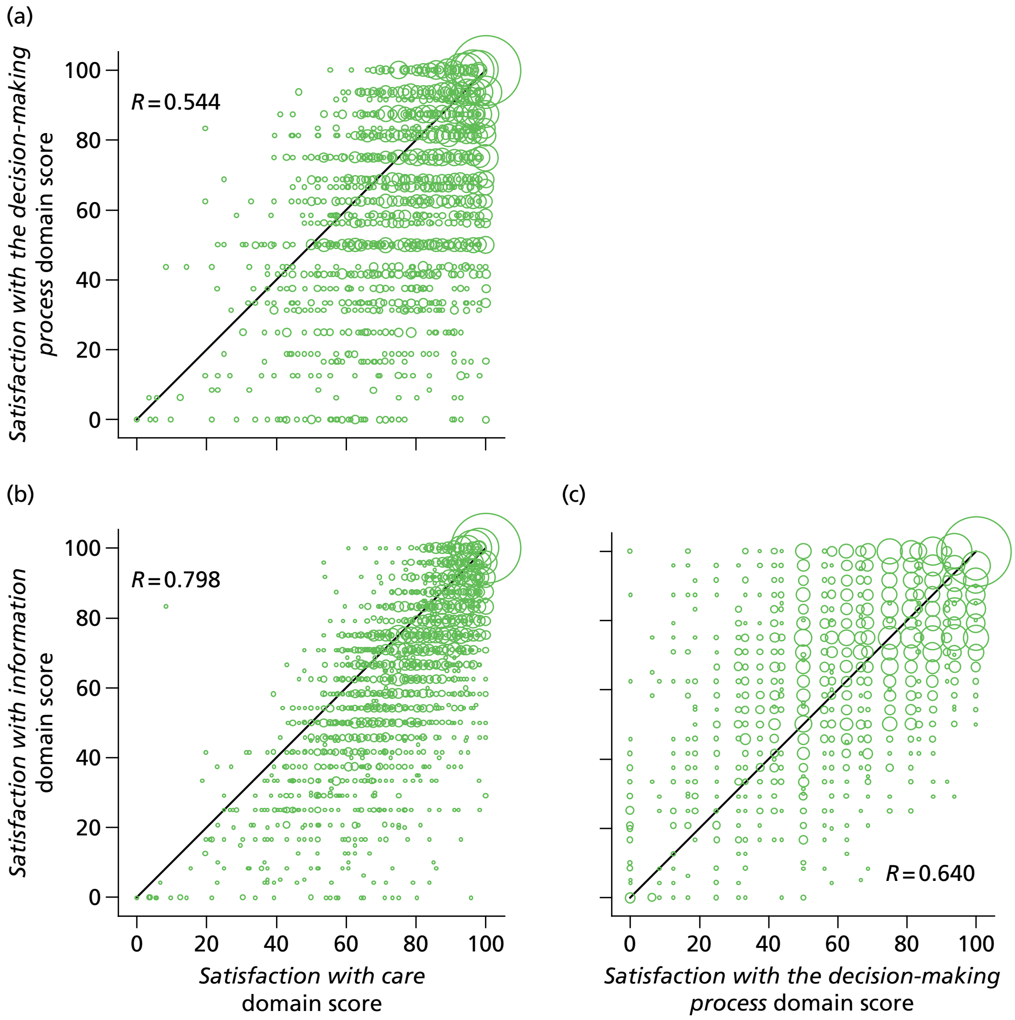


FIGURE 14 Correlation between domain scores for the FREE study three-factor solution.

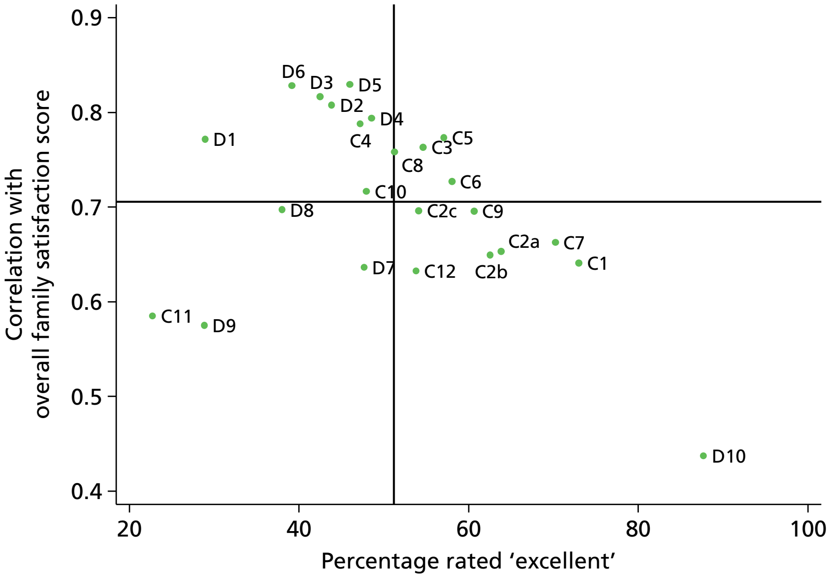


FIGURE 15 Performance-importance plot for the UK FS-ICU-24 overall family satisfaction score. C*x* denotes item *x* from the *satisfaction with care* domain; D*x* denotes item *x* from the *satisfaction with decision-making* domain.

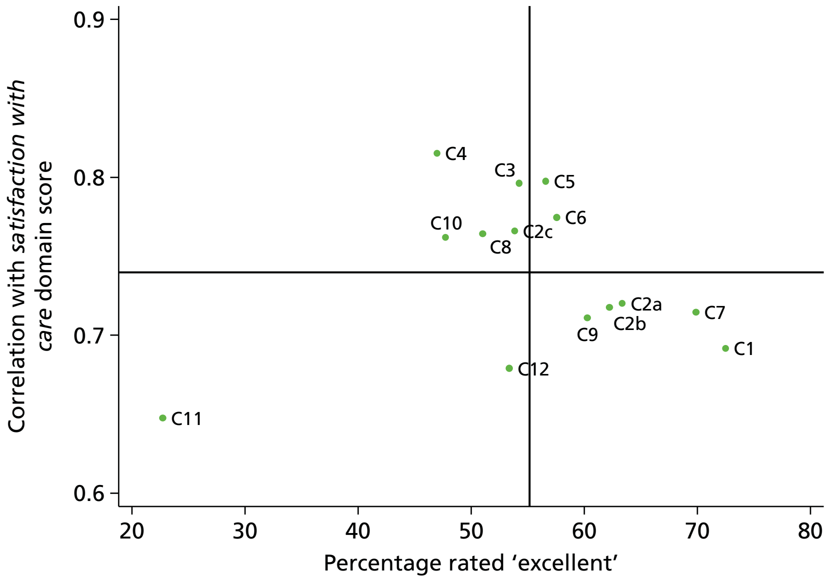


FIGURE 16 Performance-importance plot for the UK FS-ICU-24 *satisfaction with care* domain score. C*x* denotes item *x* from the *satisfaction with care* domain.

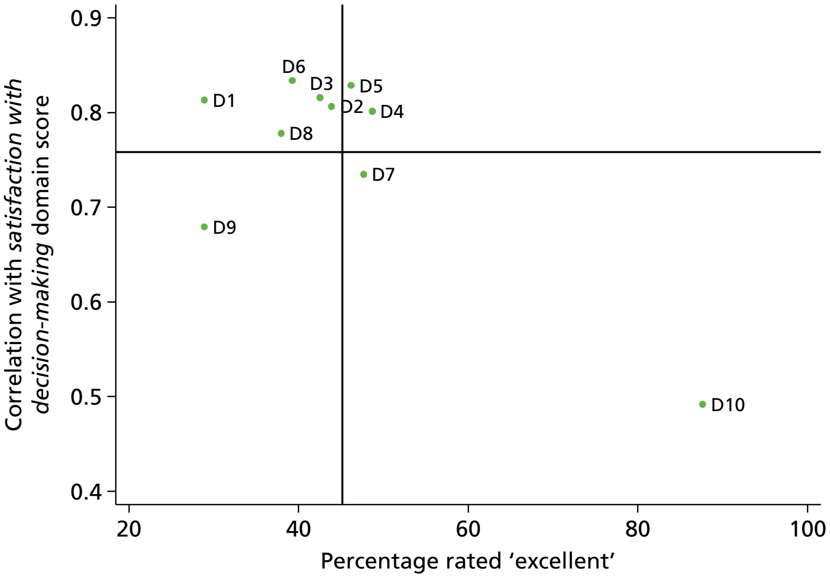


FIGURE 17 Performance-importance plot for the UK FS-ICU-24 *satisfaction with decision-making* domain score. D*x* denotes item *x* from the *satisfaction with decision-making* domain.

Discussion

The psychometric assessment of the UK FS-ICU-24 using data from the FREE study has established that the questionnaire has a high degree of internal consistency in the UK setting, demonstrated by Cronbach's alpha > 0.9 for the overall family satisfaction score and for both domain scores, and has criterion validity among family members of non-survivors (no suitable instrument was available to establish criterion validity among family members of survivors). Although response rates were lower for some items within the questionnaire, there was no evidence that this represented a lack of comprehensibility or acceptability of the questionnaire. There was some evidence of redundancy among the items within each domain; however, the detail of knowing which particular items scored higher or lower was considered to be important for the applicability of the UK FS-ICU-24 responses to drive quality improvement. Substituting an alternative question on satisfaction with the amount of control led to only a minor increase in Cronbach's alpha for the overall family satisfaction score and the *satisfaction with decision-making* domain score. The two-factor solution for the original FS-ICU-24, with domains of *satisfaction with care* and *satisfaction with decision-making*, was not a good fit to the FREE study data, and exploratory factor analysis suggested that the domain of *satisfaction with decision-making* encompassed two separate constructs, which we have termed *satisfaction with information* and *satisfaction with the decision-making process*.

The finding of high internal consistency is consistent with both the original study that derived the FS-ICU-24 in North America (Cronbach's alpha 0.94 for the overall family satisfaction score, 0.92 for *satisfaction with care* and 0.88 for *satisfaction with decision-making*)[11] and subsequent single-hospital validations in the Philippines (among family members of non-survivors only, 0.96 for the overall family satisfaction score and 0.94 for both *satisfaction with care* and *satisfaction with decision-making*),[38] Germany (≥ 0.88 for all three scores),[39] Turkey (0.95 for the overall family satisfaction score)[40] and three studies from Greece (0.9–0.96 for the overall family satisfaction score[41–43] and 0.90–0.92 for *satisfaction with care*[42]).

The three-factor solution identified in the FREE study is similar in structure to a three-factor solution recently reported from a single-centre study in Turkey.[40] Its structure of care, information and decision-making corresponded to our three constructs of care, information and the decision-making process, with the following exceptions: the item for communication by nurses loaded on information rather than care; the item for level or amount of health care loaded on decision-making rather than care; and the item for willingness of ICU staff to answer questions loaded on care rather than information. However, our structure has more in common with the original two-factor solution,[11] retaining an identical domain of *satisfaction with care* and subdividing the second domain of *satisfaction with decision-making*. In this respect, the FS-ICU-24 demonstrates a degree of construct validity across the studies that have conducted factor analyses.

Chapter 5 UK 24-item Family Satisfaction in the Intensive Care Unit questionnaire: satisfaction scores and received questionnaires

Introduction

This chapter reports the overall family satisfaction score and domain scores from the UK FS-ICU-24 across populations based on the completeness of returned questionnaires.

Methods

The original FS-ICU scores – overall family satisfaction score and the two domain scores *satisfaction with care* and *satisfaction with decision-making* – were generated and reported across five different populations of received questionnaires (listed below). Two further domain scores, informed by the results of the full psychometric assessment (see *Chapter 4*) and reflecting a further subdivision of the decision-making domain into two separate domain scores – termed *satisfaction with information* and *satisfaction with the decision-making process* – were also generated and reported across the five different populations.

Three initial populations were identified, defined by:

- all returned questionnaires (any items answered for a given score)
- complete returned questionnaires (all items answered for a given score)
- incomplete returned questionnaires (any items unanswered for a given score).

Two further populations were identified, defined by:

- returned questionnaires with ≥ 70% items answered for a given score
- returned questionnaires with ≥ 60% items answered for a given score.

The first reflected the traditional approach to scoring the FS-ICU questionnaire (as provided by the developers), defined by a response rate of ≥ 70% to items for a given score. The second, a modification on the traditional approach, informed by the results of the full psychometric assessment (see *Chapter 4*), was identified and defined by a response rate of ≥ 60% to items for a given score. Note: both 'no response' and 'not applicable' were considered as unanswered.

Results

Sample sizes for each population for each score are presented in *Table 36*.

Overall family satisfaction score

Across the five populations (*Table 37*), the median overall family satisfaction score varied from 81.3 for incomplete questionnaires to 87.5 for complete questionnaires. All scores showed skewed distributions towards higher scores (*Figure 18*).

TABLE 36 Sample size for populations of questionnaires by overall/domain score

Population	Overall family satisfaction score	*Satisfaction with care* domain score	*Satisfaction with decision-making* domain score	*Satisfaction with information* domain score	*Satisfaction with the decision-making process* domain score
All	7017	7016	6848	6807	5752
Complete	2898	5008	3476	6238	3520
Incomplete	4119	2008	3372	569	2232
≥ 70% complete	6607	6872	5605	6577	4786
≥ 60% complete	6800	6937	6463	6705	5301

TABLE 37 Overall family satisfaction scores across populations of questionnaires

Population of returned questionnaires	Median	IQR	Mean (SD)	95% confidence interval
All	83.8	70.8–93.4	80.3 (16.8)	79.9 to 80.7
Complete	87.5	76.0–95.8	83.4 (15.8)	82.8 to 84.0
Incomplete	81.3	67.9–91.7	78.1 (17.2)	77.5 to 78.6
≥ 70% complete	84.4	71.4–93.8	80.5 (16.7)	80.1 to 80.9
≥ 60% complete	84.2	71.3–93.8	80.4 (16.8)	80.0 to 80.8

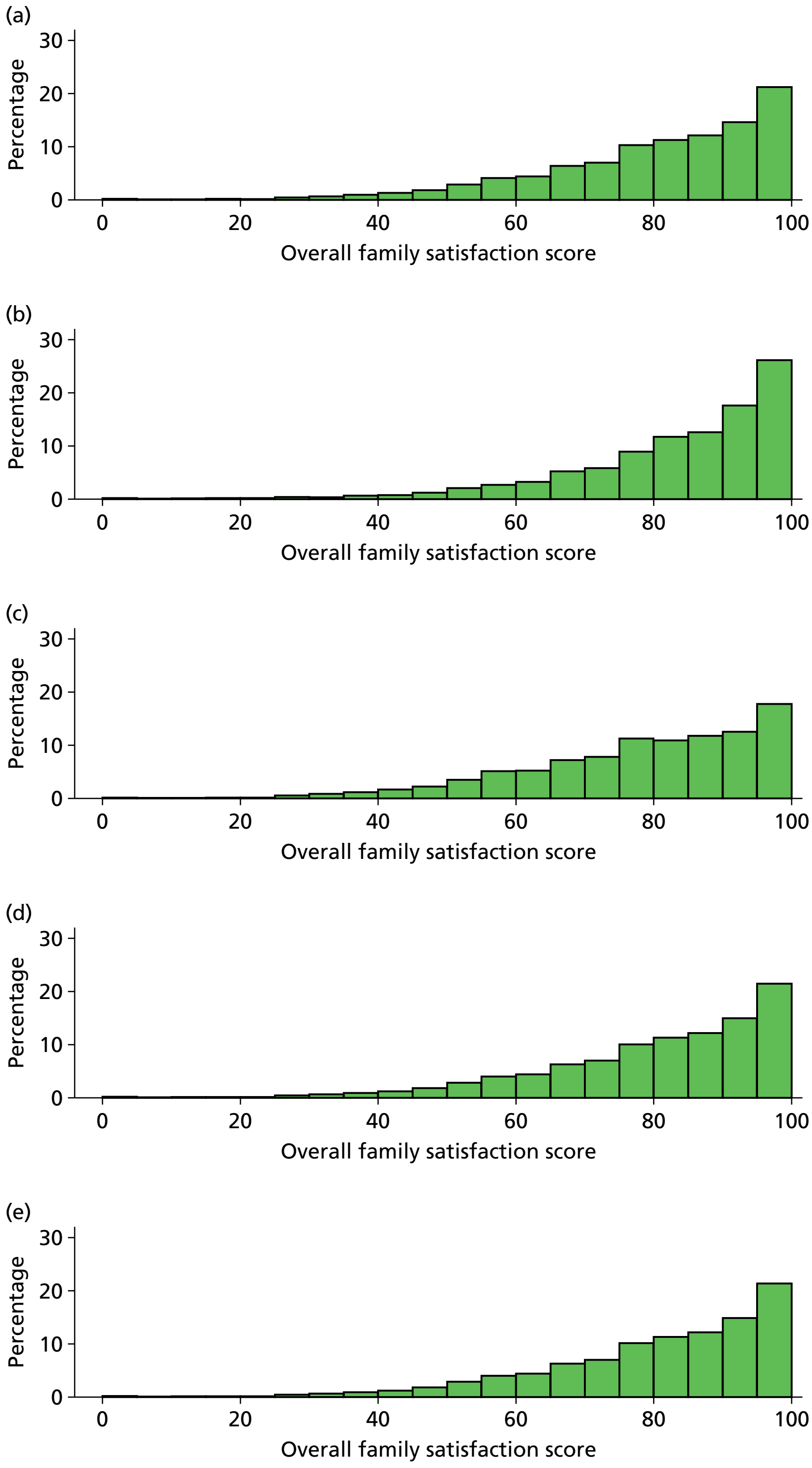


FIGURE 18 Distribution of overall family satisfaction scores across populations of questionnaires: (a) all returned questionnaires; (b) complete returned questionnaires; (c) incomplete returned questionnaires; (d) ≥ 70% complete returned questionnaires (traditional approach); and (e) ≥ 60% complete returned questionnaires (modified traditional approach).

Satisfaction with care domain score

Across the five populations (*Table 38*), the median *satisfaction with care* domain score varied from 83.3 for incomplete questionnaires to 89.3 for complete questionnaires. All scores showed skewed distributions towards higher scores (*Figure 19*).

Satisfaction with decision-making domain score

Across the five populations (*Table 39*), the median *satisfaction with decision-making* domain score varied from 75.0 for incomplete questionnaires to 85.0 for complete questionnaires. Scores showed skewed distributions towards higher scores, although there was more variability in the score for incomplete questionnaires (*Figure 20*).

TABLE 38 *Satisfaction with care* scores across populations of questionnaires

Population of returned questionnaires	Median	IQR	Mean (SD)	95% confidence interval
All	87.5	75.0–96.4	83.2 (16.0)	82.8 to 83.6
Complete	89.3	76.8–96.4	84.4 (15.5)	84.0 to 84.8
Incomplete	83.3	70.6–93.8	80.2 (16.9)	79.4 to 80.9
≥ 70% complete	87.5	75.0–96.4	83.3 (16.0)	82.9 to 83.7
≥ 60% complete	87.5	75.0–96.4	83.3 (16.0)	82.9 to 83.6

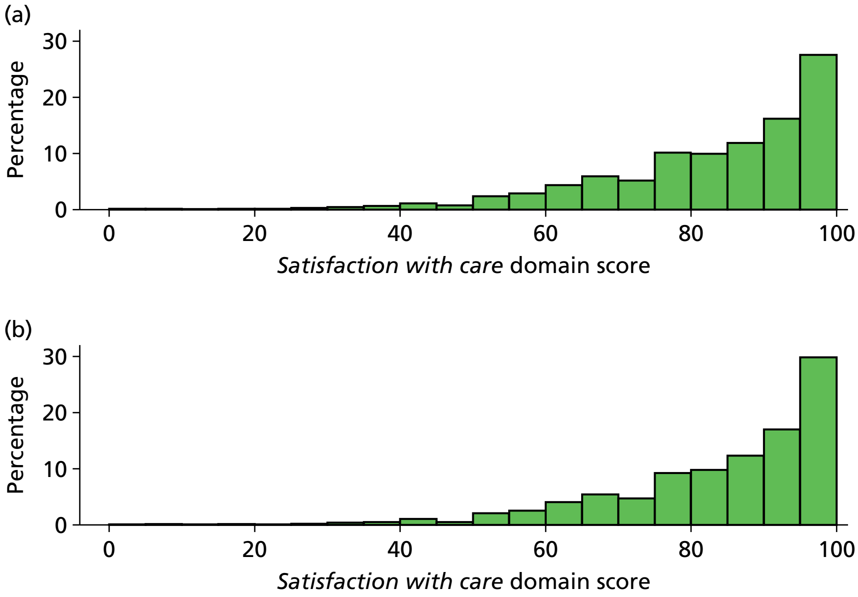


FIGURE 19 Distribution of *satisfaction with care* domain scores across populations of questionnaires: (a) all returned questionnaires; (b) complete returned questionnaires; (c) incomplete returned questionnaires; (d) ≥ 70% complete returned questionnaires (traditional approach); and (e) ≥ 60% complete returned questionnaires (modified traditional approach). (*continued*)

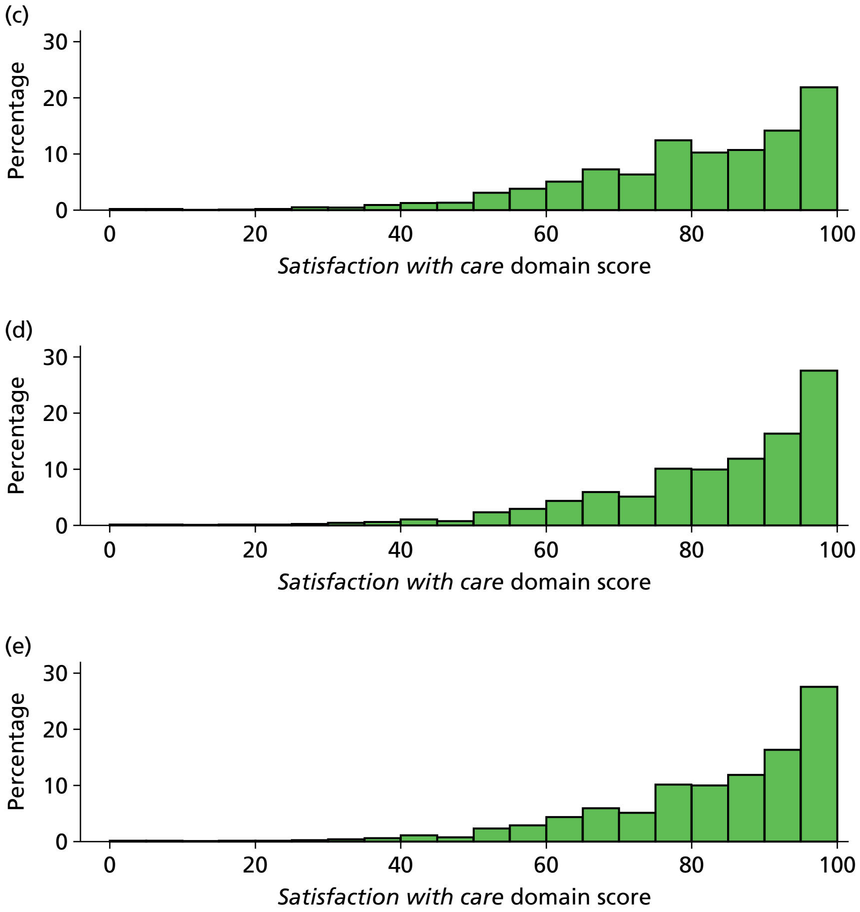


FIGURE 19 Distribution of *satisfaction with care* domain scores across populations of questionnaires: (a) all returned questionnaires; (b) complete returned questionnaires; (c) incomplete returned questionnaires; (d) ≥ 70% complete returned questionnaires (traditional approach); and (e) ≥ 60% complete returned questionnaires (modified traditional approach).

TABLE 39 *Satisfaction with decision-making* scores across populations of questionnaires

Population of returned questionnaires	Median	IQR	Mean (SD)	95% confidence interval
All	80.0	63.9–92.5	75.4 (21.0)	74.9 to 75.9
Complete	85.0	70.0–95.0	79.7 (19.4)	79.1 to 80.4
Incomplete	75.0	57.1–87.5	70.9 (21.8)	70.2 to 71.7
≥ 70% complete	80.0	64.3–92.5	75.5 (20.7)	75.0 to 76.1
≥ 60% complete	80.0	64.3–92.5	75.7 (20.8)	75.2 to 76.2

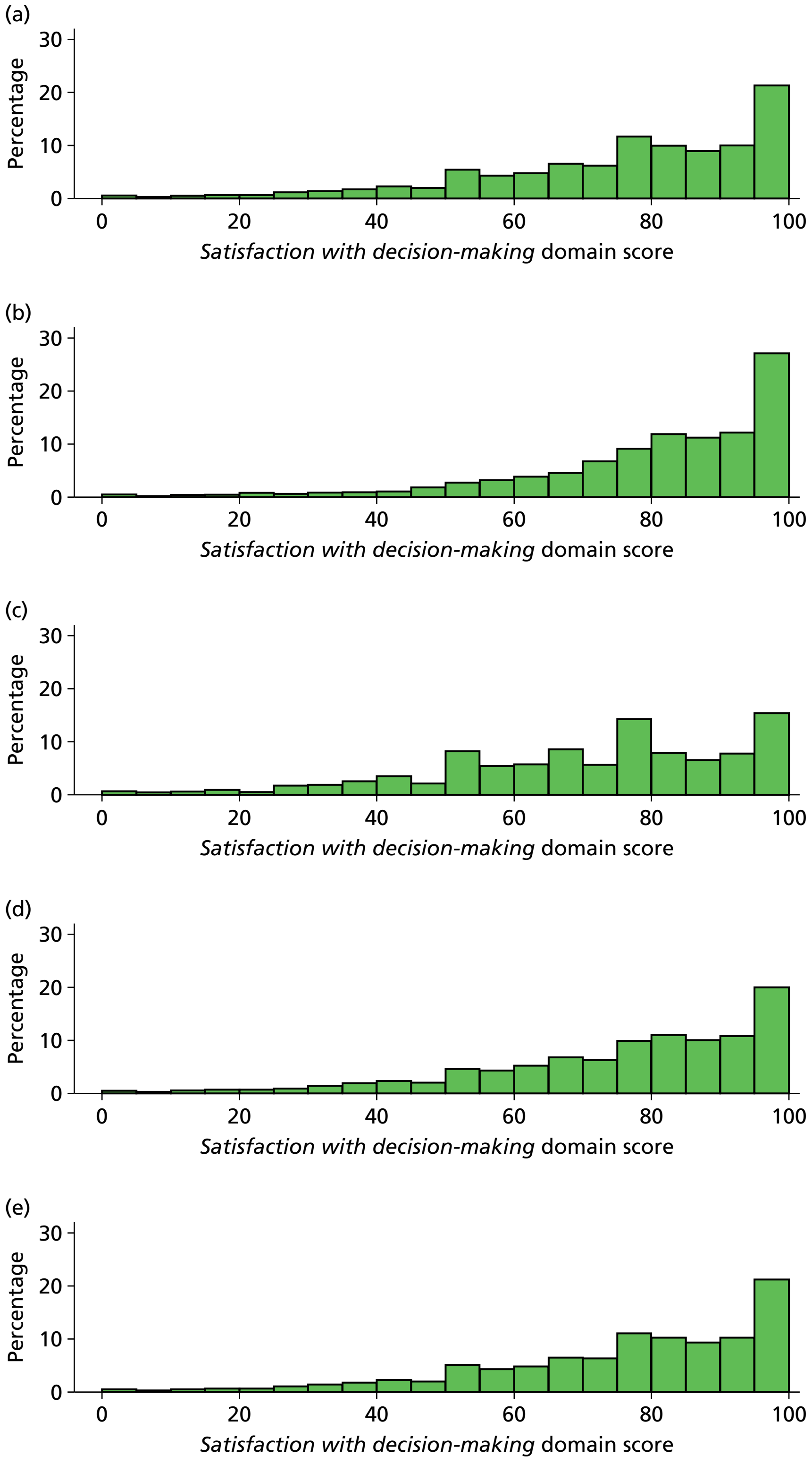


FIGURE 20 Distribution of *satisfaction with decision-making* domain scores across populations of questionnaires: (a) all returned questionnaires; (b) complete returned questionnaires; (c) incomplete returned questionnaires; (d) ≥ 70% complete returned questionnaires (traditional approach); and (e) ≥ 60% complete returned questionnaires (modified traditional approach).

Satisfaction with information domain score

Across the five populations (*Table 40*), the median *satisfaction with information* domain score was 79.2 for all populations of questionnaires except for the incomplete questionnaires, which had a median score of 75.0. Scores generally showed skewed distributions towards higher scores but there was variability in the scores, particularly for the incomplete questionnaires (*Figure 21*).

Satisfaction with the decision-making process domain score

Across the five populations (*Table 41*), the median *satisfaction with the decision-making process* domain score varied from 58.3 for incomplete questionnaires to 87.5 for complete questionnaires. There was variability in the distribution of scores for incomplete questionnaires and, although the distribution of scores was generally skewed towards higher scores for the other populations of questionnaires, this was most pronounced for the complete questionnaires (*Figure 22*).

TABLE 40 *Satisfaction with information* domain scores across populations of questionnaires

Population of returned questionnaires	Median	IQR	Mean (SD)	95% confidence interval
All	79.2	66.7–95.8	76.3 (22.2)	75.8 to 76.9
Complete	79.2	66.7–95.8	76.9 (21.9)	76.4 to 77.4
Incomplete	75.0	55.0–90.0	70.2 (24.8)	68.1 to 72.2
≥ 70% complete	79.2	66.7–95.8	76.6 (22.0)	76.1 to 77.1
≥ 60% complete	79.2	66.7–95.8	76.5 (22.1)	76.0 to 77.1

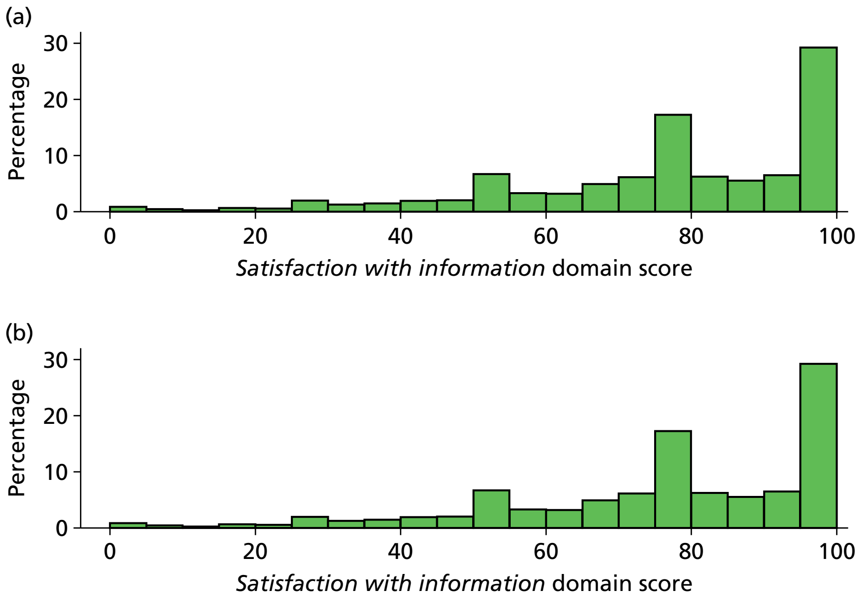


FIGURE 21 Distribution of *satisfaction with information* domain scores across populations of questionnaires: (a) all returned questionnaires; (b) complete returned questionnaires; (c) incomplete returned questionnaires; (d) ≥ 70% complete returned questionnaires (traditional approach); and (e) ≥ 60% complete returned questionnaires (modified traditional approach). (*continued*)

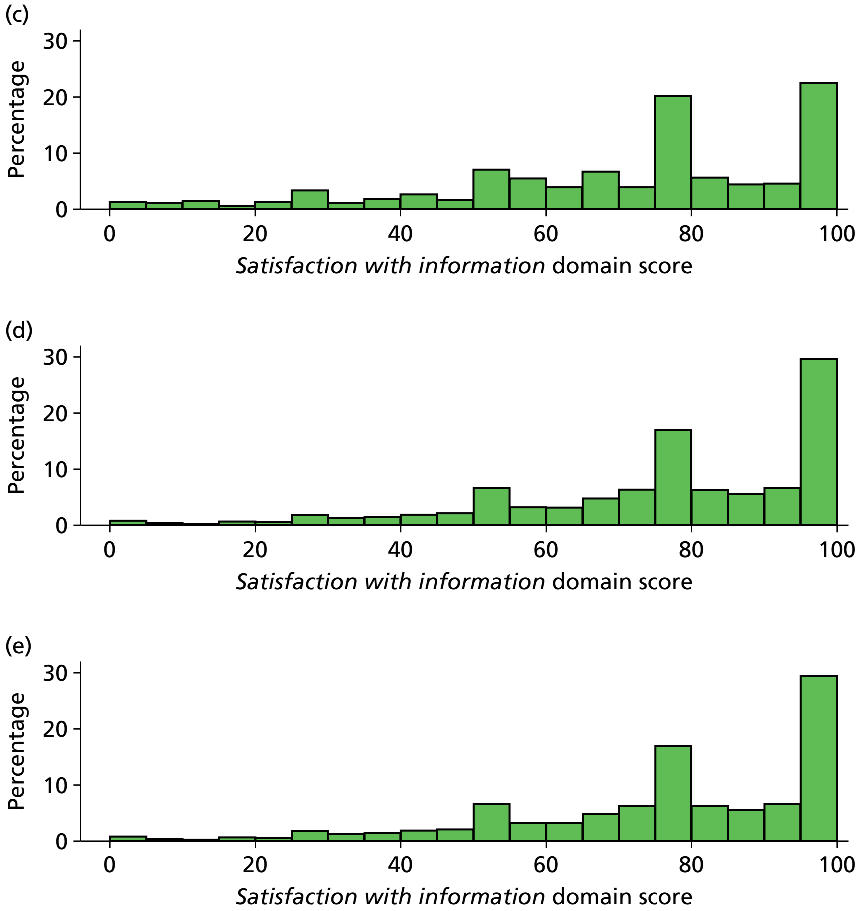


FIGURE 21 Distribution of *satisfaction with information* domain scores across populations of questionnaires: (a) all returned questionnaires; (b) complete returned questionnaires; (c) incomplete returned questionnaires; (d) ≥ 70% complete returned questionnaires (traditional approach); and (e) ≥ 60% complete returned questionnaires (modified traditional approach).

TABLE 41 *Satisfaction with the decision-making process* scores across populations of questionnaires

Population of returned questionnaires	Median	IQR	Mean (SD)	95% confidence interval
All	75.0	50.0–93.4	72.7 (24.8)	72.0 to 73.3
Complete	87.5	68.8–100.0	79.7 (21.9)	79.0 to 80.4
Incomplete	58.3	50.0–83.3	61.6 (25.2)	60.6 to 62.7
≥ 70% complete	81.3	58.3–93.4	74.3 (23.9)	73.6 to 74.9
≥ 60% complete	81.3	58.3–93.4	74.3 (23.9)	73.6 to 74.9

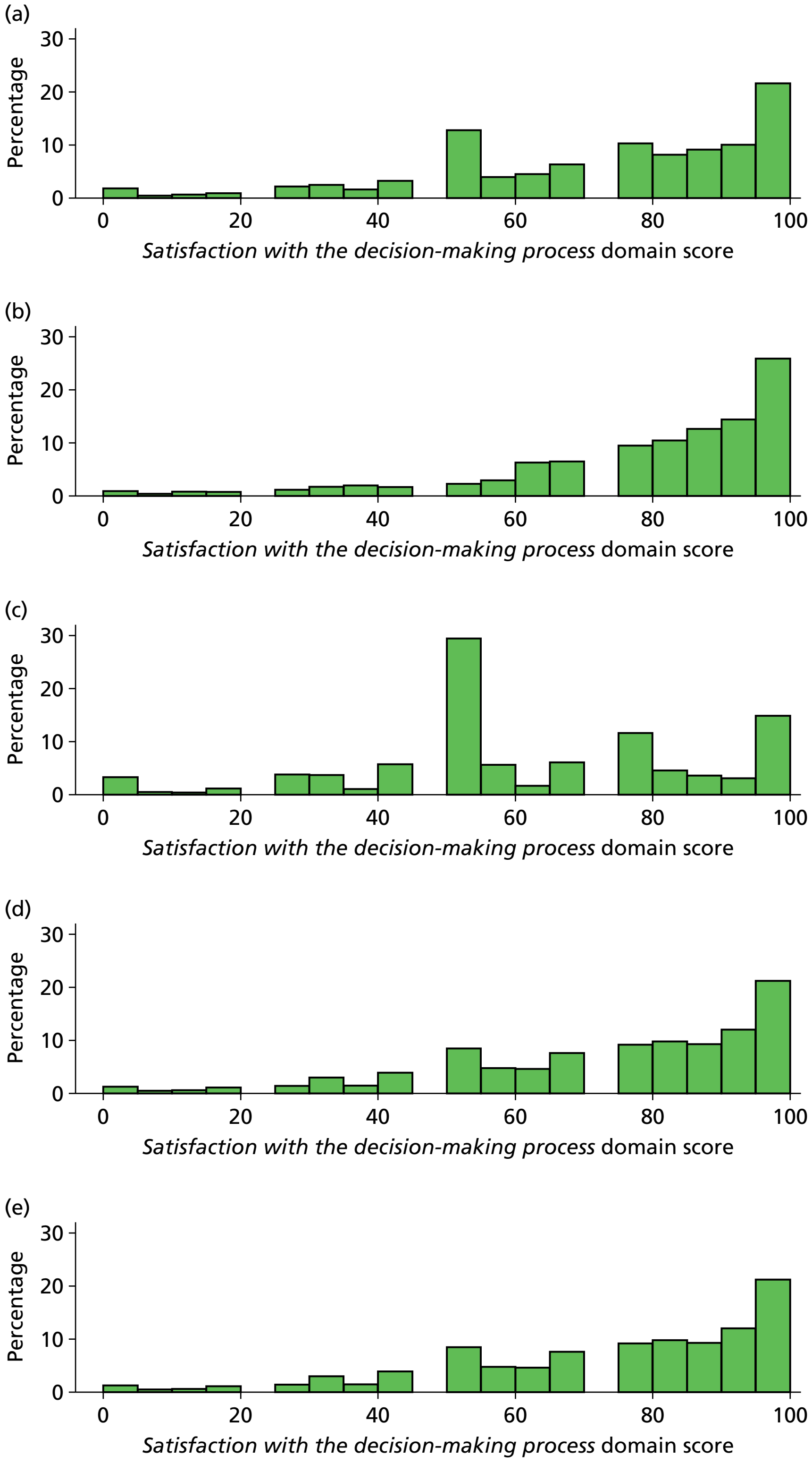


FIGURE 22 Distribution of *satisfaction with the decision-making process* domain scores across population of questionnaires: (a) all returned questionnaires; (b) complete returned questionnaires; (c) incomplete returned questionnaires; (d) ≥ 70% complete returned questionnaires (traditional approach); and (e) ≥ 60% complete returned questionnaires (modified traditional approach).

Discussion

In general, scores from complete questionnaires provided the highest mean and median values for the overall family satisfaction score and domain scores. Overall and domain scores were high (mean values ranging from 76 to 88 across overall and domain scores) and all showed a left-skewed distribution. Values from the traditional approach to scoring, defined by a response of $\geq 70\%$ to items, did not differ when defined by a modified response rate of $\geq 60\%$.

Chapter 6 Missing data and imputation

Introduction

The approaches for handling missing data in questionnaire-based scales vary. Alternative approaches include deleting the items that have missing responses, using complete case data (i.e. removing respondents with missing responses) and imputing either the missing responses or the final scale. For the first approach, if the item that has missing data is crucial for the assessment, deleting that item may cause a violation of the content validity of the scale. For the second approach, because of the reduced sample size, the reliability of the estimated scale values will be underestimated. Therefore, the third approach, imputing the missing responses using the available data, is more appealing than the other approaches in terms of validity and reliability. This chapter describes the missing data in UK FS-ICU-24 responses and the approach to imputation employed in the FREE study.

Methods

Selection of data

Completed questionnaires were received from 7173 family members. Of these, 154 family members of patients admitted to one ICU were excluded from further analyses because CMP data were not available for the patients admitted to this ICU. This resulted in a data set of 7019 family member responses for analysis.

Family members who did not return a questionnaire are referred to as 'non-responders', those who returned a questionnaire but with missing or 'not applicable' responses to one or more of the 24 items as 'partial responders' and those who returned a questionnaire with all 24 items completed as 'complete responders', used as the reference category.

Statistical analysis

Responses to each individual item in the UK FS-ICU-24 were summarised, with particular attention to 'not applicable' and missing responses. The numbers and patterns of missing items were also explored within each domain (*satisfaction with care* and *satisfaction with decision-making*) and overall.

Logistic regression models including family member, patient and ICU/hospital characteristics were constructed to identify the determinants that may be associated with (mutually exclusive) patterns of missing items as well as the pattern of any missing item. The outcome for each model was a binary indicator of family members having the particular pattern of missing items.

Methods of imputation were used to complete non- and partial responses. This allows observations with missing items to be included, to address the potential bias and loss of precision that could result from complete case analysis. The imputation of family member characteristics and outcomes is complicated by several issues: the variables are hierarchical in nature, with a small number of family members (level 1) for each patient (level 2) and a large number of patients in each ICU/hospital (level 3). This could complicate the application of traditional approaches to dealing with missing data, taking into account the multilevel structure in the imputation model. In addition, several variables of various types (categorical, continuous and ordinal) at level 1 needed to be imputed. All variables to be included in the analysis were 100% complete at the ICU/hospital and patient level.

When applying multiple imputation to incomplete questionnaire data, one can either impute the incomplete items prior to computing scores (item level) or impute the scores directly from the available scores (scale level). The latter approach imputes satisfaction scores for both partial and non-responders, including the average response to the completed questions as an auxiliary variable for partial responders in an attempt to recapture much of the item-level information that a scale-level approach ignores. Previous work addressing this question[44] found that item-level imputation is preferable to scale-level imputation in that it provides eventual estimates that are consistently more reliable. In addition, one of the problems when imputing the scores at the scale level was the asymmetric distribution of the scores and, although transforming is recommended[45] to get better imputed values, transformation can yield substantial bias if the transformed variable is not close to normal.[46]

We therefore considered two alternative approaches to how the outcome of family satisfaction was imputed:

1. scale-level, following standard rules to average item responses for partial responders with at least 60% of items completed and using multiple imputation to impute satisfaction scores for non-responders (including partial responders completing fewer than 60% of items)
2. item-level, using multiple imputation to impute individual missing items for both partial and non-responders and using the imputed items to calculate satisfaction scores.

