



Protocol

Understanding and improving the decision-making process surrounding admission to the intensive care unit

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Decision-making for intensive care unit admissions

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Decision-making for intensive care unit admissions

Abbreviations and acronyms used

AFR	Accountability for reasonableness
CAG	Confidentiality advisory group
CCF	Clinician consent form
CI	Chief investigator
CIS	Clinician information sheet (information sheet providing clinical staff with information about the study)
COPD	Chronic obstructive pulmonary disease
DCE	Discrete choice experiment
DoH	Department of Health
DSF	Decision support framework
FCS	Family consent form
FIS	Family information sheet (information sheet providing family members with information about the study)
FL	Family letter (letter to family)
GMC	General Medical Council
HDU	High dependency unit
HRA	Health Research Authority
ICU	Intensive care unit
NHS	National Health Service
PALS	Patient Advice and Liaison Service
PCF	Patient consent form
PI	Principle investigator
PIS	Patient information sheet (information sheet providing patients with information about the study)
REC	Research ethics committee
SCCM	Society of Critical Care Medicine
WP	Work Package

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1 Plain English Summary

NHS intensive care bed capacity is limited and under constant pressure. This is likely to increase with an ageing population. Admission to an intensive care unit (ICU) allows critically ill patients access to life-saving treatments but this care involves invasive and distressing interventions. Approximately one in three people admitted to ICU do not survive to go home. For those that do survive, many continue to have serious problems. Given the burdens of therapy on an intensive care unit and the limited prognosis for many critically ill patients, admission to an ICU bed will not be appropriate for all patients. Clinicians must decide whether less invasive care might achieve the same goals, or whether the burdens of ICU care outweigh any potential benefit and that palliative care is in the best interests of a particular patient. However, determining which patients will benefit from ICU and who will be harmed is not straightforward. Most patients considered for ICU admission are too ill to make decisions for themselves and clinicians therefore must make difficult practical and ethical judgements about balancing the benefits of ICU with the burdens of care. Despite this uncertainty there is no agreed process for deciding who should be admitted to ICU. Research suggests that there is large variation in how decisions regarding admission to ICU are made, and that doctors under-estimate the benefit that ICU can provide to certain groups of patients, including the elderly. Evidence also suggests that admission decisions are seldom explained to patients and families. Given the serious consequences of these decisions and the difficult circumstances under which they are made, it is important that they are based on good evidence, ensure fairness for all patients, and take into account the values relevant to patients and their families.

This research will investigate how these decisions are made and how we can improve this process. We will conduct a systematic review of the literature to inform our research. We will identify current practice and explore the experiences and perspectives of those involved in these decisions (ICU doctors, doctors referring patients to ICU and patients' families), and their views on how these decisions should be made. We will do this by observing the process of decision-making and interviewing health professionals and families in six NHS hospitals across the East and West Midlands. Information from the interviews and observations will be used to develop a questionnaire survey that will be sent to ICU doctors and nurses to further investigate the factors that they consider most important in making these decisions. From the analysis of all the information gathered, we will develop a decision support framework to guide doctors through the decision making process and provide information for patients and their families. This framework will be refined at a consensus conference including health professionals, policy makers and patient groups. We will pilot it in three NHS trusts chosen to represent a range of hospital and ICU sizes. We will study how the framework has been used and whether it is fulfilling its aims.

Little is known about how decisions regarding ICU admission are made, or how they should be made for patients in the NHS. By studying this area of clinical practice we will develop a mechanism to improve the quality and consistency of decision-making surrounding access to ICU for critically ill patients.

2 Background

2.1 Intensive Care

The UK Faculty of Intensive Care Medicine (FICM) defines an intensive care unit as ‘a specifically staffed and equipped, separate and self-contained area of a hospital dedicated to the management and monitoring of patients with life-threatening conditions’.(1) ICU care improves the chances of survival for critically ill patients,(2, 3) and timely admission to the intensive care unit is associated with more favourable outcomes.(4) The average potential survival benefit (the difference between survival probabilities if admitted or not) for patients admitted to ICU is between 17% and 23%.(5) Despite the potentially life-saving nature of care in an ICU it places significant burdens on individual patients. Long term psychological morbidity such as post-traumatic stress disorder after ICU admission is well recognised.(6) ICU admission can also have serious physical adverse effects for example patients with mild to moderate strokes have worse survival outcomes if they are admitted to ICU rather than to a general ward,(7) and ICU patients have an increased frequency of sepsis compared to matched patients on general wards.(8) ICU mortality is around 30%. A further 10% of those who survive ICU will die before leaving hospital.(9) Furthermore there is an increased mortality rate for patients following ICU discharge that continues for at least fifteen years.(10, 11) Additionally ICU survivors may have substantial ongoing morbidity. Of patients who require renal replacement therapy on ICU only 28% survive for one year, and 12% of survivors will require on-going renal dialysis.(12)

Care provided on ICU is expensive and takes up a considerable amount of NHS resources. To provide intensive care support to a critically ill patient a higher nursing ratio is required of either one nurse to two patients for a ‘High Dependency Unit’ (HDU) bed, or one nurse to one patient for an ICU bed.(1, 13) This may be compared to standard ward based care where the ratio is typically one nurse 9 patients.(14) Pressure on ICU resources is a daily occurrence in the NHS. ICU bed occupancy rates in the six months between June and November 2013 ranged from 83% to 85.4% and the number of admissions to ICU in England is increasing year on year; from 36,110 in 2011 to 37,298 in 2012 and 38,175 in 2013.(15) Despite ICUs working to higher capacities patients who would benefit from ICU may not receive it. The 2012 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) report ‘*Time to Intervene*’ noted that 37 of the 392 patients studied who were admitted to a standard ward should have received ICU/HDU care.(16) Given the burdens of life prolonging therapy on an intensive care unit and the limited prognosis for many critically ill patients outlined above, admission to an ICU bed will not be appropriate for all patients. Clinicians must decide whether less invasive care might achieve the same goals, or whether the burdens of ICU care outweigh any potential benefit and that palliative care is in the best interests of the particular patient. However, determining which patients will benefit from ICU and who will be harmed is not straightforward. Deciding who should be admitted to an ICU is a difficult clinical and ethical challenge.

2.2 Making the decision: clinical and ethical challenges

A clinician's decision on whether or not to admit a patient to ICU is based on both evidence and values. Evidence may be available about the nature of the specific condition that the patient is suffering from and the prognosis with or without intensive care. Evidence will also be available about the kinds of treatment that will be used in ICU and the potential harm of treatment. However evidence, even unequivocal evidence, needs to be interpreted in the light of the particular patient, their circumstances, wishes, beliefs, and values (if known). A key challenge is that both the evidence and the patient's wishes or values are not always clear or accessible.

2.2.1 Evidence and prognostic indicators

If it were possible to predict with an acceptable degree of certainty the likelihood of death for an individual then decisions on whether to admit a patient to ICU would be considerably more straightforward. Some individual factors are known to be associated with increased mortality such as severity of acute illness, age, quality of life before hospital admission and presence of co-morbidities.(17) Several prognostic tools for application to critically ill patients have been developed, the most widely used in the UK being the Acute Physiology and Chronic Health Evaluation (APACHE)-II score.(18) Some attempts have been made to provide statistical tools for predicting ICU outcomes in specific patient groups such as the elderly.(19, 20) However these tools give probability of survival rather than certainty, and do not take into account quality of survival. Moreover most prognostic models predict ICU or hospital mortality, rather than long-term survival (or long term quality of life). Prognostic models are therefore primarily used to assess ICU quality and performance rather than as a framework for decision-making in individual cases. There is evidence to suggest that even if clinicians are provided with patient specific prognostic information at the time of decision-making about end-of-life this does not materially alter their clinical decision-making.(21)

2.2.2 Patients' wishes, views and values

The ethical principle of respect for patient autonomy is reflected in legal and professional regulation of clinical decision-making.(22, 23) The patient should have relevant information and appropriate time and support to contribute to a decision about their care. However, when the decision is whether to admit a patient to ICU the patient is often unable to take part in the discussion, and in most cases will lack capacity to consent to, refuse, or request treatment because of the severity of their illness. If a patient lacks capacity it is the responsibility of the clinician caring for them to first determine if there is any relevant advance statement or legal proxy to make the decision. These are currently uncommon outside palliative care practice, and so clinicians need to make a decision that is in the patient's best interests, consulting with the patient's family and those who know the patient well in order to understand what the patient's wishes or views might be. The General Medical Council (GMC) has provided detailed guidance for doctors on this decision-making process.(22) The ethical obligation is to respect as much as possible what the patient might want to happen. However, a decision to admit a patient to ICU often occurs in an emergency

situation or when a patient's condition is deteriorating rapidly and there is little time for extensive discussion with the patient's family. In such situations the family may not be present, or may be themselves distressed and confused by what is happening. Discussion with the family may not be seen as a priority in such urgent situations. Even when families are consulted about the patient's values and wishes they are not necessarily accurate in predicting what the patient might want in this situation. There is evidence that families acting as surrogate decision makers poorly predict what the patient would wish for themselves, and may prioritise their own values and preferences when asked their views on future therapy.(24)

2.2.3 The impact of the clinician's views and values on decision-making

Since clinical prognostic indicators are often uncertain and patients' views may not be known, it is likely that other values and perceptions will have a bearing on the decision about whether to admit a patient to ICU. Clinician's previous experiences of treating patients with a similar condition may influence their assessment of the probability of success or failure of ICU treatment for a particular patient. Personal moral values and views on withholding or withdrawing life prolonging treatment might also affect an individual clinician's decision. A large European study of decisions to admit to ICU found that while older people were less likely to be admitted to ICU the mortality benefit (mortality without ICU compared to with ICU) was greater for older patients than for their younger counterparts. The authors concluded that 'physicians should consider changing their intensive care triage practices for the elderly'.(19) Another study found that patients with more severe chronic obstructive pulmonary disease (COPD) were perceived by the intensive care clinicians to have a strong likelihood of a poor outcome, while objective data suggested that these patients had the best outcome of all patients admitted with COPD, and continued to value their ICU admission post-discharge.(25) Thus, erroneous perceptions of certain patient groups' likely mortality benefit reduce their chances of receiving appropriate intensive care.

2.2.4 External influences and resource constraints

Intensive care is one element in an extensive range of services provided by an acute hospital, and decision-making within intensive care is set in the context of wider organisational policies and priorities. Many hospitals have specific priority programmes such as transplant surgery or major trauma and institutional policy may prioritise these patient pathways for intensive care admission. A Canadian study described the concerns of ICU staff that patients not on a priority programme such as transplant surgery were more likely to be denied admission in favour of a transplant patient when there was a shortage of beds.(26) There is some evidence that behaviour of other clinicians and of patients' families may influence an ICU physician's decision to admit a patient. An interview study of ICU staff in a Canadian hospital found that practices of non ICU physicians (such as failure to specify end-of-life treatment plans or to secure an ICU bed before elective surgery); and family demands for life support influenced the ICU staff's perception of scarcity and perceived pressure to

admit to ICU.(27) Resource availability, such as number of ICU beds or nurses, has been shown to impact on decision-making regarding ICU admission.(28-30) The UK has a low number of ICU beds per head of population compared with many other countries,(31) and there are overall resource constraints within the NHS. Thus, it is inevitable that decisions to admit to ICU will need to take into account prioritisation of resources. This pressure adds a further ethical dimension to the decision in addition to the difficulty of balancing burdens and benefits for ICU care for a particular patient.

2.2.5 The ethical requirements of transparency and fairness

Given the degree of prognostic uncertainty in critically ill patients, and the diversity of values and external factors that influence decisions to admit to ICU, it would seem likely that decision-making varies considerably and the available evidence supports this assumption. Studies have shown variation in ICU admission decisions among individual ICU clinicians,(25, 32, 33) between ICU staff and referring clinicians,(32, 34-37) between institutions in the same country,(19, 38) and between physicians in different countries.(19, 39-42) Variation in clinical decision-making is not specific to intensive care. If, however, variation in decision-making occurs because of different personal values of clinicians or different institutional policies or practices there is a concern that this could lead to inequity in the provision of ICU care. There is an ethical requirement to be fair to every patient when making decisions about their care which means that there should be consistency in the reasons for making the decision, and that these reasons should be explicit so that they can be justified if challenged. A key finding from our scoping review of the empirical literature in this area was that reasons for a decision on whether to admit a patient to ICU were often not explicitly stated, and the non-medical reasons were even less well documented. Patients, their families, and the public are rarely asked what constitute good reasons for withholding treatments such as admission to intensive care. Decisions about the provision of potentially lifesaving but extremely burdensome treatment are clinically complex and ethically challenging. The clinicians who make these decisions are faced with clinical uncertainty, limited knowledge of the patient, and external constraints which may preclude their preferred option, as well as being under pressure to make a decision quickly if the patient is deteriorating. They also have an ethical obligation to treat all patients fairly. Critically ill patients and their families often are unaware of how or why the decision has been made and have little opportunity to contribute to or challenge the process, yet the families have to live with the consequences of these decisions and may be very distressed if they feel the decision was the wrong one, especially where the patient does not survive. There is a clear need for guidance and support for both clinicians and patients and their families when faced with these difficult decisions.

