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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Scientific summary

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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.

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