Multilevel multiple imputation was used to complete non- and partial responses for outcomes and family member characteristics. Given the natural structure of the data and the planned analysis (a multilevel approach), it was necessary to account for the multilevel structure in the imputation phase to avoid biasing parameter estimates.[47] The imputation model was an extension of the joint modelling approach to mixed numerical and categorical data with a multilevel structure. We used Stata/SE 13.0 (StataCorp LP, College Station, TX, USA) with REALCOM-Impute, a MLwiN 2.15 (MLwiN, Centre for Multilevel Modelling, Bristol, UK) macro supported by Stata that generates imputations for hierarchical data, to generate the multiply imputed datasets.[48]

Currently, only two-level hierarchical structures can be handled in REALCOM-Impute, and the FREE study data have a three-level structure. We therefore substituted fixed for random effects at the ICU/hospital level,[49] collapsing the data to a two-level structure with a dummy variable for each ICU. Ten completed data sets were imputed and the model of interest was fitted to each of these data sets. The results from the 10 imputed data sets were combined using Rubin's rule.[50]

Results

Satisfaction with care

Of the 14 items that constitute the original *satisfaction with care* domain score, 13 all had the same response options, 'excellent/very good/good/fair/poor', with a further response option of 'not applicable'. The response options for the final item (satisfaction with the level or amount of health care) were 'very dissatisfied/slightly dissatisfied/mostly satisfied/very satisfied/completely satisfied', with no response option for 'not applicable'. The distributions of responses to each of the 14 items are presented in *Figure 23*.

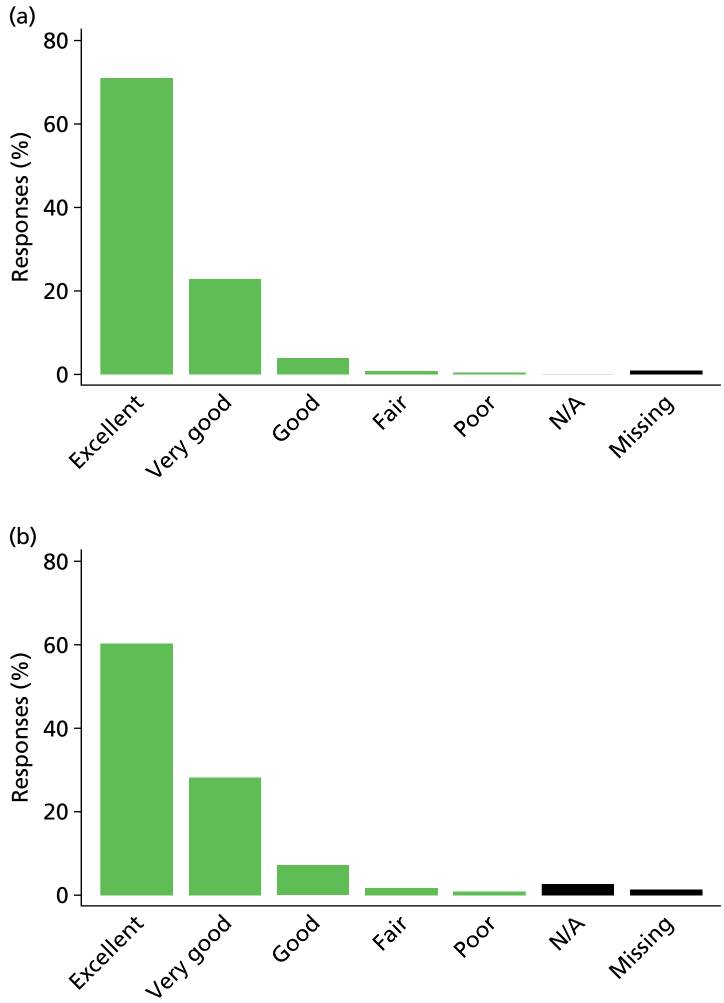


FIGURE 23 Responses to the 14 items constituting the *satisfaction with care* domain score. N/A, not applicable. (a) How did we treat your family member (the patient)? Q1. Concern and caring by ICU staff? [The courtesy, respect and compassion your family member (the patient) was given.] (b) Q2. Symptom management? (How well the ICU staff assessed and treated your family member's symptoms) Pain. (c) Breathlessness. (d) Agitation. (e) How did we treat you? Q3. Consideration of your needs? (How well the ICU staff showed an interest in your needs.) (f) Q4. Emotional support? (How well the ICU staff provided emotional support.) (g) Q5. Concern and caring by ICU staff? (The courtesy, respect and compassion you were given.) (h) Teamwork. Q6. Co-ordination of care? (The teamwork of all the ICU staff who took care of your family member.) (i) Nurses. Q7. Skill and competence of ICU nurses? (How well the nurses cared for your family member.) (j) Q8. Frequency of communication with ICU nurses? (How often nurses communicated to you about your family member's condition.) (k) Doctors. Q9. Skill and competence of ICU doctors? (How well doctors cared for your family member.) (l) The ICU. Q10. The atmosphere (mood) of the ICU was? (m) The waiting room. Q11. The atmosphere (mood) in the ICU waiting room was? (n) Level/amount of health care. 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? (*continued*)

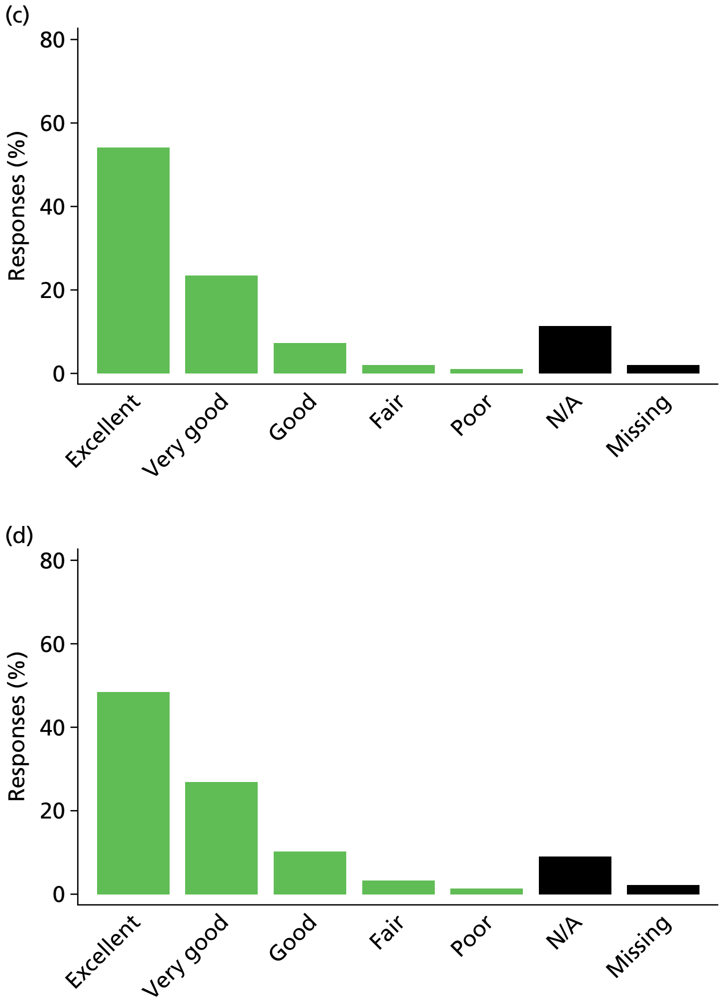


FIGURE 23 Responses to the 14 items constituting the *satisfaction with care* domain score. N/A, not applicable. (a) How did we treat your family member (the patient)? Q1. Concern and caring by ICU staff? [The courtesy, respect and compassion your family member (the patient) was given.] (b) Q2. Symptom management? (How well the ICU staff assessed and treated your family member's symptoms) Pain. (c) Breathlessness. (d) Agitation. (e) How did we treat you? Q3. Consideration of your needs? (How well the ICU staff showed an interest in your needs.) (f) Q4. Emotional support? (How well the ICU staff provided emotional support.) (g) Q5. Concern and caring by ICU staff? (The courtesy, respect and compassion you were given.) (h) Teamwork. Q6. Co-ordination of care? (The teamwork of all the ICU staff who took care of your family member.) (i) Nurses. Q7. Skill and competence of ICU nurses? (How well the nurses cared for your family member.) (j) Q8. Frequency of communication with ICU nurses? (How often nurses communicated to you about your family member's condition.) (k) Doctors. Q9. Skill and competence of ICU doctors? (How well doctors cared for your family member.) (l) The ICU. Q10. The atmosphere (mood) of the ICU was? (m) The waiting room. Q11. The atmosphere (mood) in the ICU waiting room was? (n) Level/amount of health care. 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? (*continued*)

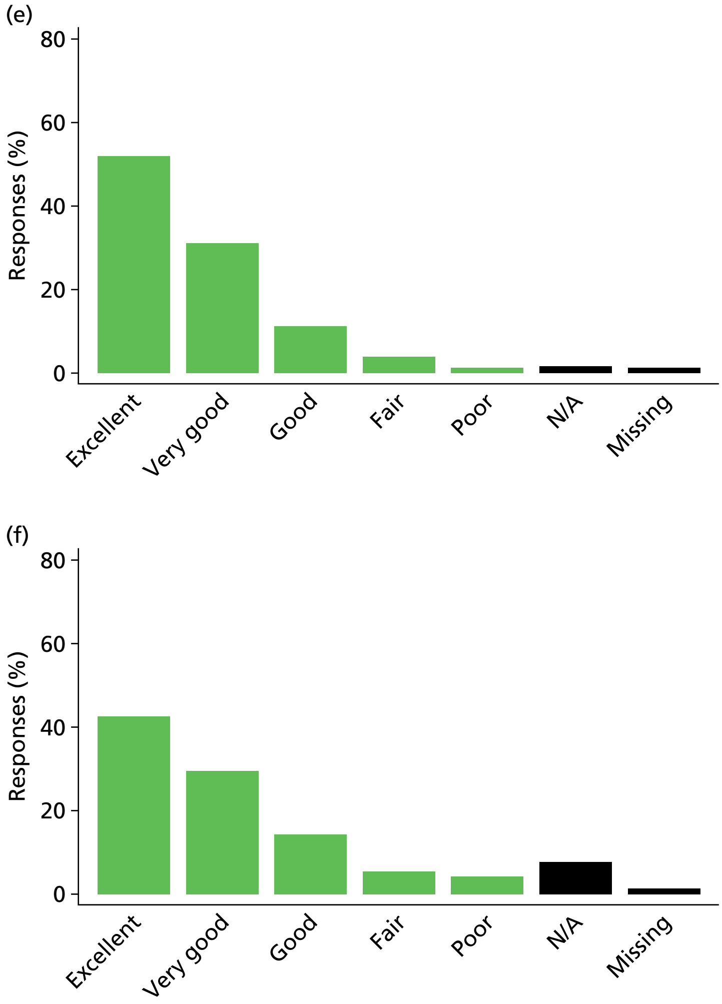
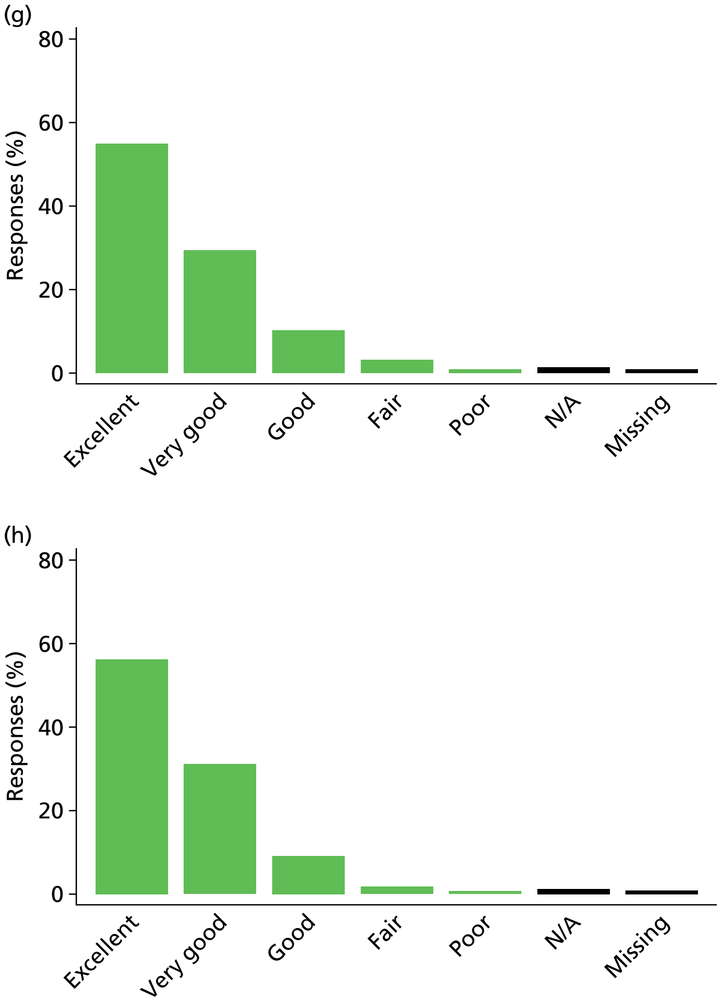


FIGURE 23 Responses to the 14 items constituting the *satisfaction with care* domain score. N/A, not applicable. (a) How did we treat your family member (the patient)? Q1. Concern and caring by ICU staff? [The courtesy, respect and compassion your family member (the patient) was given.] (b) Q2. Symptom management? (How well the ICU staff assessed and treated your family member's symptoms) Pain. (c) Breathlessness. (d) Agitation. (e) How did we treat you? Q3. Consideration of your needs? (How well the ICU staff showed an interest in your needs.) (f) Q4. Emotional support? (How well the ICU staff provided emotional support.) (g) Q5. Concern and caring by ICU staff? (The courtesy, respect and compassion you were given.) (h) Teamwork. Q6. Co-ordination of care? (The teamwork of all the ICU staff who took care of your family member.) (i) Nurses. Q7. Skill and competence of ICU nurses? (How well the nurses cared for your family member.) (j) Q8. Frequency of communication with ICU nurses? (How often nurses communicated to you about your family member's condition.) (k) Doctors. Q9. Skill and competence of ICU doctors? (How well doctors cared for your family member.) (l) The ICU. Q10. The atmosphere (mood) of the ICU was? (m) The waiting room. Q11. The atmosphere (mood) in the ICU waiting room was? (n) Level/amount of health care. 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? (*continued*)



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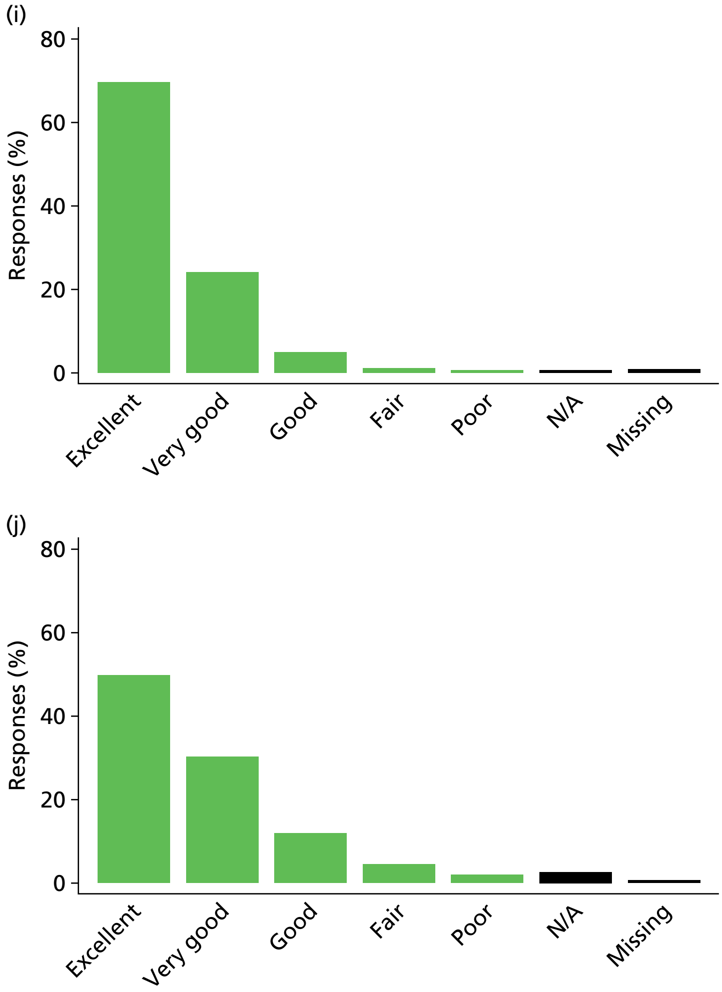

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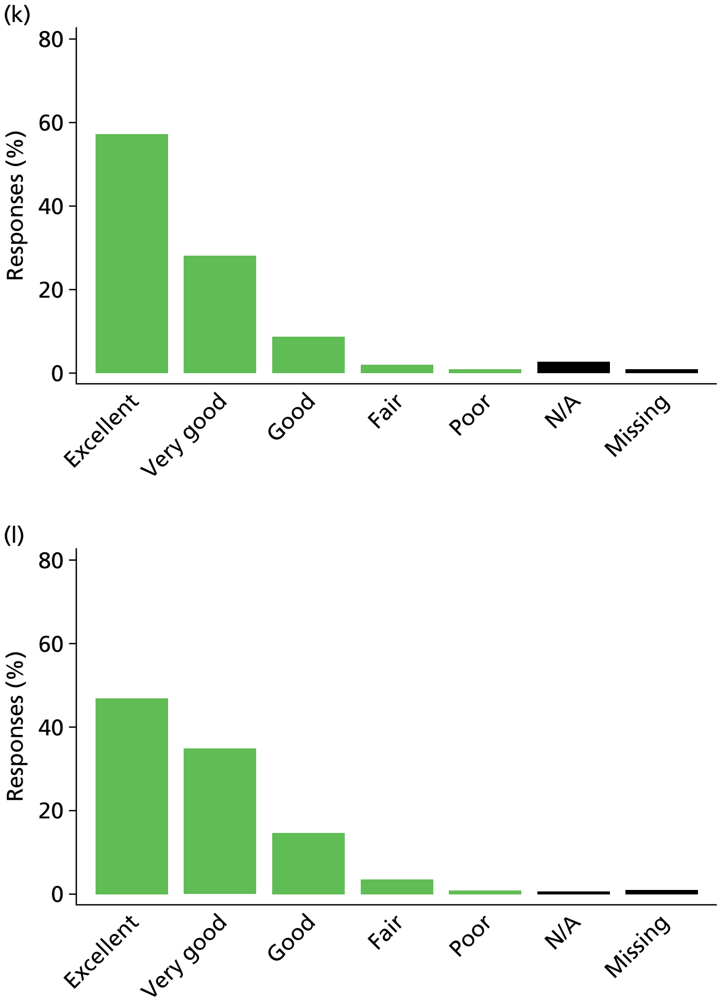


FIGURE 23 Responses to the 14 items constituting the *satisfaction with care* domain score. N/A, not applicable. (a) How did we treat your family member (the patient)? Q1. Concern and caring by ICU staff? [The courtesy, respect and compassion your family member (the patient) was given.] (b) Q2. Symptom management? (How well the ICU staff assessed and treated your family member's symptoms) Pain. (c) Breathlessness. (d) Agitation. (e) How did we treat you? Q3. Consideration of your needs? (How well the ICU staff showed an interest in your needs.) (f) Q4. Emotional support? (How well the ICU staff provided emotional support.) (g) Q5. Concern and caring by ICU staff? (The courtesy, respect and compassion you were given.) (h) Teamwork. Q6. Co-ordination of care? (The teamwork of all the ICU staff who took care of your family member.) (i) Nurses. Q7. Skill and competence of ICU nurses? (How well the nurses cared for your family member.) (j) Q8. Frequency of communication with ICU nurses? (How often nurses communicated to you about your family member's condition.) (k) Doctors. Q9. Skill and competence of ICU doctors? (How well doctors cared for your family member.) (l) The ICU. Q10. The atmosphere (mood) of the ICU was? (m) The waiting room. Q11. The atmosphere (mood) in the ICU waiting room was? (n) Level/amount of health care. 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? (*continued*)

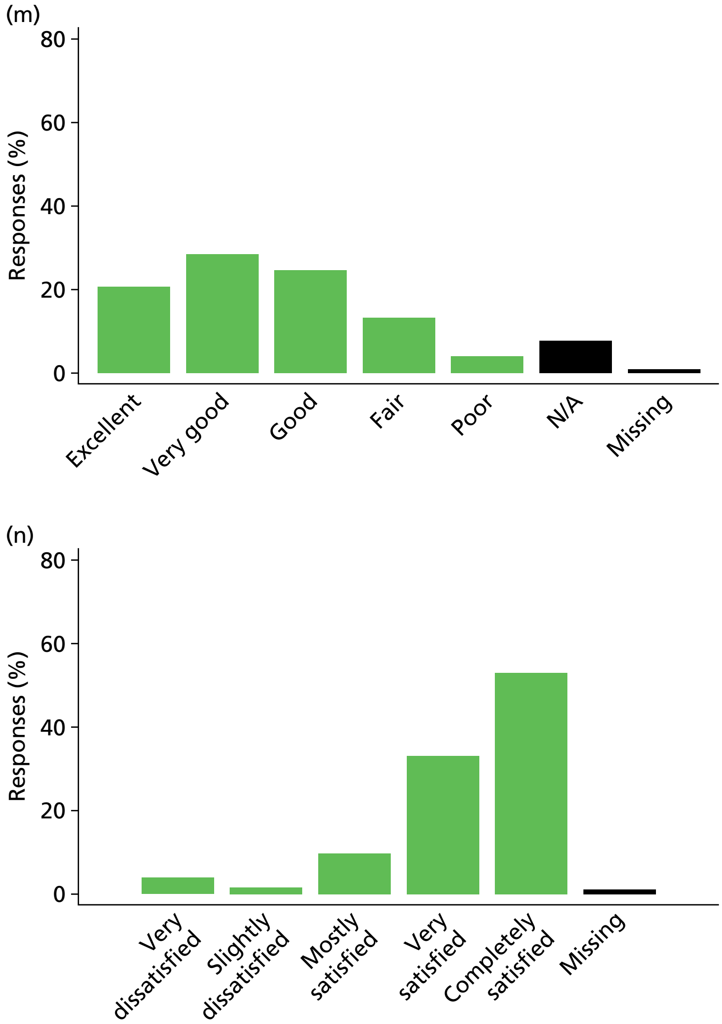


FIGURE 23 Responses to the 14 items constituting the *satisfaction with care* domain score. N/A, not applicable. (a) How did we treat your family member (the patient)? Q1. Concern and caring by ICU staff? [The courtesy, respect and compassion your family member (the patient) was given.] (b) Q2. Symptom management? (How well the ICU staff assessed and treated your family member's symptoms) Pain. (c) Breathlessness. (d) Agitation. (e) How did we treat you? Q3. Consideration of your needs? (How well the ICU staff showed an interest in your needs.) (f) Q4. Emotional support? (How well the ICU staff provided emotional support.) (g) Q5. Concern and caring by ICU staff? (The courtesy, respect and compassion you were given.) (h) Teamwork. Q6. Co-ordination of care? (The teamwork of all the ICU staff who took care of your family member.) (i) Nurses. Q7. Skill and competence of ICU nurses? (How well the nurses cared for your family member.) (j) Q8. Frequency of communication with ICU nurses? (How often nurses communicated to you about your family member's condition.) (k) Doctors. Q9. Skill and competence of ICU doctors? (How well doctors cared for your family member.) (l) The ICU. Q10. The atmosphere (mood) of the ICU was? (m) The waiting room. Q11. The atmosphere (mood) in the ICU waiting room was? (n) Level/amount of health care. 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?

Of the 7019 questionnaires received, 5008 (71.4%) had complete responses to all 14 items constituting the *satisfaction with care* domain. The proportion of missing data (no response) for all items was low but was highest for the items relating to symptom management of the patient (agitation, 1.9%; breathlessness, 1.8%; pain, 0.9%). When combined with a response of 'not applicable' – considered as missing when generating the score – the proportion of missing data was higher – again, highest for two of the items about symptom management of the patient (breathless, 12.9%; agitation, 10.7%), followed by the item on atmosphere/mood of the waiting room (8.7%) and the item about emotional support of the family member (8.1%).

When we examined patterns of missing data (*Figure 24*), we found that most frequently a response was missing for item C2b only (symptom management: breathlessness), item C11 only (the atmosphere/mood of the ICU waiting room) or a combination of items C2b (symptom management: breathlessness) and C2c (symptom management: agitation).

The distribution of the numbers of items with missing responses is presented in *Figure 25*.

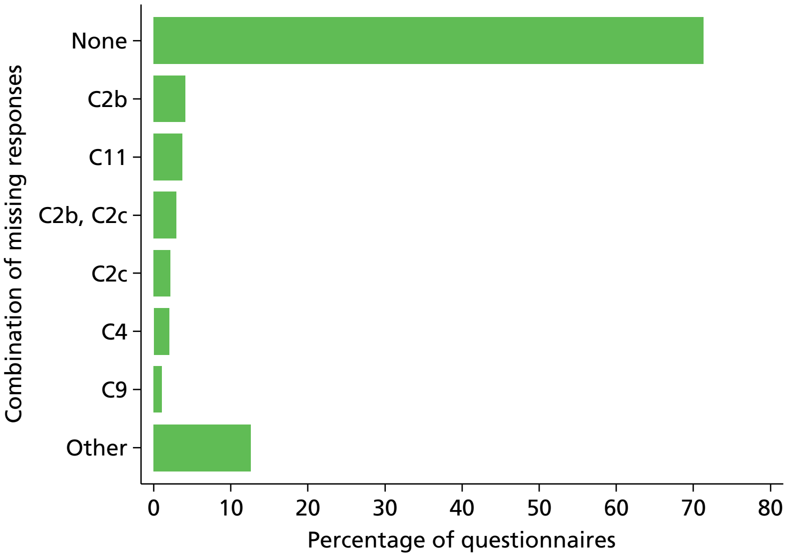


FIGURE 24 Common patterns of missing data for the *satisfaction with care* domain.

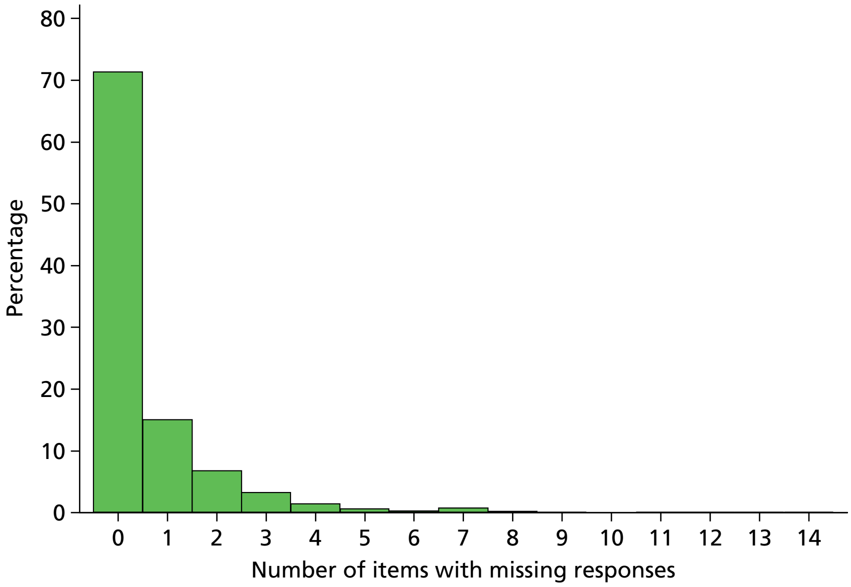


FIGURE 25 Distribution of the number of items with missing responses for the *satisfaction with care* domain.

Satisfaction with decision-making

Six of the 10 items that constitute the original *satisfaction with decision-making* domain score all had the same response options, 'excellent/very good/good/fair/poor', with a further response option of 'not applicable'. The response options for the remaining four items were as follows:

- Q7 (being 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
- Q8 (feeling 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
- Q9 (control over the care of the patient) – 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
- Q10 (adequate time for making decisions and to have concerns addressed and questions answered) – I could have used more time/I had adequate time
- Q7–10 all had a further response option of 'not applicable'.

The distributions of responses to each of the 10 items are presented in *Figure 26*.

Of the 7019 questionnaires received, 3476 (40.5%) had complete responses for all 10 items constituting the *satisfaction with decision-making* domain. The proportion of missing data (no response) for all items was low but was highest for the items about the process of making decisions (had adequate time for making decisions, 2.0%; felt control over the care of the patient, 1.8%; felt included in the decision-making process, 1.6%; felt supported during the decision-making process, 1.6%). When combined with a response of 'not applicable', the proportion of missing data was high – again, highest for the process of making decisions items (had adequate time for making decisions, 44.8%; felt supported during the decision-making process, 28.6%; felt included in the decision-making process, 26.5%; felt control over the care of the patient, 24.4%).

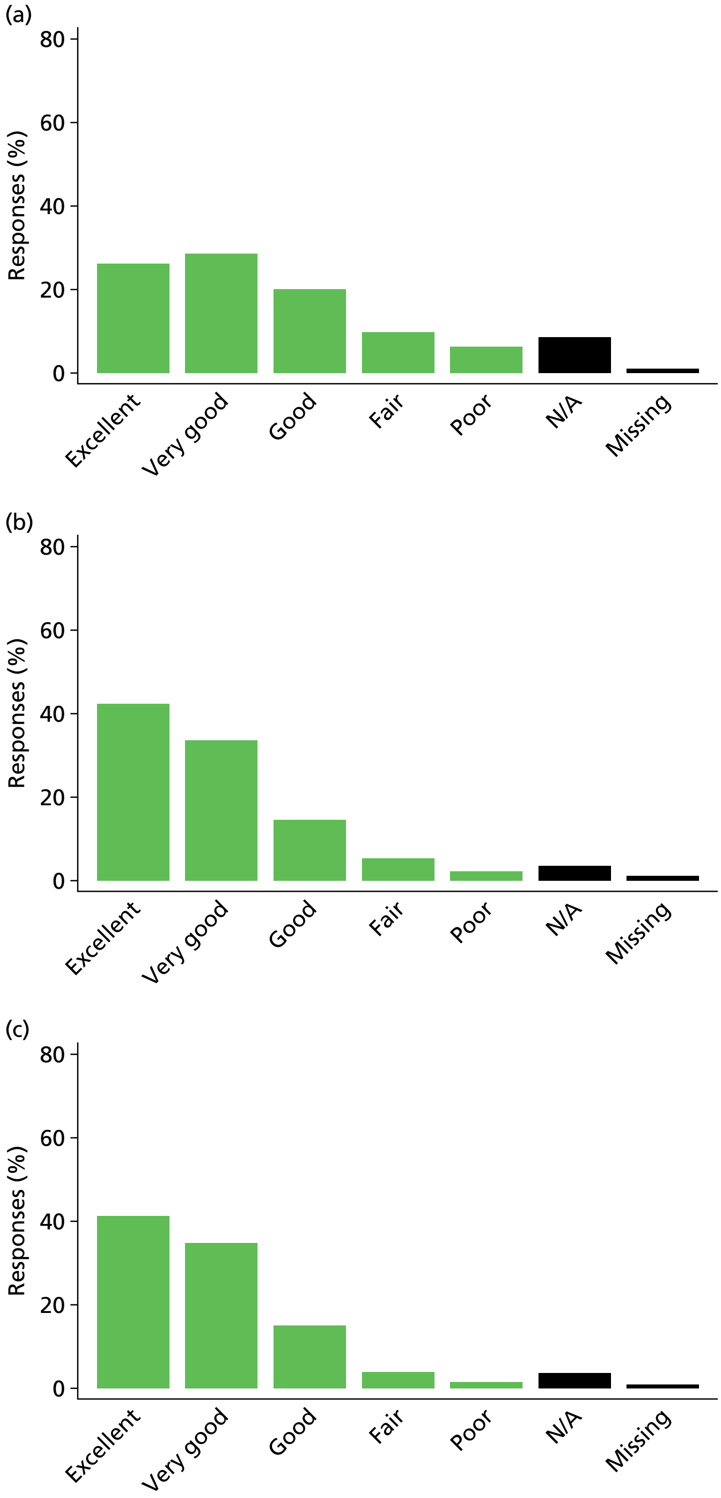
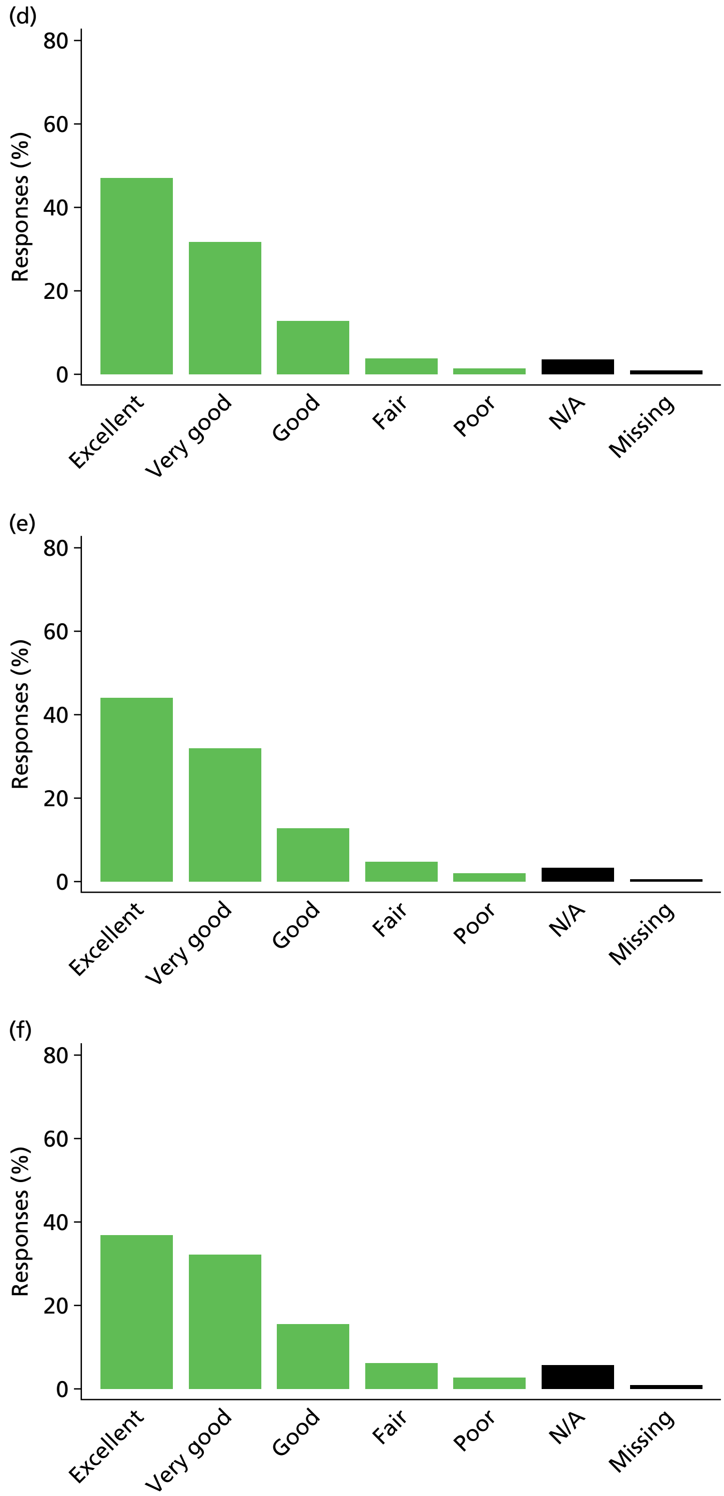


FIGURE 26 Responses to the 10 items constituting the *satisfaction with decision-making* domain score. N/A, not applicable. (a) Information needs. Q1. Frequency of communication with ICU doctors? (How often doctors communicated to you about your family member's condition.) (b) Q2. Ease of getting information? (Willingness of ICU staff to answer your questions.) (c) Q3. Understanding of information? (How well ICU staff provided you with explanations that you understood.) (d) Q4. Honesty of information? (The honesty of information provided to you about your family member's condition.) (e) Q5. Completeness of information? (How well ICU staff informed you what was happening to your family member and why things were being done.) (f) 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.)]. (g) The process of making decisions. Q7. Did you feel included in the decision-making process? (h) Q8. Did you feel supported during the decision-making process? (i) Q9. Did you feel you had control over the care of your family member? (j) Q10. When making decisions, did you have adequate time to have your concerns addressed and questions answered? (*continued*)



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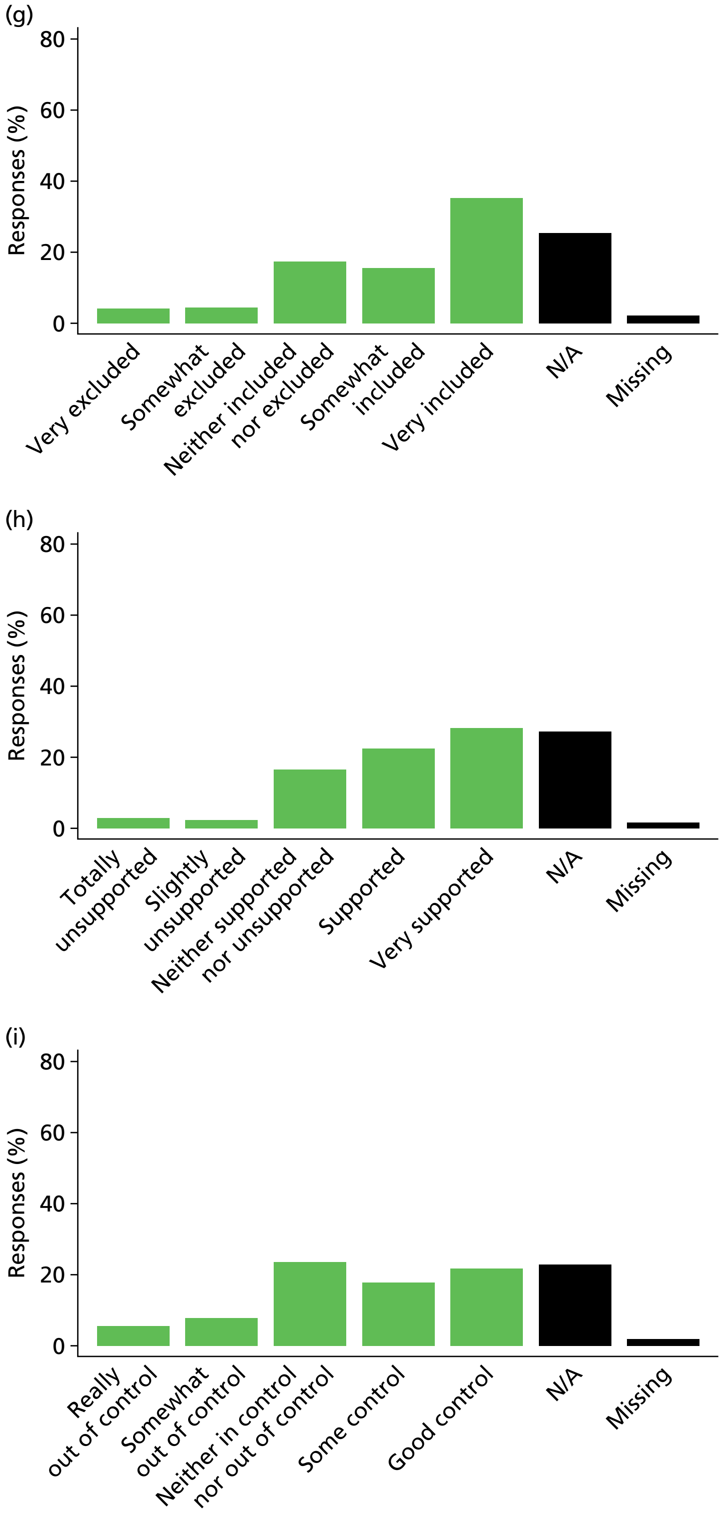
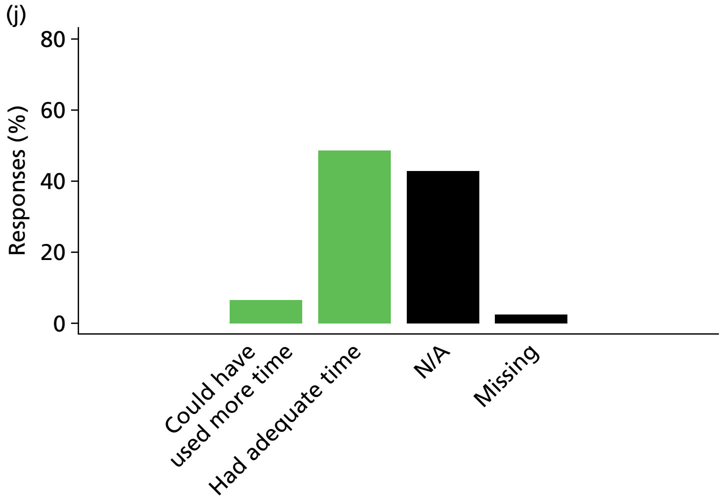


FIGURE 26 Responses to the 10 items constituting the *satisfaction with decision-making* domain score. N/A, not applicable. (a) Information needs. Q1. Frequency of communication with ICU doctors? (How often doctors communicated to you about your family member's condition.) (b) Q2. Ease of getting information? (Willingness of ICU staff to answer your questions.) (c) Q3. Understanding of information? (How well ICU staff provided you with explanations that you understood.) (d) Q4. Honesty of information? (The honesty of information provided to you about your family member's condition.) (e) Q5. Completeness of information? (How well ICU staff informed you what was happening to your family member and why things were being done.) (f) 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.)]. (g) The process of making decisions. Q7. Did you feel included in the decision-making process? (h) Q8. Did you feel supported during the decision-making process? (i) Q9. Did you feel you had control over the care of your family member? (j) Q10. When making decisions, did you have adequate time to have your concerns addressed and questions answered? (*continued*)



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When we examined patterns of missing data (*Figure 27*), we found that most frequently a response was missing for item D10 only ('when making decisions, did you have adequate time to have your concerns addressed and questions answered?'), a combination of items D7 ('did you feel included in the decision-making process?'), D8 ('did you feel supported during the decision-making process?'), D9 ('did you feel you had control over the care of your family member?') and D10, or a combination of items D9 and D10.