2.3 Current guidance on decisions to admit to ICU

There is little national or international guidance on ICU admission decisions. In 1996 the UK Department of Health (DoH) published guidelines on the admission and discharge of patients to intensive care and high dependency units.(43) The main criteria for ICU

admission in this guidance were whether the condition is reversible and the absence of a significant co-morbidity, in addition to the need for ventilator or multiple organ support. This document, although 18 years old, remains the only national UK guidance concerning admission to ICU. A DoH report on the organisation of critical care services in the UK was published in 2000.(44) This report did not further develop admission policy for critical care. But it did call for further guidance to be developed and implemented both locally and nationally. Some regional critical care networks have now developed admission policies but it is of concern that the national guidance has not been updated to take into account new evidence or developments in professional guidance and legal frameworks such as the Mental Capacity Act 2005. The international picture is also one of scarcity in relation to national guidance. In the US both the American Thoracic Society (ATS) in 1997 and the Society of Critical Care Medicine (SCCM) in 1999 published guidance. The ATS guidelines were designed 'to establish an ethical framework for sound decision-making in ICU resource allocation'(45) and provided a number of position statements for the fair allocation of ICU resources. The SCCM guidelines state that patients should be admitted to ICU if they are likely to benefit from ICU care.(46) We have been unable to identify any more recent national guidance in the international literature.

2.4 Review of current literature

We conducted a scoping literature review to determine the extent of current evidence on the process of and influences on decisions relating to admission to ICU. Forty eight papers reported original research specifically relevant to the decision whether or not a patient should be admitted to an adult ICU including three UK based studies.

The key themes emerging from this scoping review are:

1. A range of factors appear to influence decisions on whether to admit a patient to ICU. These include:
Severity of illness (2, 32-34, 39-41, 47-57); severity of co-morbidities (47, 48, 56); functional status of patient (34, 38, 49, 50, 56, 58); previously assessed for admission (54); clinical trajectory of patient's condition (34); medical /surgical patient (medical patients less likely to be admitted) (2, 19, 51, 52, 54, 56, 57); assessment by junior or senior physician (26, 28, 39, 51, 59); patient's age, advanced age was repeatedly shown to be associated with reduced likelihood of admission to ICU (2, 32, 39, 47-49, 51, 52, 55-58); patient's gender, men appear more likely to be admitted than women (53, 56, 60, 61); insurance status of patient (in USA), uninsured patients are less likely to be admitted (62); availability of ICU resources (27, 32, 36, 37, 39-42, 50-52, 63); presence of written criteria for admission or hospital policies on priority conditions.(64)
2. Attitudes and practice regarding ICU admission varies among ICU clinicians within individual units; across hospitals, and across different countries.(19, 26, 33, 39-42, 48, 58, 65-69)
3. Doctors tend to be too pessimistic about the prognosis in certain patient groups (COPD, the elderly, heart failure) compared to either prognostic tools or actual outcomes (prognostic pessimism).(2, 25, 32, 33, 50, 57, 70, 71)

2.5 The need for a study

There is limited evidence specific to the decision whether or not to admit a patient to ICU, and little that is directly relevant to practice in the NHS. The empirical evidence suggests that this decision-making process is a complex interaction of a number of factors relating to the patient, the circumstances in which the decision is made, the organisational pressures present in the hospital, and the society to which the patient and doctor belong. That non-clinical factors play an important role in determining whether a patient is admitted to ICU and that there is considerable variation in decision-making among clinicians and organisations requires further exploration. It is not clear what patients and their families think about non-clinical factors being considered, and which factors, if any, they would think relevant to such decisions. Evidence gaps identified highlight the need for research that includes multicentre studies, high quality qualitative research to explore the context of decision-making, and inclusion of the views of patients and their families.

3 Research question

We intend to provide an answer to the following research question:

'What is required for an ethically justifiable, patient-centred decision-making process for unplanned and emergency admissions to adult intensive care?'

3.1 Aims and objectives

The aims of the study are threefold:

- A. To explore how decisions on whether to admit a patient to adult intensive care are made in the acute and emergency situation.
- B. To identify and critically analyse the factors that should inform ICU admission decisions from the perspective patients and their families and the clinical decision makers.
- C. To facilitate ethically justifiable, patient and family centred decision-making in these situations.

Specific objectives:

1. To describe current practice in decision-making for referral and admission to ICU. (WP1)
2. To explore the experience of patients, families, and clinicians involved in the decision-making process and their views on how these decisions should be made. (WP1)
3. To determine the influence of different factors on decisions to admit a patient to ICU from the perspective of ICU clinicians and the general public. (WP2)
4. To develop and test a decision support framework (DSF) including education and support materials that will facilitate ethically informed decision-making including reasons and process. (WP3)
5. To develop information for patients and families to help them understand, and contribute to, the decision-making process. (WP3)
6. To develop and test a tool for assessing the impact of the decision support framework on ICU referral and admission decisions. (WP4)

4 Methods

This project has been designed as a mixed methods study, which is divided into four distinct work packages (WP) as well as supporting literature reviews.

4.1 Systematic reviews to inform the research

We will conduct three focussed systematic reviews that will feed into the empirical work packages (WP). Specific research questions addressed in these reviews are:

- What are the patient and clinician related factors that affect decisions around unplanned admissions to an intensive care unit? (feeds into WP1 and 2)
- What are the experiences of clinicians, patients and families of the process of referral and admission to an intensive care unit? (feeds into WP1 and 2)
- What measures or models of evaluation have been used to assess impact of interventions to improve ethical decision making in acute medicine and emergency care?? (feeds into WP4)

4.1.1 Methods

We will develop a broad search strategy to identify both quantitative and qualitative literature to address the research questions using free text and thesaurus terms. The strategy will be refined using an iterative approach and tailored to individual databases. The searching will necessarily be sensitive to capture relevant studies in the qualitative literature where indexing is less well developed. Databases searched will include; Medline, Embase, and ASSIA, all sections of the Cochrane Library, CINAHL, PsychINFO, and Web of Science. Searches will include “grey literature” (Dissertation abstracts online, Index to theses, Open Grey) and references from key papers will also be screened. We will use a similar approach for each planned review. All systematic review processes for both the quantitative and qualitative literature will be carried out independently in duplicate to minimise bias. Disagreement will be resolved through discussion, and when needed, through a third reviewer. The Cochrane Handbook will be followed where appropriate.⁽⁷²⁾ For quantitative studies we will, if appropriate, consider statistical pooling using meta-analysis. No attempt will be made to pool studies with different study designs. We expect the diversity of qualitative research identified to require a narrative synthesis.⁽⁷³⁾ Each review will feed into relevant empirical work and the final design of the intervention. The systematic review protocols will follow the PRISMA guidelines and will be registered on the PROSPERO database.

4.2 Work package 1: Understanding the process of unplanned referrals for admission to ICU

This work package is designed to explore the reality of the process of decision-making whether or not a patient is admitted to the intensive care unit using case studies of index events - unplanned referrals for admission to ICU, and semi-structured interviews with the clinical decision-makers involved in this process. We will include the values and perspectives of those involved and interpret and evaluate the ethical or moral dimension of this reality using an integrated empirical ethics approach.(74-76) The use of case studies allows for the actual observation of the index events including events such as clinician conversations which may otherwise not be documented, and for those involved in the index events to reflect on the event, provide explanations and their interpretations of the event.(77) Integrated empirical ethics refers to studies in which ethicists and social scientists cooperate together continuously and intensively to integrate moral theory and empirical data in order to reach a normative conclusion with respect to a specific social practice; in this case the decisions both to refer a patient and admit a patient to ICU.(75) The focus of the case study is the decision to refer /admit, and not the clinical case itself; therefore specific patient related data will only be collected for the purpose of seeking patient consent when the patient is well enough to be approached.

4.2.1 Research questions:

This particular element of the project will address the following questions:

1. How are decisions about whether to admit a patient to an intensive care unit made?
2. What are the experiences of patients, families and clinicians involved in the decision-making process, and what are their views on how these decisions should be made?
3. What do members of the public think about how these decisions should be made?
4. What would constitute an ethically justifiable process for these decisions?

4.2.2 Methods

Non participant observation, including informal conversations with clinicians, of the process of decision-making surrounding a referral to the intensive care unit, focussing on the decision whether or not a patient is to be admitted to the intensive care unit.

Semi structured interviews with clinicians, families, and, if appropriate, patients involved in these decisions.

Interviews with clinicians involved in referring patients to ICU who are not interviewed as part of the observation process.

4.2.3 Setting

Six hospitals across two NHS regions (East and West Midlands) purposively sampled by type of hospital (university/district general hospital); number of ICU beds (we will use the following classification: small 0-20 ICU beds; medium 21-40 beds; large > 40 beds); deprivation score of population served; and ethnic diversity of local population (<http://www.neighbourhood.statistics.gov.uk/dissemination/>).

4.2.4 Recruitment of hospitals and ICU clinicians

Our initial approach will be a telephone call to the clinical director responsible for intensive care in hospitals across the East and West Midlands to seek expressions of interest about the study. For those hospitals where the clinical director expresses an interest we will visit these hospitals to present information about the study to ICU staff and consultants from potential referring specialties and to answer any questions they may have about the study. Prior to the visit we will provide an information sheet outlining the study and what will be involved for different staff members (see attached documents: CIS1). If following this visit the clinical director, on behalf of the intensive care unit, agrees that the unit will participate in the study (CCF1) we will use the integrated research application system to apply to the Trust R&D department for appropriate approvals to conduct the study in the Trust. Once approvals have been granted, we will approach all ICU consultants in the unit individually to invite them to participate in the shadowing process, and ask for individual consent for this observation (see attached documents: CIS2 and CCF2).

We will ask the clinical directors of participating ICUs to facilitate dissemination of information about the study to the clinical directors of specialties from which referrals to ICU are likely to come (acute /emergency medicine, respiratory medicine, cardiology, renal medicine, elderly care, general surgery) so that referring clinicians are aware of the study and that they might be approached to take part in an interview (CIF3).

4.2.5 Data collection

1. *Collation of documents:* Local policies and guidelines on ICU admission from each hospital will be collated as contextual information for data collection.

2. *Observational study:* The observational study will be conducted consecutively in each of the six recruited hospitals by a researcher based in that hospital for a period of around three weeks. Following R&D approval and consent from the clinical director from each site we will liaise with the hospital to find out about rotas, working patterns and leave schedules for ICU admitting clinicians in order to timetable sessions of observation to involve different ICU clinicians, and to cover the period from 8am to midnight and weekends as well as week days. This will ensure diversity of practice is observed within each hospital. Within each session of observation (usually a three hour session within any 24 hours) a researcher will shadow the admitting clinician until up to two completed referral events have been observed. Shadowing for each session will cease after the second event to limit the burden of participation on the clinician and to allow sufficient time for collection of data

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related to each event. Sessions will be timetabled as far as possible for when the admitting clinician will be available over the subsequent 24 hours for interview (see below). Session timetabling will be reviewed during the observation period to ensure observation of referral events is spread across the week, across the day and across the team of ICU admitting clinicians. Observation of events will continue until a diversity of cases has been recruited (medical and surgical cases, patients admitted from the emergency department, medical assessment unit and normal wards, and a range of patient age) and data saturation is reached. A minimum of five events will be observed in each site to ensure we capture context related variation, and in total we estimate approximately 40 events will be required across all sites.

A template will be used by the researcher to guide data collection, and key factors to observe while shadowing the ICU clinicians. The template will include role and seniority of clinicians; location of discussion; date and time of discussion; duration of conversation; key elements of the discussion; other observations such as the use of jargon; and who else is involved. This template will be refined during the first 2-3 observations. In common with other studies of this type important but unanticipated factors influencing the subject process may be encountered. The researcher will be trained to notice and note any such unanticipated factors.

The researcher aims to witness the decision making process from the point at which a referring clinician contacts the ICU admitting team, through the assessment of the patient, up to the communication of the decision made. While shadowing the ICU admitting clinician the researcher will note contextual factors that potentially influence decision-making such as number of available ICU beds. They will clarify with clinicians any local practice and terminology used. The researcher aims to witness events where a referring clinician contacts the ICU admitting physician (although there may be some practical constraints depending on exactly when the call is taken). These discussions take place both in person and over the phone. When done over the telephone the researcher will only usually hear the admitting clinician side of the conversation but will ask about the content of the referral immediately after the telephone discussion. The researcher will shadow the clinician during any assessment of the patient made on other wards/in the emergency department, focusing on the clinician actions and decisions. During observation the researcher will hold informal conversations with the clinician being shadowed and other health care staff encountered, clarifying what is happening. The researcher will take field notes which will include how the decision was made, where and when, the reason for the referral, the outcome of the decision, what was taken into account in reaching the decision, any reasons for the decision given during the process of making the decision, what was recorded and how it was recorded. We will identify what systems, if any, each of the participating hospitals has for informing both ICU clinicians and referring clinicians of bed availability (in ICU and in the host wards). We will explore with participating ICUs the use of routine data sources such as ICU admission records or early warning score data that could provide an additional data source for our analysis. Soon after each observation session the researcher will type up the field notes.

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A unique identifying number will be attributed to each patient on behalf of whom such a decision regarding ICU admission is being made, which will be linked to any data arising from this case. This will be used in all hand written and typed notes. This number will be used to link data from interviews and direct observation. The researcher will only have access to the patients name and other identifying details for the purposes of research if the patient gives consent or a family member acting as a personal consultee gives their agreement (please see section on consent below). An identifying number will also be used for referring clinicians. A sheet with the names of patients and clinicians with their IDs will be locked in a secure cabinet within the ICU department of the hospital after each observation session. When not being used they will be kept in the locked cabinet until the project is complete and will then be destroyed.

Inclusion and exclusion criteria

Inclusion criteria: All unplanned and emergency cases of adult patients who are referred to the intensive care team for consideration of ICU admission are eligible for inclusion.

Exclusion criteria:

1. lack of consent to participate
2. Inability of participant to speak or understand English
3. Family members who did not receive initial information about the study and whose relative did not survive the illness episode will not be approached for interview at 2 months in WP1
4. Planned admissions to ICU.
5. Patients who do not regain capacity.

4.2.6 Informing clinicians, patients and families about the observation study

While participating ICU consultants will have given explicit consent for the observational study, other clinicians, patients, and family members will be part of the overall environment that is being observed. It is important that these people are aware that an observational research study is occurring and that they are able to ask questions about the study. In preparation for the observation period, posters about the project will be displayed in areas of the hospital where ICU admitting clinicians and clinicians who refer to ICU would usually work, and where potential patients may be encountered e.g. corridors, family waiting areas, common rooms, ward entrances and wards. These posters will alert health professionals, patients, and families to the presence of an observer, and provide details of where more information may be obtained (see attached documents: poster 1). We will provide more detailed information about the study to be available within the hospital from appropriate information points. We will liaise with each hospital to ascertain the most appropriate place for further information to be made available (see attached documents: GIS1). All written information will have the researcher and PI's contact details included. The researcher will be identified by wearing a clinical 'scrubs' type uniform that clearly identifies them as a

researcher. The researcher will also wear a photo-ID badge displaying their name, role and organisation. When the researcher is shadowing a consultant during an assessment of the patient or discussion with the family, the ICU consultant will introduce the researcher and inform the family (and patient if appropriate) that they are observing the clinical process and seek permission from the family (or patient if appropriate) for the researcher to be present. If any patient or family member objects to the presence of the researcher the researcher will leave.

4.2.7 Interviews

Interview schedules (see attached documents) will be refined, informed by systematic reviews 1&2 and refined with the lay advisory group. Where possible all interviews will be audio recorded to capture as much data as possible, but where this is not practical or the interviewee refuses permission, field notes will be taken. For each observed index event we aim to undertake interviews with the ICU admitting clinician, referring clinician and family members. Patient interviews will not be attempted at the time of the referral to the intensive care team, as the patient will be seriously ill at the time of the decision-making. We estimate a total of 90 interviewees associated with 40 events, as some potential interviewees, particularly family members, may not agree to interview. Data collection will continue until initial analysis indicates data saturation has been reached and the data includes index events from across a range of referring specialties. Interview data from all interviews will be confidential and care will be taken not to convey any sense to interviewees of what other interviewees said about the same event.

Intensive care clinicians: Intensive care clinicians will have given consent to be interviewed as part of the consent process for shadowing. Interviews about index events will be undertaken usually during the period of shadowing, for example during a meal break. Where this is not possible due to work-load, a time will be scheduled within the next 48 hours for an interview while the referral is still fresh in the clinician's memory. During the interview the ICU admitting clinician will be asked to talk about their process of decision-making for each of the observed ICU admission decisions. They will be prompted for a description of the case, what they took into account about the case, factors that influenced their decision such as age and resource availability, and dilemmas they faced. They will also be asked to reflect on how the decision-making process could be improved and what types of support, and in what format, would be useful to them (we estimate a 20 min interview for each index event as the researcher will already be known to the interviewee and have previously consented to be interviewed when consenting to shadowing).

Referring clinicians: Information about the study will have been previously disseminated to referring specialties through clinical directors. During or immediately after each observation session the researcher will contact the referring clinician by telephone or in person for each of the index events to provide further information (written and verbal) about the study and

to seek an interview. We will aim to schedule the interview within 48 hours of the event and consent will be obtained at the time of the interview (see attached documents: CIS3 and CCF3 for information sheet and consent form). The referring clinician will be asked to describe the case, what led up to the referral, and discussions held with the patient or their family, their perception of the discussion with the ICU clinician and the decision and any factors they perceived as influencing the decision. They will also be asked to reflect on how the decision-making process could be improved (we estimate 30 minute per interview).

In addition we will recruit up to five consultants not included in the referring consultants from the observation study in each participating hospital selected from a range of specialties from which patients are likely to be admitted to ICU (e.g. respiratory medicine, acute medicine, elderly care) to participate in an interview. Consultants will be identified from the staff list of each hospital and approached by initial email and information sheet further explaining the study (see attached documents: CL4 and CIS4 for email letter text and information sheet). Consultants who express an interest in taking part will be contacted by the researcher who will answer any questions and arrange an interview time. Consent will be taken immediately prior to the interview (see attached documents: CCF4). In these interviews we will ask participants about any cases that they have considered for ICU referral in the preceding weeks and who they then made a decision not to refer. From these interviews we will identify reasons, external influences, and reasoning processes that impact on the decision not to refer as well as the decision to refer. In this way we hope to capture the views of consultants who may be less likely to refer patients who might benefit from ICU care.

4.2.8 Family members and patients;

Initial approach: We are aware that patients and their relatives will be distressed at the time that decisions are being made whether or not they are admitted to ICU. We have carefully considered how best to approach patients and family members in order to both facilitate freely informed consent and to provide patients and families with an opportunity to participate if they wish. We have provided a detailed description of our processes in the section on consent.

Following a referral to ICU identified during a shadowing period the referring clinician an initial approach to the family will be considered. This will be in the form of a member of the clinical team presenting them with a brief participant information sheet (FIS1). We will aim to make this approach and conduct interviews as soon as possible after the decision event but we are aware that this is an extremely difficult time for families. We will therefore be guided by the health professionals who are supporting them: If it is deemed by either the researcher or the clinical team that approaching the family at this stage would cause undue distress then any approach will be deferred until both the clinical team and the researcher are sure that any initial approach to the family is unlikely to cause any harm. If these conditions are not met then no approach will be made.

The researcher will discuss with the clinical team who is the most appropriate person to approach the family. The ICU admitting clinician, the ICU outreach nurse, or the lead nurse or doctor on the ward or unit hosting the patient at the time of referral (whoever is considered most appropriate), will be asked to approach family members of the index cases who are available to give them information about the study (FIS1). Family members who express initial interest in the study will be approached by the researcher and offered more information (FIS2). If the family member agrees to be interviewed the researcher will arrange a convenient time for an initial brief interview. The researcher will be a health care professional and have experience of, or will receive specific training, in working with families who are experiencing distressing situations.

4.2.9 Conducting the interviews

Initial interviews with family members: The purpose of our initial interviews with families is to gather information on their involvement and understanding of events as they are happening. However, due to the distressing nature of the events, which may have led to their potential inclusion in the study, these interviews may have been deferred for some days. Nevertheless initial interviews are still likely to be whilst the patient themselves are still in hospital. The initial interview with family members is therefore likely to be undertaken on the hospital premises, but could be undertaken at the home of a family member if they prefer. This brief interview (up to 20 minutes) will explore the family member's experience of the decision-making process and their reflections on this. It will be made clear to the family that the researcher is seeking information about the family member's experience of the decision making process, not about the patient or their condition. If more than one family member is interested in being interviewed, they will usually be interviewed together. In order to minimise any distress caused to family members the interviews will be framed in such a way not to challenge the decision that has been made but to describe the experience and perceptions of those close to the patient (see attached documents for interview schedule). Any clinical questions that the family address to the researcher will be referred to the relevant clinicians involved.

Follow up interviews with family members and patients: A further follow-up or late-stage interview will be conducted approximately 2 months after the initial decision-making event with patients and their family members who give consent (separately or together depending on their preferences). Whether family members and patients are approached, and the manner in which they are approached will be determined by the consents obtained and circumstances at the time of the initial event (see section on consent below).

If the family member and/or patient agrees to be interviewed the interview will be arranged for a venue agreed by the participant: their home, the hospital or university, whichever is preferable to the interviewee. In this interview they will be asked to reflect on the decision made; in particular how it was made including their own involvement, and to suggest improvements to the process and what kind of information, and in what format, would have been helpful to them (we estimate up to 50 minutes for the interview).

4.2.10 Tracking patients through their hospital stay

Depending on their capacity to decide whether they wish to take part in the research, patients will be tracked through their hospital stay by the local research team or the study researcher themselves (see section on consent below). If they regain capacity during their hospital stay they will be approached by the local team and given further information about the study. They will be asked whether they can be contacted at 2 months after the initial event and invited to an interview. They will also be asked to consent to the research team approaching their family for a follow up interview.

4.2.11 Other sources of patient and family-member perspectives

The family and patient perspective is highly relevant in this study, but recruitment of patients and family members at the very early stage of acute critical illness is challenging given the severity of illness and the possibility of bereavement. In order to ensure that sufficient voice is given to patients and their families, and to achieve data saturation we may seek to recruit further participants with experience of ICU from patients and their families attending ICU follow-up clinics and members of ICU patient and family support groups.

ICU follow up-clinics: Patients attending ICU follow up clinics at sites participating in Work Package 1 will be given a leaflet giving brief details of the study and contact details of the study team (OIL1). If they are interested in participating they will be invited to either complete an expression of interest form and leave this in the clinic to be collected by the research nurse, or contact the study team at a later date to arrange an interview. Those potential participants who complete an expression of interest form or who contact the study team will be sent a more detailed information sheet regarding the study (OIS1) and the researcher (Dr Mia Svantesson Sandberg) will contact them by telephone to answer any further questions. If they are still interested in participating an interview will be arranged. The information sheet will explain that we are also interested in interviewing family members and that the information sheet can be given to a member of the family if they are interested in participating. Prior to conducting the interview with the patient written documentation of consent will be obtained (OCF1). If a family member is also willing to take part in an interview they will also be asked to sign a consent form. (OCF2) The patient's consent for the family member to be interviewed will also be obtained prior to any family member interview (OCF1).

ICU support groups: Patient and family members of intensive care support groups will be contacted by email with details of the study and an attached information sheet (OIS1). If they are interested in participating they will be invited to reply to the study team to arrange an interview. Those potential participants who contact the study team will be offered an interview with the researcher by an initial telephone call. At this initial phone call we will enquire about whether their experience of intensive care was as a patient or relative. If they are a patient's relative we will ask whether the patient is still alive, and how they are. If the patient has died or is still very unwell and unable to give an opinion about the study we will offer the potential participant an interview once a consent form has been signed by the

participant (OCF2), and will where appropriate obtain their agreement as a personal consultee that the patient would not object to their participation on the study (OPCF). If at the initial telephone call the relative indicates that the patient has capacity to give an opinion about the study then prior to any interview taking place signed consent from both the relative (OCF2) and the patient (OCF1) will be obtained.

It is possible that these participants will be spread over the country, and it will not be possible for the researcher to visit each of them. They will therefore be offered a telephone interview if they are happy to conduct the interview in this way.

4.2.12 Consent:

4.2.12.1 Patients and Family Members:

In developing this protocol we have considered at length how best we can approach patients and families at this critical time. The proposed approach is the result of deliberations among the co-investigators, specifically our two lay members (one of whom has been a patient in intensive care) and our clinician members. The key principles underpinning our proposed approach are as follows.

- Patients should be given information about the study as early as their clinical condition allows.
- Patients' ability and desire to receive information about or be involved in the study may change during the course of their illness. The study design therefore needs to incorporate different levels and points of involvement.
- Any initial approach to families should be brief, not over-burdensome, and guided by the clinical team.
- Families who initially do not wish to talk to a researcher in the acute situation may want an opportunity to talk about their experience at a later date.
- A patient's capacity to consent may change throughout the study therefore it will be necessary to review a patient's capacity status and seek appropriate consent as the study progresses.
- Initial contact with patients and families must be through the clinical team or a local research nurse employed in the hospital and not the research team.

Initial observation following a referral to the ICU consultant:

The researcher will be introduced as a researcher shadowing the intensive care team whenever they are with a patient or a family member. At the time of the referral the consultant will introduce the researcher to the patient (if appropriate) and family members and explain that the researcher is studying decision making about very sick patients and part of this is to observe the clinicians making these decisions.

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The research team, including the lay co-applicants, (and the patient and public involvement group) felt that providing detailed information about the study at this time would have a very high likelihood of adversely interfering with the clinical care of the patient and might cause undue distress to the family members involved. Posters will have been displayed in the clinical areas so families may have some awareness that a researcher is observing clinicians in the unit. If the patient or family objects to the presence of the researcher then the researcher will leave.