The distribution of the numbers of items with missing responses is presented in *Figure 28*.

Satisfaction with information

Six items from within the *satisfaction with decision-making* domain (items D1–D6) constitute the *satisfaction with information* domain score. Of the 7019 questionnaires received, 6238 (88.9%) had complete responses for all six items. Although the proportion of missing data (no response) was low, a response was most frequently missing for either D1 only ('frequency of communication with ICU doctors') or all six items (*Figure 29*).

The distribution of the numbers of items with missing responses is presented in *Figure 30*.

Satisfaction with the decision-making process

Four items from within the *satisfaction with decision-making* domain (items D7–D10) constitute the *satisfaction with the decision-making process* domain score. Of the 7019 questionnaires received, 3476 (49.5%) had complete responses for all four items. Most frequently, a response was missing for D10 only ('when making decisions, did you have adequate time to have your concerns addressed and questions answered?'), all four items – D7 ('did you feel included in the decision-making process?'), D8 ('did you feel supported during the decision-making process?'), D9 ('did you feel you had control over the care of your family member?') and D10 – or a combination of items D9 and D10 (*Figure 31*).

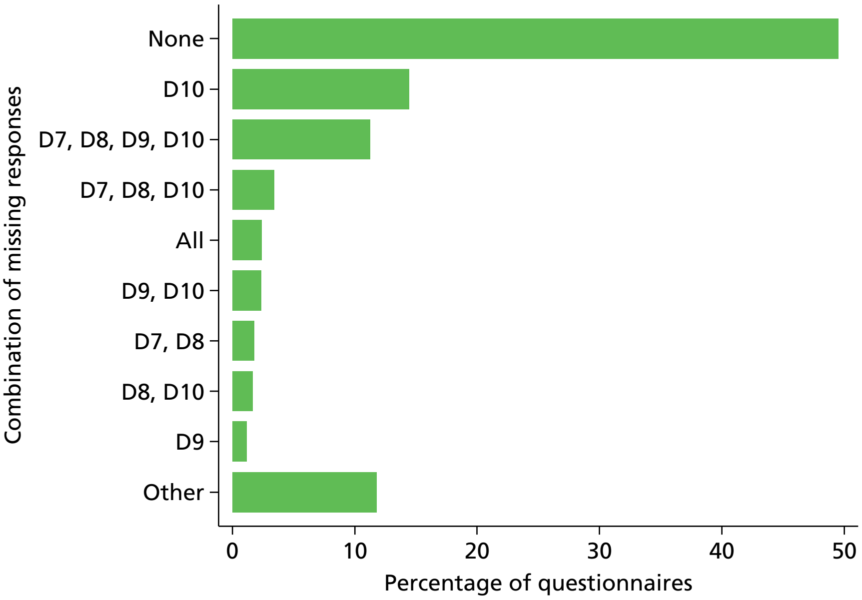

FIGURE 27 Common patterns of missing data for the *satisfaction with decision-making* domain.

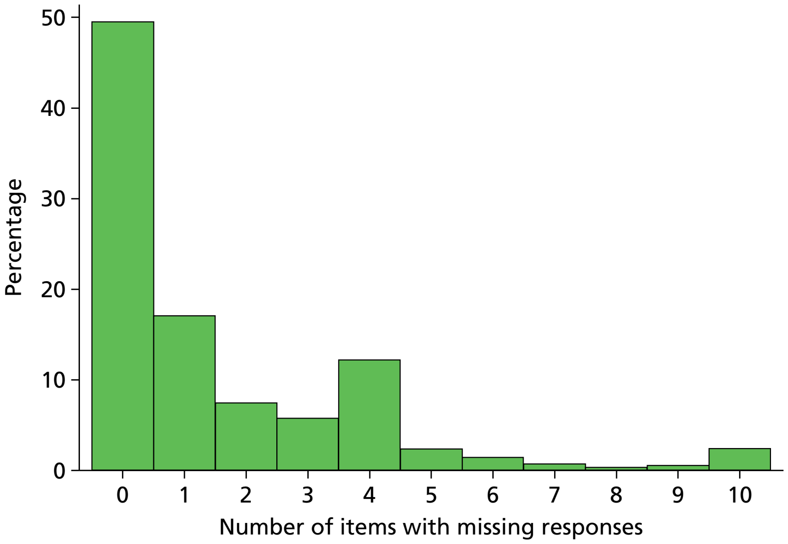

FIGURE 28 Distribution of the numbers of items with missing responses for the *satisfaction with decision-making* domain.

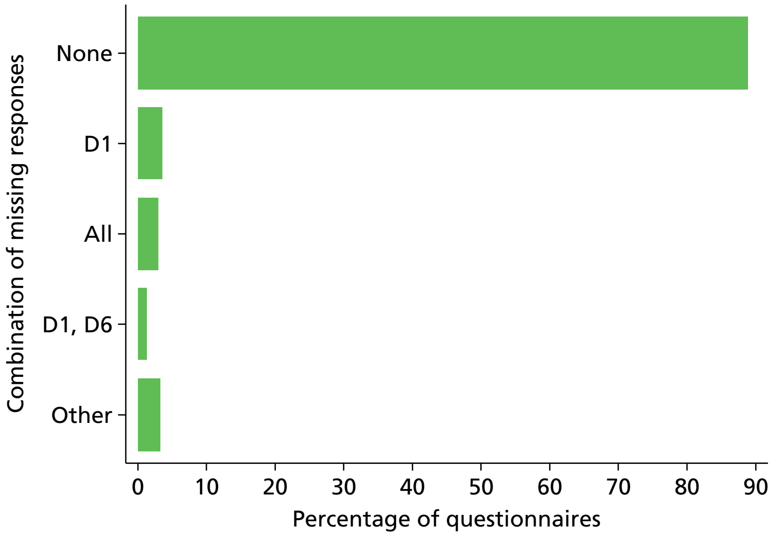

FIGURE 29 Common patterns of missing data for the *satisfaction with information* domain.

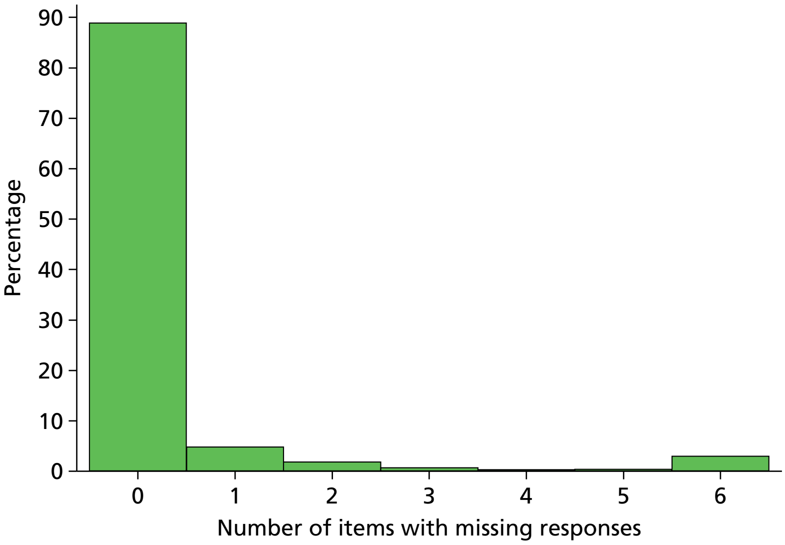

FIGURE 30 Distribution of the numbers of items with missing responses for the *satisfaction with information* domain.

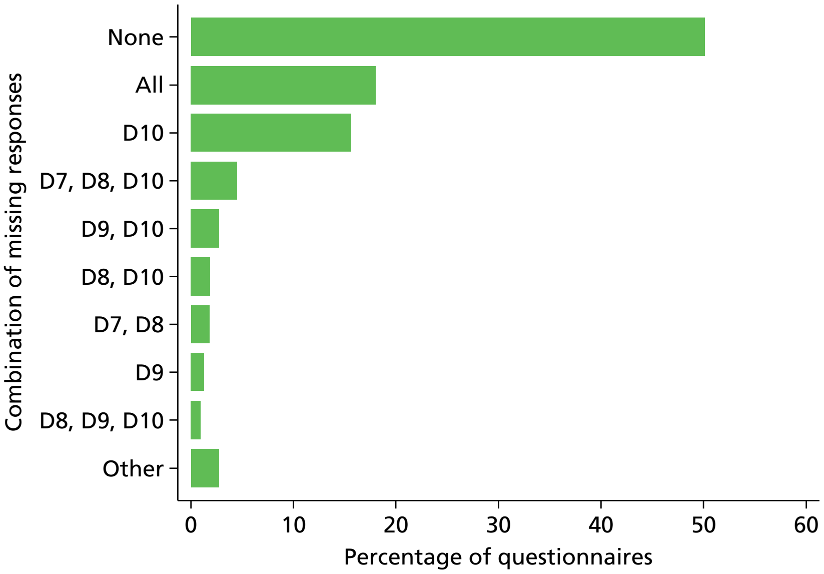

FIGURE 31 Common patterns of missing data for the *satisfaction with the decision-making process* domain.

The distribution of the numbers of items with missing responses is presented in *Figure 32*.

Overall family satisfaction

Twenty-four items (items C1–C14 and D1–D10) constitute the overall family satisfaction score. Of the 7019 questionnaires received, 2898 (41.3%) had complete responses for all 24 items. Most frequently a response was missing for either D10 only ('when making decisions, did you have adequate time to have your concerns addressed and questions answered?') or a combination of D7 ('did you feel included in the decision-making process?'), D8 ('did you feel supported during the decision-making process?'), D9 ('did you feel you had control over the care of your family member?') and D10 (*Figure 33*).

The distribution of the number of items with missing responses is presented in *Figure 34*.

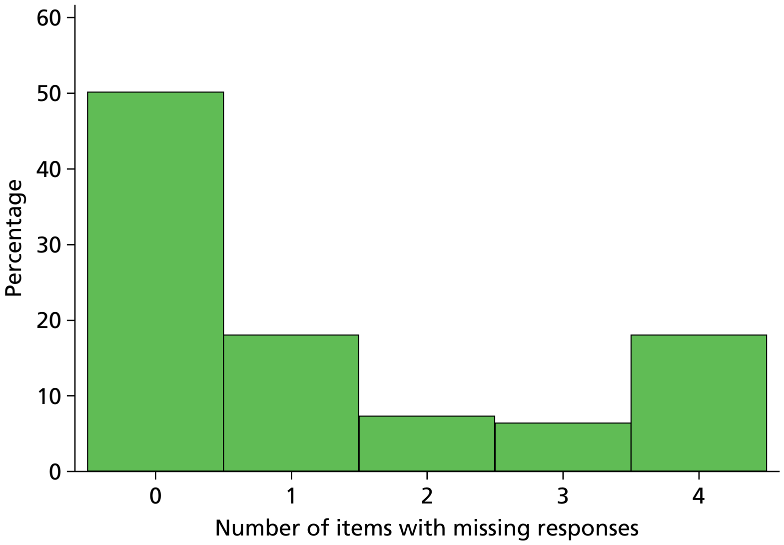

FIGURE 32 Distribution of the number of items with missing responses for the *satisfaction with the decision-making process* domain.

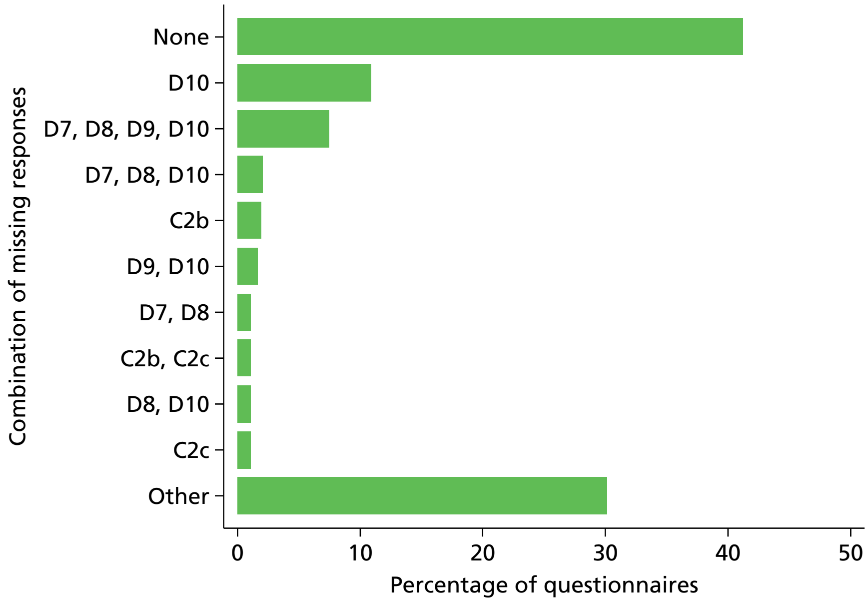

FIGURE 33 Common patterns of missing data for the overall family satisfaction score.

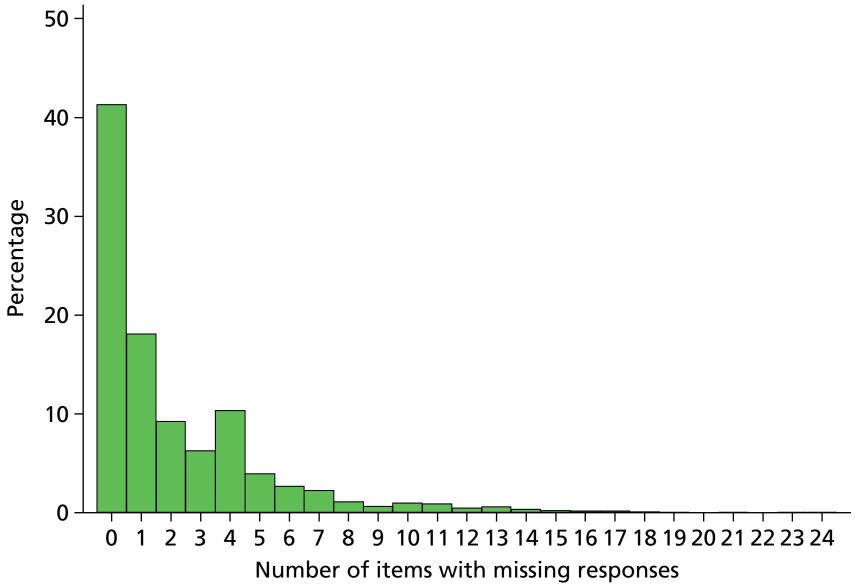

FIGURE 34 Distribution of the number of items with missing responses for the overall family satisfaction score.

Multiple imputation

As a considerable number of respondents had not completed the question regarding number of visits but instead had given free-text responses such as ‘every day’ or ‘stayed continuously’, we derived a frequency of visits variable categorising a family member as a frequent visitor if they visited at least once per day (including these free-text responders). Dependency was recoded into three categories combining the middle two groups (none, some and total dependency) and type of admission was recoded into non-surgical, elective surgical and emergency surgical. We categorised ethnicity combining all non-white into one category. Age of the family member was analysed as categories rather than continuous, as exact age was available only for respondents.

Preliminary analyses indicated a low percentage of missing values across the family member characteristics used in the main analyses. Where possible, family member characteristics were taken from questionnaire responses; however, before imputation, we recovered information for missing data in key variables from available data recorded on the web portal (age group, sex, relationship to patient, next of kin and lives with patient).

Overall, a complete case analysis model-fitting procedure would eliminate 59% of the sample, potentially biasing the inferences.

Apart from UK FS-ICU-24 items, data were imputed for family member age group (1.1% missing in the full data, respondents and non-respondents), family member sex (0.8%), next of kin (1.9%) and frequency of visits (2.4% missing among respondents, after taking account of free-text responses, but 42.8% missing among all family members, as it was not recorded on the web portal).

The evaluation of the imputed score values (scale-level imputation) for the FREE study showed that, although the observed and imputed values had the same mean and variance, they did not have the same distribution of values, since the imputed values had no skew. When each item was imputed as ordinal (item-level imputation), the mean and variance were consistent as well as the distribution, so this was the approach used for the final analysis.

Summary measures for the overall family satisfaction score and domain scores after multiple imputation of missing values, compared with the alternative approaches reported previously, are shown in *Table 42*. A comparison of the scores for ICU survivors and non-survivors in the multiply imputed data is shown in *Table 43*. Family satisfaction was substantially higher among family members of ICU non-survivors than among family members of ICU survivors, particularly for the *satisfaction with decision-making* domain score and its subdomains.

TABLE 42 Overall family satisfaction score and domain scores in multiply imputed data compared with populations of returned questionnaires

Summary measures	All	Complete	Incomplete	≥ 70% complete	≥ 60% complete	Multiply imputed data
Overall family satisfaction score						
Median (IQR)	83.8 (70.8–93.4)	87.5 (76.0–95.8)	81.3 (67.9–91.7)	84.4 (71.4–93.8)	84.2 (71.3–93.8)	83.3 (70.4–93.0)
Mean (SD)	80.3 (16.8)	83.4 (15.8)	78.1 (17.2)	80.5 (16.7)	80.4 (16.8)	79.7 (16.7)
95% CI	79.9 to 80.7	82.8 to 84.0	77.5 to 78.6	80.1 to 80.9	80.0 to 80.8	79.2 to 80.1
Satisfaction with care domain score						
Median (IQR)	87.5 (75.0–96.4)	89.3 (76.8–96.4)	83.3 (70.6–93.8)	87.5 (75.0–96.4)	87.5 (75.0–96.4)	87.5 (74.3–96.4)
Mean (SD)	83.2 (16.0)	84.4 (15.5)	80.2 (16.9)	83.3 (16.0)	83.3 (16.0)	83.1 (16.0)
95% CI	82.8 to 83.6	84.0 to 84.8	79.4 to 80.9	82.9 to 83.7	82.9 to 83.6	82.7 to 83.4
Satisfaction with decision-making domain score						
Median (IQR)	80.0 (63.9–92.5)	85.0 (70.0–95.0)	75.0 (57.1–87.5)	80.0 (64.3–92.5)	80.0 (64.3–92.5)	79.0 (63.3–90.0)
Mean (SD)	75.4 (21.0)	79.7 (19.4)	70.9 (21.8)	75.5 (20.7)	75.7 (20.8)	74.9 (20.0)
95% CI	74.9 to 75.9	79.1 to 80.4	70.2 to 71.7	75.0 to 76.1	75.2 to 76.2	74.5 to 75.4
Satisfaction with information domain score						
Median (IQR)	79.2 (66.7–95.8)	79.2 (66.7–95.8)	75.0 (55.0–90.0)	79.2 (66.7–95.8)	79.2 (66.7–95.8)	79.2 (66.7–95.8)
Mean (SD)	76.3 (22.2)	76.9 (21.9)	70.2 (24.8)	76.6 (22.0)	76.5 (22.1)	76.2 (22.0)
95% CI	75.8 to 76.9	76.4 to 77.4	68.1 to 72.2	76.1 to 77.1	76.0 to 77.1	75.7 to 76.7
Satisfaction with the decision-making process domain score						
Median (IQR)	75.0 (50.0–93.4)	87.5 (68.8–100.0)	58.3 (50.0–83.3)	81.3 (58.3–93.4)	81.3 (58.3–93.4)	75.6 (59.3–93.1)
Mean (SD)	72.7 (24.8)	79.7 (21.9)	61.6 (25.2)	74.3 (23.9)	74.3 (23.9)	73.1 (22.3)
95% CI	72.0 to 73.3	79.0 to 80.4	60.6 to 62.7	73.6 to 74.9	73.6 to 74.9	72.5 to 73.6

CI, confidence interval.

TABLE 43 Comparison of overall family satisfaction score and domain scores in multiply imputed data for all family members and by the patient's ICU outcome

Summary measures	All family members ($n = 7{,}017$[a])	Family members of ICU survivors ($n = 6{,}147$[a])	Family members of ICU non-survivors ($n = 870$)
Overall family satisfaction score			
Median (IQR)	83.3 (70.4–93.0)	82.7 (69.9–92.7)	87.1 (74.4–94.8)
Mean (SD)	79.7 (16.7)	79.3 (16.5)	82.0 (17.5)
95% CI	79.2 to 80.1	78.9 to 79.8	80.9 to 83.2
Satisfaction with care domain score			
Median (IQR)	87.5 (74.3–96.4)	87.5 (73.6–96.4)	88.1 (76.8–96.4)
Mean (SD)	83.1 (16.0)	83.0 (15.9)	83.8 (16.9)
95% CI	82.7 to 83.4	82.6 to 83.4	82.7 to 84.9
Satisfaction with decision-making domain score			
Median (IQR)	79.0 (63.3–90.0)	77.5 (62.5–90.0)	85.0 (71.8–95.0)
Mean (SD)	74.9 (20.0)	74.3 (19.9)	79.6 (20.3)
95% CI	74.5 to 75.4	73.8 to 74.8	78.2 to 80.9
Satisfaction with information domain score			
Median (IQR)	79.2 (66.7–95.8)	79.2 (62.5–95.8)	83.3 (70.8–100.0)
Mean (SD)	76.2 (22.0)	75.7 (22.0)	79.6 (22.9)
95% CI	75.7 to 76.7	75.1 to 76.2	78.1 to 81.0
Satisfaction with the decision-making process domain score			
Median (IQR)	75.6 (59.3–93.1)	75.0 (57.5–88.8)	87.5 (68.8–100.0)
Mean (SD)	73.1 (22.3)	72.1 (22.0)	79.6 (22.9)
95% CI	72.5 to 73.6	71.6 to 72.7	78.1 to 81.1

CI, confidence interval.

[a] Two family members returned questionnaires but did not complete any of the 24 FS-ICU items; responses were not imputed for these family members.

Discussion

Levels of non-response to items in the UK FS-ICU-24 varied considerably across the items, particularly with regard to responses of 'not applicable'. A complete-case analysis, using only family members who completed all 24 items, would therefore be based on only 59% of respondents, giving considerable potential for bias, particularly as the complete responders tended to have higher levels of satisfaction. Using an item-level approach to multiple imputation of missing values resulted in scores with a similar distribution to alternative approaches such as the traditional approach of averaging responses for family members who completed either 70% or 60%, but it enabled inclusion of all responders, regaining potentially important information from the family members who completed fewer than 60% of items.

Item-level responses were also imputed for non-responders, based on the information recorded on the FREE study web portal, allowing the potential to also include these family members in subsequent analyses. However, as these family members do not provide any additional information on the associations between patient/family member characteristics and satisfaction (as their satisfaction scores are entirely imputed), we concluded that the primary approach for subsequent analyses would be to use multiply imputed data for responders only, with complete case analysis, the traditional approach (based on 60% response) and imputation of satisfaction for non-responders conducted in parallel as sensitivity analyses.

Family satisfaction was substantially higher for family members of ICU non-survivors than for family members of ICU survivors. This may be related to the fact that including family is part of the end-of-life decision-making process in intensive care. These higher family satisfaction scores, in combination with the potential for factors to have different relationships with satisfaction for survivors and non-survivors, led us to select a stratified approach to the subsequent analysis to identify determinants of family satisfaction, developing separate models for ICU survivors and non-survivors.

Chapter 7 Assessing the determinants of family satisfaction using multilevel modelling

Introduction

The aim of this chapter is to explore how family satisfaction, measured with the UK FS-ICU-24, varied by family member characteristics, patient characteristics, ICU/hospital characteristics and other contextual factors.

Methods

Selection of data

The final analysis of the FREE study was based on family members of patients (excluding readmissions) who were discharged from, or died in, the ICU up to 15 August 2014. Family members of patients remaining in the ICU beyond 15 August 2014 were excluded, as they would not have had an opportunity to complete and return a questionnaire before the follow-up database was closed on 12 September 2014 (note that, as family members were not recruited for patients admitted after 30 June 2014, there were very few patients remaining in the ICU beyond this date). Patients with no family members recruited to the FREE study were excluded from the analysis.

Primary analyses were undertaken using responders only (both complete responders and partial responders with missing items imputed). To test if our findings were influenced by using imputed data, we also conducted sensitivity analyses using complete case data (i.e. complete responders only), the modified traditional approach to scoring (using complete responders and partial responders with at least 60% of items completed) and all family members (additionally including non-responders, with their satisfaction imputed).

Statistical analysis

The following family member characteristics were described by mean and SD, median and quartiles, or number and percentage for all family members included in the final analysis, stratified by the patient's ICU outcome (alive/dead): age in years; age group (<30 years, 30–39 years, 40–49 years, 50–59 years, 60–69 years, 70–79 years, ≥ 80 years); sex; ethnicity (white, mixed, Asian or Asian British, black or black British, other ethnic group); relationship to patient (partner, parent, child, sibling, other relative, other non-relative); next of kin (yes/no); lives with patient (yes/no); highest level of education (NVQ level 1 or 2, equivalent to GCSE or O level; NVQ level 3, equivalent to A level, AS level or Higher School Certificate; NVQ level 4 or 5, equivalent to degree, higher degree, HNC or HND; other); deprivation (quintiles, using the Index of Multiple Deprivation 2010 for England, Welsh Index of Multiple Deprivation 2008 or Northern Ireland Multiple Deprivation Measure 2010, assigned according to the family member's postcode); distance from home address to hospital (calculated in kilometres as the straight-line distance from the mid-point of the postcode for the family member to the midpoint of the postcode for the hospital); previous experience of ICU as a family member (yes/no); and frequency of visits.

The following patient characteristics were described by mean and SD, median and quartiles, or number and percentage for patients with a family member included in the final analysis, stratified by the patient's ICU outcome (alive/dead): age in years; age group (<30 years, 30–39 years, 40–49 years, 50–59 years, 60–69 years, 70–79 years, ≥ 80 years); sex; ethnicity (white, Asian or Asian British, black or black British, mixed ethnicity or other ethnic group); deprivation (quintiles, defined as for the family members); distance from home address to hospital (defined as for the family members); severe chronic conditions in the past medical history (liver, renal, respiratory, cardiovascular, metastatic cancer, haematological malignancy, immunocompromise – defined according to APACHE II[26]); prior dependency (able to live without assistance in daily activities, either minor or major assistance with daily activities, total assistance with daily activities); surgical status (planned admission direct from theatre following elective or scheduled surgery, unplanned admission direct from theatre following surgery of any urgency, non-surgical); ICNARC physiology score[27] (mean and SD); APACHE II score[26] (mean and SD); ICU length of stay (median and quartiles); receipt (number and percentage) and duration (median and quartiles in calendar days) of organ support in the ICU (advanced respiratory support, advanced cardiovascular support, renal support, neurological support); and, for ICU survivors, whether or not the patient died before ultimate discharge from acute hospital.

Variation in family satisfaction was analysed across the following factors: family member characteristics (as above); patient characteristics (as above); ICU/hospital characteristics (hospital teaching status and number of beds in the ICU); and other contextual factors (month of ICU admission and, for family members of ICU survivors, whether or not the questionnaire was received while the patient was still in hospital). These were explored using univariable and multivariable, multilevel linear regression models. There were three levels of the models: family member; patient/ICU admission; and ICU/hospital. The outcome for the primary analyses was the overall family satisfaction score. As secondary analyses, separate models were fitted for each of the original domain scores as well as those resulting from the full psychometric assessment (see *Chapter 4*). All models were stratified by the patient's ICU outcome (i.e. separate models were fitted for family members of survivors and non-survivors). The multilevel models were fitted using the 'xtmixed' command in Stata/SE version 13.0 (StataCorp, College Station, TX, USA) using 'mi estimate' to analyse multiply imputed data.

A simple random intercepts model was fitted to decompose the amount of variance that existed between patient and ICU/hospital levels. The level effect was assessed by the relative contribution of these variances (note: likelihood-based approaches to testing are not applicable with multiply imputed data). The variance partition coefficient reports the proportion of the observed response variation that lies at each level of the model hierarchy and was used to confirm that both the ICU/hospital variance and the patient variance are separately significant.

In order to evaluate the distribution of variance between levels while analysing the contribution of each level's characteristics, a two-stage model building approach was applied, as follows.

Stage 1: to select the significant characteristics at each level, the step-by-step approach was adopted, following an approach suggested by Raudenbush and Bryk[51] and Snijders and Bosker.[52] Three models with fixed slopes were developed. In the first model, family-member-level variables were included in a simple random intercepts model. The second model was extended to include patient-level variables. The third model additionally contained the ICU/hospital-level variables and contextual factors. The opposite, backwards, approach of entering all possible variables at one time and then removing the non-significant ones was not feasible because of the large number of variables and multicollinearity problems. At each step, relationships between the outcome and each variable at that level were tested, one at a time, in multilevel models adjusted for the outcome and the lower-level variables. A significant *Z*-test for the variable coefficient confirmed that adjusting for this variable significantly improved the fit of the model. The differential explanatory power of the variable was evaluated by examining the total and level-specific changes in variance and adjusted intraclass correlation coefficient. A number of key variables were identified a priori to be carried forward to the full multivariable models (family member age, sex, relationship to the patient, next of kin and lives with the patient, and patient age, sex and ICU length of stay). Other variables were carried forward to the multivariable model if the results of the significance test and or the evaluation of explanatory power showed an important effect in the model. At each step, a Wald test was used to confirm the joint significance of all variables added at that level.

The variables that were not selected in the original multivariable model were added into the final model to assess the joint significance of these variables, adjusted for the selected variables, and changes were made to the model, if necessary.

Stage 2: in the final, three-level, model, with random intercepts at level 2 (patient) and level 3 (ICU/hospital), interaction terms specified a priori were considered (patient age with sex and ICU length of stay with receipt of advanced respiratory support). Determinants in the model that might better be modelled with random coefficients at level 2 were investigated, one at a time, to judge the impact of setting them as random effects. The inclusion of interactions as well as models with random slopes were judged by the size of the variance corresponding to the slope.

Results

Descriptive statistics and univariable analyses

The comparisons of family member and patient characteristics for ICU survivors and non-survivors are presented in *Tables 44* and *45*, respectively. Univariable analyses of the association between each variable and family satisfaction are shown in *Table 46* (family characteristics), *Table 47* (patient characteristics) and *Table 48* (ICU/hospital characteristics and contextual factors).

TABLE 44 Family member characteristics stratified by the patient's ICU outcome

Family member characteristic	Family members of ICU survivors ($n = 6149$)	Family members of ICU non-survivors ($n = 870$)
Mean age (years)[a] (SD) [*N*]	54 (15.0) [5937]	52 (15.2) [846]
Age group (years),[b] *n* (%)	6142	869
< 30	448 (7.3)	68 (7.8)
30–39	605 (9.9)	106 (12.2)
40–49	1273 (20.7)	180 (20.7)
50–59	1454 (23.7)	215 (24.7)
60–69	1396 (22.7)	179 (20.6)
70–79	786 (12.8)	87 (10.0)
≥ 80	180 (2.9)	34 (3.9)
Sex,[b] *n* (%)	6147	870
Male	2080 (33.8)	277 (31.8)
Female	4067 (66.2)	593 (68.2)
Ethnicity,[c] *n* (%)	6149	870
White	5738 (93.3)	817 (93.9)
Asian	114 (1.9)	24 (2.8)
Black	50 (0.8)	4 (0.5)
Mixed ethnicity or other ethnic group	84 (1.4)	4 (0.5)
Not stated	163 (2.7)	21 (2.4)

continued

TABLE 44 Family member characteristics stratified by the patient's ICU outcome (*continued*)

Family member characteristic	Family members of ICU survivors (*n* = 6149)	Family members of ICU non-survivors (*n* = 870)
Relationship to patient,[b] *n* (%) ('I am the patient's . . .')	6148	870
Partner	1891 (30.8)	205 (23.6)
Child	1893 (30.8)	346 (39.8)
Parent	622 (10.1)	32 (3.7)
Sibling	624 (10.1)	80 (9.2)
Other relative	799 (13.0)	170 (19.5)
Other non-relative	319 (5.2)	37 (4.3)
Next-of-kin,[b] *n* (%) [*N*]	3153 (51.4) [6138]	367 (42.3) [868]
Lives with patient,[b] *n* (%) [*N*]	2311 (37.6) [6148]	248 (28.5) [870]
Highest level of education,[c] *n* (%)	5071	748
NVQ level 1 or 2	1465 (28.9)	218 (29.1)
NVQ level 3	989 (19.5)	134 (17.9)
NVQ level 4 or 5	1537 (30.3)	232 (31.0)
Other	1080 (21.3)	164 (21.9)
Quintile of deprivation,[c] *n* (%)	5861	818
1 (least deprived)	1164 (19.9)	159 (19.4)
2	1281 (21.9)	181 (22.1)
3	1238 (21.1)	181 (22.1)
4	1189 (20.3)	169 (20.7)
5 (most deprived)	989 (16.9)	128 (15.6)
Median distance (km) from home to hospital[c] (IQR) [*N*]	12.4 (5.5–34.1) [5890]	12.3 (5.1–33.2) [824]
Previous experience of ICU as a family member,[a] *n* (%) [*N*]	1641 (27.1) [6052]	200 (23.3) [860]
Frequent visitor,[a] *n* (%) [*N*]	4713 (78.6) [6000]	690 (81.2) [850]

[*N*], number of family members for whom the information was available.
[a] Source: questionnaire.
[b] Source: questionnaire or web portal.
[c] Source: web portal.

TABLE 45 Patient characteristics stratified by ICU outcome

Patient characteristics	ICU survivors ($n = 4007$)	ICU non-survivors ($n = 499$)
Mean age (years) (SD)	62.5 (17.3)	68.5 (13.2)
Age group (years), *n* (%)		
< 30	246 (6.1)	8 (1.6)
30–39	223 (5.6)	9 (1.8)
40–49	384 (9.6)	28 (5.6)
50–59	586 (14.6)	57 (11.4)
60–69	966 (24.1)	134 (26.9)
70–79	1003 (25.0)	156 (31.3)
≥ 80	599 (14.9)	107 (21.4)
Sex, *n* (%)		
Male	2264 (56.5)	297 (59.5)
Female	1743 (43.5)	202 (40.5)
Ethnicity, *n* (%)		
White	3706 (92.5)	470 (94.2)
Asian or Asian British	69 (1.7)	12 (2.4)
Black or black British	39 (1.0)	3 (0.6)
Mixed ethnicity or other ethnic group	74 (1.8)	5 (1.0)
Not stated	119 (3.0)	9 (1.8)
Quintile of deprivation, *n* (%)	3974	495
1 (least deprived)	690 (17.4)	84 (17.0)
2	812 (20.4)	93 (18.8)
3	822 (20.7)	106 (21.4)
4	841 (21.2)	109 (22)
5 (most deprived)	809 (20.4)	103 (20.8)
Median distance (km) from home to hospital (IQR)	9.5 (4.4–20.2)	8.2 (4.1–16.4)
APACHE II severe comorbidities, *n* (%)		
Liver	94 (2.3)	30 (6.0)
Renal	97 (2.4)	11 (2.2)
Respiratory	119 (3.0)	27 (5.4)
Cardiovascular	100 (2.5)	17 (3.4)
Metastatic cancer	110 (2.7)	11 (2.2)
Haematological malignancy	81 (2.0)	22 (4.4)
Immunocompromise	318 (7.9)	51 (10.2)

continued

TABLE 45 Patient characteristics stratified by ICU outcome (*continued*)

Patient characteristics	ICU survivors ($n = 4007$)	ICU non-survivors ($n = 499$)
Prior dependency, *n* (%)		
Able to live without assistance	2944 (73.5)	323 (64.7)
Minor or major assistance	1004 (25.1)	167 (33.5)
Total assistance	42 (1.0)	5 (1.0)
Unknown	17 (0.4)	4 (0.8)
Surgical status, *n* (%)		
Non-surgical	2396 (59.8)	412 (82.6)
Planned admission following elective or scheduled surgery	686 (17.1)	16 (3.2)
Unplanned admission following surgery of any urgency	925 (23.1)	71 (14.2)
Mean ICNARC physiology score (SD)	17.5 (7.9)	25.7 (8.1)
Mean APACHE II score (SD)	16.2 (6.1)	21.2 (6.2)
Median ICU length of stay (days) (IQR)	4.8 (2.8–9.0)	6.0 (3.6–10.6)
Organ support received in the ICU, *n* (%)		
Advanced respiratory support	2124 (53.0)	416 (83.4)
Advanced cardiovascular support	1037 (25.9)	288 (57.7)
Renal support	510 (12.7)	181 (36.3)
Neurological support	503 (12.6)	114 (22.8)
Median duration (calendar days) of organ support among those receiving the support (IQR)		
Advanced respiratory support	4 (2–9)	6 (4–10)
Advanced cardiovascular support	2 (2–4)	3 (2–5)
Renal support	4 (3–8)	4 (3–8)
Neurological support	3 (2–7)	3 (2–5)
Death before acute hospital discharge, *n* (%)	353 (8.9)	Not applicable

[*N*], number of patients for whom the information was available.

TABLE 46 Univariable analyses of factors associated with overall family satisfaction score by ICU outcome: family member characteristics

	Family members of ICU survivors ($n = 6147^a$)			Family members of ICU non-survivors ($n = 870$)		
Variable	Coefficient	95% CI	*p*-value	Coefficient	95% CI	*p*-value
Age (years) (vs. < 30)			0.031			0.033
30–39	1.56	–0.22 to 3.33		2.68	–1.80 to 7.17	
40–49	0.42	–0.10 to 0.94		1.61	0.21 to 3.01	
50–59	2.12	0.61 to 3.64		5.49	1.49 to 9.50	
60–69	1.96	0.39 to 3.52		6.01	1.78 to 10.25	
70–79	1.98	0.28 to 3.68		7.39	2.58 to 12.19	
≥ 80	–0.55	–3.05 to 1.95		2.62	–3.48 to 8.73	
Female (vs. male)	0.40	–0.34 to 1.14	0.29	0.44	–1.59 to 2.47	0.67
White ethnicity (vs. non-white)	3.60	1.46 to 5.75	0.001	8.78	1.85 to 15.70	0.013
Relationship (vs. partner)			< 0.001			0.28
Parent	0.00	–1.39 to 1.39		0.08	–5.73 to 5.90	
Child	–0.94	–1.83 to –0.05		–1.274	–3.69 to 1.14	
Sibling	–2.16	–3.50 to –0.82		0.909	–3.02 to 4.84	
Other-relative	–1.63	–2.81 to –0.44		–0.619	–3.60 to 2.36	
Other-non relative	–3.42	–5.22 to –1.62		–6.134	–11.69 to -0.58	
Next of kin	1.74	1.05 to 2.44	< 0.001	2.69	0.78 to 4.59	0.006
Lives with patient	1.95	1.20 to 2.69	< 0.001	1.15	–0.99 to 3.29	0.29
Education (vs. NVQ 1 or 2)			< 0.001			0.16
NVQ 3	–0.60	–1.77 to 0.57		1.14	–2.09 to 4.37	
NVQ 4 or 5	–2.43	–3.49 to –1.37		–2.07	–4.92 to 0.77	
Other	–0.18	–1.35 to 0.98		–1.75	–4.73 to 1.24	
Quintile of deprivation (vs. 1, least deprived)			0.63			0.77
2	0.49	–0.74 to 1.72		0.64	–2.73 to 4.01	
3	0.96	–0.29 to 2.20		0.84	–2.59 to 4.26	
4	0.32	–0.97 to 1.60		–1.07	–4.59 to 2.44	
5 (most deprived)	0.67	–0.70 to 2.05		0.79	–3.10 to 4.69	
Distance from home to hospital (per 10 km)	–0.05	–0.11 to 0.01	0.12	0.05	–0.09 to 0.18	0.49
Previous experience of ICU as a family member	0.25	–0.63 to 1.14	0.58	–0.68	–3.22 to 1.87	0.60
Frequent visitor	2.52	1.63 to 3.41	< 0.001	2.91	0.36 to 5.47	0.030

CI, confidence interval.

a Two family members returned questionnaires but did not complete any of the 24 FS-ICU items; responses were not imputed for these family members.

TABLE 47 Univariable analyses of factors associated with overall family satisfaction score by ICU outcome: patient characteristics

	Family members of ICU survivors ($n = 6147^a$)			Family members of ICU non-survivors ($n = 870$)		
Variable	Coefficient	95% CI	*p*-value	Coefficient	95% CI	*p*-value
Age (per 10 years)	–0.09	–0.36 to 0.17	0.49	1.12	0.11 to 2.14	0.030
Female (vs. male)	0.67	–0.25 to 1.59	0.16	2.04	–0.66 to 4.74	0.14
White ethnicity (vs. non-white)	2.39	0.11 to 4.68	0.040	9.25	2.38 to 16.12	0.008
Quintile of deprivation (vs. 1, least deprived)			0.76			0.95
2	0.86	–0.66 to 2.38		–1.28	–5.85 to 3.29	
3	0.62	–0.90 to 2.13		–0.68	–5.12 to 3.75	
4	0.77	–0.75 to 2.28		–1.62	–6.03 to 2.78	
5 (most deprived)	1.00	–0.57 to 2.57		–1.49	–6.04 to 3.06	
Distance from home to hospital (per 10 km)	0.12	0.00 to 0.24	0.047	0.18	–0.05 to 0.41	0.12
Severe comorbidities						
Liver	3.18	–0.01 to 6.38	0.050	1.25	–4.67 to 7.19	0.68
Renal	–0.45	–3.57 to 2.66	0.77	–8.87	–18.35 to 0.60	0.067
Respiratory	0.01	–2.84 to 2.85	1.00	–1.02	–7.23 to 5.19	0.75
Cardiovascular	–0.14	–3.23 to 2.94	0.93	1.40	–6.46 to 9.26	0.73
Metastatic cancer	–2.81	–5.78 to 0.15	0.063	3.26	–6.38 to 12.90	0.51
Haematological malignancy	2.25	–1.09 to 5.61	0.19	–7.88	–14.62 to –1.13	0.022
Immunocompromise	–0.91	–2.74 to 0.90	0.33	–3.90	–8.55 to 0.74	0.10
Dependency (vs. none)			0.30			0.85
Minor or major	–0.14	–1.36 to 1.08		0.63	–2.34 to 3.60	
Total	–3.63	–8.21 to 0.94		2.73	–10.21 to 15.67	
Surgical status (vs. non-surgical)			0.005			0.78
Planned elective/ scheduled	–2.17	–3.51 to –0.83		–2.83	–10.75 to 5.10	
Unplanned	–0.17	–1.29 to 0.96		–0.06	–3.89 to 3.76	
ICNARC physiology score (per point)	0.19	0.13 to 0.25	< 0.001	0.19	0.02 to 0.35	0.026
ICU length of stay (per day)	0.02	–0.03 to 0.06	0.44	–0.34	–0.48 to –0.20	< 0.001
Advanced respiratory support	3.62	2.63 to 4.61	< 0.001	1.96	–1.84 to 5.76	0.31
Advanced cardiovascular support	2.06	0.89 to 3.22	0.001	0.83	–2.06 to 3.72	0.58
Renal support	1.52	0.11 to 2.93	0.034	0.04	–2.83 to 2.91	0.98
Neurological support	1.96	0.39 to 3.54	0.014	2.95	–0.42 to 6.32	0.086
Duration of advanced respiratory support (per day)	0.11	0.05 to 0.16	< 0.001	–0.16	–0.32 to 0.00	0.051

TABLE 47 Univariable analyses of factors associated with overall family satisfaction score by ICU outcome: patient characteristics (*continued*)

	Family members of ICU survivors ($n = 6147^a$)			Family members of ICU non-survivors ($n = 870$)		
Variable	Coefficient	95% CI	*p*-value	Coefficient	95% CI	*p*-value
Duration of advanced cardiovascular support (per day)	0.40	0.15 to 0.65	0.002	0.11	–0.33 to 0.56	0.62
Duration of renal support (per day)	0.16	0.00 to 0.32	0.048	–0.15	–0.43 to 0.13	0.28
Duration of neurological support (per day)	0.10	–0.09 to 0.29	0.31	0.05	–0.43 to 0.53	0.84
Death before acute hospital discharge	–0.49	–1.52 to 0.55	0.36	Not applicable		

CI, confidence interval.

a Two family members returned questionnaires but did not complete any of the 24 FS-ICU items; responses were not imputed for these family members.

TABLE 48 Univariable analysis of factors associated with overall family satisfaction score by ICU outcome: ICU/hospital characteristics and contextual factors

	Family members of ICU survivors ($n = 6147^a$)			Family members of ICU non-survivors ($n = 870$)		
Variables	Coefficient	95% CI	*p*-value	Coefficient	95% CI	*p*-value
Hospital type (vs. non-university)			0.51			0.62
University	0.06	–3.63 to 3.75		–0.32	–4.72 to 4.07	
University affiliated	1.93	–1.56 to 5.42		1.68	–2.29 to 5.65	
Number of ICU beds (per bed)	–0.05	–0.23 to 0.14	0.63	0.02	–0.22 to 0.26	0.85
Month of ICU admission (vs. January)			0.95			0.85
February	–0.61	–2.87 to 1.65		–0.03	–6.90 to 6.83	
March	0.09	–2.12 to 2.30		–0.06	–6.73 to 6.60	
April	0.54	–1.71 to 2.79		0.07	–6.93 to 7.07	
May	–0.06	–2.31 to 2.18		0.73	–5.62 to 7.08	
June	–0.66	–2.65 to 1.34		0.84	–4.95 to 6.64	
July	0.85	–1.41 to 3.11		3.91	–2.71 to 10.52	
August	0.65	–1.64 to 2.93		–0.70	–6.87 to 5.46	
September	0.09	–2.14 to 2.31		1.74	–4.76 to 8.25	
October	0.44	–1.76 to 2.63		1.15	–5.69 to 7.98	
November	0.60	–1.65 to 2.85		2.21	–4.10 to 8.53	
December	0.69	–1.57 to 2.96		5.16	–1.13 to 11.46	
Questionnaire received while patient still in hospital	0.087	–1.50 to 1.67	0.91	Not applicable		

CI, confidence interval.

a Two family members returned questionnaires but did not complete any of the 24 FS-ICU items; responses were not imputed for these family members.

Multilevel multivariable models

Family satisfaction was not associated with the deprivation of the family member for survivors or non-survivors. Although family satisfaction declined with increasing level of education among family members of survivors, it was not considered in the multivariable models because there were higher than expected proportions of both not stated (17%) and other (21% of complete responses), suggesting a lack of comprehension of the categorisation used. Neither distance from home to hospital nor previous experience of ICU as a family member was associated with satisfaction. Other family-member-level variables (ethnicity and frequent visitor) were statistically significant and were carried forward to the multivariable models along with the a priori key family member variables (age, sex, relationship to the patient, next of kin and lives with patient).

Although statistically significant, patient ethnicity was not carried forward to the multivariable models because it was collinear with family member ethnicity. As for family members, patient deprivation was not associated with family satisfaction for either survivors or non-survivors. Distance from home to hospital was significant for survivors, but did not remain significant when carried forward to the multivariable model and was dropped. None of the severe comorbidities were associated with family satisfaction for either survivors or non-survivors, except for haematological malignancy for non-survivors, and neither was dependency prior to acute hospital admission. However, dependency was carried forward to the multivariable model because of its controlling effect on the estimates of other coefficients in the model. Once included in the multivariable model for non-survivors, haematological malignancy was no longer significant and was dropped from the model. Surgical status was significant for survivors but not for non-survivors; however, it was retained in the multivariable models for both survivors and non-survivors because of its controlling effect on other coefficients. Acute severity of illness (ICNARC physiology score) was significant for both survivors and non-survivors and was carried forward to the multivariable models. Organ support received in the ICU and duration (calendar days) of organ support among those receiving the support were significant among the family members of survivors, but not among the family members of non-survivors. Once included in the multivariable model for survivors, only advanced respiratory support remained significant and the other organ support variables were dropped from the model. The binary variable of receipt of advanced respiratory support was found to be preferable to the alternative variable of the duration of advanced respiratory support, which was correlated with ICU length of stay. Death before acute hospital discharge was not associated with satisfaction for family members of patients who survived to ICU discharge.

There was no evidence of differences in family satisfaction according to hospital teaching status or the number of beds in the ICU; however, these ICU/hospital level variables were retained in the multivariable models because of their controlling effect on the other coefficients in the models.

No variations in family satisfaction were associated with the contextual factors of month of admission to the ICU or, for family members of survivors only, the questionnaire being received while the patient was still in hospital. These variables were not carried forward to the multivariable models.

There was a strong multicollinearity between relationship to the patient and the other key variables of 'next of kin' and 'lives with patient', with very high proportions of family members who were both the next of kin and living with the patient for certain relationships (especially partner, 96.9%) and relatively small proportions for others (particularly other relatives and other non-relatives). We found that the variables were confounded with each other and attempts to separately disentangle their effects led to very imprecise estimates because of the multicollinearity. For these reasons, we chose not to use the variables 'next of kin' or 'lives with patient' in the same multivariable model as relationship to the patient. The information from the two variables 'next of kin' and 'lives with patient' were combined into a single variable with three categories (lives with patient; next of kin, does not live with patient; and not next of kin, does not live with patient) in a first multivariable model (model 1). This combined variable was replaced with the relationship with the patient variable in a second, alternative, multivariable model (model 2).

Interaction terms and random slopes specified a priori did not improve the fit of the models, so these terms were not retained.

The results of model 1 (including the next of kin/lives with patient combination) are shown in *Table 49*. Among family members of ICU survivors, there was evidence of an independent association with overall family satisfaction for each of the following variables: family member age group; family member ethnicity; next of kin/lives with patient; frequency of visits; ICNARC physiology score; and receipt of advanced respiratory support. Among family members of ICU non-survivors, the only variables found to be significant were family member ethnicity; patient age; ICNARC physiology score; and ICU length of stay.

Variances at both the patient and ICU/hospital levels were statistically significant but the variance partition coefficients at the ICU/hospital level were small in both the null and final multilevel models (4% and 3% for ICU survivors and 2% and 2% for ICU non-survivors, respectively; *Tables 49* and *50*), which means that differences in overall family satisfaction scores were mainly at the patient and family member levels. Variance at the patient level represented 44% of the total variance in overall family satisfaction in the final models for family members of both ICU survivors and ICU non-survivors.

Similar findings of the determinants of overall family satisfaction found in model 2 (incorporating relationship to the patient; *Table 51*). Compared with partners of ICU survivors, family members with other relationships had lower satisfaction ($p = 0.029$), particularly siblings, with a reduction of between 0.49 and 3.40 points, and 'other non-relatives', with a reduction of between 0.67 and 4.75 points. No significant variation in overall family satisfaction was found according to relationship to the patient for family members of ICU non-survivors ($p = 0.23$). The coefficients for other variables were similar to those from model 1.

Secondary analyses

The overall family satisfaction score was split into the original and new domain scores to further explore determinants of variation in family satisfaction (*Tables 52–55*).

For family members of ICU survivors, frequency of visits, the patient's acute severity of illness and receipt of advanced respiratory support were significantly associated with satisfaction for all domain scores, and ethnicity and whether or not the family member was the patient's next of kin and/or lived with the patient were significant for all domain scores except for *satisfaction with the decision-making process*. The association with family member age was stronger for the *satisfaction with care* domain score than the overall family satisfaction score, and was not significantly associated with the *satisfaction with decision-making* domain score or either of the new subdomain scores. The patient's dependency prior to admission to acute hospital was also found to be significantly associated with the *satisfaction with care* domain score ($p = 0.006$).

For family members of ICU non-survivors, the patient's age was significantly associated with satisfaction for all domain scores except *satisfaction with information*, and the patient's ICU length of stay was significantly associated with all domain scores except *satisfaction with the decision-making process*. Although the coefficients were similar in magnitude across all models to those from the model for the overall family satisfaction score, the family member's ethnicity was statistically significant in the models only for the *satisfaction with care* and *satisfaction with information* domain scores, and the patient's acute severity of illness (ICNARC physiology score) was not statistically significant in any of the domain models. The number of beds in the ICU was significantly, but weakly, associated with the *satisfaction with the decision-making process* domain score, with an average increase of 0.05 points for each additional bed [95% confidence interval (CI) 0.01 to 0.93; $p = 0.042$]. All other factors considered in the multilevel models were non-significant, as for the model for the overall family satisfaction score.

TABLE 49 Multilevel multivariable models for overall family satisfaction score

	Family members of ICU survivors ($n = 6143^a$)			Family members of ICU non-survivors ($n = 869^a$)		
Variables	Coefficient	95% CI	*p*-value	Coefficient	95% CI	*p*-value
Fixed effects: family member level						
Constant	68.30	63.42 to 73.17	< 0.001	55.70	42.26 to 69.14	< 0.001
Family member age (years) (vs. < 30)			*0.041*			*0.18*
30–39	1.97	0.11 to 3.82		2.01	–2.64 to 6.66	
40–49	1.65	0.02 to 3.29		3.37	–1.01 to 7.75	
50–59	1.96	0.35 to 3.56		4.12	–0.09 to 8.33	
60–69	1.35	–0.31 to 3.01		4.26	–0.25 to 8.79	
70–79	1.32	–0.52 to 3.17		5.92	0.69 to 11.14	
≥ 80	–1.34	–4.06 to 1.37		–0.18	–6.80 to 6.43	
Family member sex: female (vs. male)	0.32	–0.48 to 1.12	0.44	0.66	–1.45 to 2.77	0.54
Family member ethnicity: white (vs. non-white)	3.59	1.38 to 5.80	0.001	7.12	–0.00 to 14.25	0.050
Next of kin/lives with patient (vs. lives with patient)			*< 0.001*			*0.26*
Next of kin, does not live with patient	–1.39	–2.56 to –0.22		1.08	–2.39 to 4.55	
Not next of kin, does not live with patient	–2.33	–3.26 to –1.41		–1.24	–3.88 to 1.40	
Frequent visitor	2.83	1.82 to 3.84	< 0.001	1.53	–1.34 to 4.39	0.30
Fixed effects: patient level						
Patient age (per 10 years)	0.01	–0.28 to 0.31	0.93	1.18	0.09 to 2.27	0.033
Patient sex: female (vs. male)	0.26	–0.73 to 1.25	0.61	1.92	–0.85 to 4.70	0.17
Dependency (vs. none)			*0.15*			*0.74*
Minor or major	–0.30	–1.60 to 1.00		–0.22	–3.36 to 2.92	
Total	–4.62	–9.32 to 0.07		4.98	–8.10 to 18.07	
Surgical status (vs. non-surgical)			*0.15*			*0.82*
Planned elective/ scheduled	–0.74	–2.24 to 0.77		–2.61	–10.77 to 5.54	
Unplanned	–0.26	–1.46 to 0.94		–0.08	–3.95 to 3.80	
ICNARC physiology score (per point)	0.16	0.09 to 0.24	< 0.001	0.17	0.00 to 0.34	0.045
ICU length of stay (per day)	–0.02	–0.07 to 0.03	0.44	–0.30	–0.46 to –0.15	< 0.001
Advanced respiratory support	2.96	1.80 to 4.11	< 0.001	Not included		

TABLE 49 Multilevel multivariable models for overall family satisfaction score (*continued*)

	Family members of ICU survivors ($n = 6143^a$)			Family members of ICU non-survivors ($n = 869^a$)		
Variables	Coefficient	95% CI	*p*-value	Coefficient	95% CI	*p*-value
Fixed effects: ICU/hospital level						
Hospital type (vs. non-university)			*0.49*			*0.55*
University	0.86	–3.61 to 5.32		–1.51	–7.51 to 4.50	
University affiliated	1.97	–1.26 to 5.20		1.77	–2.55 to 6.09	
Number of ICU beds (per bed)	–0.00	–0.23 to 0.23	0.97	0.26	–0.08 to 0.61	0.13
Random effects, SD (SE)						
Between ICUs	2.91 (0.60)			2.81 (1.10)		
Within ICUs between patients	10.94 (0.29)			11.16 (0.69)		
Within patients between family members	11.98 (0.21)			12.26 (0.44)		
Variance partition (%)						
Between ICUs	3			2		
Between patients	44			44		

CI, confidence interval; SE, standard error.

a Five patients were missing age group on both the questionnaire and the web portal; because of the very small amount of missing data in this key variable, these missing values were not imputed.

TABLE 50 Null multilevel models for overall family satisfaction score

Variables	Family members of ICU survivors ($n = 6143^a$)	Family members of ICU non-survivors ($n = 869^a$)
Fixed effect (SE; 95% CI)		
Constant (predicted mean score)	79.85 (0.74; 78.39 to 81.31)	82.62 (0.85; 80.95 to 84.28)
Random effects, SD (SE)		
Between ICUs	3.14 (0.58)	2.20 (0.97)
Within ICUs between patients	10.78 (0.27)	11.47 (0.64)
Within patients between family members	11.41 (0.18)	11.92 (0.41)
Variance partition (%)		
Between ICUs	4	2
Between patients	45	48

CI, confidence interval; SE, standard error.

a Five patients were missing age group on both the questionnaire and the web portal; because of the very small amount of missing data in this key variable, these missing values were not imputed.

TABLE 51 Alternative multilevel multivariable models for the overall family satisfaction score using relationship to patient

	Family members of ICU survivors ($n = 6143^a$)			Family members of ICU non-survivors ($n = 869^a$)		
Variable	Coefficient	95% CI	*p*-value	Coefficient	95% CI	*p*-value
Fixed effects: family member level						
Constant	68.22	63.18 to 73.26	< 0.001	52.97	39.03 to 66.92	< 0.001
Family member age, years (vs. < 30)			*0.11*			*0.18*
30–39	1.59	–0.28 to 3.46		2.06	–2.59 to 6.72	
40–49	1.39	–0.30 to 3.08		3.70	–0.78 to 8.18	
50–59	1.80	0.06 to 3.55		4.49	–0.02 to 8.99	
60–69	1.38	–0.57 to 3.34		4.72	–0.54 to 9.97	
70–79	1.46	–0.77 to 3.70		6.16	–0.03 to 12.35	
≥ 80	–1.17	–4.26 to 1.92		0.13	–7.61 to 7.88	
Family member sex: female (vs. male)	0.30	–0.51 to 1.10	0.46	0.60	–1.51 to 2.71	0.58
Family member ethnicity: white (vs. non-white)	3.40	1.18 to 5.61	0.003	7.25	0.12 to 14.36	0.046
Relationship to patient (vs. partner)			*0.027*			*0.23*
Parent	–0.08	–1.85 to 1.67		1.17	–5.43 to 7.77	
Child	–0.86	–2.20 to 0.47		–0.45	–4.10 to 3.20	
Sibling	–2.03	–3.49 to –0.58		1.25	–2.87 to 5.37	
Other relative	–1.42	–2.84 to –0.01		1.10	–2.72 to 4.91	
Other non-relative	–2.62	–4.65 to –0.58		–6.21	–12.18 to –0.26	
Frequent visitor	2.92	1.87 to 3.96	< 0.001	2.00	–0.88 to 4.89	0.17
Fixed effects: patient level						
Patient age (per 10 years)	–0.01	–0.42 to 0.39	0.94	1.36	0.06 to 2.66	0.040
Patient sex: female (vs. male)	0.28	–0.72 to 1.26	0.59	1.94	–0.84 to 4.72	0.17
Dependency (vs. none)			*0.20*			*0.76*
Minor or major	–0.27	–1.58 to 1.03		–0.04	–3.18 to 3.11	
Total	–4.24	–8.94 to 0.47		4.77	–8.34 to 17.88	
Surgical status (vs. non-surgical)			*0.65*			*0.71*
Planned elective/ scheduled	–0.70	–2.21 to 0.81		–2.82	–10.98 to 5.33	
Unplanned	–0.25	–1.45 to 0.95		–0.11	–4.00 to 3.78	
ICNARC physiology score (per point)	0.16	0.09 to 0.24	< 0.001	0.17	0.00 to 0.34	0.050
ICU length of stay (per day)	–0.02	–0.07 to 0.04	0.43	–0.29	–0.45 to –0.14	< 0.001
Advanced respiratory support	2.93	1.77 to 4.08	< 0.001	Not included		

TABLE 51 Alternative multilevel multivariable models for the overall family satisfaction score using relationship to patient (*continued*)

	Family members of ICU survivors ($n = 6143^a$)			Family members of ICU non-survivors ($n = 869^a$)		
Variable	**Coefficient**	**95% CI**	***p*-value**	**Coefficient**	**95% CI**	***p*-value**
Fixed effects: ICU/hospital level						
Hospital type (vs. non-university)			*0.49*			*0.56*
University	0.86	–3.59 to 5.30		–1.25	–7.31 to 4.80	
University affiliated	1.96	–1.26 to 5.18		1.85	–2.50 to 6.20	
Number of ICU beds (per bed)	–0.00	–0.23 to 0.23	0.99	0.28	–0.07 to 0.62	0.11
Random effects, SD (SE)						
Between ICUs	2.90 (0.60)			2.86 (1.11)		
Within ICUs between patients	10.96 (0.29)			11.18 (0.69)		
Within patients between family members	12.00 (0.21)			12.23 (0.44)		
Variance partition (%)						
Between ICUs	3			3		
Between patients	44			44		

CI, confidence interval; SE, standard error.

a Five patients were missing age group on both the questionnaire and the web portal; because of the very small amount of missing data in this key variable, these missing values were not imputed.

TABLE 52 Multilevel multivariable models for the *satisfaction with care* domain score

	Family members of ICU survivors ($n = 6143^a$)			Family members of ICU non-survivors ($n = 869^a$)		
Variable	**Coefficient**	**95% CI**	***p*-value**	**Coefficient**	**95% CI**	***p*-value**
Fixed effects: family member level						
Constant	71.45	66.67 to 76.22	< 0.001	55.29	41.76 to 68.82	< 0.001
Family member age (years) (vs. < 30)			*0.001*			*0.16*
30–39	2.60	0.81 to 4.38		2.50	–1.97 to 6.97	
40–49	2.73	1.16 to 4.31		4.31	0.09 to 8.54	
50–59	2.91	1.36 to 4.44		4.99	0.93 to 9.04	
60–69	2.67	1.08 to 4.26		4.89	0.54 to 9.23	
70–79	2.66	0.90 to 4.41		5.91	0.88 to 10.94	
≥ 80	–0.17	–2.76 to 2.41		1.85	–4.51 to 8.21	
Family member sex: female (vs. male)	0.42	–0.35 to 1.20	0.29	0.22	–1.81 to 2.25	0.83
Family member ethnicity: white (vs. non-white)	3.87	1.77 to 5.97	< 0.001	6.99	0.19 to 13.81	0.044

continued

TABLE 52 Multilevel multivariable models for the *satisfaction with care* domain score (*continued*)

	Family members of ICU survivors ($n = 6143^a$)			Family members of ICU non-survivors ($n = 869^a$)		
Variable	**Coefficient**	**95% CI**	***p*-value**	**Coefficient**	**95% CI**	***p*-value**
Next of kin/lives with patient (vs. lives with patient)			*< 0.001*			*0.15*
Next of kin, does not live with patient	–1.14	–2.26 to –0.02		0.95	–2.39 to 4.29	
Not next of kin, does not live with patient	–2.44	–3.32 to –1.55		–1.58	–4.11 to 0.94	
Frequent visitor	2.49	1.52 to 3.46	< 0.001	1.49	–1.27 to 4.25	0.29
Fixed effects: patient level						
Patient age (per 10 years)	0.03	–0.25 to 0.31	0.83	1.21	0.16 to 2.26	0.024
Patient sex: female (vs. male)	0.06	–0.85 to 0.98	0.87	1.85	–0.79 to 4.5	0.17
Dependency (vs. none)			*0.006*			*0.68*
Minor or major	–0.74	–1.96 to 0.46		–0.94	–3.98 to 2.09	
Total	–6.77	–11.18 to –2.36		3.62	–8.71 to 15.95	
Surgical status (vs. non-surgical)			*0.68*			*0.47*
Planned elective/ scheduled	–0.62	–2.04 to 0.78		–4.85	–12.71 to 2.99	
Unplanned	–0.15	–1.27 to 0.95		–0.57	–4.29 to 3.13	
ICNARC physiology score (per point)	0.14	0.07 to 0.21	< 0.001	0.14	–0.03 to 0.30	0.10
ICU length of stay (per day)	–0.02	–0.06 to 0.02	0.39	–0.30	–0.45 to –0.15	< 0.001
Advanced respiratory support	2.74	1.66 to 3.82	< 0.001	Not included		
Fixed effects: ICU/hospital level						
Hospital type (vs. non-university)			*0.51*			*0.58*
University	0.94	–3.58 to 5.47		–1.48	–7.8 to 4.84	
University affiliated	1.92	–1.34 to 5.19		1.79	–2.75 to 6.34	
Number of ICU beds (per bed)	–0.01	–0.24 to 0.23	0.96	0.24	–0.12 to 0.59	0.19
Random effects, SD (SE)						
Between ICUs	2.98 (0.60)			3.25 (1.11)		
Within ICUs between patients	9.76 (0.28)			10.47 (0.66)		
Within patients between family members	11.96 (0.19)			11.92 (0.42)		

CI, confidence interval; SE, standard error.

a Five patients were missing age group on both the questionnaire and the web portal; because of the very small amount of missing data in this key variable, these missing values were not imputed.

TABLE 53 Multilevel multivariable models for the *satisfaction with decision-making* domain score

Variable	Family members of ICU survivors ($n = 6143^a$) Coefficient	95% CI	*p*-value	Family members of ICU non-survivors ($n = 869^a$) Coefficient	95% CI	*p*-value
Fixed effects: family member level						
Constant	64.11	58.43 to 69.77	< 0.001	49.89	33.97 to 65.82	< 0.001
Family member age (years) (vs. < 30)			*0.19*			*0.21*
30–39	0.91	–1.46 to 3.28		1.26	–4.36 to 6.9	
40–49	0.06	–2.01 to 2.13		2.07	–3.2 to 7.35	
50–59	0.56	–1.46 to 2.60		2.97	–2.11 to 8.06	
60–69	–0.58	–2.71 to 1.54		3.69	–1.75 to 9.15	
70–79	–0.61	–2.97 to 1.73		6.08	–0.26 to 12.42	
≥ 80	–3.11	–6.60 to 0.36		–2.77	–10.83 to 5.29	
Family member sex: female (vs. male)	0.12	–0.87 to 1.12	0.81	1.22	–1.33 to 3.79	0.35
Family member ethnicity: white (vs. non-white)	3.13	0.37 to 5.88	0.026	8.01	–0.54 to 16.55	0.066
Next of kin/lives with patient (vs. lives with patient)			*< 0.001*			*0.51*
Next of kin, does not live with patient	–1.8	–3.31 to 0.31		1.45	–2.71 to 5.62	
Not next of kin, does not live with patient	–2.19	–3.38 to 1.01		–0.63	–3.85 to 2.59	
Frequent visitor	3.38	2.06 to 4.69	< 0.001	1.74	–1.7 to 5.19	0.32
Fixed effects: patient level						
Patient age (per 10 years)	–0.02	–0.39 to 0.35	0.92	1.43	0.13 to 2.73	0.031
Patient sex: female (vs. male)	0.50	–0.74 to 1.74	0.43	1.72	–1.57 to 5.01	0.31
Dependency (vs. none)			*0.80*			*0.60*
Minor or major	0.28	–1.34 to 1.92		0.98	–2.67 to 4.65	
Total	–1.62	–7.51 to 4.26		7.18	–8.71 to 23.07	
Surgical status (vs. non-surgical)			*0.63*			*0.97*
Planned elective/ scheduled	–0.91	–2.81 to 0.98		–1.08	–10.71 to 8.53	
Unplanned	–0.39	–1.92 to 1.13		0.07	–4.51 to 4.67	
ICNARC physiology score (per point)	0.19	0.09 to 0.28	< 0.001	0.17	–0.03 to 0.37	0.096
ICU length of stay (per day)	–0.02	–0.08 to 0.04	0.59	–0.33	–0.51 to –0.14	< 0.001
Advanced respiratory support	3.23	1.77 to 4.69	< 0.001	Not included		

continued

TABLE 53 Multilevel multivariable models for the *satisfaction with decision-making* domain score (*continued*)

	Family members of ICU survivors (*n* = 6143[a])			Family members of ICU non-survivors (*n* = 869[a])		
Variable	**Coefficient**	**95% CI**	***p*-value**	**Coefficient**	**95% CI**	***p*-value**
Fixed effects: ICU/hospital level						
Hospital type (vs. non-university)			*0.49*			*0.72*
University	0.80	–3.83 to 5.43		–1.61	–8.17 to 4.96	
University affiliated	2.06	–1.29 to 5.43		1.20	–3.51 to 5.90	
Number of ICU beds (per bed)	–0.01	–0.25 to 0.24	0.96	0.32	–0.05 to 0.69	0.097
Random effects, SD (SE)						
Between ICUs	2.92 (0.65)			2.74 (1.26)		
Within ICUs between patients	13.75 (0.36)			12.92 (0.87)		
Within patients between family members	14.61 (0.30)			14.90 (0.55)		

CI, confidence interval; SE, standard error.

a Five patients were missing age group on both the questionnaire and the web portal; because of the very small amount of missing data in this key variable, these missing values were not imputed.

TABLE 54 Multilevel multivariable models for the *satisfaction with information* domain score

	Family members of ICU survivors (*n* = 6143[a])			Family members of ICU non-survivors (*n* = 869[a])		
Variable	**Coefficient**	**95% CI**	***p*-value**	**Coefficient**	**95% CI**	***p*-value**
Fixed effects: family member level						
Constant	66.07	59.78 to 72.21	< 0.001	55.86	39.34 to 72.38	< 0.001
Family member age (years) (vs. < 30)			*0.63*			*0.28*
30–39	0.28	–2.22 to 2.79		1.23	–4.92 to 7.39	
40–49	0.00	–2.21 to 2.21		1.88	–3.92 to 7.68	
50–59	0.55	–1.62 to 2.72		2.88	–2.70 to 8.48	
60–69	–0.1	–2.35 to 2.14		4.24	–1.71 to 10.2	
70–79	–0.41	–2.89 to 2.08		6.43	–0.45 to 13.31	
≥ 80	–2.67	–6.35 to 1.01		–1.96	–10.71 to 6.79	
Family member sex: female (vs. male)	0.20	–0.89 to 1.30	0.72	1.01	–1.81 to 3.82	0.49
Family member ethnicity: white (vs. non-white)	4.73	1.78 to 7.68	0.002	9.34	0.47 to 18.21	0.039
Next of kin/lives with patient (vs. lives with patient)			*< 0.001*			*0.38*
Next of kin, does not live with patient	–2.39	–3.97 to 0.81		1.43	–3.09 to 5.95	
Not next of kin, does not live with patient	–2.57	–3.83 to 1.31		–1.21	–4.69 to 2.28	
Frequent visitor	2.11	0.74 to 3.48	0.002	0.44	–3.33 to 4.22	0.82

TABLE 54 Multilevel multivariable models for the *satisfaction with information* domain score (*continued*)

	Family members of ICU survivors ($n = 6143^a$)			Family members of ICU non-survivors ($n = 869^a$)		
Variable	**Coefficient**	**95% CI**	***p*-value**	**Coefficient**	**95% CI**	***p*-value**
Fixed effects: patient level						
Patient age (per 10 years)	–0.22	–0.61 to 0.18	0.28	0.92	–0.43 to 2.27	0.18
Patient sex: female (vs. male)	0.32	–0.98 to 1.62	0.63	1.93	–1.48 to 5.35	0.27
Dependency (vs. none)			*0.61*			*0.51*
Minor or major	–0.49	–2.2 to 1.2		–0.28	–4.11 to 3.53	
Total	–2.69	–8.92 to 3.52		9.15	–6.57 to 24.87	
Surgical status (vs. non-surgical)			*0.88*			*0.84*
Planned elective/ scheduled	–0.32	–2.32 to 1.66		–0.88	–10.97 to 9.21	
Unplanned	0.23	–1.33 to 1.80		–1.4	–6.16 to 3.36	
ICNARC physiology score (per point)	0.23	0.13 to 0.33	< 0.001	0.15	–0.04 to 0.36	0.13
ICU length of stay (per day)	–0.05	–0.11 to 0.01	0.14	–0.43	–0.62 to -0.24	< 0.001
Advanced respiratory support	3.34	1.83 to 4.85	< 0.001	Not included		
Fixed effects: ICU/hospital level						
Hospital type (vs. non-university)			*0.45*			*0.58*
University	1.69	–3.71 to 7.08		0.35	–6.42 to 7.13	
University affiliated	2.48	–1.42 to 6.40		2.53	–2.32 to 7.39	
Number of ICU beds (per bed)	–0.03	–0.31 to 0.24	0.81	0.21	–0.17 to 0.61	0.27
Random effects, SD (SE)						
Between ICUs	3.48 (0.73)			2.81 (1.37)		
Within ICUs between patients	13.64 (0.41)			12.38 (0.97)		
Within patients between family members	16.88 (0.27)			17.02 (0.60)		

CI, confidence interval; SE, standard error.

a Five patients were missing age group on both the questionnaire and the web portal; because of the very small amount of missing data in this key variable, these missing values were not imputed.

TABLE 55 Multilevel multivariable models for the *satisfaction with the decision-making process* domain score

	Family members of ICU survivors ($n = 6143^a$)			Family members of ICU non-survivors ($n = 869^a$)		
Variable	Coefficient	95% CI	*p*-value	Coefficient	95% CI	*p*-value
Fixed effects: family member level						
Constant	61.65	55.17 to 68.14	< 0.001	39.62	20.14 to 59.09	< 0.001
Family member age, years (vs. < 30)			*0.061*			*0.40*
30–39	1.66	–1.63 to 4.95		1.37	–5.35 to 8.10	
40–49	0.02	–2.76 to 2.82		2.73	–3.47 to 8.95	
50–59	0.52	–2.21 to 3.25		3.34	–2.61 to 9.31	
60–69	–1.43	–4.48 to 1.61		3.35	–3.05 to 9.77	
70–79	–1.09	–4.32 to 2.13		6.25	–1.36 to 13.88	
≥ 80	–3.87	–8.43 to 0.69		–3.13	–12.88 to 6.61	
Family member sex: female (vs. male)	–0.18	–1.42 to 1.04	0.77	1.66	–1.37 to 4.71	0.28
Family member ethnicity: white (vs. non-white)	0.81	–2.67 to 4.30	0.65	6.46	–4.24 to 17.15	0.24
Next of kin/lives with patient (vs. lives with patient)			*0.10*			*0.86*
Next of kin, does not live with patient	–0.93	–2.93 to 1.05		1.39	–3.49 to 6.28	
Not next of kin, does not live with patient	–1.65	–3.22 to 0.07		0.48	–3.49 to 4.46	
Frequent visitor	5.31	3.38 to 7.23	< 0.001	3.84	–0.21 to 7.91	0.063
Fixed effects: patient level						
Patient age (per 10 years)	0.26	–0.20 to 0.73	0.27	2.19	0.61 to 3.78	0.007
Patient sex: female (vs. male)	0.79	–0.84 to 2.43	0.34	1.29	–2.67 to 5.26	0.52
Dependency (vs. none)			*0.44*			*0.47*
Minor or major	1.34	–0.74 to 3.43		2.91	–1.48 to 7.29	
Total	0.11	–7.42 to 7.64		4.27	–17.36 to 25.91	
Surgical status (vs. non-surgical)			*0.25*			*0.68*
Planned elective/ scheduled	–1.83	–4.35 to 0.68		–1.09	–12.59 to 10.41	
Unplanned	–1.35	–3.41 to 0.71		2.35	–3.20 to 7.91	
ICNARC physiology score (per point)	0.12	0.01 to 0.24	0.040	0.19	–0.04 to 0.44	0.12
ICU length of stay (per day)	0.03	–0.04 to 0.11	0.39	–0.17	–0.39 to 0.03	0.11
Advanced respiratory support	3.03	1.08 to 4.97	0.002	Not included		

TABLE 55 Multilevel multivariable models for the *satisfaction with the decision-making process* domain score (*continued*)

	Family members of ICU survivors ($n = 6143^a$)			Family members of ICU non-survivors ($n = 869^a$)		
Variable	**Coefficient**	**95% CI**	***p*-value**	**Coefficient**	**95% CI**	***p*-value**
Fixed effects: ICU/hospital level						
Hospital type (vs. non-university)			*0.50*			*0.55*
University	–0.41	–4.27 to 3.46		–4.44	–12.41 to 3.53	
University affiliated	1.51	–1.37 to 4.39		–0.86	–6.56 to 4.83	
Number of ICU beds (per bed)	0.02	–0.19 to 0.23	0.85	0.47	0.02 to 0.93	0.042
Random effects, SD (SE)						
Between ICUs	2.06 (0.66)			3.33 (1.50)		
Within ICUs between patients	17.24 (0.50)			15.84 (1.06)		
Within patients between family members	17.02 (0.40)			16.81 (0.66)		

CI, confidence interval; SE, standard error.

[a] Five patients were missing age group on both the questionnaire and the web portal; because of the very small amount of missing data in this key variable, these missing values were not imputed.

Sensitivity analyses

Sensitivity analyses showed that, in general, the direction and order of magnitude of coefficients that were significant in the models estimated using imputed data were similar to those estimated using either the traditional approach to scoring or complete case data (*Tables 56* and *57*). However, the material loss of power led to some coefficients being estimated as non-significant in the complete case analyses. The models using data from all family members, including imputed satisfaction scores for non-responders, gave similar results to the primary models, which may be expected because the non-responders provide no additional information regarding the association between characteristics and satisfaction.

TABLE 56 Sensitivity analyses: alternative approaches to handling missing data (family members of ICU survivors)

	Complete case ($n = 2351$)			Traditional approach ($n = 5756$)			All family members ($n = 10,353$)		
Variable	Coefficient	SE	*p*-value	Coefficient	SE	*p*-value	Coefficient	SE	*p*-value
Fixed effects: family member level									
Constant	72.60	3.18	< 0.001	70.35	2.49	< 0.001	69.08	2.39	< 0.001
Family member age (years) (vs. < 30)									
30–39	0.13	1.40	0.61	1.47	0.97	0.20	0.95	0.48	0.24
40–49	0.85	1.22		1.41	0.86		0.21	0.15	
50–59	0.66	1.20		1.58	0.84		0.75	0.44	
60–69	0.65	1.30		1.47	0.88		0.50	0.48	
70–79	0.77	1.47		1.69	0.98		0.31	0.55	
≥ 80	–3.06	2.26		–1.22	1.50		–0.73	0.90	
Family member sex: female (vs. male)	0.94	0.60	0.12	0.21	0.43	0.63	0.57	0.30	0.066
Family member ethnicity: white (vs. non-white)	7.58	1.58	< 0.001	3.99	1.16	0.001	4.89	0.90	< 0.001
Next of kin/lives with patient (vs. lives with patient)									
Next of kin, does not live with patient	–1.69	0.85	0.071	–1.36	0.61	0.002	–1.19	0.43	< 0.001
Not next of kin, does not live with patient	–1.42	0.72		–1.70	0.50		–2.16	0.31	
Frequent visitor	1.18	0.82	0.15	2.21	0.55	< 0.001	1.64	0.34	< 0.001
Fixed effects: patient level									
Patient age (per 10 years)	–0.09	0.22	0.67	–0.07	0.15	0.64	0.01	0.15	0.91
Patient sex: female (vs. male)	–1.20	0.73	0.10	0.13	0.52	0.79	0.46	0.45	0.31
Dependency (vs. none)									
Minor or major	–0.44	0.92	0.70	–0.19	0.68	0.45	0.20	0.66	0.21
Total	–2.19	2.98		–3.14	2.51		–3.88	2.31	
Surgical status (vs. non-surgical)									
Planned elective/ scheduled	–3.11	1.30	0.056	–0.93	0.80	0.47	–1.11	0.87	0.39
Unplanned	–0.44	0.88		0.02	0.62		–0.19	0.60	
ICNARC physiology score (per point)	0.08	0.05	0.14	0.15	0.04	< 0.001	0.18	0.04	< 0.001
ICU length of stay (per day)	–0.04	0.03	0.28	–0.04	0.03	0.17	–0.06	0.02	0.025
Advanced respiratory support	1.39	0.87	0.11	2.40	0.60	< 0.001	2.35	0.54	< 0.001
Fixed effects: ICU/hospital level *Hospital type (vs. non-university)*									
University	0.56	2.36	0.42	1.45	2.22	0.34	0.90	2.46	0.68
University affiliated	2.24	1.72		2.34	1.61		1.54	1.75	
Number of ICU beds (per bed)	0.07	0.12	0.59	–0.02	0.11	0.83	0.02	0.13	0.87

SE, standard error.

TABLE 57 Sensitivity analyses: alternative approaches to handling missing data (family members of ICU non-survivors)

	Complete case ($n = 547$)			Traditional approach ($n = 851$)			All family members ($n = 1444$)		
Variable	Coefficient	SE	*p*-value	Coefficient	SE	*p*-value	Coefficient	SE	*p*-value
Fixed effects: family member level									
Constant	54.46	7.72	< 0.001	56.28	6.80	< 0.001	63.30	5.74	< 0.001)
Family member age (years) (vs. < 30)									
30–39	4.38	3.01	0.17	3.14	2.44	0.086	1.12	1.35	0.38
40–49	7.51	2.75		4.87	2.31		0.54	0.42	
50–59	6.19	2.62		4.50	2.22		1.80	1.27	
60–69	7.41	2.85		5.94	2.37		1.31	1.43	
70–79	6.99	3.69		7.07	2.82		2.42	1.65	
≥ 80	7.52	4.41		0.32	3.61		–1.73	2.04	
Family member sex: female (vs. male)	–0.02	1.43	0.99	0.40	1.11	0.72	0.26	0.63	0.68
Family member ethnicity: white (vs. non-white)	9.64	4.21	0.022	7.47	3.58	0.037	5.19	2.73	0.062
Next of kin/lives with patient (vs. lives with patient)									
Next of kin, does not live with patient	0.13	2.20	0.97	1.27	1.82	0.38	0.27	1.17	0.010
Not next of kin, does not live with patient	–0.32	1.81		–0.82	1.40		–1.99	0.82	
Frequent visitor	1.32	1.96	0.50	0.99	1.51	0.51	1.25	0.93	0.18
Fixed effects: patient level									
Patient age (per 10 years)	0.69	0.66	0.29	1.09	0.55	0.048	0.87	0.50	0.088
Patient sex: female (vs. male)	1.56	1.69	0.36	2.02	1.41	0.15	2.24	1.20	0.063
Dependency (vs. none)									
Minor or major	–0.61	1.86	0.47	–0.32	1.58	0.66	0.13	1.42	0.78
Total	8.53	7.42		5.59	6.45		4.36	5.99	
Surgical status (vs. non-surgical)									
Planned elective/ scheduled	–0.33	5.61	0.84	–4.86	4.22	0.51	–3.21	3.73	0.71
Unplanned	–1.38	2.33		–0.44	1.95		0.11	1.81	
ICNARC physiology score (per point)	0.24	0.10	0.022	0.18	0.09	0.041	0.18	0.08	0.020
ICU length of stay (per day)	–0.27	0.09	0.003	–0.33	0.08	< 0.001	–0.23	0.06	< 0.001
Fixed effects: ICU/hospital level									
Hospital type (vs. non-university)									
University	–1.15	3.20	0.83	–0.11	3.01	0.77	–0.56	2.66	0.59
University affiliated	0.84	2.29		1.49	2.17		1.78	2.00	
Number of ICU beds (per bed)	0.25	0.19	0.17	0.21	0.17	0.23	0.18	0.15	0.24

SE, standard error.

Discussion

For family members of ICU survivors, the factors associated with overall family satisfaction were family member age; ethnicity; whether or not the family member was the patient's next of kin and/or lived with the patient (or, in an alternative model specification, the relationship to the patient); whether or not the family member visited the patient at least once per day; the acute severity of illness of the patient; and whether or not the patient received advanced respiratory support (i.e. invasive mechanical ventilation) during their ICU stay.

For family members of ICU non-survivors, the factors associated with overall family satisfaction were the patient's age; acute severity of illness; and ICU length of stay. No family member characteristics were found to be significantly associated with satisfaction for family members of ICU non-survivors; however, the sample size for ICU non-survivors was considerably smaller than for ICU survivors, and the magnitude and direction of the model coefficients suggested that some similar associations to those seen among family members of ICU survivors may have been present. For example, the association with family member ethnicity was almost twice the magnitude for family members of ICU non-survivors as for family members of survivors but did not meet the threshold for statistical significance ($p = 0.050$). There also appeared to be a consistent association with family member age, with increasing satisfaction up to 70–79 years and a decrease thereafter, but again this was not statistically significant ($p = 0.18$). There was no association between the size or teaching status of the ICU/hospital and overall family satisfaction, and there was no evidence of seasonality in the reported levels of overall family satisfaction. Although there was significant variation in satisfaction between ICUs, this accounted for only 3% of the variation in the overall family satisfaction score among family members of ICU survivors and 2% among family members of ICU non-survivors.