When a patient is well enough to understand information and communicate (flow chart 1)

If the clinical staff caring for a patient consider that the patient can be informed that the study is taking place the consultant or senior nurse responsible for their care will do so. A brief leaflet will be left with the patient for future reference (see attached documents: PIS1). The only question that the patient will be asked in this situation is whether they agree that a researcher can speak to their family. If the patient says no at this time their wishes will be respected. The patient's name and an identifier will be given to a local research nurse so that the patient can be tracked and given further information at a later date as they recover. If the patient agrees their family will be approached as below.

When a patient lacks capacity to make a decision about the study (flow chart 2)

Family members will be approached soon after the initial observation by a member of the clinical team not directly involved in the research, who is familiar with their care. This approach will only be made once the researcher and the clinical team are confident that causing further distress to the family is unlikely. The member of staff will tell the family member that a research study is taking place and give the family a brief leaflet outlining the basic aims of the study and the request for family members who are interested to be interviewed (see attached documents: FIS1). If the family immediately refuses to consider this no further approach will be made at that time. If the family indicates that they are prepared to consider this then the researcher will approach the family, as sensitively as possible, to ask if they would like further information and to seek consent. If the family refuses at this point no further contact will be made at this time. If the family agrees to a brief interview a suitable time will be arranged for them to speak to the researcher and consent will be taken (see attached documents: FCF1). The family member will also be asked to consider whether the patient would have had any objections to this research taking place. He or she will be asked to sign a personal consultee form stating that in their opinion the patient would not object to their own or their family's participation in the research (see attached documents: PConsultee form). If they do not wish to do this then the researcher will explain that no interview can take place. If an interview does take place, the family member will be given the researcher's contact details and told that they can contact the researcher or speak to one of the ward staff who will contact the researcher for them if they have any further questions or concerns following the interview. The researcher will also explain that when their relative is well enough we will inform them about the study and seek

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their consent to be involved. For patients where an initial family interview has taken place but the patient dies or does not regain capacity after the resolution of their critical illness, data from the initial family interview and corroborative data will be used in analysis as personal consultee agreement will have been obtained.

Tracking patients to obtain retrospective consent and for approaching families for late interviews (flow chart 3)

So that we can inform patients who regain capacity during their stay about the study, and to check on a patient's status before approaching family members to seek an interview after two months, we need to track the patient's journey. If a family member has signed a personal consultee form the researcher will note the patient's name and unique identifier which will be kept in a locked filing cabinet in the hospital. If no personal consultee form has been signed in the initial stage the patient's name and unique identifier will be passed confidentially to a local research nurse working in the hospital who will store the information in the locked filing cabinet. Any research notes or interview data will be tagged with the unique identifier but no other personal details. The researcher (or local research nurse) will check each day on the patient's progress in terms of their ward location and clinical status. When a patient is thought to be well enough the researcher (or research nurse) will check with the ward staff as to whether the patient is likely to have capacity to understand information about the study and then approach the patient to inform them (or remind them if they were initially told at the time of their enrolment) about the study. The researcher/research nurse will seek the patient's retrospective consent to use the data from any initial family interview and consent to approach a family member for a two month interview (see attached documents: PIS2 and PCF2. If the patient refuses any existing family interview data will be destroyed and no contact will be made with the family. If the patient consents the family will be contacted by letter and invited to take part (see flow chart 4). The patient will also be asked if they would agree to being contacted at two months for an interview (if the patient is still in hospital at 2 months and is well enough to be approached an interview may be arranged in the hospital).

Approaching the family for late stage interview (flow charts 4, 5 and 6)

At initial interview with family members they will be asked if they would allow the research team to contact them for a further interview after approximately 2 months (see attached documents: FCF1). Family members who agree to being approached for a follow up interview at the initial interview will be sent a letter two months after the initial incident reminding them about the study. Prior to this letter being sent the researcher will cross check with the patient tracking to ensure that the patient has not refused consent for a family interview. The researcher will contact the family by telephone a few days after the letter is sent to ask if they are still interested in being interviewed and if so to arrange a convenient time for the interview to take place. If the patient has died since the initial interview the family will be asked to return an expression of interest form and telephone

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contact will only take place if this is returned to the study team. Consent will be obtained prior to the interview. If the patient tracking process has identified that the patient has died or that the patient has not regained capacity the family member will be sent an invitation letter worded to acknowledge this situation (see attached documents: FL1, FL2, FL3 and FIS for invitation letters and information sheets).

In cases where the family were informed of the study initially but did not wish to take part in an initial interview two possible approaches may occur.

1. If the patient has capacity and consents to the family being approached for a follow-up interview at two months the patient will be asked to provide the family members' contact details and the research team will write to the family member with information about the study and an expression of interest form (see attached documents: FL4 and FIS). If the family member does not wish to take part, or does not respond, no further contact will be attempted. If the family indicate an interest in taking part the researcher will contact them to seek consent and arrange an interview.
2. If the patient has not regained capacity or has died, the letter informing the family about the study will be sent by the consultant responsible for the patient's care (see attached documents: FL5 and FL6), together with an information sheet about the study (see attached documents: FIS). If the family do not wish to take part, or do not respond, no further contact will be attempted. If the family indicate an interest in taking part the researcher will contact them to seek consent and arrange an interview.

If a family was not informed about the study initially and the patient has since died or has not regained capacity, no contact will be made with the family.

Patients and their families are able to give or decline consent in a number of combinations. To ensure that their wishes are respected a careful track of consent for each aspect of the study will be recorded for each index case.

The research team are very mindful of the sensitive and distressing context in which patients and families will be approached in this study. Our detailed process for recruitment and consent has been developed in response to this unique context. The researcher will seek feedback from the clinical staff making the initial approach as to whether this has caused increased distress and the team will review the process after the first five patients/families have been approached and again at completion of observation at the first site. If we need to modify our approach we will seek approval for a protocol amendment from the Research Ethics Committee. We will ensure that patients and their families are aware that in addition to the research team, there are those in the hospital that they can talk to about their experiences including the non-denominational chaplaincy and Patient Advice and Liaison Service (PALS).

4.2.12.2 Analysis

4.2.12.2.1 Data management and quality checks;

Audio recordings will be transcribed and anonymised. Names and contact details of participants will be recorded on a separate database and stored in a locked filing cabinet. Audio recordings will be stored securely and together with the personal details database will be destroyed at the end of the project. All qualitative data including interview transcripts and observational notes, will be uploaded into NVivo software which will be used to assist data management. All transcripts will be coded with 30% being coded independently by a senior researcher and any inconsistency discussed to ensure consistency of coding. The report of each analysis will be reviewed by the lay advisors. This will then be used to inform the relevant work package

4.2.12.2.2 Data coding and summarising;

Decision event summaries: these will be prepared using all the data related to each index event. It will provide a description of the event and the clinical case including any variation in perception of the event from the different clinicians and the family member involved. No personal details of the patient in each case will be recorded.

Thematic coding: all data will be coded for decision processes (actual and ideal/desired), ethical issues and values, influences on the decision-making process, patient and family involvement, the decisions made, and other emergent themes.

4.2.12.2.3 Data analysis

Analysis will be tailored to feed into work packages 2, 3 and 4. Analysis will be guided by questions specific to each work package as described below. Sub-groups of the research team (see below) along with two PPI co-applicant /lay advisory group member will supervise sub-analyses. Coded data will be read closely and qualitative comparison undertaken across decision events to develop a descriptive and comparative account responding to each set of questions.

4.2.12.2.4 Theoretical framework for data analysis

The identification of the index event – the decision-making process for unplanned referrals – takes a realist (78) epistemological approach in that we consider the index event to have happened whatever the differences in how people perceive it. However, we also take a relativist (79) epistemological approach in that we explore the different perceptions and understandings that different actors (referring clinician, critical care clinician, family, patient) have of the index event. These epistemological positions are commonly brought together within case studies as described by Yin (77) and the somewhat similar realist evaluation described by Pawson and Tilley.(80)

Work package 1 takes a case study approach as it “investigates a contemporary phenomenon (the “case”) in its real world, especially when the boundaries between phenomenon and context may not be clearly evident”.(77) The “case” is the decision making process for unplanned referrals for admission to ICU.

From the literature review we will develop a number of theories (also known as propositions or programme theories) about decision-making for unplanned referrals to ICU. For example, one theory might be along the following lines: Critical care clinicians are influenced by current limits on resources when making a decision about admission to ICU. We will explicitly develop these theories and during work package one seek data that confirms or refute them. This does not exclude the development of new theories as data collection and analysis proceeds, which is then tested.

Ethical theory will inform our data collection and be used in our analysis of the data collected in work package one. In the interviews we will seek to elucidate the normative values that inform the reasoning processes of clinicians and the experience of families (for example do clinicians try to maximize overall benefit or use a rule of rescue approach). In our analysis we will reflect on the implicit values that emerge from the data. Ethical analysis of data collected early in work package one will inform further refinement of our data collection so we are sure to capture data related to ethical issues. In parallel with our qualitative data collection and analysis we will draw on the ethics literature to develop a normative framework for decisions to admit to ICU. The conceptual analysis will both inform and be informed by our empirical analysis in work package one and the results of the discrete choice experiment in work package two in an iterative process as described by Ives and Draper.(81) The outcome of this iterative approach will form the basis of the ethical element of the decision support framework to be developed in work package three.

4.2.12.3 Analysis questions for each further section of work

Specific questions to be addressed in the analysis of data collected in work package 1

4.2.12.3.1 Analysis to inform the design of the Discrete Choice Experiment

Analysis questions:

- i) What is the range of processes, ethical issues and values associated with the decision events?
- ii) What factors influence decision-making; iii) what is the range of cases for which decisions are made?
- iii) What is considered an ideal process for decision-making?
- iv) What value weighting is given to different aspects of the decision making process?

4.2.12.3.2 Analysis to inform the design of the decision support framework and evaluation tool:

Analysis questions:

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- i) What are the candidate processes for transparent decision-making?
- ii) What types of evidence and information are used for ICU admission decisions?
- iii) What are the ethical issues and how should values and ethical principles be taken into account;
- iv) What would constitute an ethically justifiable process for ICU admissions?
- v) What variation from the ideal process is acceptable and in what circumstances?

4.2.12.3.3 Analysis to inform the design of training and professional support to be provided with the decision support framework:

Analysis questions:

- i) What is the variation in perception of a decision event from those involved?
- ii) What is the variation of decision-making processes and decision outcomes?
- iii) What are the tensions and dilemmas in the decision-making process?
- iv) How are these/might these be resolved?

4.3 Work package 2: Discrete Choice Experiment

In this work package we will use a Discrete Choice Experiment (DCE) to analyse how ICU physicians and ICU outreach nurses make choices regarding patient's admission to ICU, specifically how they use the information available at the time of decision making. As identified in our scoping literature review, ICU physicians' decision-making can be influenced by many factors related both to the patients' characteristics and to the likely outcomes of admission to ICU. Given the high level of uncertainty regarding outcomes, and the fact clinicians have to make decisions under time pressure, it is important to understand how clinicians take into account these factors. The results of this analysis will be directly used to inform the development and implementation of the Decision Support Framework (DSF) by identifying practical ways to nudge the clinicians' decisions.(82) The ICU physicians are the main focus of this study, because they are the ones who make the final decision of admission to ICU. However, ICU outreach nurses will be also included in the analysis, because they are involved in identifying patients on the wards who may need ICU and work with referring clinicians.

4.3.1 Research questions:

1. What is the influence of patients' characteristics and ICU admission outcomes on ICU physicians' and outreach nurses' decision-making?
2. What decision rules do they use to make decisions regarding admission to ICU?
3. To what extent do decision factors and decisions rules differ between ICU physicians and outreach nurses?
4. How do ICU physicians and outreach nurses take into account patients' concerns when making a decision regarding admission to ICU?

4.3.2 Methods:

The DCE is a multi-attributes choices-based technique, which has been used in health care to investigate the preferences of patients, clinicians, and general population for a variety of issues.(83) This method is acknowledged as a valid and appropriate method to study individuals' preferences.(84, 85) The DCE methodology is appropriate for this project because it allows: (a) identification of the effect of each factor separately on the decision; (b) investigation of the interaction between the different factors in the decision making process; (c) identification of the decision rules used by clinicians; (d) investigation of heterogeneity of preferences; and (e) to experimentally accommodate specific effects on decision making. Our DCE will present both physicians and nurses with choice sets containing multi-attribute descriptions of hypothetical cases of patients' admissions (i.e. a mix of patients' characteristics and admissions' outcomes) and ask them to choose which patient should be admitted to ICU. The findings from systematic reviews 1&2, and the qualitative work in WP1 will inform the development of the case scenarios and attributes for the DCE. The DCE will provide information on the strength of preference for attribute levels, , and the probability of defined patients being admitted to ICU.(86) In addition to these

‘standard’ outcomes, we will use recent advances in DCE methodology to investigate decision rules used by physicians and nurses when making their choices.(87)

Research question 1: What is the influence of patients’ characteristics and ICU admission outcomes on ICU physicians’ and outreach nurses’ decision-making?