A number of previous studies have reported results of regression models to assess variation in family satisfaction (assessed using the FS-ICU-24) according to family member and/or patient characteristics, either as a specific aim of the study or in presenting full results of an adjusted model to assess the impact of a particular intervention or exposure. Sample sizes in these studies were generally small (between 40 and 275 family members, with the exception of one previous study among 996 family members) and the findings are inconsistent.

Curtis *et al.*[53] (in an adjusted pre-/post-intervention analysis of a quality improvement intervention to improve palliative care) found that, among 275 family members of ICU non-survivors, increasing family member age was associated with increasing satisfaction both overall and for the *satisfaction with care* domain score, but the other factors included in the model (family member sex and patient age, sex, ethnicity and diagnoses) were not. However, in a subsequent publication using data from the same study, Lewis-Newby *et al.*[54] reported that patient age (analysed in three categories of < 35, 35–64 and ≥ 65 years) was associated with satisfaction both before and after adjustment for other patient and family member characteristics (the effects of other factors included in the adjusted model were not reported).

Stricker *et al.*[55] (in a multicentre evaluation of factors associated with family satisfaction using the German version of the FS-ICU-34 but scored using the 24 items of the FS-ICU-24) found that, among 996 family members of both ICU survivors and non-survivors in 23 ICUs, increasing acute severity of illness of the patient [evaluated using the Simplified Acute Physiology Score (SAPS) II] was associated with increasing satisfaction on the overall family satisfaction score, and lower satisfaction was associated with ICU-level characteristics of a written admission/discharge policy and a higher patient–nurse ratio. Family member characteristics of sex and relationship to the patient were included in the multivariable model but not found to be significantly associated with satisfaction. Family member age was significantly associated with the overall family satisfaction score in univariable analysis, but was not included in the multivariable model because large amounts of data were missing. Patient characteristics considered and found not to be significant were age, sex, emergency status, surgery before admission, diagnostic group, ICU length of stay and ICU outcome. ICU/hospital characteristics considered and found not to be significant were ICU type, hospital funding/teaching status, number of ICU beds, presence of an ICU waiting room, length of visiting hours, ICU information policy, provision of written information to family members and presence of an emergency department in the hospital. In a model for the *satisfaction with care* domain score, family members who were children of the patient had lower satisfaction than other relationship categories, and patients who were admitted with a gastroenterology diagnosis had lower satisfaction; the acute severity of the illness of the patient was not significant, and the only significant ICU/hospital characteristic was the patient–nurse ratio. In a model for the *satisfaction with decision-making* domain score, the only significant characteristics were the acute severity of illness of the patient and the patient–nurse ratio.

Garland *et al.*[56] (in an adjusted analysis of a pilot study comparing different ICU staffing patterns) found that, among 119 family members of both ICU survivors and non-survivors, parents had significantly lower satisfaction than spouses, but there were no significant differences according to the family member's age, sex or other categories of relationship to the patient, or between family members of ICU survivors and non-survivors.

Dalisay-Gallardo and Perez[38] (in a single-centre evaluation of satisfaction with end-of-life care using the Filipino version of the FS-ICU-24) found that, among 40 family members of ICU non-survivors, increasing closeness of relationship (spouses vs. children vs. siblings or other relatives) was associated with decreasing odds of satisfaction (defined as a score of ≥ 75) on the *satisfaction with decision-making* domain, but there was no association with family member age, sex, living with the patient or area of residence, and there was no association of any family member characteristics with the overall family satisfaction score or the *satisfaction with care* domain score.[38] In a separate model investigating patient factors, a diagnosis of stroke or pneumonia was associated with higher odds of satisfaction on the *satisfaction with decision-making* domain, but patient age, sex, 'do not resuscitate' status and ICU length of stay were not associated with satisfaction, and no patient factors were associated with the overall family satisfaction score or the *satisfaction with care* domain score.

Schwarzkopf *et al.*[39] (in a multicentre evaluation of family satisfaction using the German version of the FS-ICU-24) found no factors significantly associated with the overall family satisfaction score among 215 family members of both ICU survivors and non-survivors. The factors considered were family member age, sex, relationship to patient and number of visits per week, and patient age, sex, median Sequential Organ Failure Assessment Score, median SAPS II, admission type, development of severe sepsis, ICU length of stay and ICU mortality.

Khalaila[57] (in an adjusted analysis of the impact of unmet needs on family satisfaction using the Hebrew version of the FS-ICU-24) found that, among 70 family members of both ICU survivors and non-survivors, in addition to items from the Critical Care Family Needs Inventory, increasing years of education were associated with decreasing satisfaction, overall and on the *satisfaction with care* domain score, but not on the *satisfaction with decision-making* domain score. The family member's age, sex, employment status, marital status and relationship to the patient (parent/sibling/spouse versus others) were not associated with satisfaction, either overall or on the two domain scores.

Finally, Geramisou-Angelidi *et al.*[41] (in an adjusted analysis of the impact of nursing activities on family satisfaction using the Greek version of the FS-ICU-24) found that, among 106 family members of both ICU survivors and non-survivors, increasing nursing activities (assessed using the Nursing Activities Score) were associated with higher odds of satisfaction (defined as a score of ≥ 83 – the median in the cohort) on the overall family satisfaction score. There was no association between satisfaction and the patient's age, SAPS II or ICU length of stay. Family member characteristics were not included in the model.

It is of note that one of the largest-magnitude associations in the FREE study was the finding that white family members of both ICU survivors and non-survivors had higher satisfaction, on average, than those of other ethnicities. Further investigation of this issue is warranted to understand whether this reflects, for example, either cultural variation in family members' expectations or a need to engage better and communicate with family members who may not have English as their first language (17% of family members of non-white ethnicity indicated that their first language was not English, compared with fewer than 1% of those of white ethnicity).

Chapter 8 Variation in family satisfaction across intensive care units before and after adjustment for family member and patient characteristics

Introduction

The aim of this chapter is to explore how family satisfaction, measured with the UK FS-ICU-24, varies across ICUs, before and after adjustment for the family member and patient characteristics identified in *Chapter 7* as being associated with family satisfaction.

Methods

Selection of data

The data used for these analyses were the same as those used in *Chapter 7*.

Statistical analysis

Variation in family satisfaction across ICUs was assessed graphically using funnel plots, which plot the average family satisfaction score for each critical care unit against the number of family members returning questionnaires.[58] As sample size increases, the precision with which the average family satisfaction score can be estimated improves, so, if there were no underlying true variation in satisfaction between ICUs, the points would be expected to lie in a funnel shape, with greater variation around the overall mean at small sample sizes and less variation at large sample sizes. Control limits can be placed at 2 and 3 SDs around the overall mean to indicate the regions of the funnel within which we would expect 95% and 99.8% of points to lie if all variation were due to chance.

Funnel plots were produced based on the original responses (both using complete responders only and applying the modified traditional approach to scoring based on completion of at least 60% of items) and after multiple imputation of partial responders. Each of these approaches was applied both with and without adjustment using the multilevel multivariable models from *Chapter 7*.

Results

Figures 35–39 show the funnel plots for the overall family satisfaction score and each domain score by each alternative approach, before and after adjustment.

Table 58 summarises the number and percentage of ICUs within each funnel plot that are within the control limits ('in control'), above the upper 2-SD control limit (i.e. have higher than average satisfaction) and below the lower 2-SD control limit (i.e. have lower than average satisfaction). On average, the multiple imputation approach tended to identify larger numbers of potential outliers because the larger sample sizes led to narrower funnels. Adjusting for family member and patient characteristics reduced the variability across ICUs, resulting in fewer ICUs outside the funnel plot control limits, particularly at the upper end.

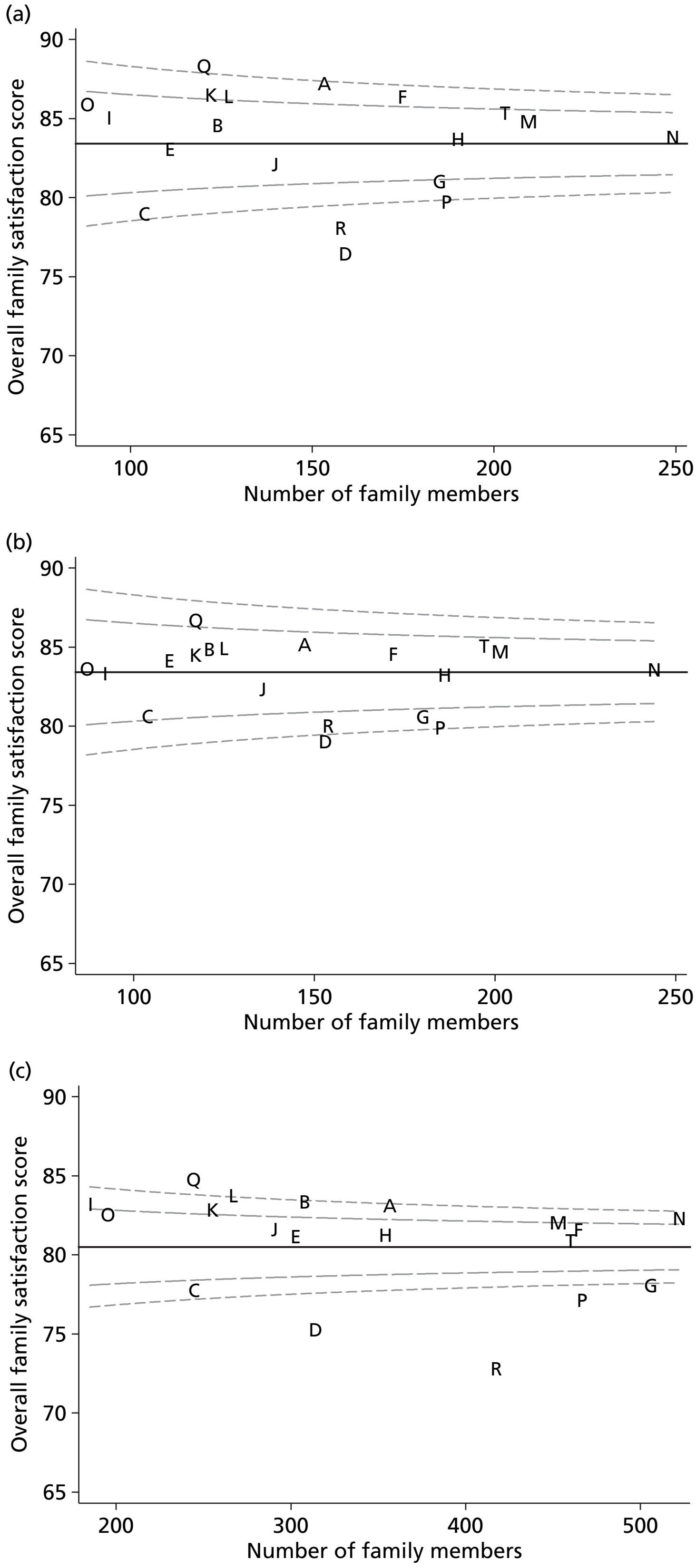

FIGURE 35 Variation across ICUs in the mean overall family satisfaction score for (a) complete responders (unadjusted); (b) complete responders (adjusted); (c) modified traditional (unadjusted); (d) modified traditional (adjusted); (e) multiple imputation (unadjusted); and (f) multiple imputation (adjusted). (*continued*)

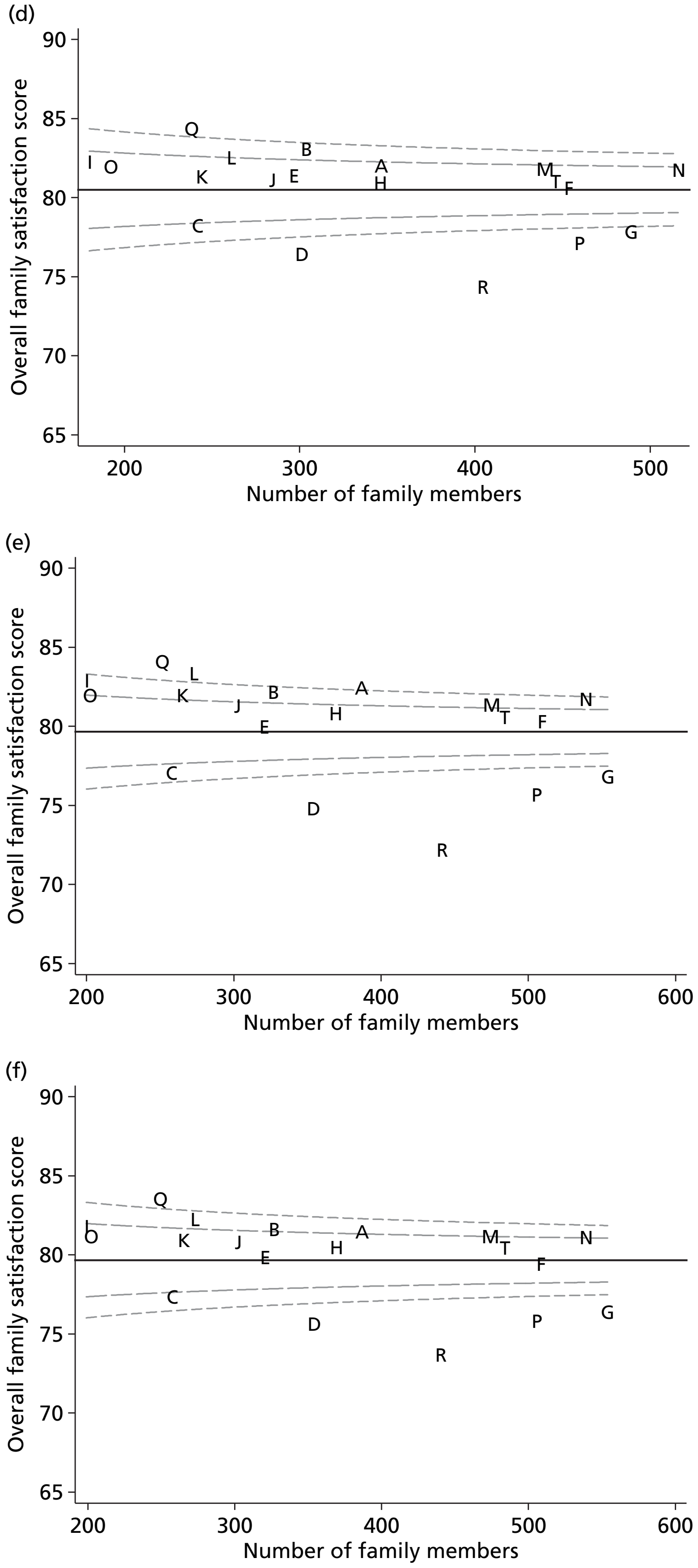

FIGURE 35 Variation across ICUs in the mean overall family satisfaction score for (a) complete responders (unadjusted); (b) complete responders (adjusted); (c) modified traditional (unadjusted); (d) modified traditional (adjusted); (e) multiple imputation (unadjusted); and (f) multiple imputation (adjusted).

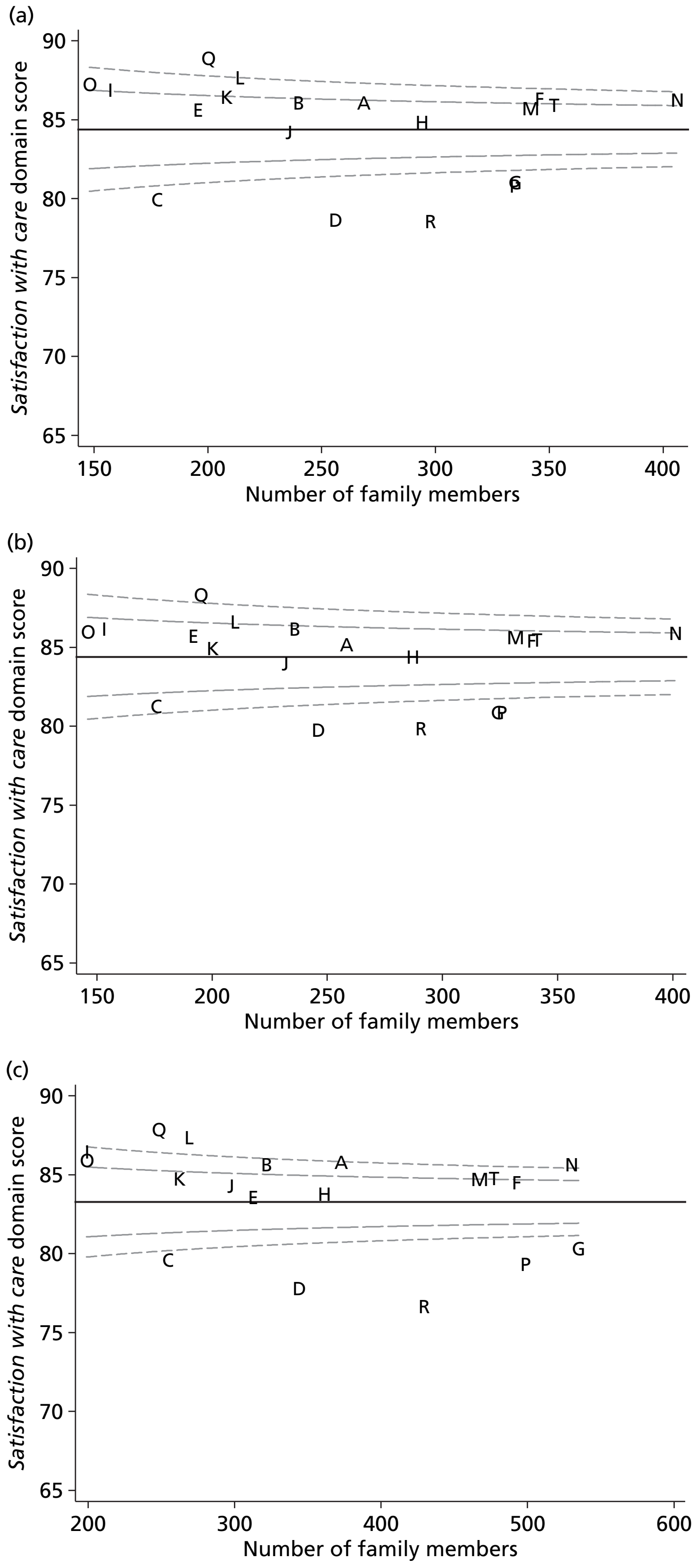

FIGURE 36 Variation across ICUs in the mean *satisfaction with care* domain score for (a) complete responders (unadjusted); (b) complete responders (adjusted); (c) modified traditional (unadjusted); (d) modified traditional (adjusted); (e) multiple imputation (unadjusted); and (f) multiple imputation (adjusted). (*continued*)

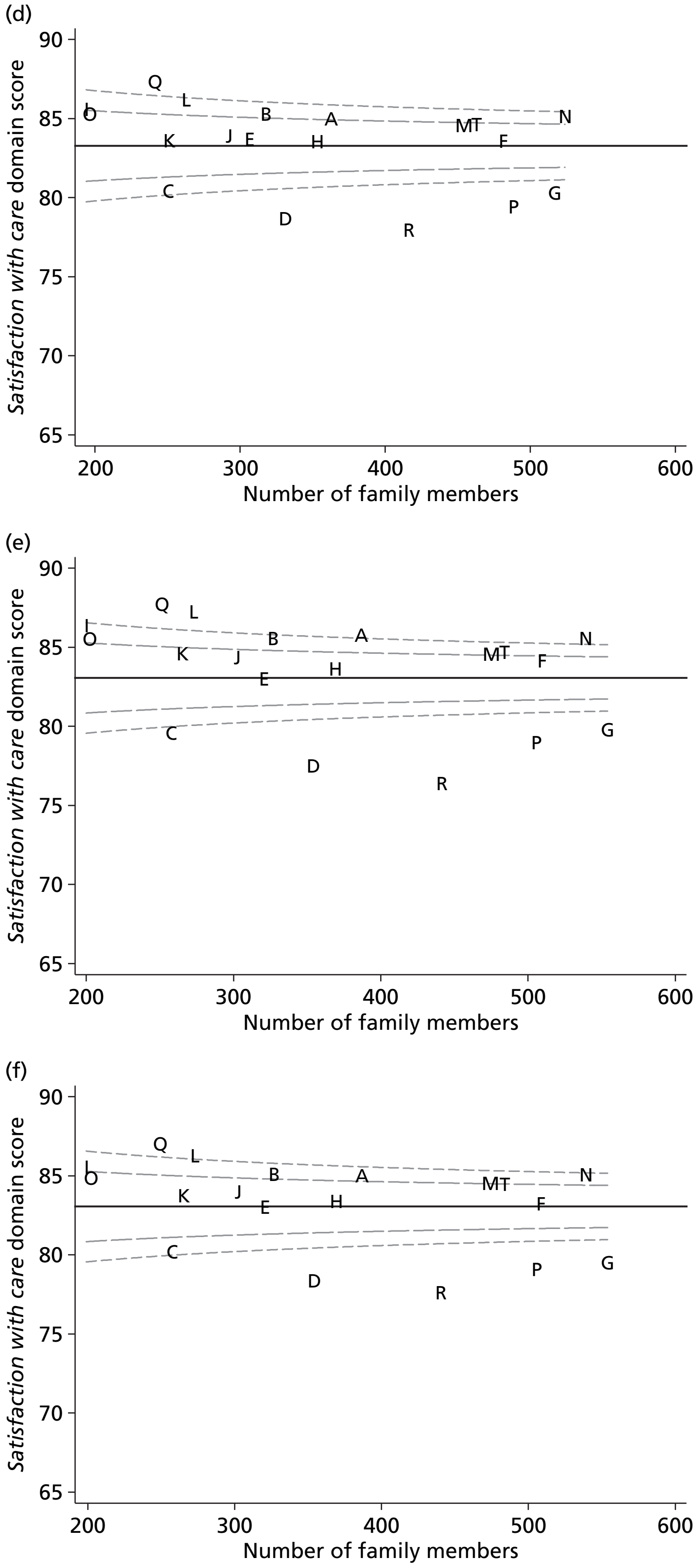

FIGURE 36 Variation across ICUs in the mean *satisfaction with care* domain score for (a) complete responders (unadjusted); (b) complete responders (adjusted); (c) modified traditional (unadjusted); (d) modified traditional (adjusted); (e) multiple imputation (unadjusted); and (f) multiple imputation (adjusted).

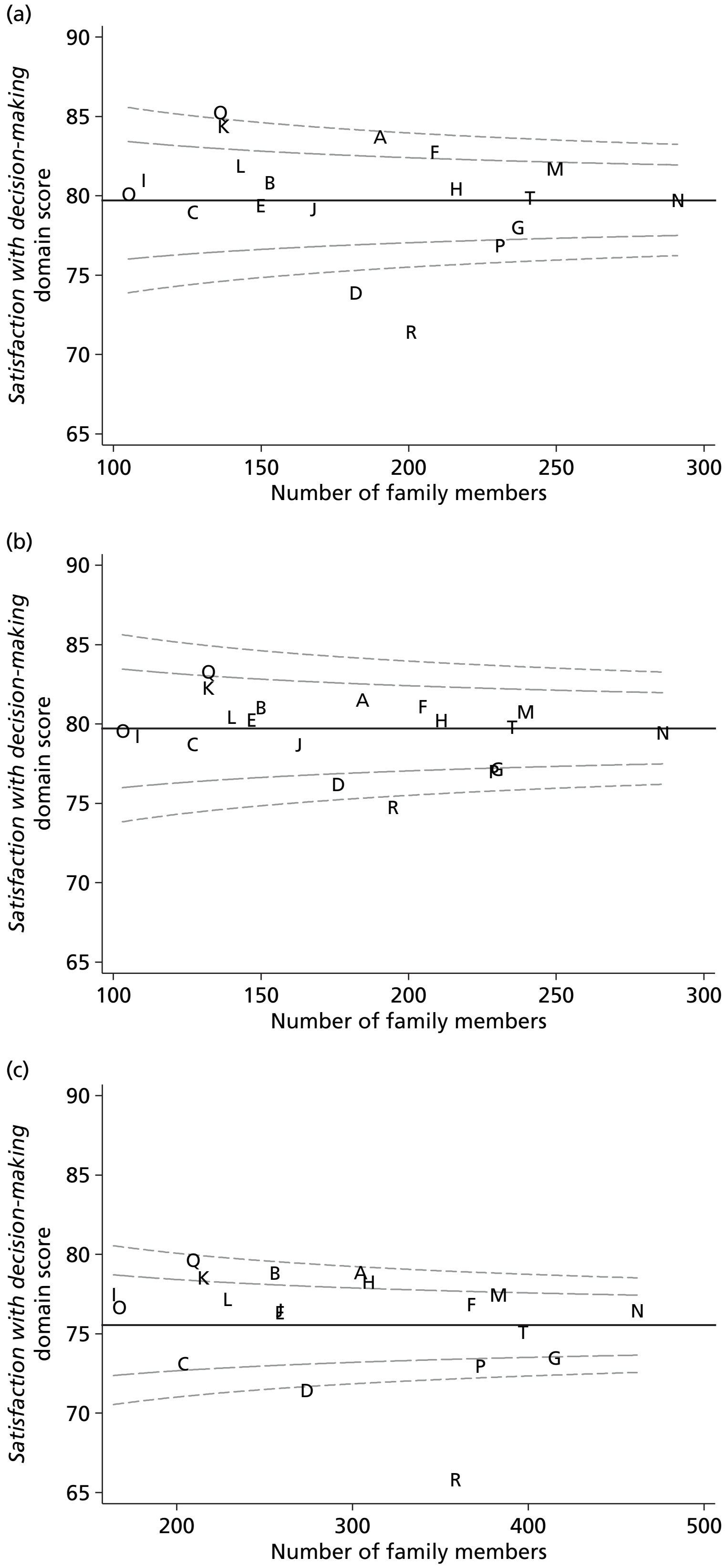

FIGURE 37 Variation across ICUs in the mean *satisfaction with decision-making* domain score for (a) complete responders (unadjusted); (b) complete responders (adjusted); (c) modified traditional (unadjusted); (d) modified traditional (adjusted); (e) multiple imputation (unadjusted); and (f) multiple imputation (adjusted). (*continued*)

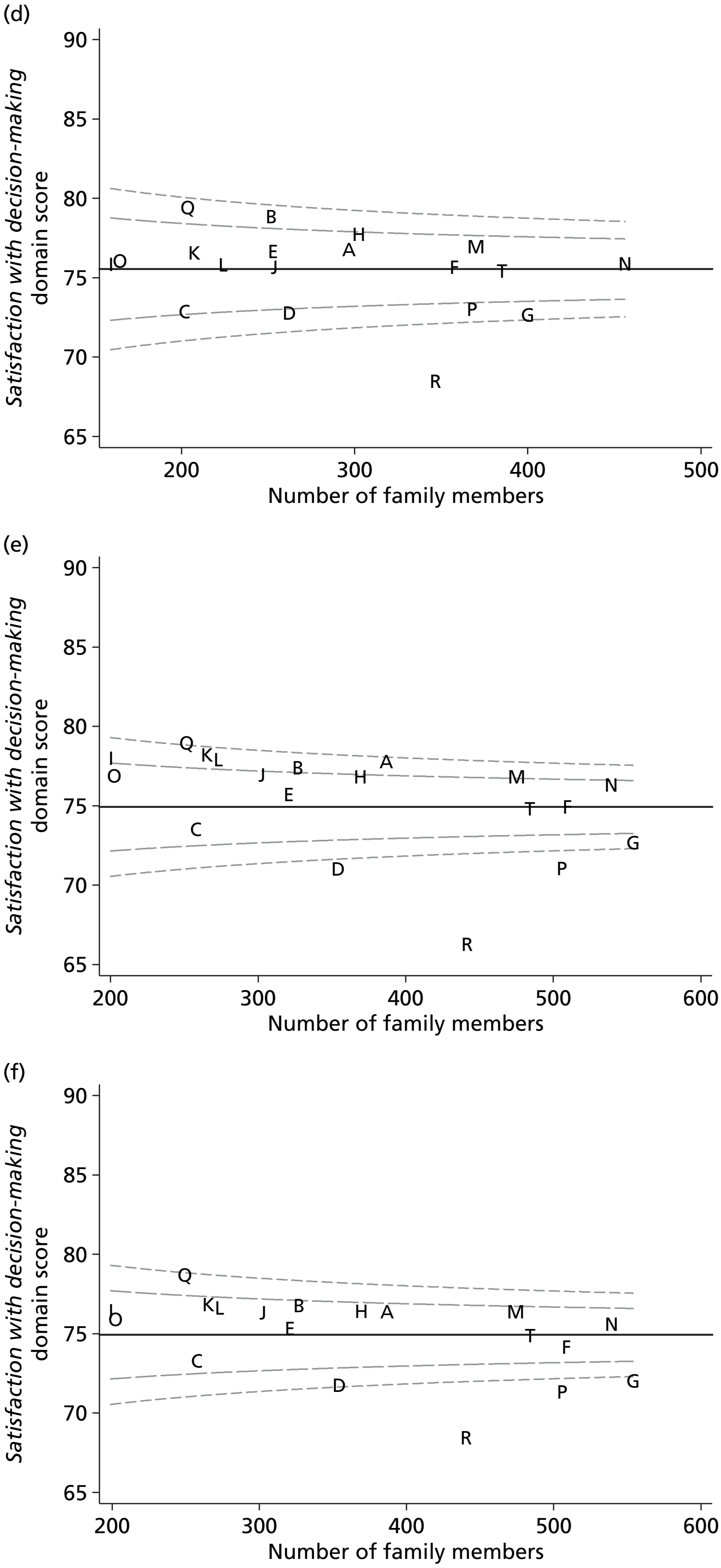

FIGURE 37 Variation across ICUs in the mean *satisfaction with decision-making* domain score for (a) complete responders (unadjusted); (b) complete responders (adjusted); (c) modified traditional (unadjusted); (d) modified traditional (adjusted); (e) multiple imputation (unadjusted); and (f) multiple imputation (adjusted).

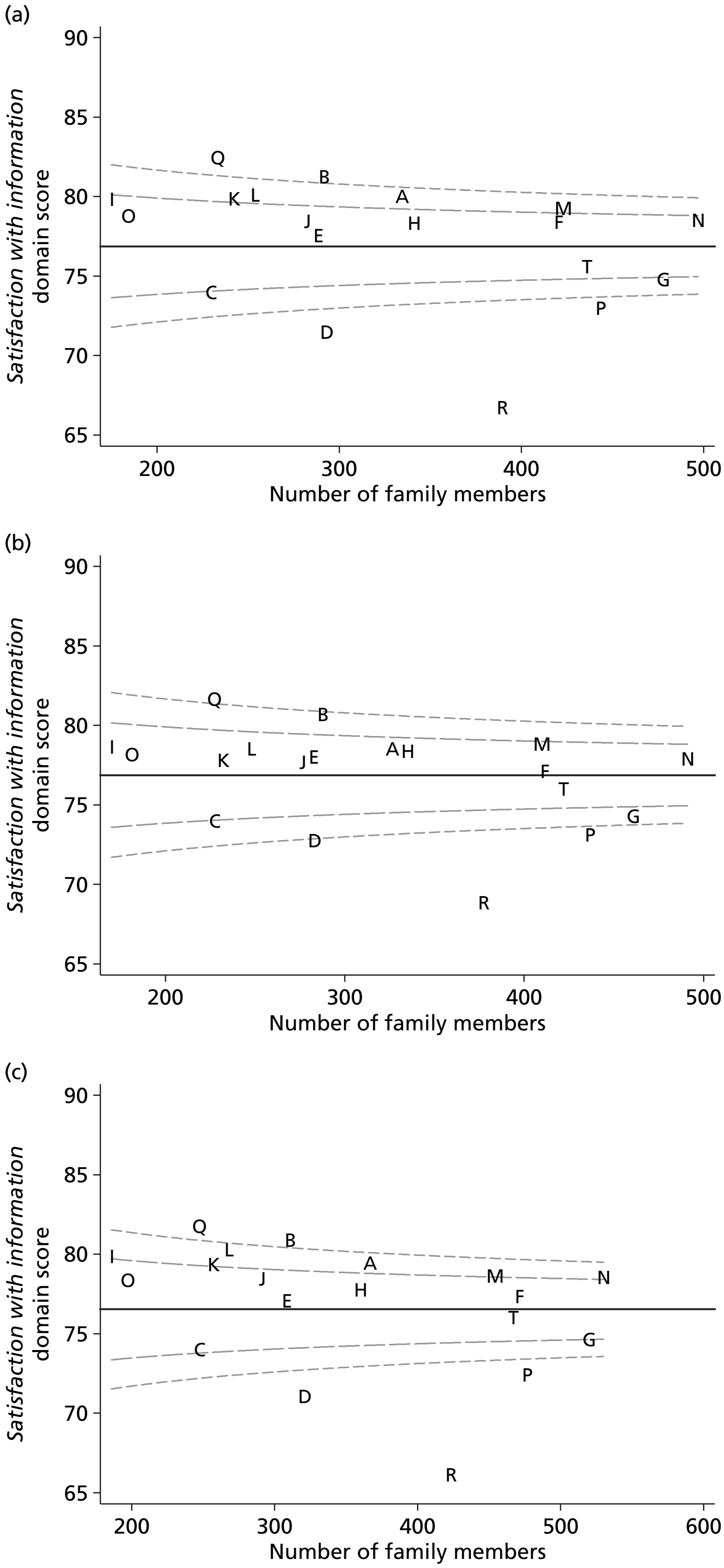

FIGURE 38 Variation across ICUs in the mean *satisfaction with information* domain score for (a) complete responders (unadjusted); (b) complete responders (adjusted); (c) modified traditional (unadjusted); (d) modified traditional (adjusted); (e) multiple imputation (unadjusted); and (f) multiple imputation (adjusted). (*continued*)

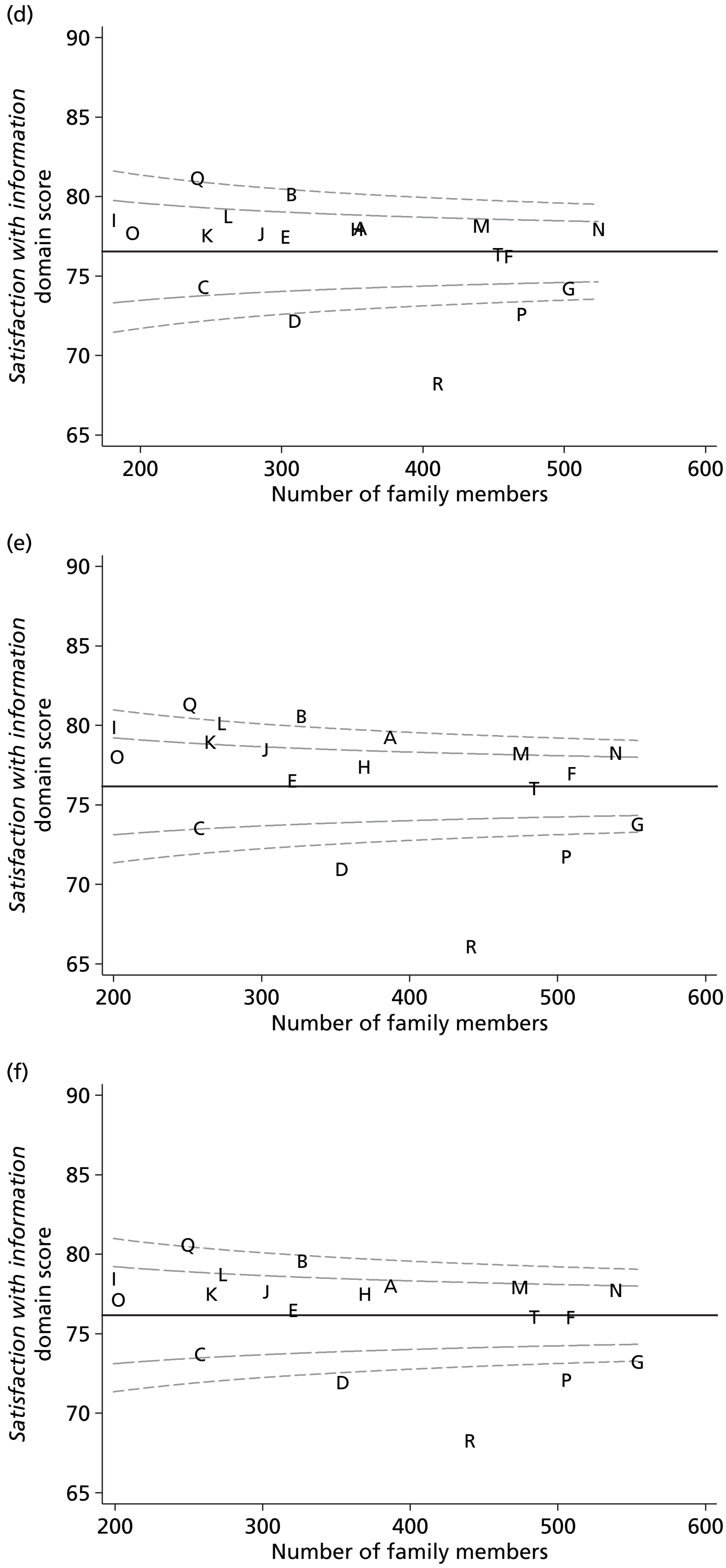

FIGURE 38 Variation across ICUs in the mean *satisfaction with information* domain score for (a) complete responders (unadjusted); (b) complete responders (adjusted); (c) modified traditional (unadjusted); (d) modified traditional (adjusted); (e) multiple imputation (unadjusted); and (f) multiple imputation (adjusted).

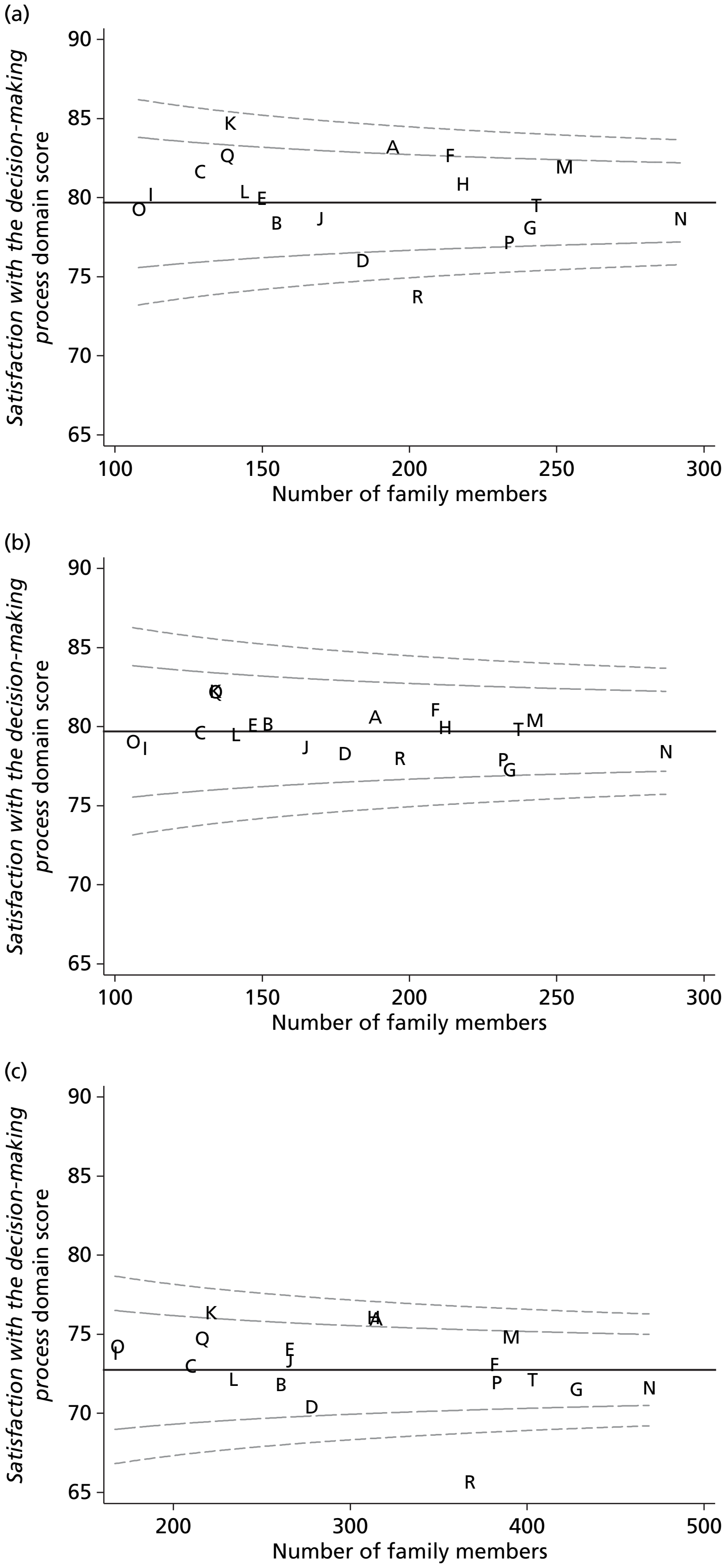

FIGURE 39 Variation across ICUs in the mean *satisfaction with the decision-making process* domain score for (a) complete responders (unadjusted); (b) complete responders (adjusted); (c) modified traditional (unadjusted); (d) modified traditional (adjusted); (e) multiple imputation (unadjusted); and (f) multiple imputation (adjusted). (*continued*)

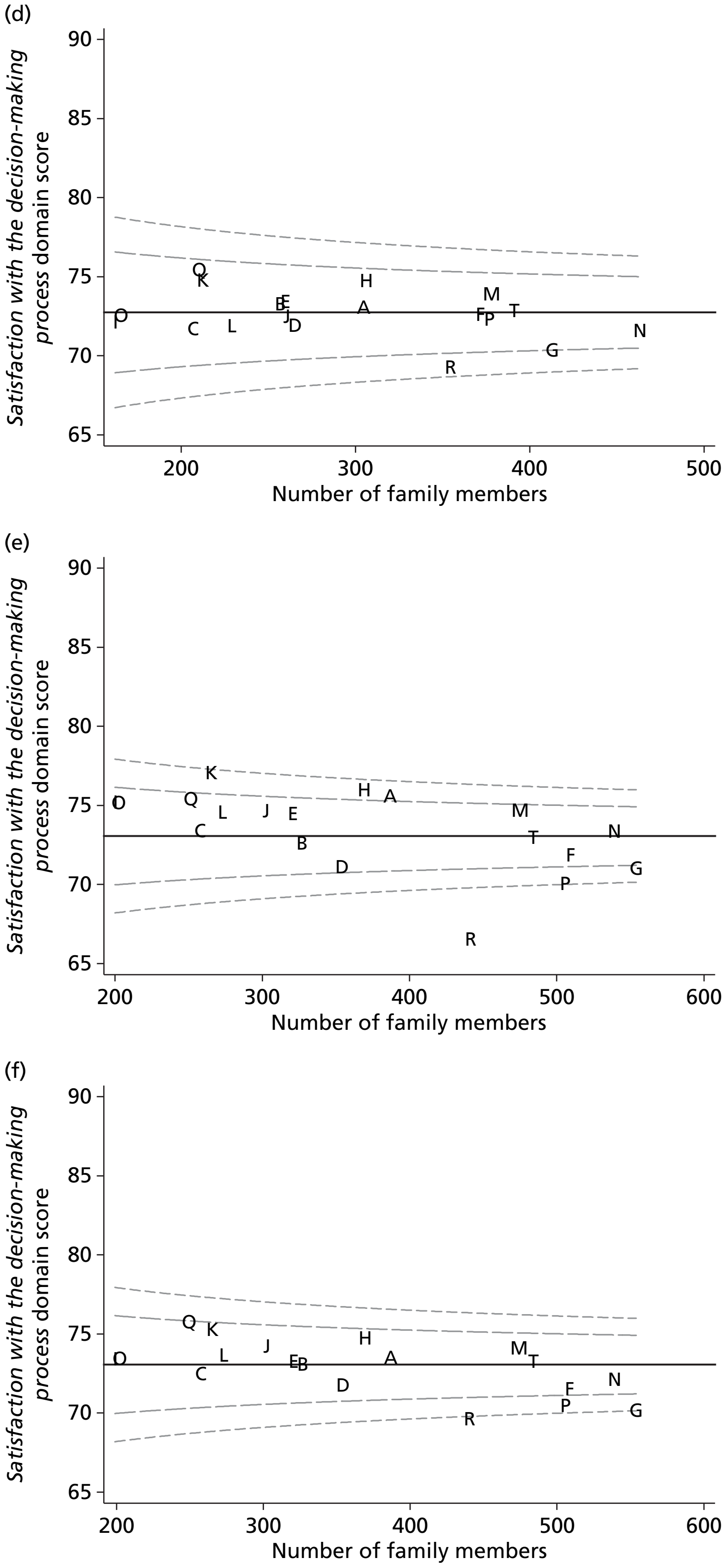

FIGURE 39 Variation across ICUs in the mean *satisfaction with the decision-making process* domain score for (a) complete responders (unadjusted); (b) complete responders (adjusted); (c) modified traditional (unadjusted); (d) modified traditional (adjusted); (e) multiple imputation (unadjusted); and (f) multiple imputation (adjusted).