Individuals’ preferences will be identified using ‘preferences elicitation (choice) tasks. Each task will be composed of two hypothetical alternatives describing a patient to be admitted to ICU and an additional ‘Neither patient’ option. Each participant to the DCE will complete several preferences elicitation tasks, the exact number of choice tasks administered to a single respondent will be determined after piloting on a small sample of participants thus limiting the cognitive burden of the survey. Data analysis will use econometric models, based on the logit formulation (e.g. conditional logit model, random-parameters logit model, generalised logit model).(88) The analysis of preferences will be done separately for the clinicians and specialised nurses. The DCE results will directly inform the development of the DSF (WP3) by identifying which factors deserve more attention (i.e. which factors are the key drivers of the clinicians’ choices).

Research question 2: What are the decision rules used by clinicians and nurses to make their ICU decisions?

In a DCE analysis of the choices is usually based on two assumptions (i) individuals always try to find the best alternatives (‘maximisers’) and; (ii) individuals use all the information about the alternatives to make their choices.(89) There is increasing evidence suggesting more complex, but realistic, decision rules.(90) We will investigate decision rules underpinning admissions to ICU using a specific design for the DCE, allowing us to estimate interaction effects between the factors used to describe the hypothetical cases of the admissions to ICU. The decision rules will be analysed both by estimating the interaction effects between the factors and by using alternative specifications of the ‘utility’ function used to model the clinicians’ choices. These analyses in combinations will provide results on how ICU consultants and outreach nurses use the information about patients’ characteristics and ICU admissions’ outcomes. The DCE results will directly inform the development of the DSF by identifying the ‘best’ ways to provide relevant information to clinicians.

Research question 3: What is the variability of the decisions rules and preferences among the clinicians and nurses?

As noted in the literature review, there is a high variability of decisions to admit patients to ICU). In our DCE, this variability (or heterogeneity) will be accounted for in two ways. First, systematic differences of preferences or decisions rules between the clinicians will be investigated by taking into account their characteristics (e.g. age, gender) in the analysis of their choices. This approach can be understood as a subgroup analysis of the clinicians’

preferences. Second, the ‘unobserved’ heterogeneity of clinicians’ preferences will be explored using recent advances in discrete choice modelling, such as random-parameters logit model, and latent class logit model.(91-93) The DCE results will directly inform the development of the DSF by identifying whether (and how) the framework should be adapted to specific clinicians’ needs or not.

Research question 4: How do patients’ concerns influence decisions around admissions to ICU?

Developing an efficient DSF to promote patient-centred decisions requires analysing whether clinicians take into account patients’ concerns in their choices and to what extent. We will use the DCE as an experimental setup to analyse the influence of patients’ concerns on clinicians’ choices. In our DCE, this issue will be specifically addressed by using two kinds of choice tasks, a ‘standard’ one without any further information about patients’ concerns (referred to as preferences-elicitation task) and an alternative format including additional information about patients’ concerns (referred to as group decision-making tasks). The group decision-making tasks will be similar in every aspect to the preferences-elicitation task except that the consultants and outreach nurses will be explicitly informed of what would be the patients’ decisions in that particular choice context.(94-96) The precise wording and format of the group decision-making task will be finalised after the pilot study. The independent effect of group decision-making on individuals’ preferences will be tested using a between-subject design in the two experiment groups (i.e. with and without group decision making task). The DCE results will directly inform the development of the DSF by measuring how and to what extent ICU consultants and outreach nurses react to external information about patients’ concerns.

4.3.2.1 Developing the discrete choice experiment

Experimental design methods will be used to derive the choice sets, allowing estimation of both main effects and interaction effects. An online questionnaire will be developed by the research team using SNAP software developed and used by Aberdeen University. The sample size will be defined according to the DCE minimal requirements. In turn these minimal requirements depend on the number of choice tasks used in the DCE, which depend on the number of attributes’ levels. Given our different research objectives, we compute a conservative sample size as following: (a) we plan to use six factors each with three levels; (b) we plan to estimate eight second-order interaction effects out of 15 possible; (c) based on the (a) and (b) parameters, we can obtain an efficient design for the DCE in 48 tasks; (d) we want to limit to 16 the maximum number of choice tasks per participant, then we need to allocate the 48 tasks into three versions/blocks of 16 tasks each; (e) three DCE versions x two experiment groups =six survey versions; (f) based on the Louviere et al formulae,(89) we need 49 respondents per version, $49 \times 6 = 294$ respondents (rounded up to 300). Given our two profiles of health professionals, the study requires a total of 600 respondents (300 consultants + 300 nurses).

4.3.2.2 Recruitment of clinicians:

ICU clinicians will be recruited in the following ways:

1. We will present the DCE at the national conferences for the relevant professional organisations; the Intensive Care Society for ICU consultants and Critical Care Outreach Forum for critical care outreach nurses. Participants at these conferences will be provided with the link to access the online information sheet and questionnaire.
2. By email through the Intensive Care Society, and the National ICU Outreach Forum. We have provisional agreement from each organisation to send an invitation email to all members including information about the study and how to complete the DCE on line questionnaire (see attached documents for email text and information sheet).
3. National clinical research network nurses working in NHS Trusts will email ICU consultants and ICU outreach nurses in their NHS Trust with the same information sheet and link to the online questionnaire.

Completion of the questionnaire will be deemed to indicate consent to participate in the study. The questionnaires will not include any personal identifiable details of the participants. For involvement of CLRN research nurses in recruitment it is necessary for their research nurses to log the names of participants recruited in their Trust. We will therefore ask participants to enter their NHS Trust name and email address on a separate page of the online questionnaire. This will be separated from the questionnaire and stored in a separate file. Once separation has occurred it will not be possible to link the data to an individual clinician or Trust hence all data for analysis will be anonymous. Research nurses will be given the email address of those clinicians who have completed the questionnaire so they can send a reminder to clinicians who have not completed it four weeks after the initial approach.

4.4 Work Package 3: The development of a Decision Support Framework (DSF) and the testing of its implementation

Analysis of preceding work packages will inform the development of a decision support framework (DSF) to facilitate the process of decision-making regarding whether an individual patient is or is not admitted to ICU. The DSF will provide a framework to support consistent, transparent and ethically justifiable patient centred decision-making through prompting consideration; of relevant factors identified in the previous work packages. It is not intended to determine whether an individual patient should or should not be admitted to ICU. If considered appropriate, it will provide links to relevant guidance, evidence and statistical calculations. It will support the referring team to deliver a quality referral that takes into account all relevant details, and ensure all details are available to the decision-making individual or team. It will also provide a mechanism for documentation hence audit of the decision-making process including factors taken into account by the decision maker.

The specifics of its format and content will be dependent on the findings that emerge from the first two work packages, but given the current NHS policy for hospitals to become paperless by 2018 the DSF will need to be developed in a format that has the potential to be hosted on servers at individual trusts or accessed through the NHS net (noting patient confidentiality issues). It will be designed and tested in versions intended for referring as well as receiving clinicians based upon relevant evidence and values. In addition, in order to be practicable in routine care across the NHS it will be designed to be adaptable to varied contextual factors, such as organisational settings, patient presentation, times of day, and availability of ICU resources. We will develop associated education and support materials to facilitate its implementation in individual Trusts.

4.4.1 Objectives

1. To develop a decision support framework for decisions around referral and admission to ICU
2. To develop support and training materials for clinicians using the DSF
3. To develop information for patients and families on decisions to refer and admit to ICU
4. To test the feasibility of implementing the DSF in an NHS Trust

4.4.2 Development of the DSF

The development of the DSF and the testing of its implementation will draw on Normalization Process Theory (NPT).(97) This describes four constructs, Coherence, Cognitive Participation, Collective Action, and Reflexive Monitoring, which represent the mechanisms by which change occurs in organisations.

Defining the intervention specification:

We will draw on the findings generated from the earlier work packages and systematic reviews to identify 1) the key ethical and procedural principles that will inform the DSF and 2) the features that are likely to promote or inhibit its adoption. We will specifically draw out factors that are associated with the way admissions to ICU are organised (Coherence), the beliefs and behaviours of those who are involved in making and accepting referrals (Cognitive Participation), the ways in which the referral of patients to ICU is enacted and the constraints that affect this (Collective Action) and how referrals are appraised by the individuals and teams that are involved (Reflexive Monitoring). From this analysis we will develop an initial specification for the DSF and associated supporting materials. All members of the research team plus two members of the lay advisory group will be involved in critiquing and refining the specification.

Consensus conference:

In order to be relevant to practice the DSF must be acceptable to all stakeholder groups nationally, but adaptable to local hospital requirements. The initial DSF and support materials will be presented to a consensus conference of key stakeholders so that it may be refined and adapted prior to its pilot implementation. The meeting will take place at the University of Warwick, with the first part of the day involving the presentation of evidence from the first three work packages, and rest of the day involving consideration and critique of the proposed specification for the DSF and its implementation. The group will be asked to consider the possible nature and format of a computerised DSF, and potential IT suppliers, both NHS and commercial companies (e.g. Map of Medicine, Capita Health, Advanced Health & Care), may be invited to demonstrate their products in order to inform this discussion. We will use recommended consensus development methods.

Production of DSF and associated support materials:

Following the consensus conference, the specification for the DSF will be finalised and providers will be invited to tender to undertake development of the web platform to support implementation. We will seek a provider that has experience of delivering DSF-type interventions to the NHS and has an existing N3-based online system that can be adapted at low cost and within a short timeframe to deliver the DSF specified for the purposes of this study. The research team will author the clinical and ethical content to be incorporated into the DSF, and the development of the support and training materials according to the requirements agreed at the consensus conference. We will pilot the use of the Normalisation Process Theory Toolkit (NPT) (www.normalizationprocess.org/npt-toolkit.aspx) with the decision support framework to facilitate implementation. The toolkit was developed from and for health care settings and is used to think through implementation of new initiatives. We will recruit volunteers from among relevant clinicians and managers in Trusts involved in WP1 to join one of two workshops, each of duration 2 hours, to use the NPT Toolkit to think

through the implementation of the DSF. The workshops will reveal concepts/sub-concepts of particular importance and suggest illustrative scenarios to assist with using the toolkit to think through implementation. This will then form part of the DSF implementation process.

4.4.3 Feasibility study

Specific objectives of the feasibility study are:

1. To demonstrate the feasibility of implementing the DSF at an organisational level, including its associated materials and training, in the context of a busy NHS trust.
2. To explore intervention fidelity reviewing the actual use of the DSF, its impact on decision-making, and how this compares to its intended use.
3. To explore the acceptability of the intervention, including the training and DSF materials to referring and admitting clinicians.

4.4.3.1 Setting

The feasibility study will be conducted in three acute NHS trusts which did not contribute to data collection in work package 1.

4.4.3.2 Recruitment of Trusts

We will approach NHS Trusts not involved in the observational study to invite them to participate in the feasibility study. Initial contact will be made through ICU Clinical Directors and Medical Directors. Those Trusts expressing an interest in the study will be visited by members of the study team to further discuss the study and seek agreement to participate. (see attached documents for letter of invitation and information sheet). We will identify three acute NHS Trusts, purposively sampled by size of ICU, one small (less than 20 ICU beds), one medium (less than 40 ICU beds) and one large (greater than 40 ICU beds), from those Trusts expressing interest. Once consent and the appropriate R&D approvals have been obtained for each Trust we will work with the medical Director and ICU Director to identify an implementation champion.

4.4.3.3 Ethics approvals

Prior to commencing implementation of the DSF we will submit final versions of participant information sheets, consent forms and publicity material for the evaluation study to the research ethics committee for approval. This work package includes accessing the records of patients who have been referred to ICU to ascertain whether the DSF has been used in their care. As it will not be possible to seek consent from patients at the time of accessing the records we will seek, approval from the Research Health Authority Confidentiality Advisory Group (CAG) to access records without consent. The application for CAG approval will occur in tandem with the research ethics application and no data collection will occur for this work package until both approvals are in place.

4.4.3.4 Implementation process

Implementation champions will be identified at each participating trust through discussions with the medical director and clinical director for ICU, and will include one senior doctor and one senior nurse in intensive care outreach. Information on the implementation study will be given to these champions, and consent taken for contact and interviews during the study. The research team will introduce the champions to the DSF and support materials. Prior to the commencement of Trust recruitment we will provide copies of the DSF and support materials to the relevant research ethics committee for approval. The champions will be asked to implement the DSF in their own way but with the request that the research team are enabled to collect data about feasibility. During the first eight weeks following commencement of the implementation process the Trusts will each attempt to implement the DSF with the ICU team and clinical teams responsible for most referrals to the ICU. The teams will be asked to continue using the DSF for all referrals to ICU for a further 6-week period so that its use can be explored from the perspective of referring clinicians and ICU staff and the relevance and effectiveness of the support and training can be explored.

4.4.3.5 Informing clinicians about the feasibility study

Posters and Information sheets about the implementation feasibility study will be made available on the ICU and referring wards identified to take part by the champions. During the training sessions for clinicians the researcher will be introduced and his/her role in observing the training explained.

4.4.3.6 Recruitment of interview participants

During the initial implementation period individual clinicians (consultants, specialist registrars and outreach nurses) on the participating units will be contacted by the researcher and invited to take part in an interview to explore the acceptability and usefulness of the intervention (see attached documents). For those clinicians who agree to be interviewed the researcher will arrange a suitable time to interview them and consent will be taken prior to the interview.

4.4.4 Assessing the outcomes of the implementation of the feasibility study

The implementation of the decision support framework will be assessed in a number of ways

- 1. Assessment of the implementation*
- 2. Assessment of the fidelity, reach, and reception of training*
- 3. Assessment of the consistency of the use of the DSF*
- 4. Assessment of the acceptability of the intervention*

4.4.4.1 Assessment of intervention implementation

Data collection will include: telephone interviews with champions every two- to three-weeks during the 8-week implementation period exploring how they are implementing the DSF and any Trust specific issues that may be relevant; observation of meetings arranged by champions with relevant clinicians (referring clinicians, ICU consultants and ICU outreach teams) to introduce the DSF, explain its rationale and to demonstrate how it is to be used in clinical practice. Disagreements/obstacles/other issues that are identified which may affect the implementation and subsequent usage of the DSF and any Trust specific modifications to the DSF or its mode of delivery will be recorded.

4.4.4.2 Assessment of intervention fidelity, reach, reception and consistency of use

- i) Fidelity, reach and reception of training: We will directly observe ICU staff and referring clinicians in each Trust undertake the training and will use a checklist to record the delivery of the training, participants, completion of the training, and their competence in using the DSF within the training context.
- ii) Consistency of DSF use: A research nurse will review the notes of all unplanned and emergency referrals to ICU over a 6-week period and record whether the clinicians used the DSF for decisions. We anticipate that there will be about 100 referrals in each Trust during the relevant period. Referrals will be identified through the records of the intensive care clinical team and the critical care outreach team at the Trust. We will look for evidence of selection bias related to DSF usage and time (time of day, day of week, week of month), ICU bed occupancy, the patient (age, sex, condition), the referring clinician (identity, specialty, grade), and the admitting clinician (identity, grade).

4.4.4.3 Intervention acceptability

To provide in-depth data on the acceptability of the training, implementation materials and DSF, face-to-face semi-structured interviews will be conducted with referring and admitting clinicians (or telephone interviews if preferred). We will interview up to five referring and five receiving clinicians in each Trust exploring: the acceptability of the intervention to clinicians; how it was perceived to affecting referral/admitting decisions, including decisions about when not to refer a patient; the experience of using the DSF; how the DSF might be improved. Thematic content analysis of the data will be undertaken.

4.4.4.4 Assessment of feasibility

The data from this study will be used to 1) demonstrate the feasibility of the DSF and its implementation at Trust level, and 2) identify modifications and refinement that may be needed to enhance its usability, acceptability and effectiveness. Feasibility will be judged against the following success criteria:

Decision-making for intensive care unit admissions

- i) Evidence of high level commitment of Trusts to champion the use of the DSF, enable clinicians to participate in the training, deliver the training, and promote the use of the DSF in everyday practice;
- ii) Use of the DSF in admitting patients to the ICU (> 50% of eligible patients), a high level of intervention fidelity (> 50% of eligible patients assessed with the DSF according to the instructions provided in the training and associated materials), and the acceptability to staff (interview data suggest staff enthusiasm to continue to use of the DSF beyond the 6-week feasibility period, although recognising that enthusiastic staff are more likely to agree to be interviewed).

4.5 Work Package 4: The Development of an Evaluation Tool to Assess the Impact of the DSF

We are not aware of any standard instruments for evaluating the quality of ethical decision-making in clinical practice or for evaluating interventions to improve ethical decision making. Further literature review will confirm this and identify any new studies that inform the development of an evaluation tool, or new tools developed that could be used or adapted. Studies of interventions to support ethical decision making have usually used clinicians' views on the effect of the interventions on their practice to evaluate its impact.(98) A randomised controlled trial of ethics case consultation in ICU used the outcome of ICU length of stay to assess effectiveness of the intervention but did not look at the impact on the process of decision making.(99) We will develop an evaluation tool specifically aimed at assessing the impact of interventions to facilitate ethical decision-making that focuses on the decisions and decision-making process rather than secondary outcomes. Within the context of this project we will conduct initial testing for reliability, validity, and responsiveness.

Following our systematic review of evaluation models for ethical decision making to inform the development of our evaluation tool, we will consult with our project lay advisory and stakeholder groups to finalise which model to use. However, we envisage that it will draw on the 'Accountability for Reasonableness' framework (AFR).(100) This is the most commonly used ethical framework for allocation of limited medical resources and focuses on the process of decision making rather than relying on a specific moral theory. AFR has four requirements, decisions must be transparent; based on reasons stakeholders can agree are relevant; revisable in the light of new evidence and arguments; and that there should be an appeals process. Other authors have highlighted the requirement for priority setting decisions by clinicians (including ICU admissions) to be transparent (AFR requirement 1) and ethically justifiable (AFR requirements 2 and 3).(101, 102) Any DSF therefore should improve the transparency and ethical justification of decisions regarding referral and admission to ICU. A further ethical requirement is one of equity, which can be interpreted as consistency of process (the factors taken into account and the process of decision making should be consistent across all patients and all decision makers). If this framework is agreed on, we will develop an evaluation model that examines these three requirements. This evaluation will use both a quantitative and qualitative approach to evaluate the impact of the DSF on the decision-making process. Transparency and a basis in ethical reasons are qualities of the decision-making process that can be operationalised qualitatively as categories.(103) Decisions can then be categorised and a quantitative comparison made before and after the implementation of the decision support tool. Consistency of process across a Trust will be assessed qualitatively.

4.5.1 Objectives:

1. To develop a tool to evaluate the impact of the decision support framework

2. To pilot its use and test its reliability, face validity and responsiveness in two NHS Trusts in parallel with the DSF implementation feasibility study.

4.5.2 Setting

Data collection in this work package will take place in a total of five acute NHS trusts. Data collection for the development of the evaluation tool will occur in two trusts that are participating in WP1. Data collection to test the evaluation tool will occur in the three NHS trusts which are taking part in the implementation study (work package 3).

4.5.3 Data collection for categorisation development and testing of evaluation tool

An NHS research nurse will identify the clinical records of a consecutive series of patients where a referral to ICU was received (if referrals are not specifically logged by the unit we will use unplanned or emergency ICU admissions and the records of the critical care outreach team to identify patients referred to ICU). The section of the records relating to the discussion about referral to ICU and any decision made will be copied and any patient identifiers removed.

Data collection will continue until the team have a consistent system for categorisation. The research team will examine the records and categorise them as

- i) Including evidence of transparency or not; and
- ii) Including evidence of ethical reasoning or not.

Examples of evidence of transparency might be: the clinical notes include a clear description of the reasons for the decision; there is a summary of discussion with patient's family; the names of those consulted and their views are recorded. Evidence of ethical reasons might be: the clinical notes include a summary of the likely outcome of admission to ICU based on patient data and relevant evidence; advance directives have been asked about; there is a clearly argued case for the decision referring to relevant reasons. Two researchers will undertake categorisation independently and disagreements in categorisation will be resolved by consensus or by a third assessor where necessary. We will develop the categorisation using the first 10-20 cases. The categorisation will then be applied to a further 10-20 cases and consistency reviewed and categorisation criteria revised. This will continue until consistency of categorisation is achieved and no further revisions are made.(104) The lay advisory group will review and advise on this process.

Face Validity: We will use one of our stakeholders meetings to present the evaluation tool and the categorisation developed by the research team. We will ask members to comment on whether they agree that our categorisation criteria are measuring the requirements of transparency and ethical justification in the context of decisions to refer or admit to ICU. Any comments or suggestions will be recorded and if necessary adjustments to the categorisation criteria will be made.

4.5.4 Testing reliability and responsiveness in the feasibility study

In each of the three Trusts participating in the DSF feasibility study, data will be collected from a consecutive sample of 20 cases, using the same method as in data collection for categorisation, in the month prior to implementation of the decision framework. Two months following implementation data collection will be repeated.

Responsiveness to change: We will test the responsiveness of the decision tool by assessing the proportion of records categorised as transparent and ethical in the pre and post implementation records. This will be calculated for each category by a t-test of proportions.

Reliability; Two assessors, one from the study team and one independent assessor will categorise each decision event identified as i) transparent or not and ii) following ethical reasoning or not using the categorisation framework agreed in the development stage. Inter-rater reliability for each category will be calculated using the kappa statistic, along with its 95% confidence interval.

Consistency; Consistency of decision making will be assessed through configurational comparative methods,(105, 106) at this stage of developing the tool, undertaken by hand so subtle inconsistencies are not missed. This involves the comparison of configurations of attributes of cases and their supporting data. The criteria (probably two or three) used for each categorisation of transparency and ethical reasoning will form the attributes (e.g. family members consulted) and there will be data to support the attributes for each case. The data on each attribute (usually one or two sentences from the clinical record or DSF) for each of 120 cases (see sample size below) will be transcribed into a database. Comparative analysis will be undertaken comparing each case with each other case. The comparative analysis will be undertaken independently by two analysis teams and the results compared and discussed. The potential for quantitating this qualitative approach will be explored.(105, 107)

4.5.5 Sample size calculation:

As this work package pilots the evaluation tool, no prior research hypotheses can be stated and hence no formal sample size calculations can be constructed. Hence, in each of the three Trusts participating in the decision support framework feasibility study, we will simply collect data from a consecutive sample of 20 cases in the month prior to implementation of the decision framework. Two months following implementation, data collection will be repeated. Sixty cases in each sampling period is anticipated to be an achievable number of decisions to scrutinise by the research team and easily obtainable over a month of data collection at most Trusts. Furthermore, assuming that the initial percentage of decisions categorised as transparent (or ethical) lies between 10% - 85%; an overall number of 120 cases (60 in each group) is sufficient to detect a minimum increase of between 14% (if the initial proportion is 85%) and 25% (initial proportion of 40%).

4.5.6 Access to patient records

Because of the nature of the patients' clinical condition (recently referred and/or admitted to an ICU) it will not be possible to seek their consent for access to their records to extract the required data for developing the categorisation and testing reliability and responsiveness. The data we wish to collect is the record of the decision making process rather than specific patient clinical information but because this is an integral part of the patient record it will be necessary for the research nurse to have access to identifiable patient information (the patient record) in order to extract the relevant information which will be transferred to the researchers in an anonymised form. Therefore we will seek approval to access these patient records for this purpose from the Health Research Authority Confidentiality Advisory Group concurrently with our application for ethics approval for the study. The same situation will apply for accessing patient records to check if the DSF has been used in the implementation feasibility study in WP3 and we will seek HRA CAG approval for this data collection also.

5 Ethics and governance

5.1 Ethical issues.

This study raises a number of ethical issues given the sensitivity of the subject under investigation:

5.1.1 Observation in a hospital environment

It is not possible to obtain individual consent from all patients and their families for the presence of a researcher conducting observation within a hospital ward or ICU. We will ensure that information about the study is displayed in all areas that the researcher is likely be working and he/she will be clearly identified. If the researcher is shadowing when the ICU consultant is asked to see a patient or speaks to the family during a referral the consultant will seek permission of the family (or patient if appropriate) for the researcher to be present as an observer. Information about the study will be given to the family following the encounter explaining that they can ask that any information collected during the observation of the meeting can be excluded from further analysis if they change their mind at a later date.

5.1.2 Interviews with family members soon after the decision event

Approaching family members around the time of the referral/admission decision raises concerns about intrusion of privacy and causing further distress. We will be guided by the clinical team caring for the patient and supporting the family as to whether it is appropriate to approach them and the timing of any approach. The approach would be from the clinical team in the first instance. Any initial interview would be brief and it would be made clear that the interview could be stopped at any time if the family member wished. The researcher will have experience of and/or training in interviewing patients or families experiencing distressing situations.

5.1.3 Interviews with families one- two months after the decision event

We will ask families who agree to the initial interview if we can contact them 1-2 months later. If families do not wish to agree to the initial interview we will contact them at a later date to ask if they would consider being interviewed. It is likely that for some of these families their relative will have not survived or may still be very ill. However it is important to allow these families to share their experiences if they wish. We will approach these families either through the patient if they have capacity and give consent, or through the responsible clinician if the patient lacks capacity. There will be no direct contact with the researcher unless the family gives consent.

5.1.4 Informing patients who have survived of their involvement in the study

We will track patients (either directly or through a local research nurse) so that we can inform them of the study (and their family's participation in it) when they have recovered sufficiently to receive this information. We will ask the patient if they agree to the use of data from any previous family interview and if they agree to their relative being interviewed again about their experience of the ICU referral. If a patient has capacity we will not use data from family interviews without the patient's consent.