TABLE 58 Summary of position of ICUs relative to the control lines for the alternative approaches to producing funnel plots, *n* (%)

	Complete responders		Modified traditional		Multiple imputation	
Position	Unadjusted	Adjusted	Unadjusted	Adjusted	Unadjusted	Adjusted
Overall family satisfaction score						
Above	5 (26)	1 (5)	7 (37)	2 (11)	9 (47)	7 (37)
In control	9 (47)	14 (74)	7 (37)	12 (63)	5 (26)	7 (37)
Below	5 (26)	4 (21)	5 (26)	5 (26)	5 (26)	5 (26)
Satisfaction with care domain score						
Above	5 (26)	2 (11)	8 (42)	4 (21)	8 (42)	6 (32)
In control	9 (47)	12 (63)	6 (32)	10 (53)	6 (32)	8 (42)
Below	5 (26)	5 (26)	5 (26)	5 (26)	5 (26)	5 (26)
Satisfaction with decision-making domain score						
Above	4 (21)	1 (5)	5 (26)	2 (11)	6 (32)	1 (5)
In control	12 (63)	14 (74)	11 (58)	13 (68)	9 (47)	14 (74)
Below	3 (16)	4 (21)	3 (16)	4 (21)	4 (21)	4 (21)
Satisfaction with information domain score						
Above	6 (32)	2 (11)	7 (37)	2 (11)	7 (37)	2 (11)
In control	8 (42)	12 (63)	8 (42)	13 (68)	8 (42)	13 (68)
Below	5 (26)	5 (26)	4 (21)	4 (21)	4 (21)	4 (21)
Satisfaction with the decision-making process domain score						
Above	3 (16)	0 (0)	3 (16)	0 (0)	3 (16)	0 (0)
In control	14 (74)	19 (100)	15 (79)	18 (95)	13 (68)	16 (84)
Below	2 (11)	0 (0)	1 (5)	1 (5)	3 (16)	3 (16)

Discussion

Funnel plots of the overall family satisfaction score and domain scores confirmed that there was significant variation in family satisfaction across the ICUs participating in the FREE study. The same ICUs tended to be identified as potential outliers, both across the alternative scores and across the alternative methods. The multiple imputation approach had greater power to identify potentially outlying ICUs due to regaining information through the imputation. Adjusting for family member and patient characteristics using the FREE study multilevel multivariable models reduced the variation across ICUs and resulted in fewer ICUs being identified as potential outliers. Adjustment is, therefore, important to avoid falsely identifying ICUs as outliers as a result of characteristics of the patients or their family members.

Chapter 9 Simulation study of alternative sampling frames for roll-out of family satisfaction surveys into routine practice in the NHS

Introduction

The aim of this chapter is to evaluate, through simulations based on the FREE study data set, alternative sampling frames for selecting family members to survey in any future roll-out of family satisfaction surveys into routine practice in adult general intensive care in the NHS.

Methods

Selection of data

The data used for these analyses were the same as those used in *Chapter 7*.

Statistical analysis

A number of different approaches to sampling family members were defined, based on varying the duration of recruitment, the patient's ICU length of stay and which family member to recruit, and these sampling frames were applied to the FREE study data set to obtain simulated results of applying each approach in routine practice.

All sampling frames considered involved recruiting a single family member for each patient; as a significant proportion of variation was found at the patient level in the multilevel models, this is a more efficient approach. The criteria included within the sampling frames were based on the earlier findings of the FREE study: first, that family members of patients with a longer ICU length of stay were more likely to be successfully recruited and, second, that next of kin were more likely to respond than other family members. Although other family member characteristics, for example age and sex, were also associated with response rates, it would be inappropriate to target family members according to these characteristics.

The sampling frames (*Table 59*) consisted of each combination of the following: a duration of recruitment of either 4 weeks or 6 weeks (based on the date of the patient's discharge or death) or each ICU recruiting until 40 family members had been recruited; recruiting family members of patients who stayed either 24 hours or 48 hours; recruiting the patients' nominated next of kin or recruiting the first family member to visit the patient. As no significant seasonality was identified in *Chapter 6*, time of year of the survey was not considered as a factor in the sampling frames, but rather four alternative start dates were selected (the second Monday of each alternate month from September 2013 to March 2014) and results for each approach were averaged across the four resulting simulations. For each sampling frame, it was assumed that data entry of questionnaires would end 12 weeks after the final family member was recruited (i.e. allowing 9 weeks from the first questionnaire being sent).

Within each simulation, the overall family satisfaction score and domain scores were calculated using the modified traditional approach (based on responders who had completed at least 60% of items). The resulting scores were adjusted for the characteristics of the patients and recruited family members using the FREE study multilevel multivariable models.

TABLE 59 Characteristics of alternative sampling frames

	Characteristics of sampling frame		
Approach	Duration	Patient	Family member
1	4 weeks	ICU stay ≥ 24 hours	Next of kin
2	6 weeks	ICU stay ≥ 24 hours	Next of kin
3	Until 40 family members	ICU stay ≥ 24 hours	Next of kin
4	4 weeks	ICU stay ≥ 48 hours	Next of kin
5	6 weeks	ICU stay ≥ 48 hours	Next of kin
6	Until 40 family members	ICU stay ≥ 48 hours	Next of kin
7	4 weeks	ICU stay ≥ 24 hours	First family member
8	6 weeks	ICU stay ≥ 24 hours	First family member
9	Until 40 family members	ICU stay ≥ 24 hours	First family member
10	4 weeks	ICU stay ≥ 48 hours	First family member
11	6 weeks	ICU stay ≥ 48 hours	First family member
12	Until 40 family members	ICU stay ≥ 48 hours	First family member

Results

Recruiting for only 4 weeks (approaches 1, 4, 7 and 10) resulted in mean sample sizes (of returned questionnaires) ranging from 12 to 14 (*Table 60*). For some smaller ICUs, the sample with these approaches was as low as five family members, which would probably be too small to calculate reliable averages. With a 6-week recruitment window (approaches 2, 5, 8 and 11), the sample size was, as expected, approximately 50% higher. Alternatively, if each ICU continued to recruit until 40 family members were recruited (approaches 3, 6, 9 and 12), then the sample sizes were, on average, larger (mean 25–26) and also less variable across ICUs (SD 2–3). The cost of this was that recruitment periods were both longer (mean 57–70 days) and more variable (SD 24–29 days) across ICUs.

Recruiting next of kin (approaches 1–6), compared with recruiting the first family member to visit the patient (approaches 7–12), resulted in slightly lower recruitment rates (as some patients did not have a next of kin identified) but higher response rates (*Table 61*). Recruiting family members of only patients who stayed at least 48 hours in the ICU (approaches 4–6 and 10–12), compared with recruiting family members of patients who stayed 24 hours (approaches 1–3 and 7–9), resulted in higher recruitment rates and similar response rates (see *Table 61*) but lower overall sample sizes for the fixed-duration approaches (see *Table 60*).

As compared with the reference values from the full FREE study data set after applying multiple imputation, the unadjusted overall and domain scores (*Table 62*) tended to be overestimated by all approaches to sampling, except for the *satisfaction with the decision-making process* domain score, which was slightly underestimated by most approaches. Adjustment using the multivariable, multilevel model, developed in *Chapter 7*, resulted in estimates that were closer to the reference values (*Table 63*). The average precision of the estimates (reflected by the mean value across ICUs of the standard error of the ICU-specific estimates) improved as sample sizes increased and the variability in the precision (SD across ICUs of the standard error) was lower for approaches with a similar sample size in each ICU. Individual ICU estimates for the overall family satisfaction score and domain scores against the reference values are shown in *Figures 40–44*.

TABLE 60 Duration of recruitment and numbers of family members recruited and followed up under each sampling frame

Approach	Duration of recruitment (days), mean (SD)	Number of eligible patients per site, mean (SD)	Number of family members recruited per site, mean (SD)	Number of family members returning questionnaires per site, mean (SD)
1	28 (0)	49 (25)	22 (10)	14 (5)
2	42 (0)	73 (37)	33 (14)	21 (8)
3	62 (25)	90 (16)	40 (0)	26 (2)
4	28 (0)	34 (18)	19 (9)	12 (5)
5	42 (0)	51 (26)	28 (13)	18 (7)
6	70 (29)	71 (10)	40 (0.6)[a]	25 (3)
7	28 (0)	49 (25)	23 (10)	14 (5)
8	42 (0)	73 (37)	35 (15)	22 (8)
9	57 (24)	84 (15)	40 (0)	25 (3)
10	28 (0)	34 (18)	20 (9)	12 (5)
11	42 (0)	51 (26)	30 (13)	19 (7)
12	66 (28)	66 (10)	40 (0.3)[a]	25 (3)

[a] In the final simulation (recruitment window commencing March 2014), two ICUs did not reach 40 family members eligible for these approaches before the end of recruitment to the FREE study.

The value for each ICU was calculated as the mean across the four simulations (based on alternative start dates). The values reported are the mean and SD across the ICUs.

TABLE 61 Recruitment and follow-up rates under each sampling frame

Approach	Recruitment rate, mean (SD)[a]	Follow-up rate, mean (SD)[b]
1	45.9 (9.6)	65.0 (7.1)
2	45.9 (8.0)	65.4 (6.2)
3	46.7 (7.4)	64.3 (5.7)
4	57.7 (9.7)	64.3 (7.8)
5	57.6 (8.5)	65.0 (6.6)
6	57.7 (7.2)	63.9 (6.4)
7	49.3 (9.8)	62.1 (6.5)
8	49.3 (8.3)	63.4 (6.2)
9	50.0 (7.8)	62.2 (6.6)
10	61.6 (9.5)	61.1 (6.8)
11	61.7 (8.1)	62.8 (6.4)
12	62.3 (7.9)	62.0 (6.5)

[a] Percentage of eligible patients with a family member recruited.

[b] Percentage of recruited family members returning a questionnaire.

The value for each ICU was calculated as the mean across the four simulations (based on alternative start dates). The values reported are the mean and SD across the ICUs.

TABLE 62 Unadjusted overall family satisfaction score and domain scores under each sampling frame, compared with the FREE study

	Overall family satisfaction score, mean (SD)		*Satisfaction with care* domain score, mean (SD)		*Satisfaction with decision-making* domain score, mean (SD)		*Satisfaction with information* domain score, mean (SD)		*Satisfaction with the decision-making process* domain score, mean (SD)	
Approach	**Mean**	**SE**	**Mean**	**SE**	**Mean**	**SE**	**Mean**	**SE**	**Mean**	**SE**
Reference[a]	79.7 (2.7)	–	83.2 (2.8)	–	74.9 (2.5)	–	76.2 (3.1)	–	73.0 (1.7)	–
1	81.3 (3.4)	4.4 (1.0)	84.7 (3.2)	4.1 (1.1)	75.8 (4.2)	5.8 (1.1)	77.2 (4.9)	5.9 (1.2)	72.4 (4.3)	7.7 (1.5)
2	81.3 (3.0)	3.7 (0.6)	84.6 (3.1)	3.4 (0.7)	76.0 (3.3)	4.8 (0.8)	77.5 (4.1)	4.9 (0.8)	72.3 (3.3)	6.2 (1.4)
3	81.0 (3.0)	3.2 (0.4)	84.5 (3.0)	3.0 (0.5)	75.7 (3.5)	4.1 (0.5)	77.1 (4.1)	4.2 (0.5)	72.0 (3.4)	5.3 (0.5)
4	81.2 (3.4)	4.8 (1.1)	84.8 (3.3)	4.4 (1.2)	75.7 (4.1)	6.3 (1.4)	77.2 (4.7)	6.4 (1.5)	72.0 (4.3)	8.4 (2.0)
5	81.3 (3.0)	4.0 (0.7)	84.6 (3.1)	3.7 (0.7)	76.0 (3.3)	5.2 (1.0)	77.5 (4.2)	5.3 (0.9)	72.2 (3.2)	6.7 (1.8)
6	81.0 (2.9)	3.2 (0.4)	84.5 (2.8)	3.0 (0.4)	75.8 (3.3)	4.1 (0.5)	77.3 (3.9)	4.3 (0.5)	71.9 (2.8)	5.3 (0.7)
7	81.2 (3.4)	4.8 (1.6)	84.3 (3.3)	4.3 (1.1)	76.1 (4.0)	6.0 (2.0)	77.3 (5.1)	6.2 (1.9)	73.3 (3.4)	7.8 (2.4)
8	81.0 (2.9)	3.8 (0.7)	84.0 (3.2)	3.5 (0.7)	75.9 (3.0)	4.8 (0.9)	77.2 (4.1)	4.9 (0.9)	72.5 (2.8)	6.1 (1.2)
9	80.8 (2.9)	3.3 (0.5)	83.9 (3.1)	3.1 (0.5)	75.7 (3.2)	4.2 (0.5)	76.9 (4.0)	4.4 (0.6)	72.2 (3.0)	5.4 (0.5)
10	81.3 (3.4)	5.1 (1.8)	84.4 (3.4)	4.7 (1.3)	76.2 (4.0)	6.5 (2.2)	77.6 (5.0)	6.6 (2.1)	73.1 (3.8)	8.4 (3.0)
11	81.0 (3.0)	4.0 (0.9)	84.0 (3.4)	3.8 (0.9)	76.0 (3.2)	5.1 (1.1)	77.4 (4.2)	5.3 (1.1)	72.5 (3.0)	6.6 (1.4)
12	80.8 (2.9)	3.3 (0.4)	83.9 (3.2)	3.1 (0.5)	75.7 (3.1)	4.2 (0.5)	77.1 (3.8)	4.4 (0.5)	72.0 (2.9)	5.4 (0.6)

SE, standard error.

a Results from the full FREE study data set using multiple imputation.

The value for each ICU was calculated as the mean across the four simulations (based on alternative start dates). The values reported are the mean and SD across the ICUs.

TABLE 63 Adjusted overall family satisfaction score and domain scores under each sampling frame, compared with the FREE study

	Overall family satisfaction score, mean (SD)		*Satisfaction with care* domain score, mean (SD)		*Satisfaction with decision-making* domain score, mean (SD)		*Satisfaction with information* domain score, mean (SD)		*Satisfaction with the decision-making process* domain score, mean (SD)	
Approach	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Mean	SE
Reference[a]	79.7 (2.7)	–	83.2 (2.8)	–	74.9 (2.5)	–	76.2 (3.1)	–	73.0 (1.7)	–
1	80.3 (3.3)	4.5 (1.0)	83.6 (3.0)	4.2 (1.0)	75.1 (4.0)	5.8 (1.2)	76.3 (4.6)	6.0 (1.3)	71.9 (4.1)	7.6 (1.5)
2	80.2 (2.7)	3.8 (0.7)	83.4 (2.8)	3.5 (0.7)	75.1 (3.0)	4.8 (0.9)	76.5 (3.8)	5.0 (0.9)	71.6 (3.2)	6.2 (1.4)
3	80.0 (2.9)	3.2 (0.4)	83.3 (2.8)	3.0 (0.5)	74.9 (3.4)	4.1 (0.5)	76.2 (3.8)	4.3 (0.5)	71.4 (3.5)	5.2 (0.5)
4	80.1 (3.4)	4.9 (1.1)	83.5 (3.3)	4.5 (1.1)	74.8 (3.9)	6.4 (1.5)	76.2 (4.6)	6.5 (1.5)	71.2 (4.2)	8.3 (1.9)
5	80.1 (2.8)	4.0 (0.8)	83.3 (2.9)	3.7 (0.7)	74.9 (3.2)	5.2 (1.1)	76.4 (3.9)	5.4 (1.0)	71.3 (3.3)	6.6 (1.8)
6	79.8 (2.8)	3.2 (0.4)	83.2 (2.7)	3.0 (0.4)	74.6 (3.2)	4.1 (0.5)	76.0 (3.6)	4.3 (0.5)	71.0 (3.1)	5.3 (0.7)
7	80.8 (3.2)	4.8 (1.6)	83.7 (3.0)	4.3 (1.1)	75.8 (3.9)	6.0 (2.0)	77.0 (4.9)	6.2 (1.9)	73.0 (3.4)	7.8 (2.4)
8	80.5 (2.8)	3.8 (0.7)	83.4 (3.0)	3.5 (0.7)	75.5 (3.0)	4.8 (0.9)	76.8 (4.0)	4.9 (0.9)	72.1 (2.8)	6.1 (1.2)
9	80.3 (2.7)	3.3 (0.5)	83.4 (2.9)	3.1 (0.5)	75.3 (3.0)	4.2 (0.5)	76.6 (3.7)	4.4 (0.6)	71.8 (3.1)	5.4 (0.4)
10	80.7 (3.3)	5.1 (1.8)	83.7 (3.3)	4.7 (1.3)	75.7 (3.9)	6.5 (2.2)	77.1 (4.9)	6.6 (2.1)	72.5 (3.9)	8.4 (3.0)
11	80.4 (3.0)	4.0 (0.9)	83.3 (3.2)	3.8 (0.9)	75.4 (3.2)	5.1 (1.1)	76.8 (4.2)	5.3 (1.1)	71.9 (3.0)	6.6 (1.4)
12	80.2 (2.7)	3.3 (0.4)	83.2 (2.9)	3.1 (0.5)	75.2 (3.1)	4.2 (0.5)	76.6 (3.6)	4.4 (0.5)	71.4 (3.1)	5.4 (0.6)

SE, standard error.

[a] Results from the full FREE study data set using multiple imputation.

The value for each ICU was calculated as the mean across the four simulations (based on alternative start dates). The values reported are the mean and SD across the ICUs.

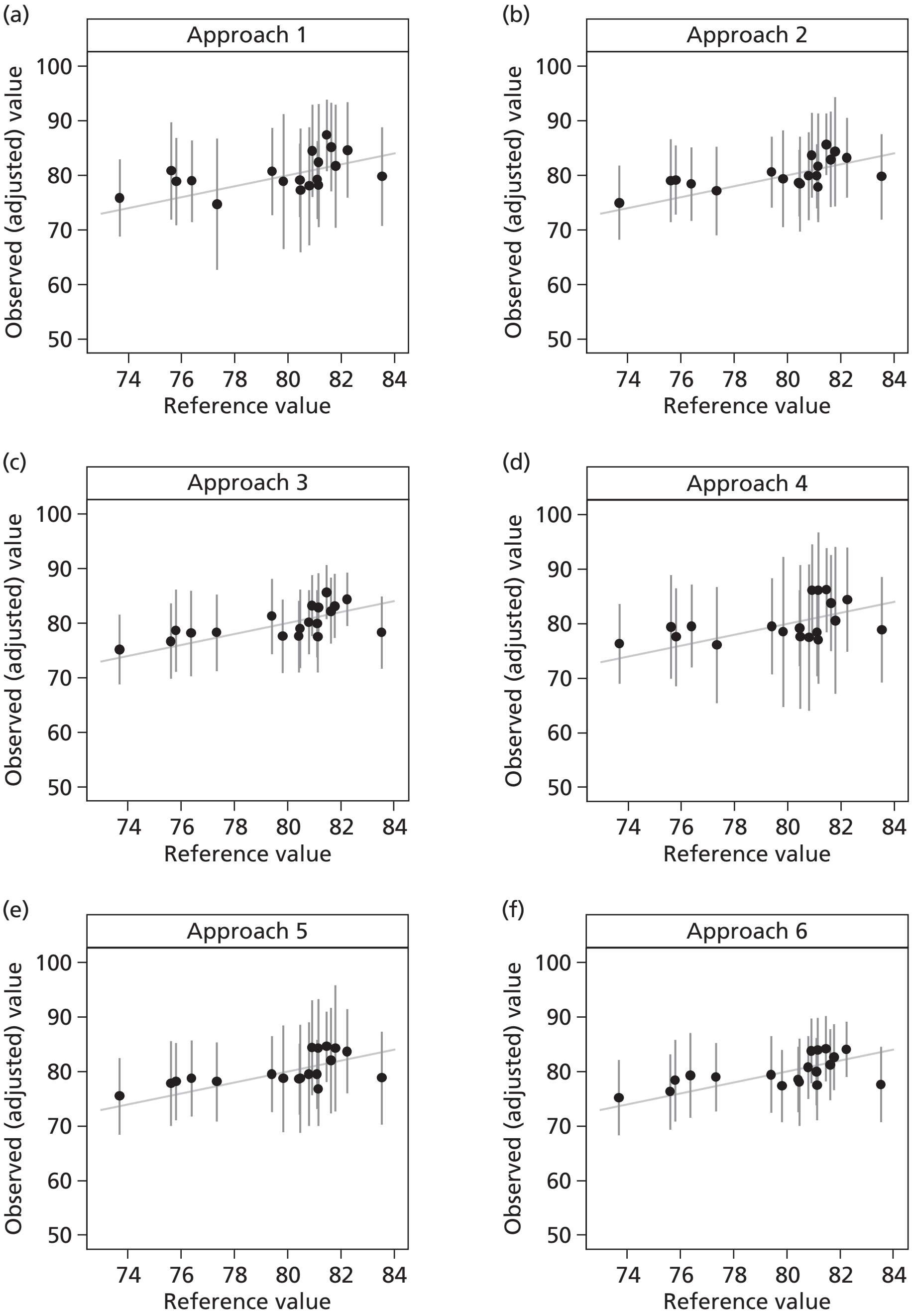

FIGURE 40 Individual ICU estimates of overall family satisfaction score under each sampling frame, compared with the FREE study (reference value). The diagonal line indicates perfect agreement between the observed and reference values. (*continued*)

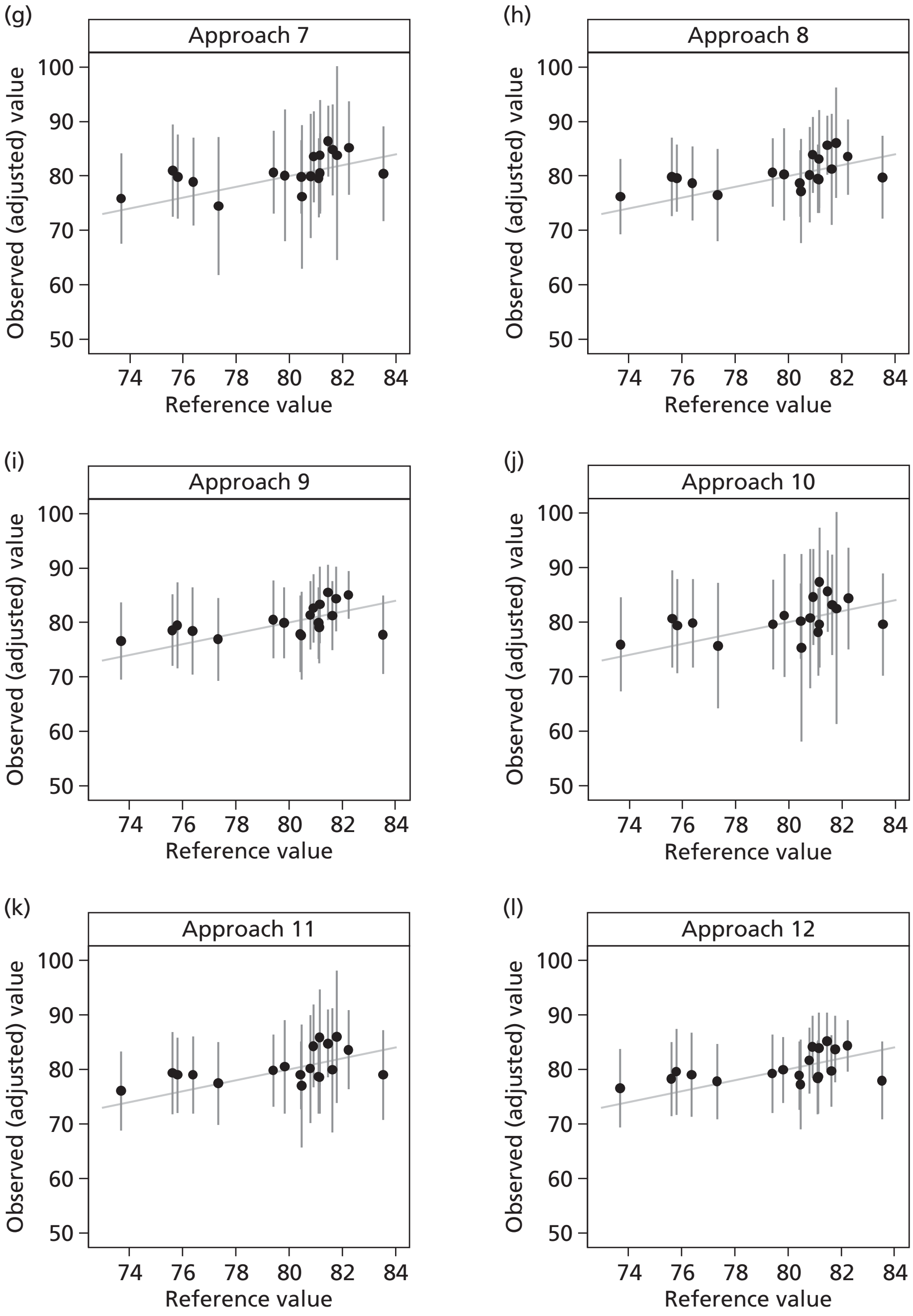

FIGURE 40 Individual ICU estimates of overall family satisfaction score under each sampling frame, compared with the FREE study (reference value). The diagonal line indicates perfect agreement between the observed and reference values.

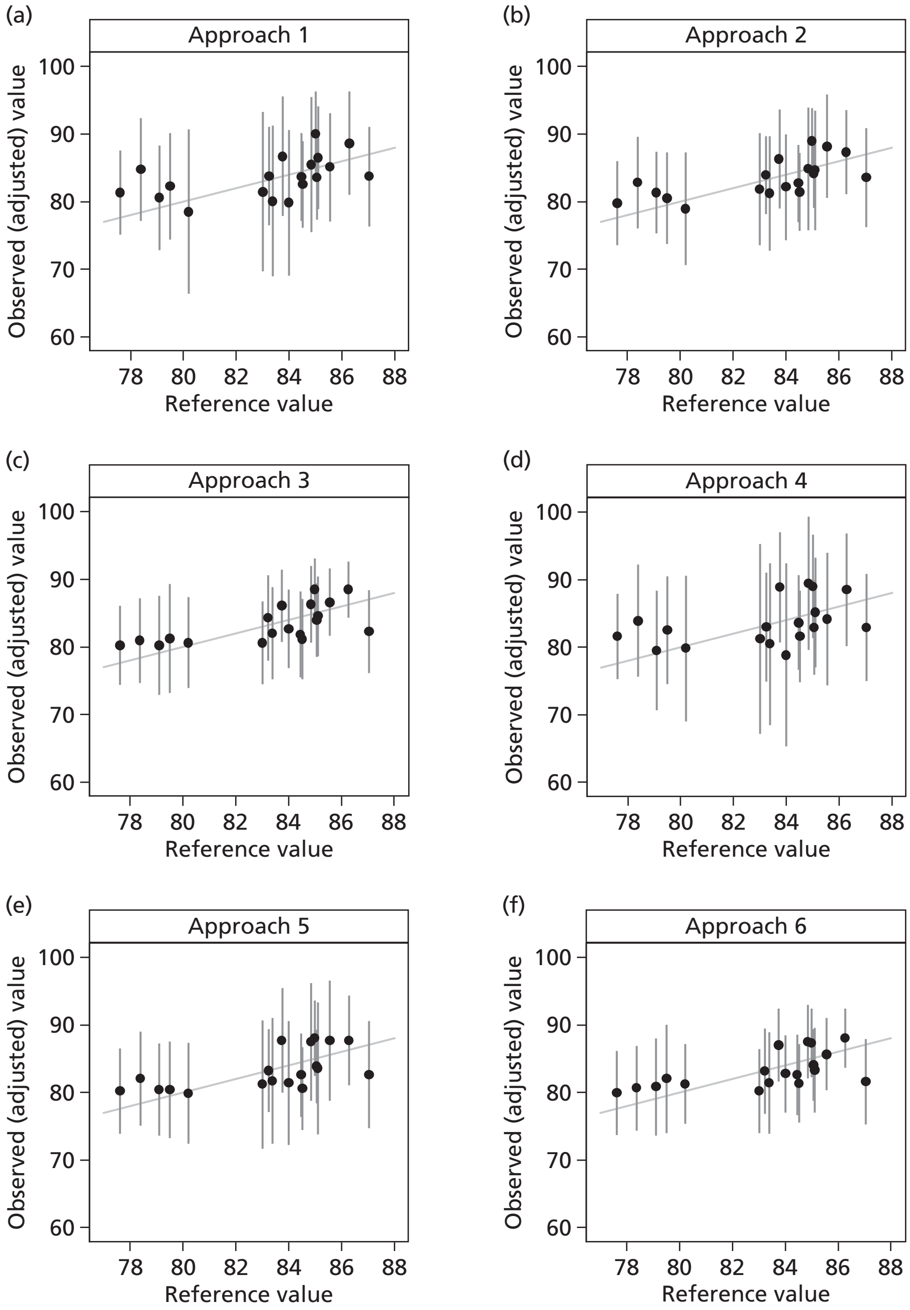

FIGURE 41 Individual ICU estimates of *satisfaction with care* domain score under each sampling frame, compared with the FREE study (reference value). The diagonal line indicates perfect agreement between the observed and reference values. (*continued*)

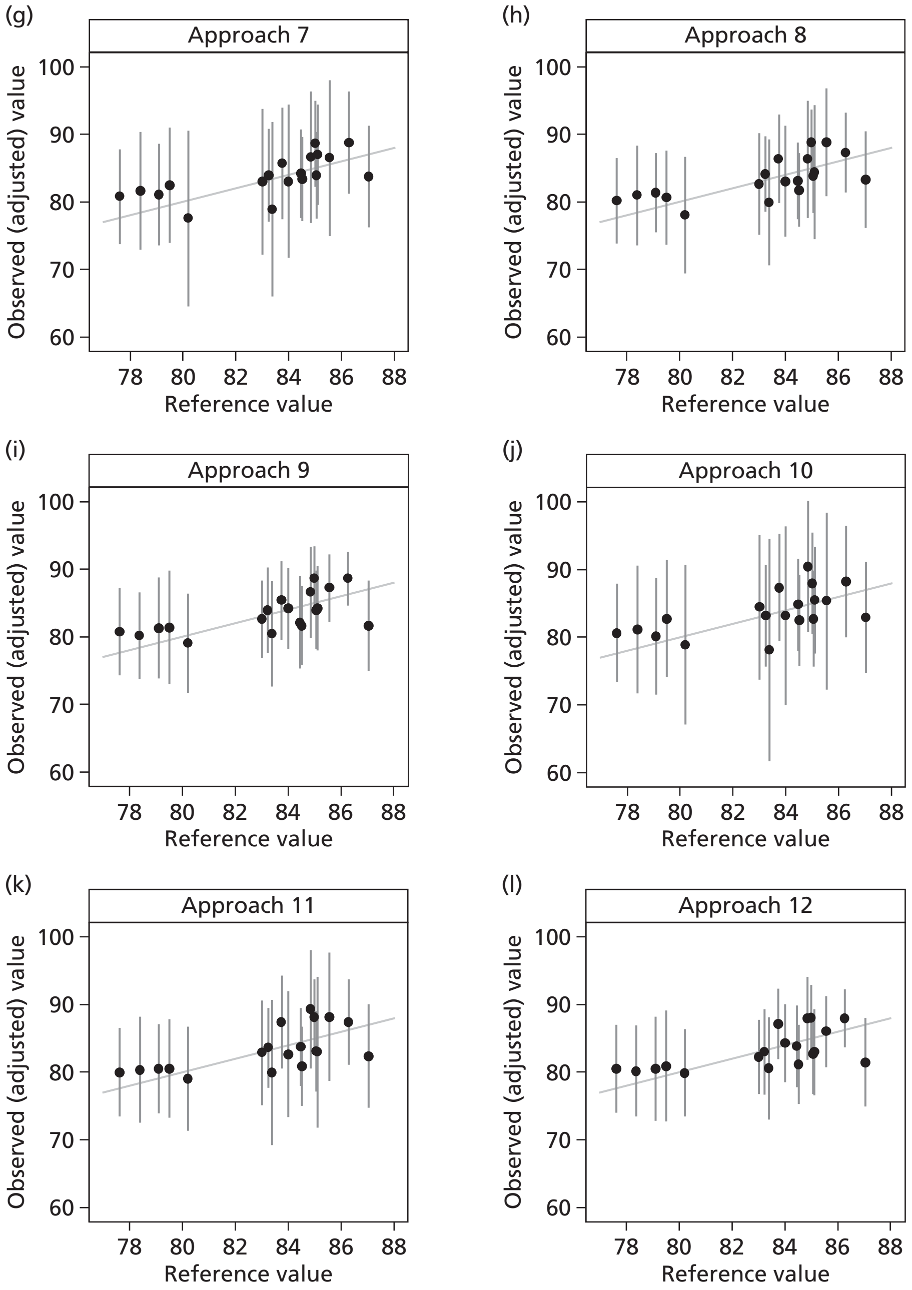

FIGURE 41 Individual ICU estimates of *satisfaction with care* domain score under each sampling frame, compared with the FREE study (reference value). The diagonal line indicates perfect agreement between the observed and reference values.

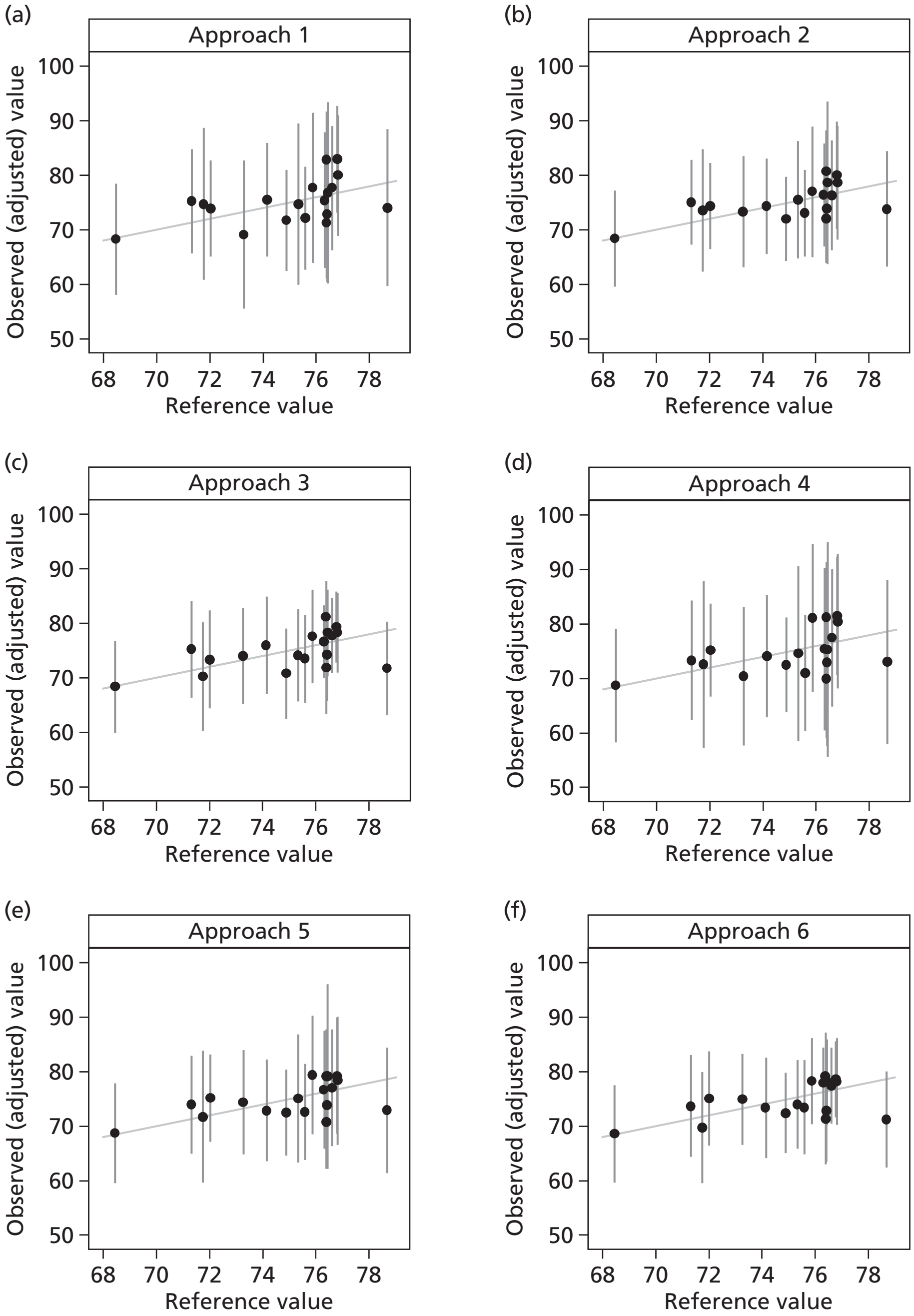

FIGURE 42 Individual ICU estimates of *satisfaction with decision-making* domain score under each sampling frame, compared with the FREE study (reference value). The diagonal line indicates perfect agreement between the observed and reference values. (*continued*)

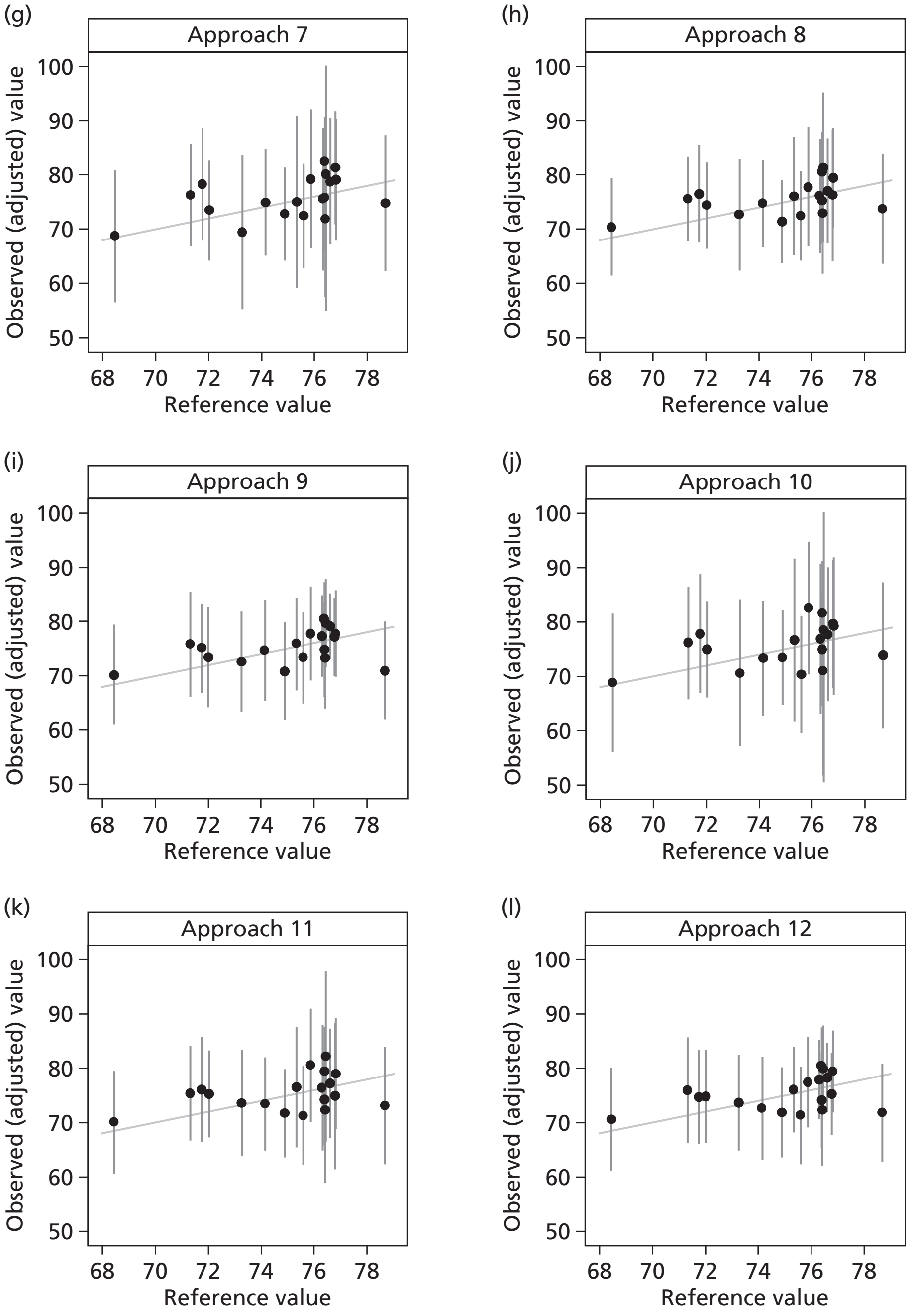

FIGURE 42 Individual ICU estimates of *satisfaction with decision-making* domain score under each sampling frame, compared with the FREE study (reference value). The diagonal line indicates perfect agreement between the observed and reference values.

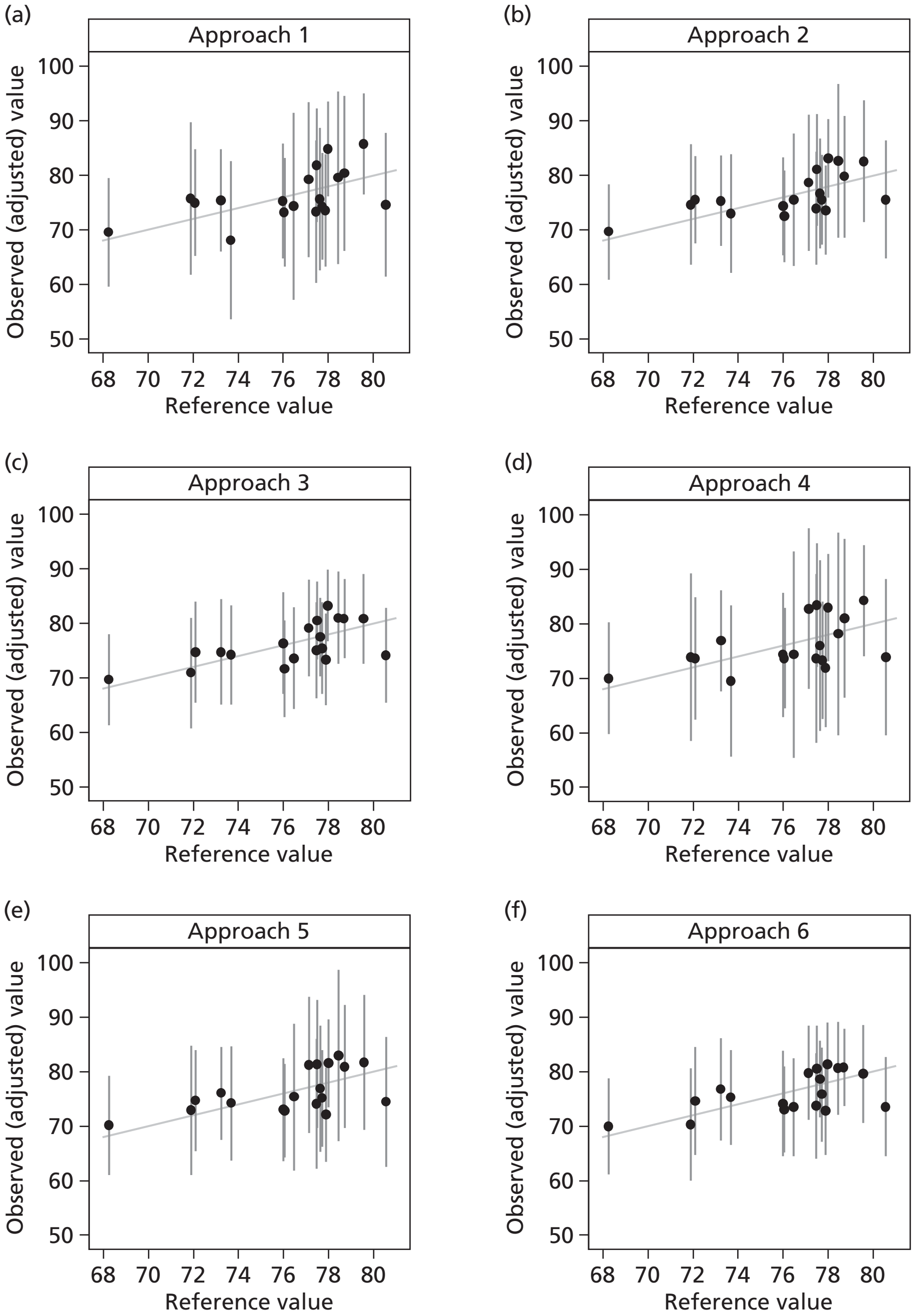

FIGURE 43 Individual ICU estimates of *satisfaction with information* domain score under each sampling frame, compared with the FREE study (reference value). The diagonal line indicates perfect agreement between the observed and reference values. (*continued*)

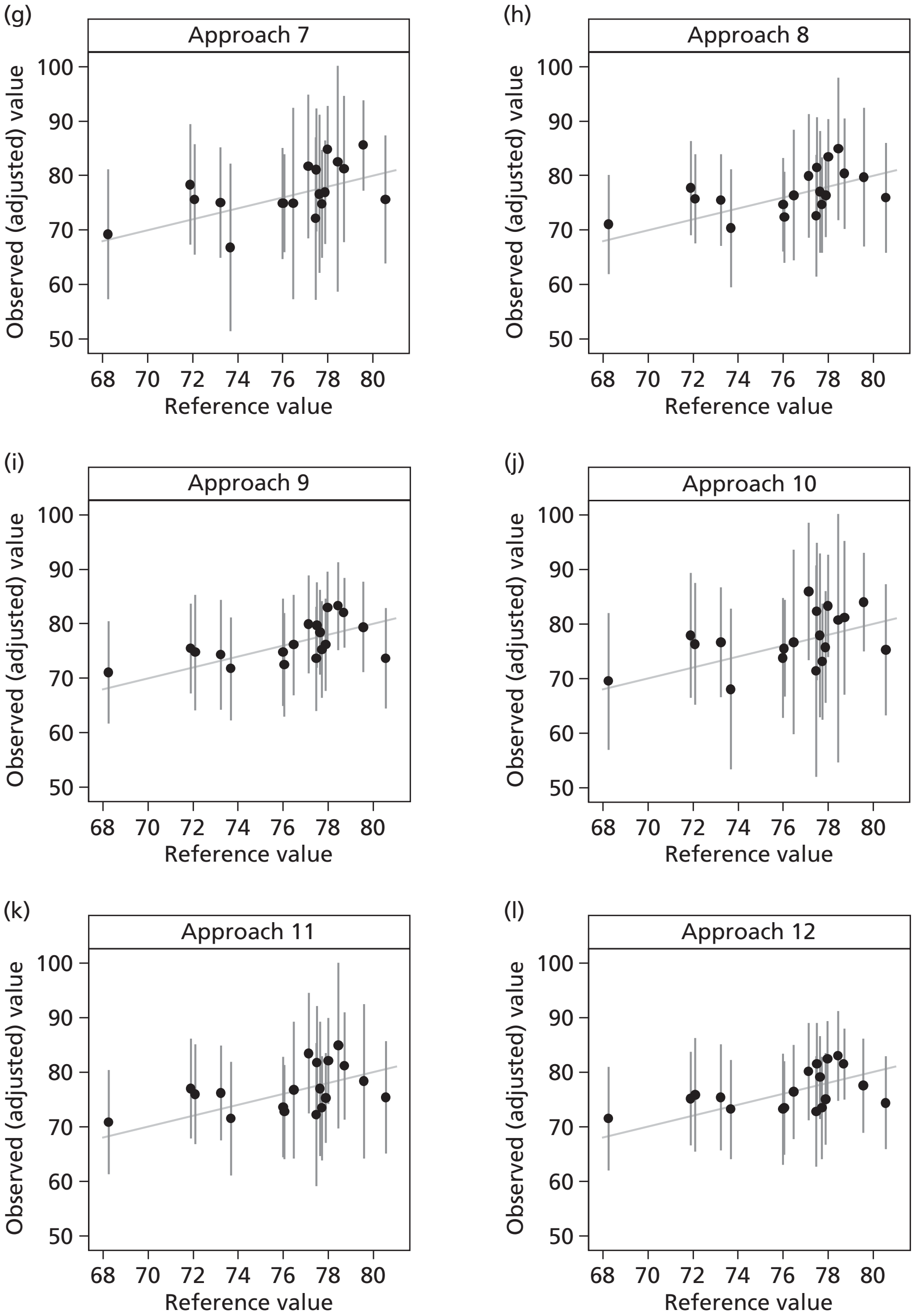

FIGURE 43 Individual ICU estimates of *satisfaction with information* domain score under each sampling frame, compared with the FREE study (reference value). The diagonal line indicates perfect agreement between the observed and reference values.

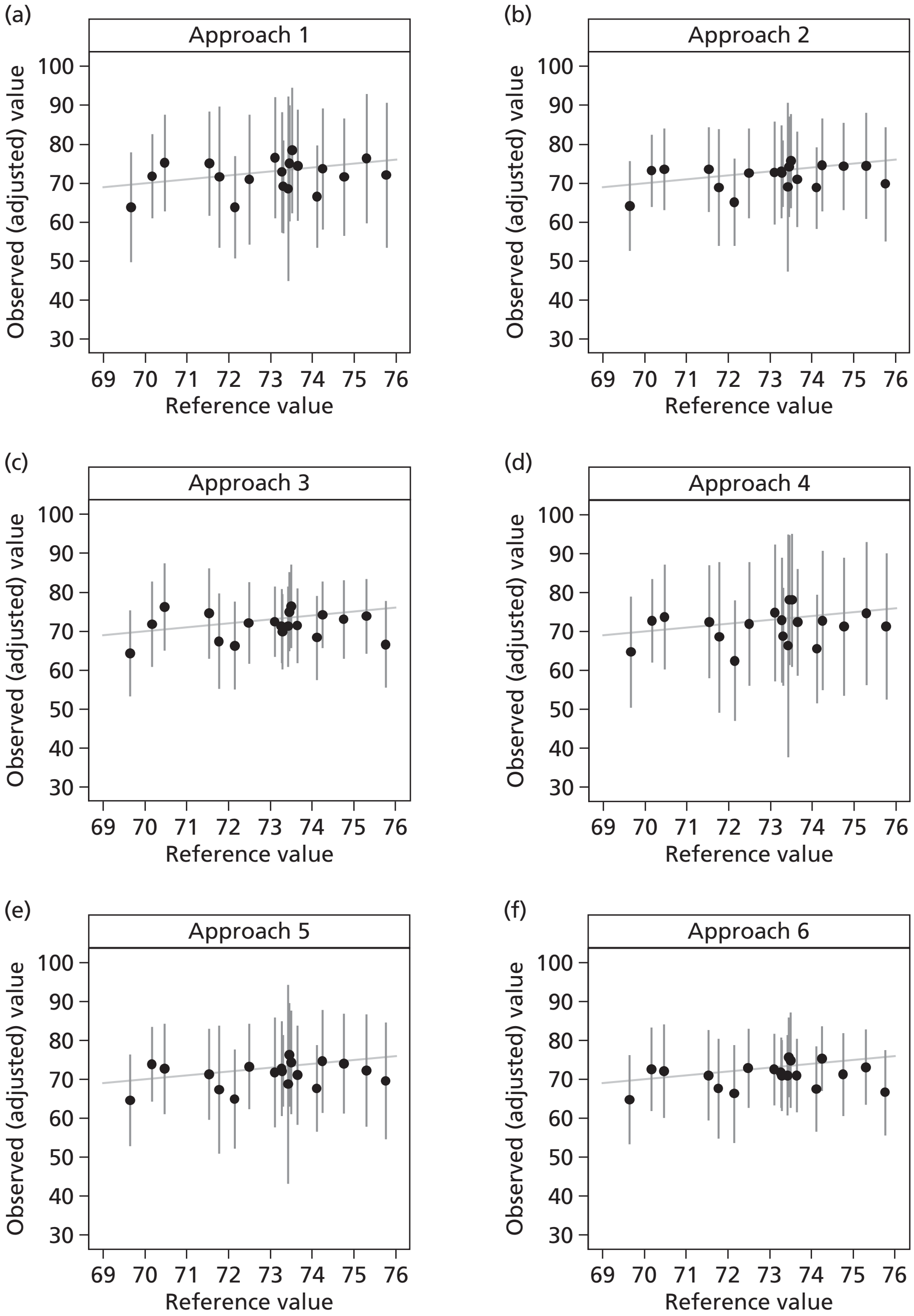

FIGURE 44 Individual ICU estimates of *satisfaction with the decision-making process* domain score under each sampling frame, compared with the FREE study (reference value). The diagonal line indicates perfect agreement between the observed and reference values. (*continued*)

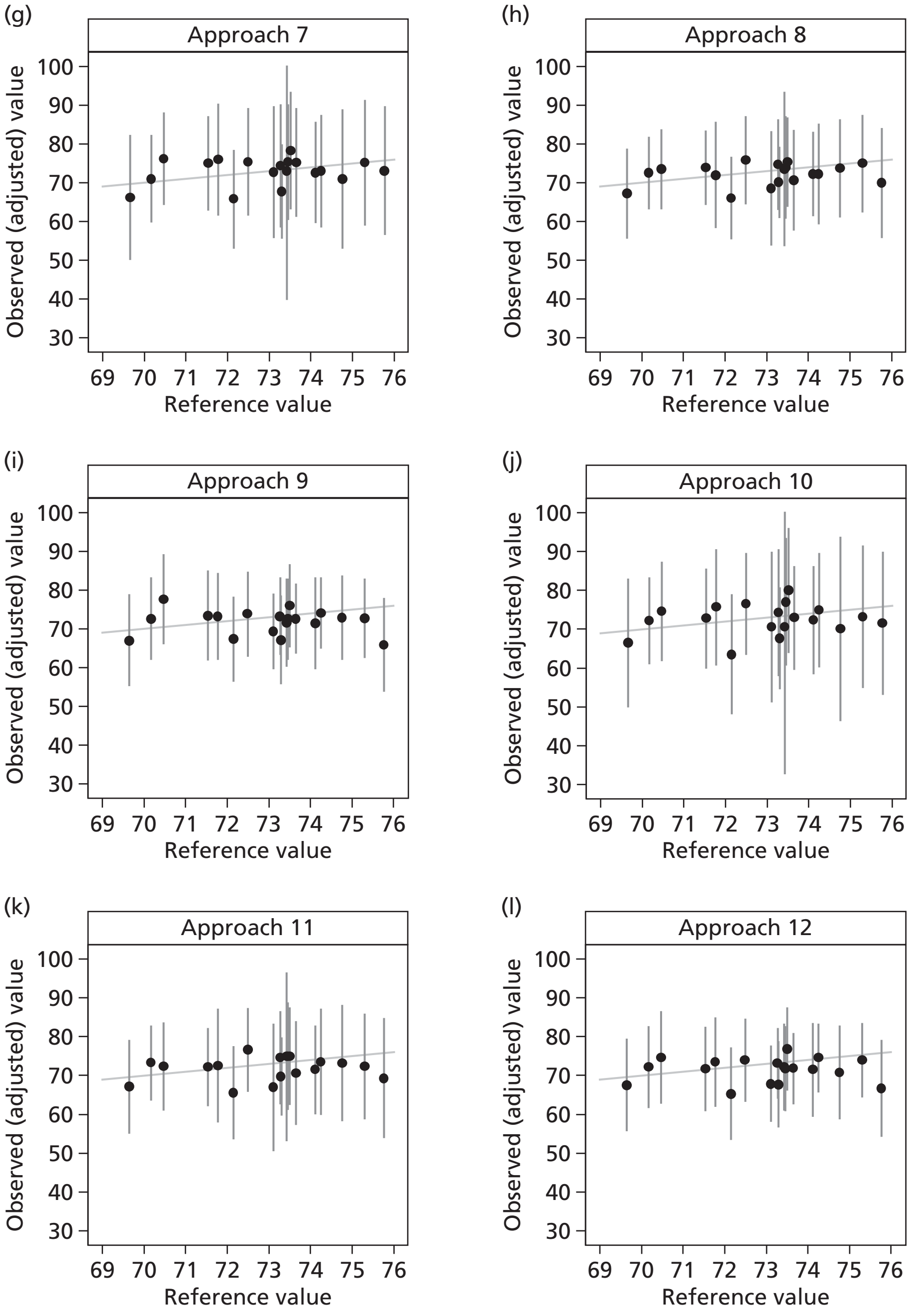

FIGURE 44 Individual ICU estimates of *satisfaction with the decision-making process* domain score under each sampling frame, compared with the FREE study (reference value). The diagonal line indicates perfect agreement between the observed and reference values.

Discussion

Simulations based on the FREE study data suggest that family satisfaction surveys using short recruitment windows can produce relatively unbiased estimates of the 'true' average family satisfaction. However, these recruitment windows may need to be 6 weeks or longer to obtain sufficient sample size from smaller ICUs, particularly if exclusion criteria are to be applied at the patient or family member level. One alternative approach is for each ICU to recruit until a fixed sample size is reached. This gave more stability in the precision of the estimated family satisfaction scores across the ICUs, but may be harder to manage in practice because of the resulting variation across ICUs in the length of the recruitment window. Recruiting each patient's nominated next of kin resulted in higher response rates and is therefore likely to be the preferred approach because of the resulting increase in efficiency. Recruiting only family members of patients who stayed in the ICU for at least 48 hours resulted in higher recruitment rates, as patients who stayed less than 48 hours were more likely to have no family members visit or to have family members missed, but required a longer recruitment window to achieve the same final sample size of returned questionnaires.

As there was no association between month of the year and family satisfaction, the timing of satisfaction surveys during the year appears to be unimportant. In the simulations, we evaluated recruiting for fixed blocks of time. An alternative approach would be to collect over a larger number of small recruitment windows, for example recruiting for 1 week every alternate month, and pooling the results at the end of each year.

One limitation of this simulation approach is that we could consider changing parameters only within the confines of the FREE study design. For example, we could explore the effect of narrowing the patient inclusion criteria to those staying at least 48 hours, but we could not investigate widening the inclusion criteria to patients staying less than 24 hours, as these patients' family members were not recruited to the FREE study.

Chapter 10 International comparison

Introduction

As described earlier (see *Chapter 1*), the FS-ICU was developed in 2001 as a 34-item questionnaire providing two domain scores: *satisfaction with care* and *satisfaction with decision-making*.[8] In 2007, the FS-ICU was further refined to a shorter, 24-item questionnaire, validating the two main conceptual domains, and reporting the concept of an overall family satisfaction score.[11]

Methods

A systematic search of the literature was conducted, from 2001 onwards, for any quantitative studies employing the FS-ICU, or any stated adaptation of the FS-ICU, to compare with the FREE study.

Results

Setting

Excluding the publications conducted to develop, validate and refine the FS-ICU (and considering publications based on either the same cohort of data or overlapping cohorts of data as a single study), 21 separate studies were identified. Brief details of these studies are presented in *Table 64*.

Of the 21 studies, 16 were based on single publications from a single cohort[17,38–42,55–57,72–75,78–80] and five were based on multiple publications from overlapping cohorts.[9,10,53,54,59–71,76,77] These studies are reported between 2002 and 2014.

Most of the studies were based in North America – the USA ($n = 9$)[53,54,59–73,76–80] and Canada ($n = 3$)[9,10,56,74] – with other studies based in Greece ($n = 2$),[41,42] Switzerland ($n = 2$),[17,55] Germany ($n = 1$),[39] Israel ($n = 1$),[57] the Netherlands ($n = 1$),[75] the Philippines ($n = 1$)[38] and Turkey ($n = 1$).[40]

Nine studies were single centre, with the remainder being multicentre, ranging from 2 to 23 centres. All studies were based in ICUs: adult general (mixed medical/surgical) ICUs ($n = 17$), a mix of separate specialty ICUs ($n = 2$), a surgical ICU ($n = 1$) or a paediatric cardiothoracic ICU ($n = 1$).

Six studies used the FS-ICU-34 (or a modification),[9,10,17,55,73,75] two used extensively modified versions of the FS-ICU-24 (preventing direct comparison with the FREE study)[76,77,79] and 13 studies used either the original FS-ICU-24 or a slight modification,[38–42,53,54,56,57,61–72,74,78,80] and the results of these studies formed the comparison with the FREE study.

TABLE 64 Details of studies using the FS-ICU

Study	Publication	Country	Number of ICUs	Type of ICU(s)	FS-ICU
1	Heyland *et al.* 2002[9]	Canada	6	Adult general	34
	Heyland *et al.* 2003[10]				
2	Dowling *et al.* 2005[59]	USA	2	Adult general	34
	Dowling and Wang 2005[60]				
3	Wall *et al.* 2007[61]	USA	6	Mix of separate specialty ICUs	24
	Curtis *et al.* 2008[53]				
	Lewis-Newby *et al.* 2011[54]				
	Khandelwal *et al.* 2014[62]		2[a]	Adult general	
	Johnson *et al.* 2014[63]		6	Mix of separate specialty ICUs	
4	Stricker *et al.* 2007[17]	Switzerland	1	Adult general	34
5	Stricker *et al.* 2009[55]	Switzerland	23	Adult general	34
6	Gries *et al.* 2008[64]	USA	15	Adult general	24
	Gerstel *et al.* 2008[65]				
	Curtis *et al.* 2011[66]				
	Osborn *et al.* 2012[67]				
	Kross *et al.* 2012[68]				
	DeCato *et al.* 2013[69]				
	Kross *et al.* 2014[70]				
	Long *et al.* 2014[71]				
7	Jacobowski *et al.* 2010[72]	USA	1	Adult general	24
8	Hunziker *et al.* 2012[73]	USA	9	Adult general	34
9	Garland *et al.* 2012[56]	Canada	2	Adult general	24
10	Dalisay-Gallardo and Perez 2012[38]	Philippines	1	Adult general	24
11	Dodek *et al.* 2012[74]	Canada	23	Adult general	24
12	Jongerden *et al.* 2013[75]	Netherlands	1	Adult general	34
13	Epstein *et al.* 2013[76]	USA	1	Paediatric cardiothoracic	24
	Epstein *et al.* 2014[77]				
14	Schwarzkopf *et al.* 2013[39]	Germany	4	Mix of separate specialty ICUs	24
15	Khalaila 2013[57]	Israel	1	Adult general	24
16	Shaw *et al.* 2014[78]	USA	3	Adult general	24
17	Dhillon *et al.* 2014[79]	USA	1	Surgical	24
18	Gerasimou-Angelidi *et al.* 2014[41]	Greece	1	Adult general	24
19	Kourti *et al.* 2014[42]	Greece	1	Adult general	24
20	Kodali *et al.* 2014[80]	USA	2	Adult general	24
21	Tastan *et al.* 2014[40]	Turkey	2	Adult general	24

a They used data from only two of the six ICUs from the same cohort of data.

Methodological detail for studies using the 24-item Family Satisfaction in the Intensive Care Unit questionnaire

Thirteen studies used the FS-ICU-24 or a slight modification and these were reported on, completely or in part, in 24 separate publications. These studies were based either in adult general (mixed medical/surgical) ICUs or in a mix of separate specialty ICUs, ranging from 1 to 23 ICUs in any individual study (see *Table 64*).

The 13 studies using the FS-ICU-24 had data collected between 2003 and 2012. Inclusion criteria for patients (whose family members were to be surveyed) varied across studies (and sometimes across publications employing the same or overlapping cohort of data), with selection based on a combination of factors including age; receipt of mechanical ventilation; duration of stay in ICU; and survival status at discharge from ICU (or at some later time point). Few reported additional patient exclusion criteria (*Table 65*).

Selection of family members varied across the 13 studies but the family member selected was usually reported either as legal next of kin or as close family member or friend and, in all cases (where ascertainable), one family member per eligible patient was identified. Across the 24 publications (13 studies), method of consent was not reported in 10 publications. Where required (in six studies), the FS-ICU-24 was translated into the relevant language(s), with all studies employing back translation (*Table 66*).

In most studies, the family member was asked to complete a paper questionnaire (delivered either in hospital or by post); however, in three studies, it was completed through interview.[38,57,72] Timing of completion varied from while the patient was still in the ICU, through completion at patient discharge from ICU, to between 3 and 20 weeks after discharge from ICU and, in some studies, timing varied by survivorship of the patient (*Table 67*).

Mode of delivery varied from face-to-face or telephone interview, through hand-delivery of the questionnaire, to a questionnaire posted to either the patient's or the family member's address. In some studies, mode of delivery varied by survivorship of the patient. In some studies, family members were chased for response (see *Table 67*).

TABLE 65 Patient inclusion/exclusion criteria for publications using the FS-ICU-24

Publication	Year data collection commenced	Inclusion criteria	Exclusion criteria
Wall *et al.* 2007[61]	2003	≥ 6 hours in ICU	Not stated
Curtis *et al.* 2008[53]	2003	• ≥ 6 hours in ICU • ICU non-survivors only	Not stated
Lewis-Newby *et al.* 2011[54]	2003	• ≥ 6 hours in ICU • ICU non-survivors only	Not stated
Khandelwal *et al.* 2014[62]	Not stated	• ≥ 6 hours in ICU • ICU non-survivors only	Not stated
Johnson *et al.* 2014[63]	2003	• ≥ 18 years old • ≥ 6 hours in ICU • ICU non-survivors only	Not stated
Gries *et al.* 2008[64]	2003	ICU non-survivors only	Not stated
Gerstel *et al.* 2008[65]	2003	ICU non-survivors only	Died on full life support
Curtis *et al.* 2011[66]	2004	• ≥ 6 hours in ICU • ICU non-survivors only	Not stated
Osborn *et al.* 2012[67]	2004	• ≥ 6 hours in ICU • ICU non-survivors only	Not stated

continued

TABLE 65 Patient inclusion/exclusion criteria for publications using the FS-ICU-24 (*continued*)

Publication	Year data collection commenced	Inclusion criteria	Exclusion criteria
Kross *et al.* 2012[68]	2004	≥ 6 hours in ICU ICU non-survivors only	Not stated
DeCato *et al.* 2013[69]	2003	≥ 6 hours in ICU ICU non-survivors only	Not stated
Kross *et al.* 2014[70]	2003	≥ 6 hours in ICU ICU non-survivors only	Brain dead
Long *et al.* 2014[71]	2003	≥ 6 hours in ICU ICU non-survivors only	Not admitted from ED or ward ≤ 1 day on ward or > 1 day in ED Not ventilated Absence of chronic comorbidities
Jacobowski *et al.* 2010[72]	2006	≥ 24 hours in ICU	No primary contact
Garland *et al.* 2012[56]	2008	ICU experience within a single model	ICU experience over both models Only first admission used
Dalisay-Gallardo and Perez 2012[38]	2011	≥ 18 years old ≥ 48 hours in ICU ICU non-survivors only	Not stated
Dodek *et al.* 2012[74]	2006	≥ 48 hours in ICU	Not stated
Schwarzkopf *et al.* 2013[39]	2011	≥ 48 hours in ICU	Not stated
Khalaila 2013[57]	2007	≥ 48 hours in ICU	Not stated
Shaw *et al.* 2014[78]	2010	Not stated	Not stated
Gerasimou-Angelidi *et al.* 2014[41]	2009	≥ 24 hours in ICU	Not stated
Kourti *et al.* 2014[42]	2008	≥ 48 hours on mechanical ventilation	Not stated
Kodali *et al.* 2014[80]	2012	≥ 18 years old	Research opt-out indicator No next of kin
Tastan *et al.* 2014[40]	2008	≥ 48 hours in ICU	Not stated

ED, emergency department.

TABLE 66 Family member inclusion/exclusion criteria for publications using the FS-ICU-24

Publication	Selection	Inclusion criteria	Exclusion criteria	Identified	Consent
Wall *et al.* 2007[61]	Not stated	Specific weekdays for ICU survivors	• Could not be contacted • Limited English	1	Not reported
Curtis *et al.* 2008[53]	• Legal NOK • Close family member	Not stated	Not stated	1	Not reported
Lewis-Newby *et al.* 2011[54]	Not stated	Not stated	Not stated	1	Not reported
Khandelwal *et al.* 2014[62]	Close family member or friend	Not stated	Not stated	1	Not reported
Johnson *et al.* 2014[63]	Close family member or friend	Not stated	Not stated	1	Written
Gries *et al.* 2008[64]	• Legal NOK • Close family member or friend	Not stated	No contact information	1	Not reported
Gerstel *et al.* 2008[65]	• Legal NOK • Family member	Not stated	Not stated	1	Written
Curtis *et al.* 2011[66]	Close family member or friend	Not stated	Not stated	1	Not reported
Osborn *et al.* 2012[67]	Close family member or friend	Not stated	Not stated	1	Not reported
Kross *et al.* 2012[68]	• Legal NOK • Family member	Not stated	Not stated	1	Written
DeCato *et al.* 2013[69]	Close family member or friend	Not stated	Not stated	1	Not reported
Kross *et al.* 2014[70]	Not stated	Not stated	Not stated	1	Written
Long *et al.* 2014[71]	Close family member	Not stated	Not stated	1	Not reported
Jacobowski *et al.* 2010[72]	Nominated NOK	Not stated	Limited English	1	Verbal
Garland *et al.* 2012[56]	Not stated	Visited ICU within a single model	ICU experience in both models	1	Consented
[a]Dalisay-Gallardo and Perez 2012[38]	Nominated NOK	• ≥ 18 years old • ≥ 1 visit	Comprehension barriers	1	Verbal Written
Dodek *et al.* 2012[74]	Not stated	≥ 1 visit	Not stated	1	Implied
[a]Schwarzkopf *et al.* 2013[39]	Family member	≥ 1 visit	Visited outside ICU visiting times	1	Waived
[a]Khalaila 2013[57]	Family member	• ≥ 18 years old • Daily visits (≥ 3 hours)	Not stated	Not stated	Consented
Shaw *et al.* 2014[78]	Family member	Not stated	Not stated	1	Consented
[a]Gerasimou-Angelidi *et al.* 2014[41]	Not stated	• Visit within 24 hours • Present at ICU discharge	Not stated	1	Written
[a]Kourti *et al.* 2014[42]	Close family member or friend	2 consecutive visits (≥ 10 minutes)	Not stated	1	Not reported
Kodali *et al.* 2014[80]	Legal NOK	Not stated	Could not be contacted	1	Implied
[a]Tastan *et al.* 2014[40]	Close family member	• ≥ 18 years old • Read/write in Turkish	Not stated	1	Written

NOK, next of kin.
a Translated questionnaire used.

TABLE 67 Details on questionnaire distribution for publications using the FS-ICU-24

Publication	FS-ICU	Mode of delivery (ICU survivors)	Mode of delivery (ICU non-survivors)	Timing (ICU survivors)	Timing (ICU non-survivors)	Follow-up
Wall *et al.* 2007[61]	Paper	Posted	Posted	4–8 weeks	4–8 weeks	• 2 weeks • 5 weeks
Curtis *et al.* 2008[53]	Paper	N/A	Posted	N/A	4–6 weeks	• 2 weeks • 4–6 weeks
Lewis-Newby *et al.* 2011[54]	Paper	N/A	Posted	N/A	4–6 weeks	Not stated
Khandelwal *et al.* 2014[62]	Paper	N/A	Posted	N/A	4–6 weeks	Not stated
Johnson *et al.* 2014[63]	Paper	N/A	Posted	N/A	4 weeks	• 1 week • 4–6 weeks
Gries *et al.* 2008[64]	Paper	N/A	Posted	N/A	4–8 weeks	• 1 week • 4 weeks
Gerstel *et al.* 2008[65]	Paper	N/A	Posted	N/A	4–8 weeks	• 2 weeks • 5 weeks
Curtis *et al.* 2011[66]	Paper	N/A	Posted	N/A	4–6 weeks	• 3 weeks • 5 weeks
Osborn *et al.* 2012[67]	Paper	N/A	Posted	N/A	4–6 weeks	• 3 weeks • 5 weeks
Kross *et al.* 2012[68]	Paper	N/A	Posted	N/A	4–8 weeks	• 2 weeks • 4 weeks
DeCato *et al.* 2013[69]	Paper	N/A	Posted	N/A	4–6 weeks	• 3 weeks • 5 weeks
Kross *et al.* 2014[70]	Paper	N/A	Posted	N/A	4–8 weeks	• 2 weeks • 4 weeks
Long *et al.* 2014[71]	Paper	N/A	Posted	N/A	4–6 weeks	• 3 weeks • 5 weeks
Jacobowski *et al.* 2010[72]	Interview	Telephone call	Telephone call	4 weeks	12–20 weeks	Not stated
Garland *et al.* 2012[56]	Paper	In hospital	Posted	ICU discharge	4 weeks	Not stated
Dalisay-Gallardo and Perez 2012[38]	Paper; Interview	N/A	• In hospital • Telephone call	N/A	4–6 weeks	Not stated
Dodek *et al.* 2012[74]	Paper	In hospital	Posted	ICU discharge	3 weeks	Not stated
Schwarzkopf *et al.* 2013[39]	Paper	In hospital	In hospital	Next visit	Next visit	At visits to ICU or hospital
Khalaila 2013[57]	Interview	Face to face in hospital	Face to face in hospital	After consent	After consent	Not stated
Shaw *et al.* 2014[78]	Paper	Posted	Posted	4–8 weeks	4–8 weeks	Not stated
Gerasimou-Angelidi *et al.* 2014[41]	Paper	In hospital	In hospital	ICU discharge	ICU death	Not stated

TABLE 67 Details on questionnaire distribution for publications using the FS-ICU-24 (*continued*)

Publication	FS-ICU	Mode of delivery (ICU survivors)	Mode of delivery (ICU non-survivors)	Timing (ICU survivors)	Timing (ICU non-survivors)	Follow-up
Kourti *et al.* 2014[42]	Not stated	In hospital	In hospital	• (1) 7–10 days in ICU • (2) 17–22 days in ICU	• (1) 7–10 days in ICU • (2) 17–22 days in ICU	Not stated
Kodali *et al.* 2014[80]	Paper	Posted	Posted	Not stated	Not stated	• 3 weeks • 3.5 weeks
Tastan *et al.* 2014[40]	Paper	In hospital	In hospital	Not stated	Not stated	Not stated

N/A, not applicable.

Response rates

The number of family members surveyed varied from 43[38] to 3124[70] in any given publication.

Family member response, where a denominator was reported, varied from 8.3%[78] to 93.0%.[38] In those publications that surveyed family members of ICU survivors, the response rate varied from 51.6%[61] to 68.6%.[74] In those publications that surveyed family members of ICU non-survivors, the response rate varied from 37.9%[70] to 93.0%.[38]

Figure 45 shows the overall response rate in the FREE study compared with publications that reported an overall response rate (i.e. for family members of ICU survivors and ICU non-survivors). Even with the FREE study having the largest sample size, the overall response rate for the FREE study was similar to the other publications.

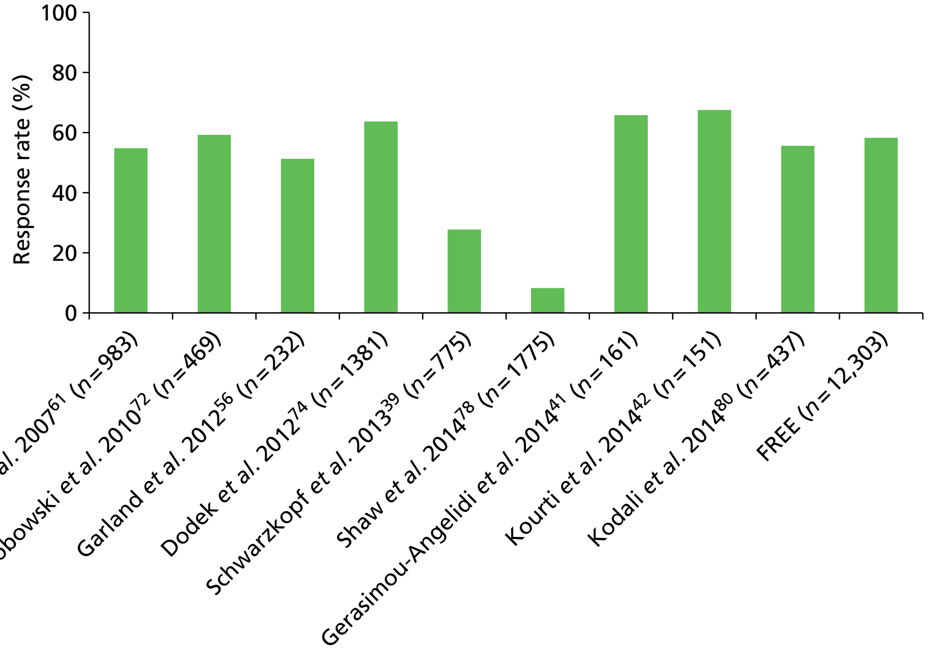

FIGURE 45 Response rate for family members of combined ICU survivors and ICU non-survivors (by publication).

Figure 46 shows the response rate for family members of ICU survivors in the FREE study compared with publications that reported a response rate for family members of ICU survivors. Like the overall response rate, the response rate for family members of ICU survivors for the FREE study was similar to the other publications.

Figure 47 shows the response rate for family members of ICU non-survivors in the FREE study compared with publications that reported a response rate for family members of ICU non-survivors. The response rate for family members of ICU non-survivors for the FREE study was higher than in most of the other publications; one publication did achieve a higher response rate (93.0%), but the sample size was relatively small.[38]

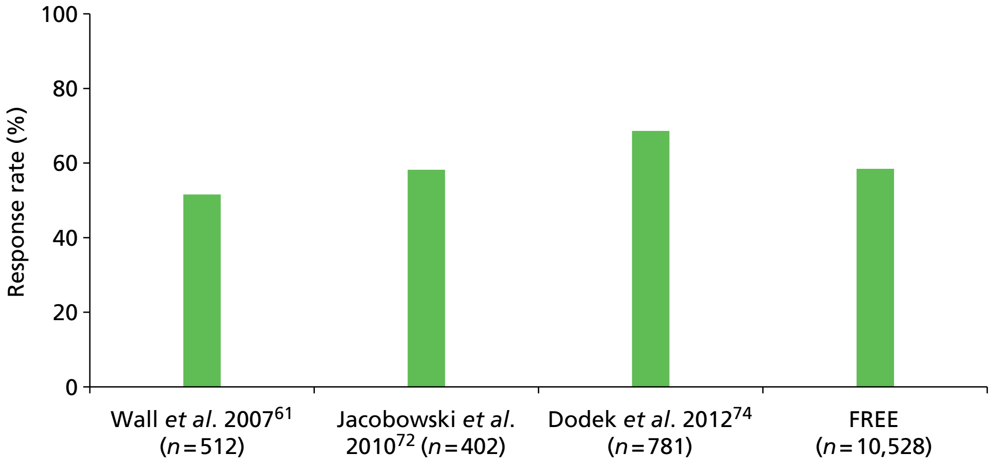

FIGURE 46 Response rate for family members of ICU survivors (by publication).

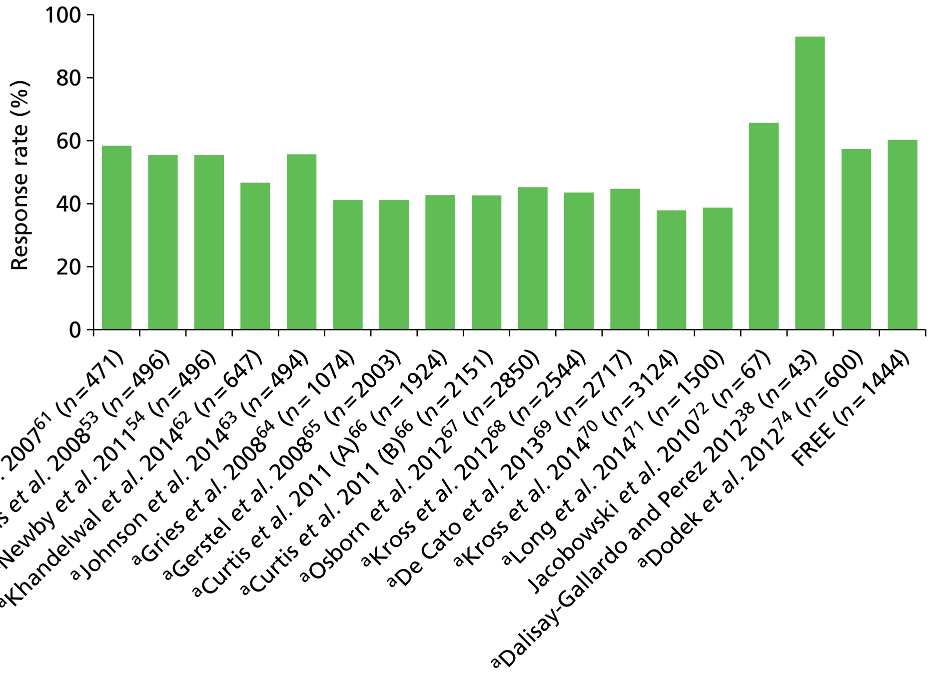

FIGURE 47 Response rate for family members of ICU non-survivors (by publication). a, Only family members of ICU non-survivors participated.

Satisfaction scores

Of the 24 publications using the FS-ICU-24, for 14 publications direct comparisons with the FREE study were not possible. This was because the patient and family member eligibility criteria reported were too specific or too broad to enable comparison, or the publication did not report the family satisfaction scores (overall and/or domain scores). The remaining 10 publications fell into two distinct surveyed groups: all family members of patients staying ≥ 48 hours in ICU;[39,40,57,74] and legal or nominated next of kin of ICU non-survivors.[53,62,66,67,69,70] Data from patients and family members in the FREE study meeting these eligibility criteria were extracted to facilitate comparison of the scores between the FREE study and the 10 publications. Of these 10 publications, one reported only the domain scores[74] and two reported only the overall family satisfaction score.[40,62]

The first group examined was all family members of patients staying ≥ 48 hours in ICU. For overall family satisfaction score, the FREE study was similar to the four publications in this group (*Figure 48*). It was also similar to these publications on the domain scores for s*atisfaction with care* (*Figure 49*) and for s*atisfaction with decision-making* (*Figure 50*).