5.1.5 Responding to distress of patients and family members during interviews

We will be interviewing families, and possibly patients, about a very difficult and emotional experience. During our initial recruitment of sites we will identify the available support services in the hospital for families of patients with critical illness or who are admitted to ICU. We will provide contact details of these support services to participants as well as details of local and national support groups such as ICU STEPS. If the researcher is concerned about a significant harm for an individual participant, for example if the participant discloses a suicidal intention, the researcher will discuss this immediately with either CB or AS who will contact the participant to assess the situation and ensure that appropriate support is provided. This may involve contacting the participant's GP or the relevant hospital clinical team. If information is disclosed participants will be informed that this is happening. WMS has a standard operating procedure for responding to disclosures of this nature by research participants.

5.1.6 Disclosure of unprofessional practice

If concern arises about unethical or unsafe clinical practice the researcher will consult a principal investigator (CB or AS) who will decide if it is necessary to initiate action through normal professional channels, which is likely to be through the relevant NHS Trust. We think it is unlikely that serious unprofessional conduct will be observed or disclosed in this study. If any disclosures are made the participant involved in the interview where this practice was revealed (clinician or family member) will be informed that this is happening. The need for a researcher to disclose any evidence of serious professional misconduct will be made clear in the relevant participant information sheets.

5.1.7 Patients or families expressing a wish to complain about medical treatment

It is possible, particularly in the two-month interviews that a patient or family member may indicate to the researcher that they wish to make a complaint about patient care. In this situation the researcher will direct them to the relevant NHS Trust's complaints procedure and the trusts PALS service.

5.1.8 Mentoring of researcher

Interviews with families and patients in this study may provoke distress and anger for participants and the researcher must deal with this in a sensitive and professional manner. The researcher will receive training in conducting sensitive interviews and will have a regular debriefing meeting with a senior investigator (CB, AS or FG) each week throughout data collection.

5.2 Information governance

The researcher's notes and interview tapes will be kept in a locked cabinet in a locked office in Warwick Medical School. If a laptop is used for field note recording this will be password protected and data transferred to a University computer at the end of each fieldwork session. Interview transcripts and any other electronic study data will be stored on password protected computers in Warwick Medical School. An identifying number will be used for ICU

and referring clinicians and will be used in both hand written and typed field notes. The identities of patients will not be recorded in field notes. A sheet with the names of clinicians and their IDs will be locked in a secure cabinet within the hospital after each observation session. When not being used they will be kept in the locked cabinet until the project is complete and will then be destroyed.

Patients in the index case studies will be given a unique identifying number and any data relevant to their case (clinician or family interviews) will be stored in a locked filing cabinet in a locked office in Warwick Medical School. The identities of patients will not be recorded in interviews. A separate file with patients' names and identifying number will be kept in a locked filing cabinet in the hospital for the purposes of tracking patients to seek consent from those with capacity prior to hospital discharge, and to ascertain the status of patients prior to contacting families for a follow up interview. The researcher will only have access to the names of patients whose families have signed a personal consultee form or if the patient has agreed. All other patients will be tracked by a local research nurse within the hospital.

Family members who agree to interview will be given an identifying number on interview transcripts. For those families who agree to a follow up interview their contact details will be kept on a separate database and only accessed to approach them for follow up interview (subject to the patient's consent if they have capacity at the time).

6 Patient and public involvement

This study is of particular sensitivity as it involves decisions with profound consequences being made about patients. It is therefore paramount that patient and public involvement is integrated at every stage of the project: Two of the co-investigators on this project are lay-members, including an ex-ICU patient. Our steering group will include two lay members to ensure that there is patient and public oversight of the conduct of the project. The steering group will meet at least twice yearly for the duration of the project. We have a separate lay advisory group whose members will contribute to interpretation of the observation and interview data in WP1, development of the discrete choice experiment (WP2), and development and analysis of the evaluation in WP4. We will have strong PPI representation on our stakeholder group and at the consensus conference as part of the development work for the Decision Support Tool in WP3.

7 Dissemination and projected outputs

We will produce academic papers reporting key findings from the research and present our findings at two national and two international conferences in the fields of intensive care and clinical ethics. We will also seek to present the DSF and supporting materials to relevant national professional meetings including the Intensive Care Society, Critical Care Outreach Forum, regional critical care networks, and the Royal College of Physicians. All academic publication will be open access. Our stakeholder group will have an important role in disseminating findings and we will seek advice regarding dissemination at our consensus conference in year two. We will work with our PPI collaborators to produce a lay summary of our findings and disseminate this to patient organisations and other stakeholder groups such as Age UK. We will send an executive summary of our report with a link to the DSF and support materials to all medical directors in UK NHS trusts. The key projected outputs from this project are:

1. Project report and executive summary for NHS Trusts
2. Decision Support Framework and implementation support materials available under license to NHS Trusts.
3. Information pack for patients and families freely available to NHS Trusts.
4. A major paper describing the experience of ICU admission decision-making: what happens, why and what are the ethical issues?
5. An evaluation tool for interventions that seek to improve ethical decision making

8 Project plan and projected timetable

The project start date is the 1st of February 2015. Projected dates for key study waypoints are listed in the table below:

Study waypoint	Projected completion date
Study start date	01/02/2015
Start clinical observation of decision making practice (work package 1)	01/05/2015
Completion of follow-up interviews with patients and family members (work package 1)	01/02/2016
Commence development of discrete choice experiment	01/08/2015
Completion of analysis of discrete choice experiment	01/05/2016
Completion of development of draft Decision support framework	01/08/2016
Completion of report from consensus meeting	01/11/2016
Completion of final decision support framework and supporting work	01/11/2016
Completion of decision support framework evaluation tool	01/11/2016
Start collection of data for feasibility of implementation study	01/11/2016
Start collection of data for testing of evaluation tool	01/11/2016
Completion of data collection for feasibility of implementation study	01/08/2017
Completion of data collection for testing of evaluation tool	01/08/2017
Completion of project reports	01/02/2018
End of project	01/02/2018

Decision-making for intensive care unit admissions

8.1 Project timelines

This table shows projected activity in each quarter year period after the start date.

Supporting work	Literature reviews								Writing of reports and dissemination of findings				
Work package 1	Ethics and governance approvals and recruitment of ICUs	Data collection: interviews with clinicians, patients and family members											
Work package 2			Discrete choice experiment										
Work package 3	Ethics and governance approvals and Recruitment of study centre ICUs			Development of Decision support framework (DSF): Presentation of DSF at consensus meeting and refinement of DSF		Implementation feasibility study							
Work package 4	Ethics and governance approvals for extraction of data from patient records for development of evaluation tool	Collection of baseline data						Development and testing of evaluation tool					
Quarter Year	1	2	3	4	5	6	7	8	9	10	11	12	

9 Appendices

9.1 Codes for REC documents

Work package one

Initial approach to patient and family

- PIS1 Brief patient information leaflet (patient has initial capacity)
- PIS2 Patient information sheet (patient regains capacity)
- FIS1 Initial Family information leaflet (initial interview)
- FIS2 Family information sheet initial interview
- FCF1 Consent form for family members for initial interview
- PConsultee form Personal consultee form
- PCF1 patient consent form for use of family interview data (patient regains capacity)

Follow up interview with patients and family

- FIS3 Family information sheet (follow up interview, initial interview held, patient survived)
- FL1 letter to family follow up interview, initial interview held, patient consents
- FL2 letter to family follow up interview, initial interview held, patient lacks capacity
- FL3 letter to family follow up interview, initial interview held, patient died
- FL4 letter to family follow up interview, initial interview declined, patient consents
- FL5 letter to family follow up interview, initial interview declined, patient lacks capacity
- FL6 letter to family follow up interview, initial interview declined, patient died
- FL7 letter to family follow up interview, no initial contact, patient consents
- PIS3 Patient information sheet for late interview
- PCF2 Patient consent form for interview
- PL1 Letter to patient requesting interview

Observation and interviews with clinicians

- CIS1 Clinician information sheet for intensive care clinical directors
- CIS2 Clinician information sheet for intensive care clinical staff taking part in observation
- CIS3 Clinician information sheet for clinical staff from teams referring patients to ICU for interview
- CIS4 Clinician information sheet for referring clinicians not observed inviting them to interview
- CL1 Clinician letter (letter to email referring clinicians not directly observed, inviting them to interview)
- SCF consent form for ICU Directors
- CCF1 ICU Clinician consent form for study
- CCF2 Consent form for referring clinicians

Information leaflet re observation study

- GIS General public information sheet

Work package two

- WP2 email email invitation questionnaire survey
- WPTIS Information sheet for questionnaire survey

Work package three

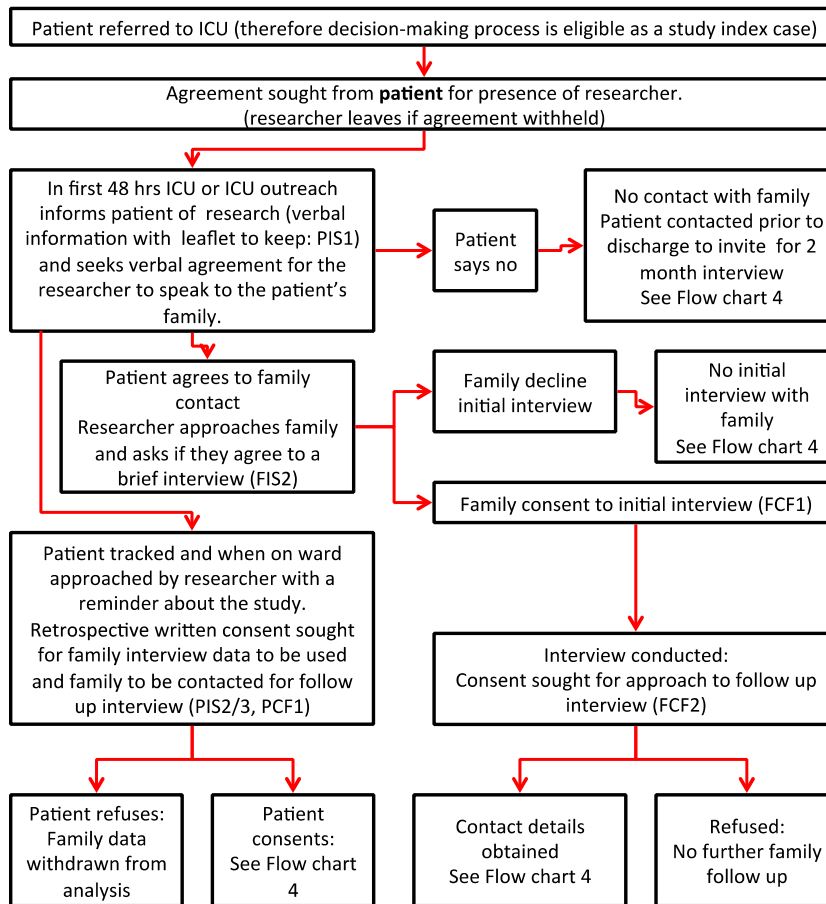
- WP3 IS1 information sheet for medical director
- WP3 IS2 Information sheet for implementation champions
- WP3 IS3 information sheet for clinician interviews
- WP3 CF1 Site consent form
- WP3 CF2 implementation champion consent form
- WP3 CF3 clinician interview consent form

9.2 Consent process flow charts

9.2.1 Flow chart 1

Flow chart 1: Initial approach to patient and family when patient has capacity

Code numbers in parentheses indicate relevant information sheet, consent form or letter (see text and appendix 1)



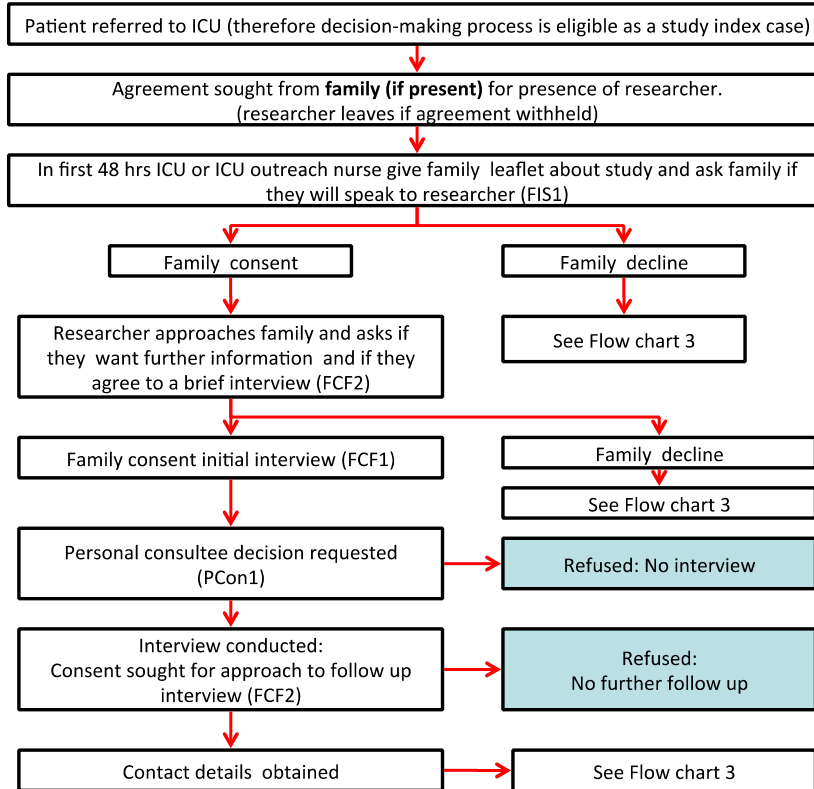
These flow charts are intended to show the processes in place to ensure patients are given sufficient information and opportunity to make an informed decision about taking part in this research; and to give them sufficient opportunity to take part in the research. They are by necessity complicated. When following these charts all pathways should be explored to ensure all circumstances are accounted for.

Decision-making for intensive care unit admissions

9.2.2 Flow chart 2

Decision Making in ICU

Flow chart 2: Initial approach to patient and family when patient lacks capacity
Code numbers in parentheses indicate relevant information sheet, consent form or letter (see text and appendix 1)



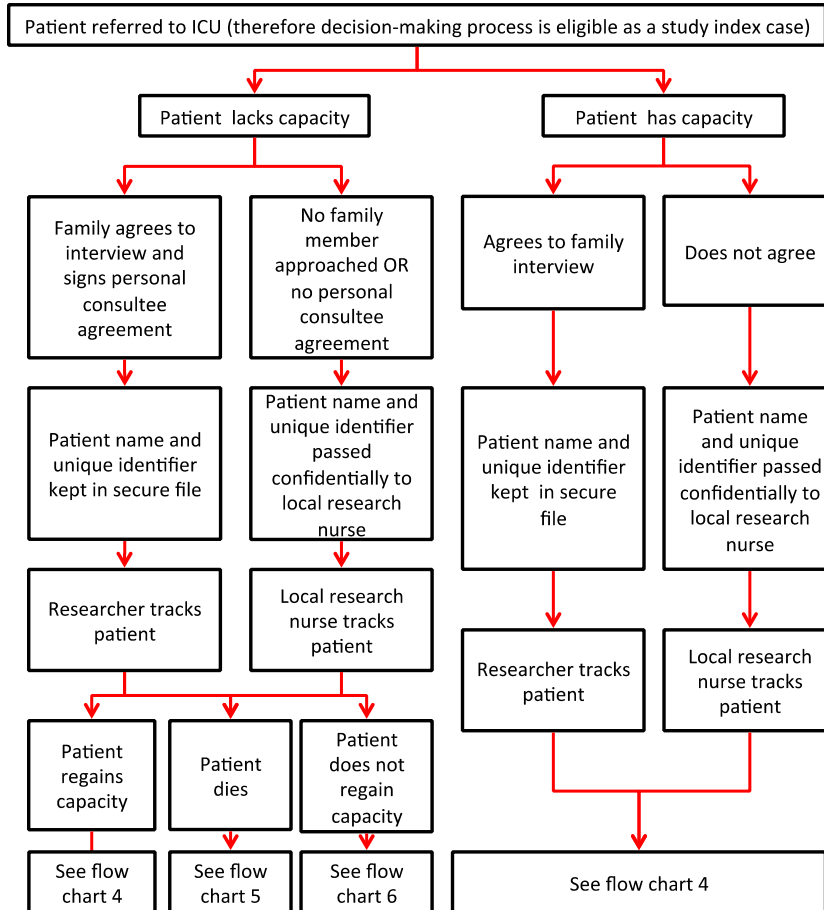
These flow charts are intended to show the processes in place to ensure patients are given sufficient information and opportunity to make an informed decision about taking part in this research; and to give them sufficient opportunity to take part in the research. They are by necessity complicated. When following these charts all pathways should be explored to ensure all circumstances are accounted for.

Decision-making for intensive care unit admissions

9.2.3 Flow chart 3

Decision Making in ICU

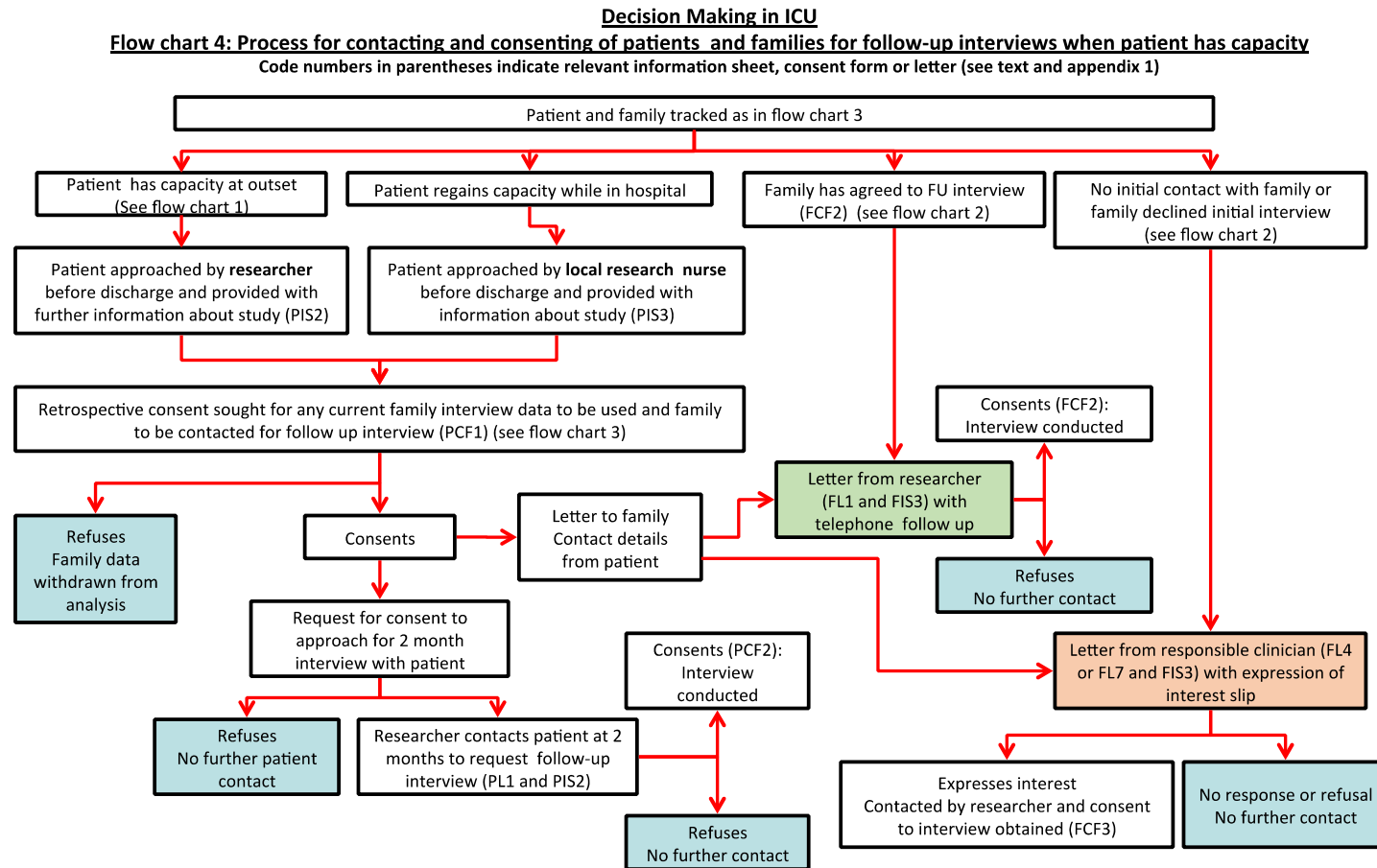
Flow chart 3: Tracking patients to ensure confidentiality and appropriate patient and family follow-up



This flow chart shows the mechanisms of tracking patients through their hospital admission in order to ensure patients and family members are given sufficient information and opportunity to make an informed decision about taking part in this research; specifically to give them sufficient opportunity to take part in a follow-up interview. This flowchart determines which subsequent pathway will be followed.

Decision-making for intensive care unit admissions

9.2.4 Flow chart 4



This flow chart shows the processes for contacting patients and the families of patients with capacity to provide them with information and to ask if they would agree to a follow-up interview. The processes are designed to ensure that patients and family members are given sufficient information and opportunity to make an informed decision about taking part in this research, without burdening them with contacts they have previously declined.

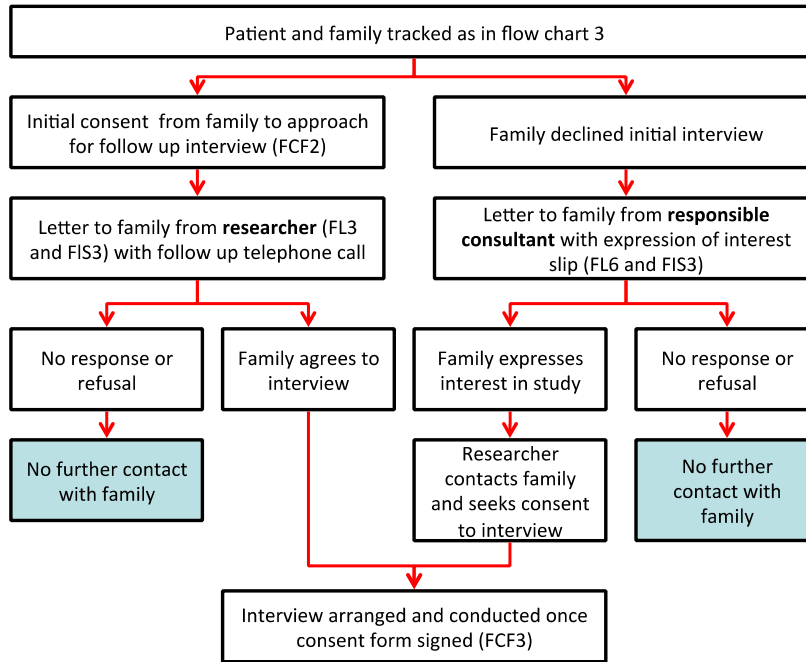
Decision-making for intensive care unit admissions

9.2.5 Flow chart 5

Decision Making in ICU

Flow chart 5: Process for contacting and consenting of family members for follow-up interviews when the patient has not survived

Code numbers in parentheses indicate relevant information sheet, consent form or letter (see text and appendix 1)



This flow chart shows the processes for contacting the families of patients who have not survived their hospital admission to provide them with information and to ask if they would agree to a follow-up interview. The processes are designed to ensure that family members are given sufficient information and opportunity to make an informed decision about taking part in this research, without burdening them at a difficult time

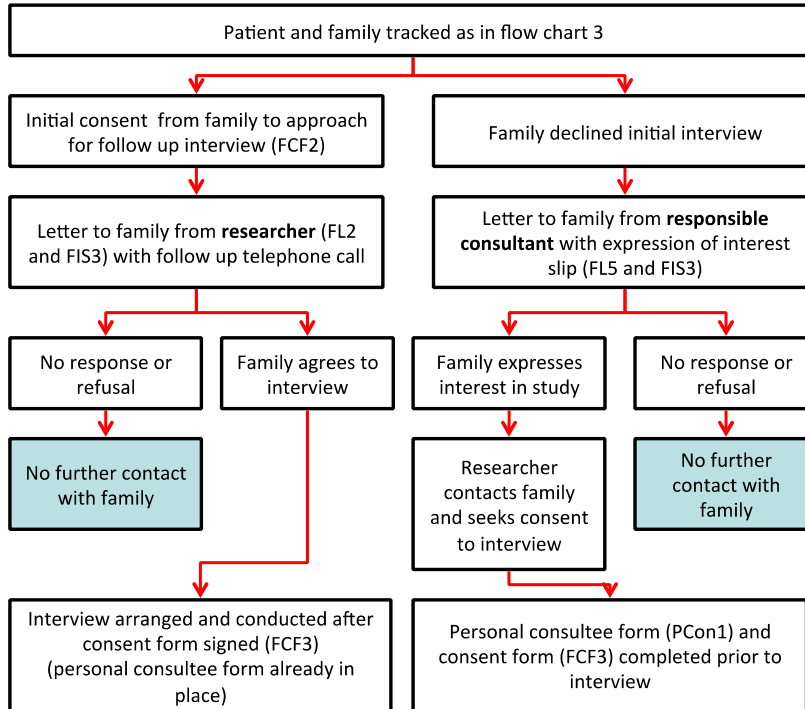
Decision-making for intensive care unit admissions

9.2.6 Flow chart 6

Decision Making in ICU

Flow chart 6: Process for contacting and consenting of family members for follow-up interviews when the patient has not regained capacity

Code numbers in parentheses indicate relevant information sheet, consent form or letter (see text and appendix 1)



This flow chart shows the processes for contacting the families of patients who have not regained capacity during their hospital admission, to provide them with information and to ask if they would agree to a follow-up interview. The processes are designed to ensure that family members are given sufficient information and opportunity to make an informed decision about taking part in this research, without unduly burdening them at a difficult time.

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