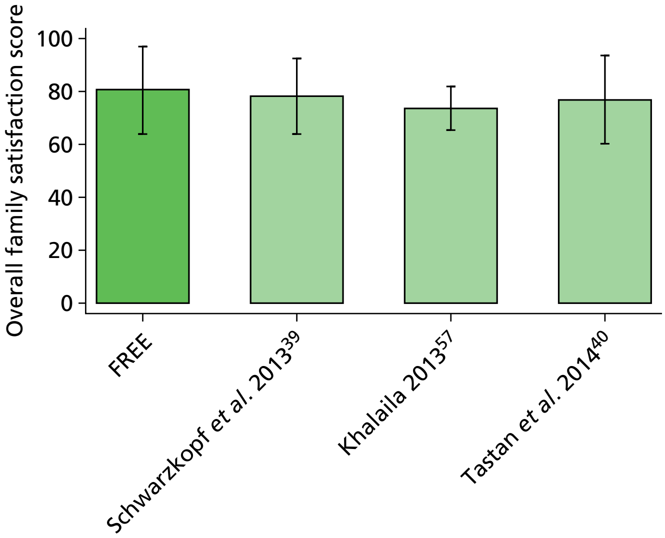

FIGURE 48 Overall family satisfaction score for all family members of patients staying ≥ 48 hours in ICU (by publication).

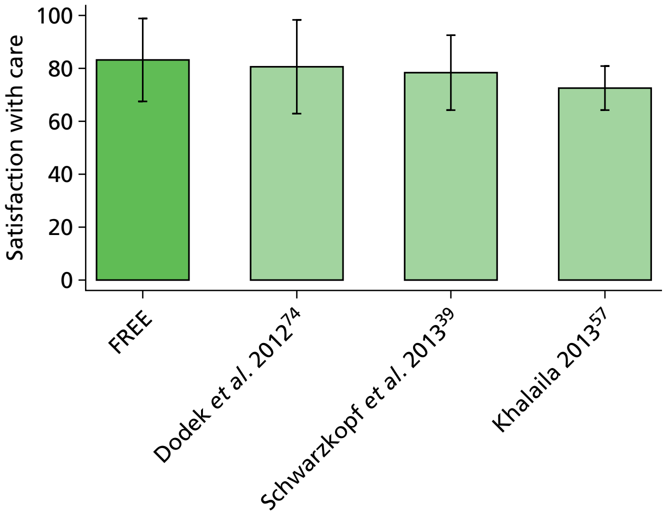

FIGURE 49 *Satisfaction with care* domain score for all family members of patients staying ≥ 48 hours in ICU (by publication).

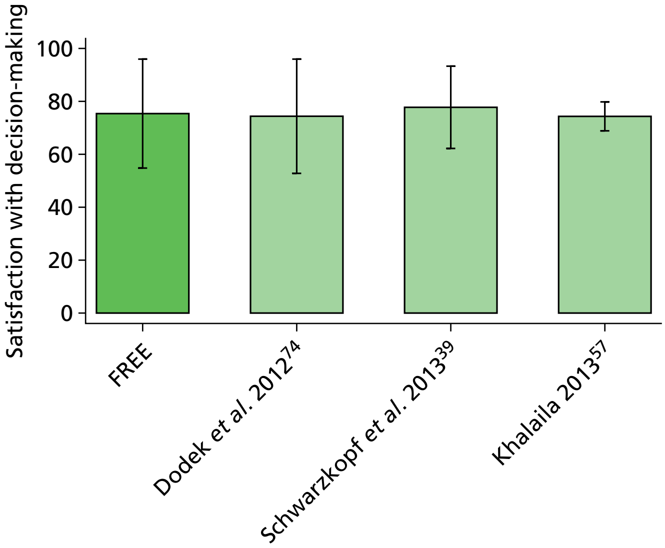

FIGURE 50 *Satisfaction with decision-making* domain score for all family members of patients staying ≥ 48 hours in ICU (by publication).

The second group examined was legal or nominated next of kin of ICU non-survivors. For two of the publications, all three scores were reported: pre- and post-intervention[53] and by study arm (control/intervention) and time point (baseline/follow-up period).[66] For overall family satisfaction score, the FREE study was similar to the six publications in this group (*Figure 51*). It was also similar to these publications on the domain scores for *satisfaction with care* (*Figure 52*) and for *satisfaction with decision-making* (*Figure 53*).

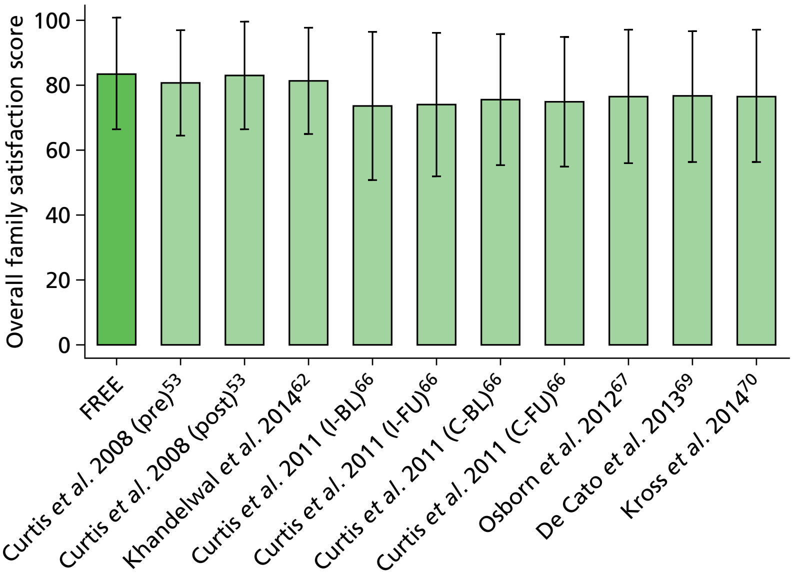

FIGURE 51 Overall family satisfaction score for next of kin of ICU non-survivors (by publication). C-BL, control group at baseline; C-FU control group at follow-up; I-BL, intervention group at baseline; I-FU, intervention group at follow-up; post, post-intervention; pre, pre-intervention.

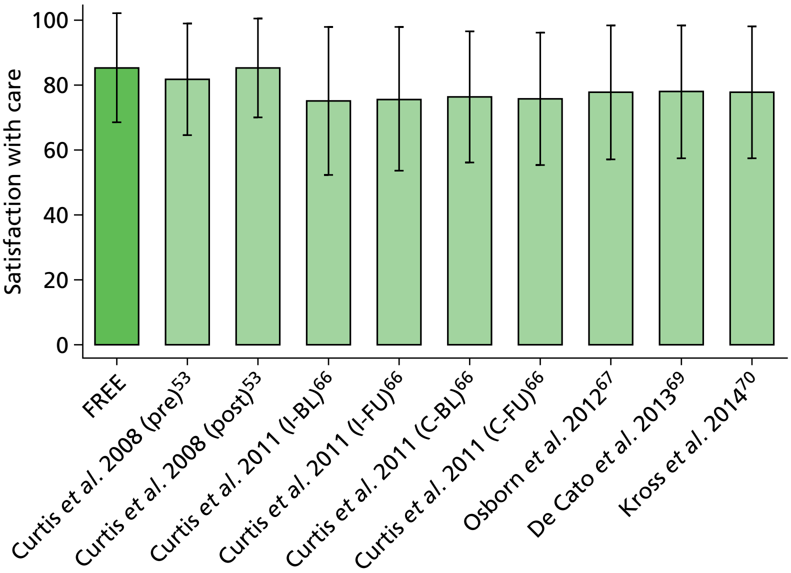

FIGURE 52 *Satisfaction with care* domain score for next of kin of ICU non-survivors (by publication). C-BL, control group at baseline; C-FU control group at follow-up; I-BL, intervention group at baseline; I-FU, intervention group at follow-up; post, post-intervention; pre, pre-intervention.

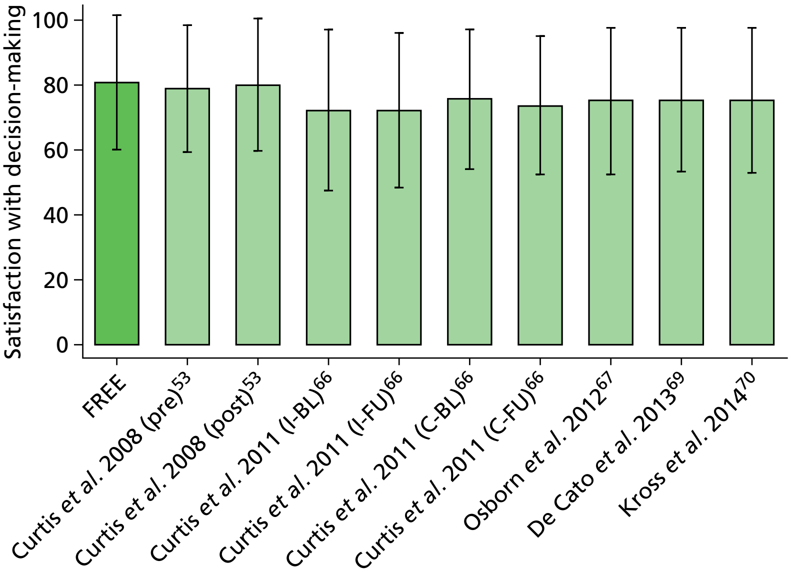

FIGURE 53 *Satisfaction with decision-making* domain score for next of kin of ICU non-survivors (by publication). C-BL, control group at baseline; C-FU control group at follow-up; I-BL, intervention group at baseline; I-FU, intervention group at follow-up; post, post-intervention; pre, pre-intervention.

Discussion

In comparison with the 13 studies (24 publications) using the FS-ICU-24, the FREE study obtained similar response rates, even with a much larger sample size, and had a similar overall family satisfaction score and domain scores for *satisfaction with care* and for *satisfaction with decision-making*. It was difficult to draw these comparisons given the lack of standardisation and consistent reporting in patient and family member eligibility criteria and method of questionnaire distribution; this led to being able to make a direct comparison on the family satisfaction scores only with fewer than half of the publications.

Chapter 11 Conclusions and recommendations

The qualitative study that constituted phase 1 of the FREE study revealed that, while there were subjective differences in how health professionals and family members interpreted some items in the original FS-ICU-24, adaptation to the UK setting required only relatively minor edits: changes to section heading titles, clarification of the wording of questions, clarification of North American English to UK English, addition to existing guidance, general formatting and enhanced design of the layout. The quantitative study that constituted phase 2 of the FREE study, nested in the CMP (the national clinical audit of adult critical care), provided a large sample of ICUs, family members and patients for the psychometric assessment of the UK FS-ICU-24, which indicated a high degree of internal consistency, criterion validity among family members of ICU non-survivors (no suitable instrument was available to establish criterion validity among family members of ICU survivors) and good comprehensibility and acceptability. However, the two-factor solution for the original FS-ICU-24, with domains of *satisfaction with care* and *satisfaction with decision-making*, was not a good fit and exploratory factor analysis suggested that the domain of *satisfaction with decision-making* encompassed two separate constructs, which we termed *satisfaction with information* and *satisfaction with the decision-making process*.

In general, overall family satisfaction mean scores and domain mean scores were high (ranging from 76 to 88 across the overall and domain scores) and all showed a left-skewed distribution. Determinants of family satisfaction varied by whether or not the patient survived the ICU. Factors associated with overall family satisfaction for family members of ICU survivors were, with respect to family members, age, ethnicity, relationship to patient (next of kin and/or lived with patient) and visit frequency; and, with respect to patients, acute severity of illness and receipt of invasive mechanical ventilation. There were no family member factors associated with overall family satisfaction for family members of ICU non-survivors; the patient factors were age, acute severity of illness and duration of stay. Despite the large size of the FREE study, there was some indication that the smaller sample size of family members of ICU non-survivors may have hindered identification of other factors seen for family members of ICU survivors, for example ethnicity. Neither the ICU/hospital factors investigated nor seasonality was associated with overall family satisfaction. The finding that ethnicity was associated with overall family satisfaction (white family members of both ICU survivors and non-survivors reported higher satisfaction, on average) warrants further investigation.

Funnel plots of overall family satisfaction scores and domain scores confirmed that there was significant variation in family satisfaction across the ICUs participating in the FREE study. Multiple imputation provided greater power to identify potentially outlying ICUs. Adjusting for family member and patient characteristics using the multilevel multivariable models from the FREE study reduced the variation across ICUs and resulted in fewer ICUs being identified as potential outliers. Adjustment is therefore important to avoid falsely identifying ICUs as outliers because of the characteristics of either their patients or the patients' family members.

Limited to the confines of the FREE study (patients staying in the ICU for 24 hours or more and timing/administration of questionnaires), simulations based on the FREE study data suggested that family satisfaction surveys using short recruitment windows can produce relatively unbiased estimates of the 'true' average family satisfaction. Recruitment windows may need to be 6 weeks or longer to obtain sufficient sample size from smaller ICUs, though an alternative approach, whereby each ICU recruits until a fixed sample size is reached, gave more stability in the precision of the estimated family satisfaction scores across ICUs. Recruiting each patient's nominated next of kin resulted in higher response rates and is therefore likely to be the preferred approach. Recruiting only family members of patients who stayed in the ICU for at least 48 hours also resulted in higher recruitment rates. Given no association with seasonality, the timing of satisfaction surveys appeared to be unimportant.

Comparison with other studies using the FS-ICU-24, internationally, indicates the strengths of the FREE study. Other than the requirement for a patient to be in the ICU for 24 hours, no further selection of patients or of family members occurred; this was, first, to avoid biases that selection might introduce and, second, to provide an empirical basis to inform selection of patients and family members in future studies evaluating family satisfaction in critical care using the FS-ICU-24 or equivalent, to maximise recruitment and response. A further strength of the FREE study was the use of evidence-based practice for maximising response to postal surveys, which yielded a very similar response rate to other studies but in a much larger sample size of family members and ICUs. Employing the same mode and timing of delivery of the FS-ICU-24, for family members both of ICU survivors and of ICU non-survivors, is a further strength, allowing meaningful comparison between these groups. The large sample size has allowed important multilevel multivariable modelling of the determinants of family satisfaction and indicates that all previous studies have been too small and, therefore, underpowered when attempting to evaluate these. One weakness of the FREE study was the burden on ICUs to recruit up to four family members for each patient staying ≥ 24 hours over a 12-month period and the resultant recruitment rate. The FREE study and the FREE study database will be an important foundation and resource for future studies evaluating family satisfaction in UK critical care.

In conclusion, the FREE study has provided a UK-adapted, psychometrically valid questionnaire providing an overall family satisfaction score and three domain scores: *satisfaction with care*, *satisfaction with information* and *satisfaction with the decision-making process*. The large sample size of both ICUs and family members has allowed robust multilevel multivariable modelling of factors associated with overall family satisfaction to inform important adjustment of any future evaluation using this questionnaire. Finally, a potential sampling frame has been proposed for routine use.

So, are we ready to move into routine evaluation alongside the CMP? We have some reservations about the current UK FS-ICU-24 questionnaire.

The UK FS-ICU-24 provides high mean overall family satisfaction scores and domain scores, in general, thus leaving little room for even higher scores to indicate the impact of any improvement measures. In addition, other, more qualitative data collected as part of the FREE study indicate that the questionnaire may not be sensitive to all aspects of family satisfaction.

In preparation for feeding back comparative and individual results of the FREE study to participating ICUs, a coding framework was developed, based on the structure of the UK FS-ICU-24, to code the free-text responses to the three questions:

- Do you have any suggestions on how to make care provided in the ICU better?
- Do you have any comments on things we did well?
- Please add any comments or suggestions that you feel may be helpful to the staff of this ICU.

Overall, 72% of family members (5157 of 7173) responded to at least one of these three questions. Although formal analysis of these more qualitative data did not form part of this proposal, brief analysis has indicated that there may be scope for improvement of the UK FS-ICU-24 and that a detailed analysis of the rich data generated as part of the FREE study, combining both quantitative and qualitative, is warranted.

A few examples are cited below.

'How did we treat your family member (the patient)?', item 1, concern and caring by ICU staff (the courtesy, respect and compassion your family member (the patient) was given), had response options 'excellent/very good/good/fair/poor/not applicable'. This item was rated excellent by one responder, yet their comment noted:

> *The only issue to detract from the excellent service given in ICU was the action of [staff name], his bedside manner was atrocious he seemed insensitive to both patient and family and his attitude continued after [patient name] left ICU, we will be putting in a formal complaint letter.*

This suggested that response options might be improved, along the lines of 'all ICU staff were concerned and caring/most ICU staff . . ./few ICU staff . . ./no ICU staff . . .' and, even with such response options, an additional item might be required to reflect that concern and caring occurred all the time/most of the time/some of the time/none of the time.

Other responders who also rated this item excellent also noted:

> *On two occasions, a doctor asked my mother fairly pressing questions (early on in care) about either pressing on with treatment or making comfortable and not carrying out any invasive surgery. These were asked early in the morning with no one from family to support her and when asked later in the day with two of us present, was surprised that mum had changed her mind. I think that the patient needs to be fully awake and supported to answer these questions.*
>
> *One member of the night staff was very curt with my husband and called him a 'very difficult patient', unfortunately I did not get a chance to see or meet with the above.*
>
> *Some of the team did not talk to my partner or explain to him what they were doing, or to myself. When I asked for help with his needs or medicine etc. one nurse did not seem to have any care or compassion in anything she was doing for my partner.*
>
> *When [patient name] was put on the pathway care he was totally alone. The screens were around him and he was left completely alone – no nurses and no medication. I came back after going home – he was cold from the feet up and no one was with him. I had to ask for help. It was as if he didn't exist.*

'How did we treat your family member (the patient)?', item 2a, symptom management: pain (how well the ICU staff assessed and treated your family member's symptoms), had response options 'excellent/very good/good/fair/poor/not applicable'. This item was rated excellent by one responder, yet their comment noted:

> *I noticed redness on my son's buttocks due to pressure. I pointed this out but the skin was allowed to deteriorate further. Pressure area care is a very basic nursing skill as prolonged pain is caused and the risk of infection is present.*

'How did we treat you?', item 4, emotional support (how well the ICU staff provided emotional support) had response options 'excellent/very good/good/fair/poor/not applicable'. This item was rated excellent by one responder, yet their comment noted:

> *I think the only thing I could suggest is at times the consultants I feel didn't have a lot of people skills. They were amazing at what they did, but when talking to family members I didn't feel compassion was there.*

Another responder who also rated this item ‘excellent’ also noted:

> *I would like to add that the ICU consultants were by and large very negative. One consultant even stated that ‘if he survives he will probably need 24 hour care’. We felt that this was a very unnecessary prognosis 10 days after his crisis and caused us much anguish for a few days. This prognosis was unfounded and was not helpful. The language use by this consultant was very harsh.*

‘Information needs’, item 2, ease of getting information (willingness of ICU staff to answer your questions) had response options ‘excellent/very good/good/fair/poor/not applicable’. This item was rated ‘excellent’ by one responder, yet their comment noted:

> *Care was excellent but whatever care was given was never discussed with the family as we were not allowed to visit when the doctors were making their rounds (and decisions).*

Other responders who also rated this item ‘excellent’ also noted:

> *I did not see or speak to a doctor at all. This would have made such a difference to me and my daughter.*

> *The doctors/nurses did not openly volunteer information unless we asked. There could have been better feedback as to how he was progressing during his time in ICU.*

Although we recognise that this is only an informal analysis of a very large number of comments (approximately 60% of family members commented), it raises concerns that the current items/response options on the FS-ICU-24 may be too insensitive and we would recommend a formal analysis of these data.

Recommendations for research

Recommendation 1: further development of the UK 24-item Family Satisfaction in the Intensive Care Unit questionnaire

We recommend a combination of (1) a formal secondary analysis of the rich quantitative and qualitative data in the FREE study data set to inform further development of the UK FS-ICU-24 questionnaire for use in evaluating family satisfaction in UK ICUs and (2) primary research to test the psychometric properties of the new questionnaire.

Recommendation 2: further testing of the new UK 24-item Family Satisfaction in the Intensive Care Unit questionnaire

We recommend primary research to test the utility of the new UK FS-ICU-24 questionnaire, focusing on its ability to detect change, that is its sensitivity.

Recommendation 3: evaluation of the association of ethnicity with family satisfaction

The finding that ethnicity was associated with overall family satisfaction (white family members of both ICU survivors and non-survivors reported higher satisfaction, on average) warrants further investigation.

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Dr Stephen E Wright (consultant in anaesthesia and intensive care) contributed to the design of the study, contributed to the acquisition, analysis and interpretation of the data, and drafted and critically reviewed the manuscript.

Emma Walmsley (study co-ordinator) co-ordinated the study, contributed to the acquisition and interpretation of the data, and drafted and critically reviewed the manuscript.

Dr Sheila E Harvey (CTU manager and senior research fellow) contributed to the design of the study, contributed to the acquisition, analysis and interpretation of the data, and drafted and critically reviewed the manuscript.

Emily Robinson (study statistician) contributed to the analysis and interpretation of the data, and drafted the manuscript.

Paloma Ferrando-Vivas (statistician/risk modeller) contributed to the analysis and interpretation of the data, and drafted and critically reviewed the manuscript.

Dr David A Harrison (senior statistician and honorary senior lecturer in medical statistics) contributed to the design of the study, contributed to the analysis and interpretation of the data, and drafted and critically reviewed the manuscript.

Ruth R Canter (research assistant) contributed to the analysis and interpretation of the data, and drafted and critically reviewed the manuscript.

Professor Elaine McColl (director of Newcastle CTU and professor of health services research) contributed to the design of the study, contributed to the acquisition, analysis and interpretation of the data, and drafted and critically reviewed the manuscript.

Annette Richardson (nurse consultant in critical care) contributed to the design of the study, contributed to the acquisition of data, and critically reviewed the manuscript.

Michael Richardson (sole proprietor) contributed to the design of the study and critically reviewed the manuscript.

Dr Lisa Hinton (senior qualitative researcher in primary care health sciences) contributed to the design of the study and critically reviewed the manuscript.

Professor Daren K Heyland (director of the Kingston General Hospital Clinical Evaluation Research Unit and professor of medicine and epidemiology) contributed to the design of the study, contributed to the analysis and interpretation of the data, and critically reviewed the manuscript.

Professor Kathryn M Rowan (director of scientific and strategic development at ICNARC and honorary professor) conceived and designed the study, contributed to the acquisition, analysis and interpretation of the data, and drafted and critically reviewed the manuscript.

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Data sharing statement

Data can be obtained from the corresponding author.

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Appendix 1 24-item Family Satisfaction in the Intensive Care Unit questionnaire (FS-ICU-24)

Study ID number: ___ :____
site pt. #

Family Satisfaction with Care in the Intensive Care Unit©
FS-ICU (24)

How are we doing?

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

Your family member was a patient in this ICU. You have been recorded as being the "next-of-kin". The questions that follow ask **YOU** about your family member's **most recent ICU admission**. We understand that there were probably many doctors and 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 we 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 we did well and what we can do to make our 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.

DEMOGRAPHICS:

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

1. I am: ☐ Male ☐ Female
2. I am __________ years old
3. I am the patient's:

☐ Wife ☐ Husband ☐ Partner
☐ Mother ☐ Father ☐ Sister ☐ Brother
☐ Daughter ☐ Son ☐ Other (Please specify):_______________

4. Before this most recent event, have you been involved as a family member of a patient in an ICU (Intensive Care Unit)?

☐ Yes ☐ No

5. Do you live with the patient? ☐ Yes ☐ No

   If no, then on average how often do you see the patient?

☐ More than weekly ☐ Weekly ☐ Monthly ☐ Yearly ☐ Less than once a year

6. Where do you live? ☐ In the city where the hospital is located ☐ Out of town

FS-ICU(24) Version 11 August 15, 2006

How are we doing?
Your Opinions about your Family Member's ICU stay

PART 1: SATISFACTION WITH CARE

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

HOW DID WE TREAT YOUR FAMILY MEMBER (THE PATIENT)

1.	**Concern and Caring by ICU Staff:** The courtesy, respect and compassion **your family member (the patient)** was given	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
	Symptom Management: How well the ICU staff assessed and treated your family member's symptoms.						
2.	**Pain**	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
3.	**Breathlessness**	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
4.	**Agitation**	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A

HOW DID WE TREAT YOU?

5.	**Consideration of your needs:** How well the ICU staff showed an interest in your needs	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
6.	**Emotional support:** How well the ICU staff provided emotional support	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
7.	**Co-ordination of care:** The teamwork of all the ICU staff who took care of your family member	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
8.	**Concern and Caring by ICU**	☐1	☐2	☐3	☐4	☐5	☐6

FS-ICU(24) Version 11 August 15, 2006

How are we doing?
Your Opinions about your Family Member's ICU stay

	Staff: The courtesy, respect and compassion **you** were given	Excellent	Very Good	Good	Fair	Poor	N/A
	NURSES						
9.	**Skill and Competence of ICU Nurses:** How well the nurses cared for your family member.	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
10.	**Frequency of Communication With ICU Nurses**: How often nurses communicated to you about your family member's condition	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
	PHYSICIANS (All Doctors, including Residents)						
11.	**Skill and Competence of ICU Doctors:** How well doctors cared for your family member.	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
	THE ICU						
12.	**Atmosphere of ICU was?**	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
	THE WAITING ROOM						
13.	**The Atmosphere in the ICU Waiting Room was?**	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A

14.	**Some people want everything done for their health problems while others do not want a lot done. How satisfied were you with the LEVEL *<u>or amount</u>* of health care your family member received in the ICU?**	☐1 Very Dissatisfied	☐2 Slightly Dissatisfied	☐3 Mostly Satisfied	☐4 Very Satisfied	☐5 Completely Satisfied

FS-ICU(24) Version 11 August 15, 2006

How are we doing?
Your Opinions about your Family Member's ICU stay

PART 2: FAMILY SATISFACTION WITH DECISION-MAKING AROUND CARE OF CRITICALLY ILL PATIENTS

INSTRUCTIONS FOR FAMILY 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 CHECK ONE BOX THAT BEST DESCRIBES YOUR FEELINGS

INFORMATION NEEDS

1.	**Frequency of Communication With ICU Doctors**: How often doctors communicated to you about your family member's condition	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
2.	**Ease of getting information:** Willingness of ICU staff to answer your questions	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
3.	**Understanding of Information:** How well ICU staff provided you with explanations that you understood	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
4.	**Honesty of Information:** The honesty of information provided to you about your family member's condition	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
5.	**Completeness of Information:** How well ICU staff informed you what was happening to your family member and why things were being done.	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A
6.	**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.)	☐1 Excellent	☐2 Very Good	☐3 Good	☐4 Fair	☐5 Poor	☐6 N/A

FS-ICU(24) Version 11 August 15, 2006

How are we doing?
Your Opinions about your Family Member's ICU stay

PROCESS OF MAKING DECISIONS:

During your family member's stay in the ICU, many important decisions were made regarding the health care she or he received. From the following questions, pick **one** answer from each of the following set of ideas that best matches your views:

7. **Did you feel included in the decision making process?**
☐1 I felt very excluded
☐2 I felt somewhat excluded
☐3 I felt neither included nor excluded from the decision making process
☐4 I felt somewhat included
☐5 I felt very included

8. **Did you feel supported during the decision making process?**
☐1 I felt totally overwhelmed
☐2 I felt slightly overwhelmed
☐3 I felt neither overwhelmed nor supported
☐4 I felt supported
☐5 I felt very supported

9. **Did you feel you had control over the care of your family member?**
☐1 I felt really out of control and that the health care system took over and dictated the care my family member received
☐2 I felt somewhat out of control and that the health care system took over and dictated the care my family member received
☐3 I felt neither in control or out of control
☐4 I felt I had some control over the care my family member received
☐5 I felt that I had good control over the care my family member received

10. **When making decisions, did you have adequate time to have your concerns addressed and questions answered?**
☐1 I could have used more time
☐2 I had adequate time

FS-ICU(24) Version 11 August 15, 2006

How are we doing?
Your Opinions about your Family Member's ICU stay

If your family member died during the ICU stay, please answer the following questions (11-13). If your family member did not die please skip to question 14.

11. Which of the following best describes your views:

☐1 I felt my family member's life was prolonged unnecessarily
☐2 I felt my family member's life was slightly prolonged unnecessarily
☐3 I felt my family member's life was neither prolonged nor shortened unnecessarily
☐4 I felt my family member's life was slightly shortened unnecessarily
☐5 I felt my family member's life was shortened unnecessarily

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

☐1 I felt that he/she was very uncomfortable
☐2 I felt that he/she was slightly uncomfortable
☐3 I felt that he/she was mostly comfortable
☐4 I felt that he/she was very comfortable
☐5 I felt that he/she was totally comfortable

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

☐1 I felt very abandoned by the health care team
☐2 I felt abandoned by the health care team
☐3 I felt neither abandoned nor supported by the health care team
☐4 I felt supported by the health care team
☐5 I felt very supported by the health care team

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

____
____
____
____
____
____

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

____
____
____
____
____
____

FS-ICU(24) Version 11 August 15, 2006

How are we doing?
Your Opinions about your Family Member's ICU stay

16. **Please add any comments or suggestions that you feel may be helpful to the staff of this hospital.**

We would like to thank you very much for your participation and your opinions. Please either return your completed survey to the designated person in the ICU or put it in the stamped, self-addressed envelope and mail it to us as soon as possible.

FS-ICU(24) Version 11 August 15, 2006

Appendix 2 UK 24-item Family Satisfaction in the Intensive Care Unit questionnaire (UK FS-ICU-24)

free
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

V1.2 18/10/13

free
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.

FS-ICU

free
Family Reported
Experiences Evaluation

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 ○

FS-ICU

free
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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Family Reported
Experiences Evaluation

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 ○

FS-ICU

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Family Reported
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 in the 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	○

FS-ICU

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Family Reported
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 ○

FS-ICU

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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.

FS-ICU

Appendix 3 Quality of Dying and Death questionnaire

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Experiences Evaluation

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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Family Reported
Experiences Evaluation

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

Q5a **How often did your loved 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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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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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 several 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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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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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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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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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.

Contact details are provided on the Information Sheet.

Thank you again for your help.

Comments

FAM-QODD

Appendix 4 Poster and leaflet

free
Family Reported
Experiences Evaluation

Tell us your experiences...

This unit is participating in a research study seeking your experiences of our intensive care unit with a view to improving our services

Trained staff may discuss this with you

Further information can be obtained from any member of the health care team.

Version 1.0, 17 December 2012

If you have any questions about
the FREE Study, then please ask a
member of staff

**Thank you for taking the time to read
this leaflet**

Research Ethics Committee
Reference Number: 13/SC/0037

Information Leaflet

V1.1 (11/04/2013)

INSERT TRUST LOGO HERE

free
Family Reported
Experiences Evaluation

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

This unit is taking partin a research study
which aims to help improve critical care (also
known as intensive care) in the NHS by
ensuring that the experiences of family
members and of those receiving care are fed
back to those organising and delivering care

What is the purpose of the study?

We want to find out how family members* feel about their experiences in the intensive care unit and if this feedback can be routinely collected across the NHS to ensure that patients and their family/loved ones have a positive experience of care.

The reason for asking family members is that patients staying in the intensive care unit are usually severely ill and often do not remember much about their stay, or sadly, some are too ill to survive. Feedback from family members is, therefore, important as you play a vital role in the support of your loved ones.

* *A 'family member' is considered to be anyone with a close familial, social or emotional relationship to the patient, including relatives, partners, friends, etc.*

NHS
National Institute for
Health Research

What will happen if I am asked to take part?

If you are asked to take part in the study, then you will be approached by a member of the intensive care team. They will provide you with a written information sheet which will fully explain the study and what is involved. You will be given the time you need to decide if you want to participate. You will have the opportunity to discuss the study with staff and to ask any questions you may have. You will be asked to sign a consent form if you decide you wish to take part.

What information will be collected?

You will be asked to provide your contact details so that a questionnaire can be posted to you.

Do I have to take part?

Joining the study is entirely voluntary and deciding not to join will not affect the standard of care your relative/friend receives

What next?

You may be approached about this study by a member of the intensive care team. An information sheet will be provided and a member of the team will go through this in detail with you.

Appendix 5 Participant information sheet

free
Family Reported
Experiences Evaluation

Information Sheet

(Version 1.2, 11 April 2013)

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

Introduction

We would like to invite you to take part in a research study which aims to help improve critical care (also known as intensive care) in the National Health Service (NHS) by ensuring that the experiences of those receiving care and their family members are fed back to those organising and delivering the care. The study is being conducted in NHS intensive care units across the UK, and is being managed by the Intensive Care National Audit & Research Centre (ICNARC) in London.

For this study, a family member is anyone with a close familial, social or emotional relationship to the patient, including relatives, partners, friends, carers etc.

Before you decide whether to take part, it is important that you understand why the research is being done and what it involves. **One of our team will go through this Information Sheet with you and answer any questions you may have.** Feel free to talk to your friends and family about the study if you wish and please ask us if there is anything that is not clear or if you would like more information. Please take the time to decide whether or not you wish to take part.

What is the purpose of the study?

We want to find out how family members feel about their experience in the intensive care unit, and if this feedback can be routinely collected across the NHS, to ensure that patients and their family/loved ones have a positive experience of care.
The reason for asking family members and not patients is that patients staying in intensive care are usually severely ill and often do not remember much about their time in the unit, or sadly, some patients are too ill to survive. Feedback from family members is therefore important as they play a vital role in the support of patients.

Why have I been asked to take part in the study?

You have been asked to participate as you have visited a relative/friend during their time in intensive care and have been identified as a family member, loved one or friend of the patient. We aim to identify up to four family members for those patients who spend more than 24 hours in the intensive care unit.

Why should I take part?

You 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. We hope that feedback from family members will help towards ensuring patients and their family members have a positive experience of the NHS.

Do I have to take part?

Joining the study is entirely voluntary. You can withdraw from the study at any time, without giving a reason, and this will not affect the standard of care your relative/friend receives.

What will I have to do?

Having read this information sheet and been given the opportunity to ask questions, if you are happy to participate then you will be asked to sign a consent form. You will also be asked to provide some basic details, including your name, address and your relationship to the patient. This information will be entered onto a secure web-based data entry system. This information is taken so that we can send a questionnaire to you by post.

Three weeks after your relative/friend leaves intensive care we will post you a questionnaire with a stamped addressed envelope (for easy return, free of charge). We would ask that you complete and return the questionnaire. If we do not receive a response within four weeks of posting the questionnaire to you, a second questionnaire will be sent as a reminder. After this, no further contact will be made.

Inevitably some patients admitted to intensive care will not survive their illness. Given that all experiences of intensive care are important, we include the experiences of these families too.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, please contact the Principal Investigator (the person leading the study at this hospital) or the Hospital's Patient Advice & Liaison Service (PALS) – details provided below.

Will my taking part in this study be kept confidential?

Yes at all times. We will follow ethical and legal practice and all information will be handled in strict confidence. Information collected will be stored securely and in strict confidence at ICNARC and at the NHS Trust [Insert relevant NHS Trust here as appropriate]. Procedures for handling, processing, storing and destroying data are compliant with the Data Protection Act 1998.

What will happen to the results of the research study?

The results of the study will be published in professional and scientific journals and will be available from ICNARC via the website at www.icnarc.org or by telephone on 020 7269 9277. They will also be available on the ICUsteps website at www.icusteps.org. ICUsteps is the intensive care support charity for patients and their families.

It will not be possible to identify any individual who has taken part in the study in any reports or articles.

Who is funding and organising the study?

This study is being funded by the National Institute for Health Research (NIHR), Health Services and Delivery Research Programme. The study is being sponsored and managed by the Intensive Care National Audit & Research Centre (ICNARC).

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the NRES Committee South Central – Berkshire B.

Thank you for taking the time to read this information

For more information about FREE you can contact the Principal Investigator:

[Insert name local Principal Investigator, Position]

[Contact telephone number local Principal Investigator]

If you are unhappy with any aspect of the study:

If you do not wish to speak to the research staff listed above, please contact the Patient Advisory and Liaison Service (PALS): [insert PALS contact details here]

Appendix 6 Questionnaire pack

free
Family Reported
Experiences Evaluation

ICNARC
Napier House
24 High Holborn
London WC1V 6AZ
tel +44 (0)20 7269 9277
fax +44 (0)20 7831 6879
email free@icnarc.org

«Title» «FirstName» «LastName_»
«Address1»
«Address1»
«Address1»
«City»
«PostalCode»

«PostalCode»

Dear «Title» «LastName_»

I write to you with regard to the Family Reported Experiences Evaluation (FREE) Study, for which you consented for us to contact you when your «PostalCode» was in the intensive care unit at «PostalCode».

I know this may be a difficult time for you but I would be very grateful if you would share your experiences relating to the recent admission of your «PostalCode» to the **intensive care unit** at «PostalCode» on the enclosed questionnaire. This should only take about ten minutes of your time. A stamped, self addressed envelope is provided for you to return your completed questionnaire to us.

The FREE Study is being coordinated by the Intensive Care National Audit & Research Centre. Information about the FREE Study is available on the enclosed information sheet and at www.icnarc.org.

If you have any questions, or would like help completing the questionnaire, then please do not hesitate to contact the FREE Study Team at ICNARC (contact details above). If you do not want to be contacted again, then please inform us either by returning the relevant slip or by telephone on 020 7269 9277 or email at free@icnarc.org.

Thank you so much for your time. I value the opportunity to hear about your experiences such that we can use them to improve intensive care services in the NHS.

Yours sincerely

Professor Kathy Rowan

Encs

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free
Family Reported
Experiences Evaluation

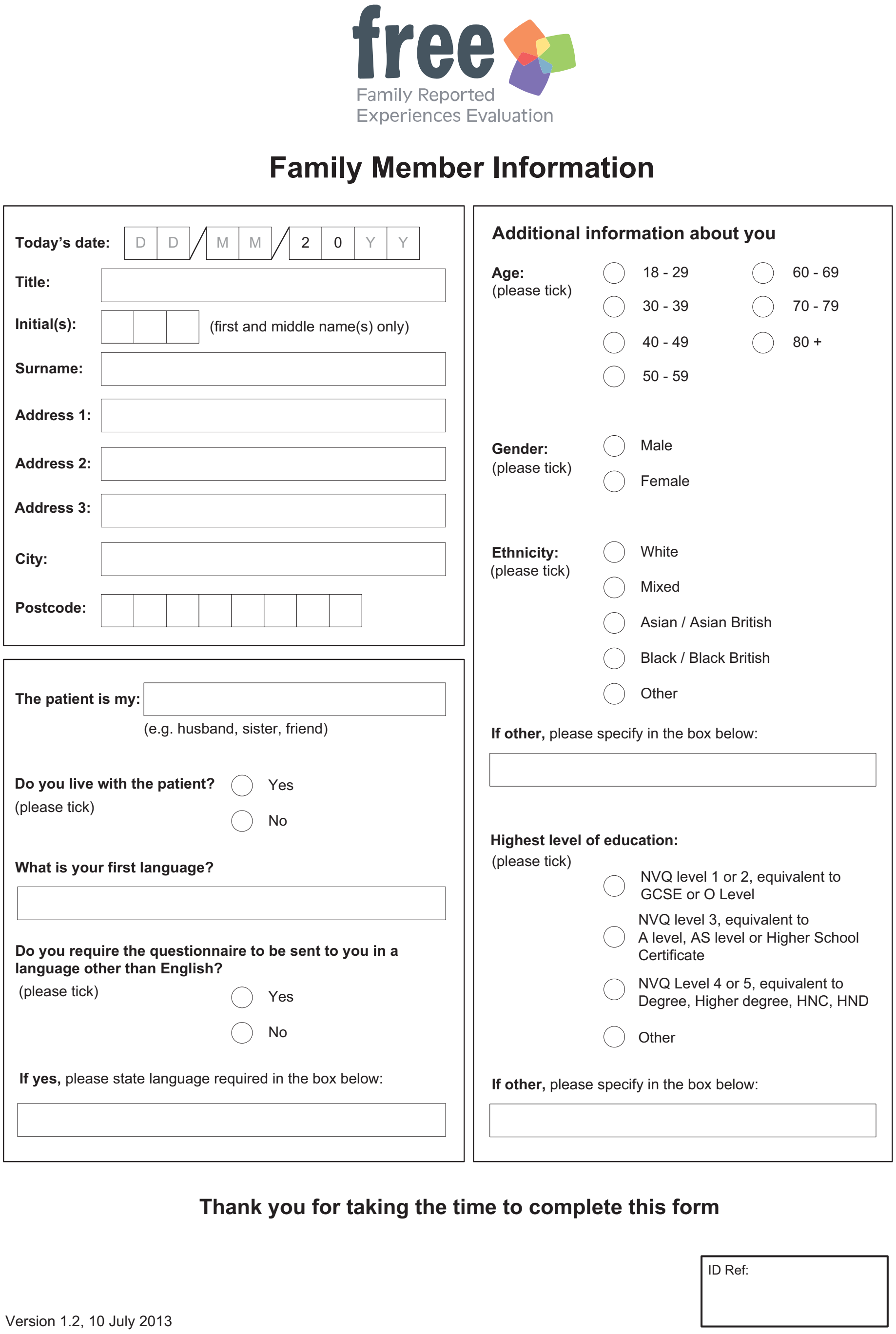
I do not wish to participate

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)

Appendix 7 Data collection form



free
Family Reported
Experiences Evaluation

Family Member Information

Today's date: D D / M M / 2 0 Y Y

Title: ☐

Initial(s): ☐☐☐ (first and middle name(s) only)

Surname: ☐

Address 1: ☐

Address 2: ☐

Address 3: ☐

City: ☐

Postcode: ☐☐☐☐☐☐☐☐

The patient is my: ☐
(e.g. husband, sister, friend)

Do you live with the patient?
(please tick)
○ Yes
○ No

What is your first language?
☐

Do you require the questionnaire to be sent to you in a language other than English?
(please tick)
○ Yes
○ No

If yes, please state language required in the box below:
☐

Additional information about you

Age:
(please tick)
○ 18 - 29
○ 30 - 39
○ 40 - 49
○ 50 - 59
○ 60 - 69
○ 70 - 79
○ 80 +

Gender:
(please tick)
○ Male
○ Female

Ethnicity:
(please tick)
○ White
○ Mixed
○ Asian / Asian British
○ Black / Black British
○ Other

If other, please specify in the box below:
☐

Highest level of education:
(please tick)
○ NVQ level 1 or 2, equivalent to GCSE or O Level
○ NVQ level 3, equivalent to A level, AS level or Higher School Certificate
○ NVQ Level 4 or 5, equivalent to Degree, Higher degree, HNC, HND
○ Other

If other, please specify in the box below:
☐

Thank you for taking the time to complete this form

ID Ref:

Version 1.2, 10 July 2013

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